# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM F-1

**REGISTRATION STATEMENT UNDER** THE SECURITIES ACT OF 1933

# Gamıda Cell Ltd.

(Exact name of Registrant as specified in its charter)

#### Not Applicable

(Translation of Registrant's name into English)

#### State of Israel

(State or other jurisdiction of incorporation or organization)

# 2834

(Primary Standard Industrial Classification Code Number)

# Not Applicable

(I.R.S. Employer **Identification Number)** 

# 5 Nahum Heftsadie Street Givaat Shaul, Jerusalem 91340 Israel Tel: +972 (2) 659-5666

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Gamida Cell Inc. 673 Boylston Street Boston, MA 02116 Telephone: (617) 892-9080

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Divakar Gunta** Daniel I. Goldberg Joshua A. Kaufman Cooley LLP New York, NY 10036

1114 Avenue of the Americas Telephone: (212) 479-6000 Facsimile: (212) 479-6275

Haim Gueta **Shachar Hadar** Meitar Liquornik Geva Leshem Tal 16 Abba Hillel Road Ramat Gan 5250608, Israel Telephone: +972 (3) 610-3100 Facsimile: +972 (3) 610-3111

Michael Kaplan **Derek Dostal** Davis Polk & Wardwell LLP 450 Lexington Avenue New York, NY 10017 Telephone: (212) 450-4000 Facsimile: (212) 701-5800

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ⊠

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. o

# **CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee		
Ordinary Shares, par value NIS 0.01 per share	\$ 34,730,000	\$	4,209.28	

<sup>(1)</sup> Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the ordinary shares that the underwriters have the option to purchase

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

**Preliminary Prospectus** 

Subject to Completion. Dated June 24, 2019

# 4,040,000 Ordinary Shares



# Gamida Cell Ltd.

All of the 4,040,000 ordinary shares in this offering are being sold by the company. Our ordinary shares are traded on The Nasdaq Global Market under the symbol "GMDA." On June 20, 2019, the last reported sale price of our ordinary shares on The Nasdaq Global Market was \$7.47 per ordinary share.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" on page <u>10</u> to read about factors you should consider before buying our ordinary shares.

	Per	Share Total	
Public offering price	\$	\$	
Underwriting discount <sup>(1)</sup>	\$	\$	
Proceeds to Gamida Cell Ltd., before expenses	\$	\$	

<sup>(1)</sup> See "Underwriting" beginning on page 158 for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than 4,040,000 ordinary shares, the underwriters have the option to purchase up to an additional 606,000 ordinary shares from us at the public offering price less the underwriting discount. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ , and the total proceeds to us, before expenses, will be \$ .

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ordinary shares against payment in New York, New York on or about 2019.

Joint Book-Running Managers

# **RBC Capital Markets**

**JMP Securities** 

Lead Manager

# Oppenheimer & Co.

, 2019

Prospectus dated

# **TABLE OF CONTENTS**

PROSPECTUS SUMMARY	<u>1</u>
RISK FACTORS	<u>10</u>
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	<u>63</u>
<u>USE OF PROCEEDS</u>	<u>65</u>
<u>DIVIDEND POLICY</u>	<u>66</u>
<u>CAPITALIZATION</u>	<u>67</u>
<u>DILUTION</u>	<u>68</u>
SELECTED CONSOLIDATED FINANCIAL DATA	<u>69</u>
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	<u>70</u>
<u>BUSINESS</u>	<u>82</u>
<u>MANAGEMENT</u>	<u>113</u>
PRINCIPAL SHAREHOLDERS	<u>135</u>
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	<u>138</u>
DESCRIPTION OF SHARE CAPITAL	<u>141</u>
<u>TAXATION</u>	<u>148</u>
<u>UNDERWRITING</u>	<u>158</u>
EXPENSES OF THIS OFFERING	<u>165</u>
<u>LEGAL MATTERS</u>	<u>166</u>
<u>EXPERTS</u>	<u>166</u>
ENFORCEMENT OF CIVIL LIABILITIES	<u>167</u>
WHERE YOU CAN FIND MORE INFORMATION	<u>168</u>
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	<u>F-1</u>

Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus, any amendment or supplement to this prospectus, or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ordinary shares and seeking offers to purchase ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

Neither we nor any of the underwriters have taken any action to permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Gamida Cell and NiCord are trademarks of ours that we use in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

The unaudited consolidated financial statements as of March 31, 2019 and 2018 and the audited consolidated financial statements for the years ended December 31, 2018, 2017 and 2016 included

i

elsewhere in this prospectus have been prepared in accordance with the international financial reporting standards, or IFRS, as issued by the international accounting standards board, or the IASB. None of the financial information in this prospectus has been prepared in accordance with accounting principles generally accepted in the United States, or GAAP.

Unless the context otherwise requires, references in this prospectus to the "Company," "Gamida Cell," "we," "us," "our" and other similar designations refer to Gamida Cell Ltd. The terms "shekel," "Israeli shekel" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, and the terms "dollar," "U.S. dollar" or "\$" refer to United States dollars, the lawful currency of the United States of America. All references to "shares" in this prospectus refer to ordinary shares of Gamida Cell Ltd., par value NIS 0.01 per share.

# MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

#### PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our ordinary shares, you should read this entire prospectus carefully, including the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

## Goal

To deliver curative cell therapies to patients with serious and life-threatening medical conditions.

#### Overview

We are a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure cancer and rare, serious hematologic diseases. While cell therapies have the potential to address a variety of diseases, they are limited by availability of donor cells, matching a donor to the patient, and the decline in donor cell functionality when expanding the cells to achieve a therapeutic dose. We have leveraged our nicotinamide-based, or NAM-based, cell expansion technology to develop a pipeline of products designed to address the limitations of cell therapies. Our proprietary technology is designed to allow for the proliferation of donor cells while maintaining the cells' functional therapeutic characteristics, which, if approved, will provide a treatment alternative for patients.

Our most advanced product candidate, omidubicel (formerly known as NiCord), is an investigational advanced cell therapy designed to expand the life-saving benefits of hematopoietic stem cell (bone marrow) transplant, or HSCT. The Company is currently enrolling patients in a pivotal Phase 3 clinical trial in approximately 120 patients with various hematologic malignancies, including high risk leukemias such as acute myeloid leukemia, or AML, acute lymphocytic leukemia, or ALL, chronic myeloid leukemia, or CML, myelodysplastic syndrome, or MDS and lymphomas. We anticipate reporting top-line data from this trial in the first half of 2020. In our Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. Data from the Phase 1/2 clinical study were published in the *Journal of Clinical Oncology* in December 2018. Based on the results of our Phase 1/2 clinical trials, we received Breakthrough Therapy Designation for omidubicel in the United States from the U.S. Food and Drug Administration, or the FDA. Furthermore, we received orphan drug designation from both the FDA and the European Medicines Agency.

In addition to hematologic malignancies, we are pursuing the development of omidubicel for the treatment of bone marrow failure disorders. Omidubicel is currently being evaluated in a Phase 1/2 clinical trial sponsored by the National Institutes of Health in patients with severe aplastic anemia, a rare, life-threatening hematological disorder. This study is designed to evaluate the safety and effectiveness of transplantation with omidubicel to overcome the high incidence of graft rejection associated with conventional cord blood for severe aplastic anemia. We reported initial data from this study at the 2019 Transplantation & Cellular Therapy Meetings of American Society for Blood and Marrow Transplantation and Center for International Blood and Marrow Transplant Research, or the TCT Annual Meeting, in February 2019.

Beyond omidubicel, we have leveraged our NAM technology to develop another product candidate, GDA-201 (formerly known as NAM-NK), an investigational, natural killer, or NK, cell-based cancer immunotherapy to be used in combination with standard-of-care therapeutic antibodies. NK cells have potent anti-tumor properties and have the advantage over other oncology cell therapies of not requiring genetic matching, potentially enabling NK cells to serve as a universal donor-based therapy when combined with certain antibodies. GDA-201 addresses a key limitation in the therapeutic potential of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation of NK cells expanded in culture conditions. GDA-201 is currently in an investigator-sponsored Phase 1 trial for the treatment of relapsed or refractory non-Hodgkin lymphoma, or NHL, and multiple myeloma, or MM.

The figure below summarizes key information about our current pipeline of product candidates:

PRODUCT	PRECLINICAL	PHASE 1/2	PHASE 3	MILESTONES
	High-Risk Hematolog	gic Malignancies		Top-line data 1H20
Omidubicel	Severe Aplastic Ane	mia		✓ Initiate Cohort 2 1H19
GDA-201	Hematologic Maligna	ancies		Additional data 2H19

## **Omidubicel for the Treatment of Hematologic Malignancies**

# Limitations of Allogeneic HSCT

Cell therapies involve the delivery of human cells to replace or repair damaged tissue or cells in order to treat a variety of cancers and other diseases. HSCT, commonly known as bone marrow transplantation, is the most frequently used cell therapy and is used to treat a variety of hematologic malignancies and other serious conditions. A person's entire blood and bone marrow can be reconstituted from a seed population of stem cells obtained from an allogeneic, or non-self, donor whose blood-forming and immune-system-forming cells are both free of cancer and effective at carrying out their functions. Approximately 90% of HSCT procedures performed in the United States are for patients with hematologic malignancies. There are approximately 30,000 patients per year receiving allogeneic HSCT in the United States, Europe and Japan, of which 8,500 are in the United States. The number of these procedures increased by 5% per year in the United States from 2006 to 2016. By 2021, the Company expects that approximately 11,000 individuals with a hematologic malignancy will be a candidate for HSCT, and the Company further projects that omidubicel, if approved, will be used to treat approximately 30% of these patients.

Despite the curative potential of HSCT, it is estimated that more than 40% of eligible patients do not receive one for various reasons, including finding a matched donor. The best source for donor cells is a sibling who is a matched related donor, or MRD, but the chances of having a sibling match in the United States are only 25% to 30%. The majority of patients rely on alternate sources of donor cells, including matched unrelated donor, or MUD, haploidentical, or "half-matched" donors, and umbilical cord blood. Notwithstanding the various potential sources of donor cells, HSCT is subject to a number of significant limitations, including: (i) delays in finding a suitable match, during which disease progression may make patients ineligible for transplant; (ii) an insufficient number or delayed engraftment of donor cells, leaving patients without a functioning immune system and leading to potentially life-threatening immune deficiency following transplant; and (iii) a lack of long-term compatibility between the donor cells and the patient's own cells, resulting in potentially fatal graft versus host disease, or GvHD.

Umbilical cord blood offers promise as a readily available source of stem cells for patients who need HSCT and do not have a MRD source. It is easier to find a match when using stem cells derived from cord blood, since a full match is not required for a successful transplant using cord blood. This broadens the pool of potential donors and shortens the process of finding a suitable match. However, on average, a typical cord blood graft contains approximately one-tenth the number of stem and progenitor cells compared to stem cell grafts from adult bone marrow or peripheral blood donors. This lower number of cells may delay engraftment of the donor cells and reconstitution of the immune system. This, in turn, increases both time in the hospital and the likelihood that a patient might contract a life-threatening infection.

# Omidubicel as a Universal Stem Cell Graft for Allogeneic HSCT

Omidubicel, our lead product candidate, is designed to address the limitations of HSCT. Omidubicel is composed of cord blood that has been manufactured using our proprietary NAM-based cell expansion technology, which is designed to increase engraftment efficiency in HSCT and enable rapid engraftment and immune system reconstitution. This reduces the risk of infections and other complications after transplant. In addition, the donor T cells in cord blood are naïve, meaning that they have not matured and may more readily adapt to the recipient. This results in greater immunologic compatibility, or the matching of the donor cells with the recipient's cells, reducing the frequency and severity of GvHD. In light of these advantages, omidubicel, if approved, may serve as a universal, readily available, reliable and effective alternative to existing sources of donor cells for HSCT.

We are currently enrolling patients in an international, multicenter, randomized, pivotal Phase 3 clinical trial in 120 patients with hematologic malignancies, AML, ALL, CML, MDS and lymphomas. We anticipate reporting top-line data from this trial in the first half of 2020. In our Phase 1/2 clinical trial, sponsored by us, we enrolled 36 patients with hematologic malignancies who did not have a suitable matched donor. For comparison, we identified 146 patients as historic controls from data collected by the Center for International Blood and Marrow Transplant Research, or CIBMTR. The primary endpoint of neutrophil engraftment was met based on recovery of neutrophils, which are infection-fighting white blood cells. Neutrophil engraftment is defined as achieving a minimum neutrophil count of at least 0.5 x 109 per liter on three consecutive measurements on different days. There was a median recovery time of 11.5 days after transplantation in omidubicel treated patients, compared to 21 days observed in the historic controls. A key secondary endpoint, platelet engraftment, was also met with a median recovery time of 34 days in omidubicel treated patients, compared to 46 days in historic controls. Platelets are required for normal blood clotting and low platelet counts are associated with life-threatening hemorrhage. Platelet engraftment is defined as achieving a platelet count of at least 20 x 109 per liter on three consecutive measurements on different days, with no platelet transfusion in the preceding seven days. Efficient engraftment and robust immune reconstitution likely contributed to an observed reduction of 20 days in the number of days, post-transplant, that patients were hospitalized as compared to similar patients treated with standard cord blood. Based on the results of this Phase 1/2 trial, we received Breakthrough Therapy Designation from the FDA.

# **Our Strategy**

Our goal is to deliver curative cell therapies to patients with serious and life-threatening medical conditions. The key strategies to achieve our goal are the following:

- Complete Phase 3 clinical development and obtain regulatory approval for omidubicel in hematologic malignancies. Assuming positive results from the Phase 3 clinical trial, we plan to seek regulatory approval for omidubicel in the United States, the European Union and other geographies. We have entered into an agreement with Lonza Netherlands B.V., or Lonza, pursuant to which Lonza will supplement our anticipated capacity for commercial production.
- Advance omidubicel for the treatment of severe aplastic anemia in an ongoing Phase 1/2 clinical trial. We reported preliminary data from our Phase 1/2 clinical trial at the 2019 TCT Annual Meeting. All three patients enrolled in the first cohort were successfully treated with reduced intensity conditioning regimens and underwent an HSCT bone marrow transplant consisting of omidubicel plus a haploidentical stem cell graft.
- Investigate the potential of GDA-201 in conjunction with therapeutic antibodies in additional cancer indications. Data reported from the first 14 patients in the ongoing investigator-sponsored Phase 1 trial of GDA-201 in patients with NHL and MM demonstrated that GDA-201 was highly active, with three complete responses observed in patients with NHL and one complete response in a patient with MM.
- Maximize commercial value of our product candidates. If omidubicel is approved for stem cell
  transplantation, we intend to independently pursue the commercialization of omidubicel in the United States.
  Outside of the United States, we may pursue the approval and commercialization of omidubicel in
  collaboration with a partner.

- Centralize manufacturing capabilities to deliver a pharmaceutical grade product to meet commercial demand. We currently have limited in-house GMP manufacturing capabilities. We are building additional manufacturing infrastructure at an identified site to diversify production of omidubicel and as we prepare for commercialization.
- **Demonstrate omidubicel's value through Health Economics Outcomes Research.** We believe that a favorable outcome of our ongoing Health Economics Outcomes Research analysis will inform price, reimbursement and adoption. Additionally, we are developing a reimbursement strategy modeled upon recently approved cell therapies in oncology through the New Technology Add-on Payment program.
- Expand our pipeline of cell therapy product candidates by leveraging our cell expansion technology. We are utilizing our platform technology to develop GDA-201. Additionally, we plan to leverage our NAM-based expansion technology for the discovery of additional product candidates.

# Management Team, Board and Investor Base

We are led by an experienced management team with extensive expertise in developing oncology therapies and manufacturing cell therapies and other complex biologics. Our director and chief executive officer, Julian Adams, played a central role in the discovery and development of bortezomib, or Velcade®, a widely used therapy for MM and other blood cancers approved by the FDA in 2003. Dr. Adams also led research and development, or R&D, efforts at Infinity Pharmaceuticals, Inc., which helped lead to the 2018 FDA approval of duvelisib, also known as Copiktra®, for the treatment of certain leukemias and lymphomas. We are also backed by a strong board of directors and an investor base that includes Novartis, Clal Biotechnology Industries and Israel Biotech Fund.

## **Risks Associated With Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include, among others, the following:

- We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- We have never generated any revenue from product sales and may never be profitable.
- We are heavily dependent on the success of our product candidates, including obtaining regulatory approval to market our product candidates in the United States, the European Union and other geographies.
- Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost
  of development and of subsequently obtaining regulatory approval.
- Our product candidates and the administration process may cause undesirable side effects or have other
  properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved
  label or result in significant negative consequences following marketing approval, if any.
- Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a
  going concern absent access to sources of liquidity.
- We rely on third parties to conduct certain elements of our preclinical studies and clinical trials and perform
  other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected
  deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or
  commercialize our product candidates.
- We rely on a limited number of third parties or, in some cases, a sole third party, for some of our raw
  materials or certain equipment that we use to create our product candidates, and may not be able to find
  replacements in the event our supplier no longer provides sufficient quantities or fails to do so at acceptable
  quality levels or prices.

- We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the
  intellectual property related to our technologies and product candidates, and we may not be able to compete
  effectively in our markets if we are unable to maintain sufficient intellectual property protection for our
  product candidates.
- We currently have no marketing and sales organization. If we are unable to establish sales and marketing
  capabilities, or enter into agreements with third parties to market and sell our product candidates, if
  approved, we may be unable to generate any product revenue.
- We do not anticipate that we will be classified as a passive foreign investment company for the current taxable year; however, if we are so classified, our U.S. shareholders could suffer adverse tax consequences.

## **Corporate Information**

We are an Israeli corporation based in Jerusalem, Israel, and were incorporated in 1998. Our principal executive offices are located at 5 Nahum Heftsadie St., Givaat Shaul, Jerusalem 91340, Israel and our U.S. subsidiary's executive headquarters are in Boston, Massachusetts. Our telephone number is +972 (2) 659-5666. Our website address is *www.gamida-cell.com*. The information contained on our website and available through our website is an inactive textual reference only.

# Implications of Being an "Emerging Growth Company" and a Foreign Private Issuer

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to include only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement;
- reduced executive compensation disclosure;
- exemptions from the requirement to hold a non-binding advisory vote on executive compensation, including golden parachute compensation; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (1) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (2) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (3) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC. We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide holders of our ordinary shares may be different than the information you might receive from other public companies in which you hold equity. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. However, given that we currently report and expect to continue to report under IFRS as issued by the IASB, the extended transition period available to emerging growth companies that report under GAAP is inapplicable to us.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

• the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;

- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading
  activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form 8-K upon the occurrence of specified significant events (although we intend to report our results of operations voluntarily on a quarterly basis).

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States.

In this prospectus, we have taken advantage of certain of the reduced reporting requirements as a result of being an emerging growth company and a foreign private issuer. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

#### THE OFFERING

Ordinary shares offered by us

4,040,000 ordinary shares

Ordinary shares to be outstanding immediately after this offering

29,180,048 ordinary shares (or 29,786,048 ordinary shares if the underwriters exercise their option to purchase an additional ordinary shares in full).

Option to purchase additional ordinary shares

We have granted the underwriters an option for a period of 30 days after the date of this prospectus to purchase up to additional 606,000 ordinary shares.

Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately \$27.7 million, or approximately \$31.9 million if the underwriters exercise their option to purchase additional ordinary shares in full, after deducting the estimated underwriting discount and estimated offering expenses payable by us, based on an assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, available for sale and short-term deposits: (i) to fund clinical development of our product candidates, including the completion of our pivotal Phase 3 clinical trial of our lead product candidate, omidubicel, and the preparation of a Biologics Licensing Application for omidubicel; (ii) to expand our commercial and manufacturing capabilities; and (iii) for general corporate purposes and working capital.

See "Use of Proceeds" for more information about the intended use of proceeds from this offering.

Passive foreign investment company considerations

Based upon the value of our assets, including any goodwill, and the nature and composition of our income and assets, we do not believe that we were classified as a passive foreign investment company, or a PFIC, for the taxable year ended December 31, 2018, and we do not believe that we will be a PFIC for the taxable year ending December 31, 2019 or in the immediately foreseeable future.

Nasdaq Global Market symbol

Our ordinary shares are listed for trading on The Nasdaq Global Market under the symbol "GMDA."

Unless otherwise stated, the number of ordinary shares to be outstanding after this offering is based on 25,140,048 ordinary shares outstanding as of March 31, 2019, and excludes:

- 3,742,416 ordinary shares reserved for issuance upon the exercise of outstanding options as of March 31, 2019, at a weighted average exercise price of \$4.21 per share;
- 456,344 ordinary shares reserved for future issuance under our 2017 Share Incentive Plan, as of March 31, 2019, as well as any automatic increases in the number of common shares reserved for future issuance under this plan;
- 466,375 ordinary shares issued upon the exercise of options after March 31, 2019; and
- 3,313,512 ordinary shares issuable upon the exercise of outstanding warrants to purchase ordinary shares, at a weighted average exercise price of \$6.72 per share, which warrants are expected to remain outstanding at the consummation of this offering.

Unless otherwise indicated, all information in this prospectus assumes that the underwriters do not exercise their option to purchase up to an additional 606,000 ordinary shares.

## SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data. We have derived the following statements of operations data for the years ended December 31, 2018, 2017 and 2016 from our audited consolidated financial statements included elsewhere in this prospectus. The following statements of operations data for the three months ended March 31, 2019 and 2018 and the balance sheet data as of March 31, 2019 have been derived from our unaudited condensed interim consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period. The following consolidated summary financial data should be read in conjunction with "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year ended December 31,					_	Three months ended March 31,				
	2018		2017		2016		2019		2018		
					_	(unaudited)					
		(ir	tho	usands, ex	сер	t share and	l pe	r share amoun	ts)		
Statements of Operations Data:											
Research and development expenses, net	\$	22,045	\$	15,018	\$	19,095	\$	7,283	\$	5,060	
General and administrative expenses		11,599		4,472		4,614		3,813		1,653	
Operating loss		33,644		19,490		23,709		11,096		6,713	
Financial expenses		20,259		718		155		4,734		974	
Financial income		(1,042)		(1,197)		(1,193)		(349)		(296)	
Loss before taxes on income		52,861		19,011		22,671		15,481		7,391	
Taxes on income		70						26			
Net Loss		52,931		19,011		22,671		15,507		7,391	
Basic and diluted net loss per ordinary share	\$	10.53	\$	27.56	\$	32.86	\$	0.62	\$	10.78	
Weighted average number of ordinary shares, basic and diluted		5,025,213	213 689,898 689,898 25,0		25,038,261		689,898				
								As of March 31, 2019			
								Actual As Adjusted <sup>(1)(2)</sup>			
							(unaudited) (in thousands)				
Balance Sheet Data:								Ì		•	
Cash and cash equivalents, available-for-sale financial assets and short-term deposits \$ 50,406 \$ 78,07								78,074			
Working Capital <sup>(3)</sup>								43,124		70,792	
Total Assets								61,047		88,715	
Total Shareholders' Equity								13,145		40,813	

<sup>(1)</sup> Data presented on an as adjusted basis to give effect to the sale of 4,040,000 ordinary shares in this offering at the assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

<sup>(2)</sup> Each \$1.00 increase (decrease) in the assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, would increase (decrease), respectively, each of cash and cash equivalents, working capital, total assets and total shareholders' equity on an as adjusted basis by approximately \$3.80/(3.80) million, assuming the number of ordinary shares offered by us, as set forth on the cover of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of ordinary shares we are offering would increase (decrease), respectively, each of cash and cash equivalents, working capital, total assets and total shareholders' equity on an as adjusted basis by approximately \$7.02/(7.02) million, assuming the assumed public offering price per ordinary share remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information is illustrative only, and we will adjust this information based on the actual public offering price and other terms of this offering determined at pricing.

<sup>(3)</sup> Working capital is defined as total current assets minus total current liabilities.

# **RISK FACTORS**

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, in addition to the other information set forth in this prospectus, including the consolidated financial statements and the related notes included elsewhere in this prospectus, before purchasing our ordinary shares. If any of the following risks actually occurs, our business, financial condition, cash flows and results of operations could be negatively impacted. In that case, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

# Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company. We have incurred net losses each year since our inception in 1998, including net losses of \$15.5 million and \$7.4 million for the three months ended March 31, 2019 and 2018, respectively, and \$52.9 million, \$19.0 million and \$22.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of March 31, 2019, we had an accumulated deficit of \$184.7 million.

We have devoted substantially all of our financial resources to designing and developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our ability to ultimately achieve recurring revenue and profitability, which we do not expect to occur for at least several years, is dependent upon our ability to successfully complete the development of our product candidates, obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products.

We anticipate that our expenses will increase substantially based on a number of factors, including to the extent that we:

- continue our clinical development of omidubicel for the treatment of hematologic malignancies and other rare, serious hematologic diseases;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- identify, assess, acquire, license and/or develop other product candidates;
- establish and validate our commercial-scale current good manufacturing practices, or cGMP, manufacturing facilities:
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may
  obtain marketing approval:
- hire personnel and invest in additional infrastructure to support our operations as a public company and expand our product development;
- · enter into agreements to license intellectual property from, or to, third parties;
- · develop, maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with respect to any of the above, including but not limited to, failed studies, complex results, safety issues or other regulatory challenges that require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

To date, we have financed our operations primarily through our initial public offering of equity securities, private placements of equity securities and royalty-bearing grants that we received from the Israeli Innovation Authority, or the IIA, formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations,

or grants. Even if we obtain regulatory approval to market one or more product candidates, our future revenue will depend upon the size of any markets in which such product candidates receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors for such product candidates. Further, the net losses that we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. We may also incur other unanticipated costs from our operations.

We will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations.

Our audited consolidated financial statements for each of the three years in the period ended December 31, 2018 and our unaudited financial statements for the three months ended March 31, 2019, included elsewhere in this prospectus, note that there is substantial doubt about our ability to continue as a going concern, absent sources of additional liquidity. In order to fund further operations, we will need to raise capital. We may seek these funds through a combination of private and public equity offerings, debt financings, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. These conditions raise substantial doubt about our ability to continue as a going concern, and we will be required to raise additional funds, seek alternative means of financial support, or both, in order to continue operations. The accompanying audited consolidated financial statements have been prepared assuming that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. If we are unable to raise the requisite funds, we will need to curtail or cease operations.

Developing our product candidates is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through preclinical studies and clinical development in an effort to obtain regulatory approval. We are conducting a Phase 3 clinical trial of our lead product candidate, omidubicel, for the treatment of hematologic malignancies. We expect to report top-line data in the first half of 2020. Assuming positive results from the Phase 3 clinical trial, we plan to seek regulatory approval for omidubicel in the United States and the European Union, and we may seek such approvals in other geographies. We also plan to continue our Phase 1/2 investigator-sponsored clinical trial of omidubicel for the treatment of severe aplastic anemia and our Phase 1 investigator-sponsored clinical trial of our GDA-201 product candidate for the treatment of relapsed or refractory non-Hodgkin lymphoma, or NHL, and multiple myeloma, or MM. We also incur additional ongoing costs associated with operating as a public company.

As of March 31, 2019, we had cash and cash equivalents and available-for-sale financial assets of \$50.3 million. We currently believe that our existing capital resources will be sufficient to meet our projected operating requirements through March 2020. We will require significant additional financing in the future to fund our operations. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, results and costs of our current and planned clinical trials of omidubicel and our other future product candidates;
- the cost, timing and outcomes of regulatory review of omidubicel and our other future product candidates;
- the costs of establishing and maintaining one or more of our planned commercial-scale cGMP manufacturing facilities, including in Kiryat Gat, Israel, and/or engaging third-party manufacturers;
- the scope, progress, results and costs of product development, laboratory testing, manufacturing, preclinical
  development and clinical trials for any other product candidates that we may develop or otherwise obtain in the
  future;

- the cost of our future activities, including establishing sales, marketing and distribution capabilities for any
  product candidates in any particular geography where we receive marketing approval for such product
  candidates:
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the level of revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenue, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, and the terms of any financing may adversely affect the interests or rights of our shareholders. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to obtain additional capital through a combination of equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish certain rights to our technologies or our product candidates, or to grant licenses on terms that are not favorable to us.

If we are unable to obtain funding on acceptable terms and on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research, development or manufacturing programs or the commercialization of any approved product, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

## We have never generated any revenue from product sales and may never be profitable.

We have no products approved for marketing in any jurisdiction, and we have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for at least the next several years. Our ability to generate future revenue from product sales will depend heavily on our ability to:

 complete research and preclinical and clinical development of our product candidates in a timely and successful manner;

- obtain regulatory and marketing approval for those of our product candidates for which we complete clinical studies;
- develop and obtain regulatory approval for a sustainable and scalable in-house and/or third-party manufacturing process that meets all applicable regulatory standards for our approved product candidates;
- establish and maintain supply and, if applicable, manufacturing relationships with third parties that can provide
  adequate, in both amount and quality, products to support clinical development and the market demand for our
  product candidates, if and when approved:
- launch and commercialize our product candidates for which we obtain regulatory and marketing approval, either directly by establishing a sales force, marketing and distribution infrastructure, and/or with collaborators or distributors;
- expose, educate and train physicians and other medical professionals to use our products;
- obtain market acceptance, if and when approved, of our product candidates from the medical community and third-party payors;
- ensure procedures utilizing our product candidates are approved for coverage and adequate reimbursement from governmental agencies, private insurance plans, managed care organizations, and other third-party payors in jurisdictions where they have been approved for marketing;
- address any competing technological and market developments that impact our product candidates or their prospective usage by medical professionals;
- · identify, assess, acquire and/or develop new product candidates;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and perform our obligations under such collaborations;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, patent applications, trade secrets and know-how;
- avoid and defend against third-party interference, infringement or other intellectual property related claims;
- attract, hire and retain qualified personnel; and
- locate and lease or acquire suitable facilities to support our clinical development, manufacturing facilities and commercial expansion.

Even if one or more of our product candidates is approved for marketing and sale, we anticipate incurring significant incremental costs associated with commercializing such product candidates. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies or ethical committees in medical centers, to change our manufacturing processes or assays or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. Even if we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue earned from such product candidates will be dependent in part upon the size of the markets in the territories for which we gain regulatory approval for such products, the accepted price for such products, our ability to obtain reimbursement for such products at any price, whether we own the commercial rights for that territory in which such products have been approved and the expenses associated with manufacturing and marketing such products for such markets. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Further, if we are not able to generate significant revenue from the sale of our approved products, we may be forced to curtail or cease our operations. Due to the numerous risks and uncertainties involved in product development, it is difficult to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

# Risks Related to the Discovery, Development and Clinical Testing of Our Product Candidates

We are heavily dependent on the success of our product candidates, including obtaining regulatory approval to market our product candidates in the United States, the European Union and other geographies.

To date, we have deployed all of our efforts and financial resources to: (i) research and develop our nicotinamide-based, or NAM-based, cell expansion technology, our lead product candidate, omidubicel, for the treatment of hematologic malignancies, and our other product candidates, including conducting preclinical and clinical studies and providing general and administrative support for these operations; and (ii) develop and secure our intellectual property portfolio for our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our current and future product candidates. Our product candidates' marketability is subject to significant risks associated with successfully completing current and future clinical trials and commercializing our product candidates that receive regulatory approval, including:

- completion of our ongoing international, multicenter, randomized, pivotal Phase 3 clinical trial of omidubicel for
  the treatment of hematologic malignancies and the clinical trials of our other product candidates, and for any
  other product candidates for which we may file an Investigational New Drug, or IND, application, without which
  we would be unable to commence such clinical trials;
- acceptance by the FDA, EMA or other regulatory agencies of our parameters for regulatory approval relating to omidubicel and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways;
- the acceptance by the FDA, EMA or other regulatory agencies of the number, design, size, conduct and
  implementation of our clinical trials, our trial protocols and the interpretation of data from preclinical studies or
  clinical trials;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient
  enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the
  product candidates undergoing such clinical trials;
- our ability to complete our Phase 3 clinical trial of omidubicel for the treatment of hematologic malignancies in the United States in a timely fashion, and that such single pivotal Phase 3 clinical trial, even if successfully completed, will be sufficient to support approval of a Biologics License Application, or BLA;
- the FDA's acceptance of the sufficiency of the data we collect from our preclinical studies and our investigatorsponsored Phase 1/2 clinical trial of omidubicel for the treatment of severe aplastic anemia and of GDA-201 for the treatment of NHL and MM:
- the willingness of the FDA, EMA or other regulatory agencies to schedule an advisory committee meeting in a timely manner to evaluate and decide on the approval of our regulatory filings, if such advisory committee meetings are required;
- the recommendation of the FDA's advisory committee to approve our applications to market omidubicel and our
  other product candidates in the United States, and the EMA in the European Union, if such advisory committee
  reviews are scheduled, without limiting the approved labeling, specifications, distribution or use of the products,
  or imposing other restrictions;
- the satisfaction of the FDA, EMA or other regulatory agencies with the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- the timely and satisfactory performance by third-party contractors, trial sites and principal investigators of their obligations in relation to our clinical trials;
- our success in educating medical professionals and patients about the benefits, administration and use of our product candidates, if approved;

- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by our product candidates;
- the effectiveness of our marketing, sales and distribution strategy, and operations, as well as that of any current and future licensees;
- the extent to which third-party payors provide coverage and adequate reimbursement for procedures utilizing our products;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP:
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our product candidates; and
- · changes to regulatory guidelines.

Many of these clinical, regulatory and commercial risks are beyond our control. Accordingly, we cannot assure you that we will be able to advance any of our product candidates through clinical development, or to obtain regulatory approval of or commercialize any of our product candidates. If we fail to achieve these objectives or overcome the challenges presented above, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we may not be able to generate sufficient revenue through the sale of our product candidates to enable us to continue our business.

## We may be unable to obtain regulatory approval for our product candidates.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting and export and import of drug products are subject to extensive regulation by the FDA, the EMA and by regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide data from well-controlled clinical trials that adequately demonstrate the safety and efficacy of the product for the intended indication to the satisfaction of the FDA, EMA or other regulatory authority. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. The FDA, EMA or other regulatory agencies can delay, limit or deny approval of our product candidates for many reasons, including:

- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- our inability to demonstrate that the product candidates are safe and effective for the target indication to the satisfaction of the FDA, EMA or other regulatory agencies;
- the FDA's, EMA's, or other regulatory agencies' disagreement with our clinical trial protocol, the interpretation of data from preclinical studies or clinical trials, or adequacy of the conduct and control of clinical trials;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the patient population for which we seek approval:
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of our product candidates observed in clinical trials;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- any determination that a clinical trial presents unacceptable health risks to subjects;

- our inability to obtain approval from institutional review boards, or IRBs, to conduct clinical trials at their respective sites;
- the non-approval of the formulation, labeling or the specifications of our product candidates;
- the failure to accept the manufacturing processes or facilities at our manufacturing site or those of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA, EMA or other regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval; or
- resistance to approval from the advisory committees of the FDA, EMA or other regulatory agencies for any reason including safety or efficacy concerns.

In the United States, we will be required to submit a BLA, to obtain FDA approval before marketing any of our product candidates. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency, or efficacy, for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA may further inspect our manufacturing facilities to ensure that they can manufacture our product candidates and our products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of a BLA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approval, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the United States, such as in the European Union, also have requirements for approval of biologics for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking additional regulatory approvals outside the United States and European Union could require additional non-clinical studies or clinical trials, which could be costly and time consuming. These regulatory approvals may include all of the risks associated with obtaining FDA or EMA approval. For all of these reasons, if we seek such regulatory approvals for any of our other product candidates, we may not obtain such approvals on a timely basis, if at all.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly and potentially time-consuming additional post-approval clinical trials or subject to contraindications, black box warnings, restrictive surveillance or a Risk Evaluation and Mitigation Strategy, or REMS. Further, the FDA, EMA or other regulatory authorities may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and these regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. To the extent we seek regulatory approval in jurisdictions outside of the United States and European Union, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would thus negatively impact our business, results of operations and prospects.

# Clinical development is difficult to design and implement and involves a lengthy and expensive process with uncertain outcomes.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Bone marrow transplant and cell-based therapies that appear promising in the early phases of development may fail to reach the market. Further, a failure of one or more of our clinical trials can occur at any time during the clinical trial process. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, in order to commence a trial;
- · identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain IRB approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial or return for post-treatment follow-up;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of product candidate for use in clinical trials; or
- raise sufficient capital to fund a trial.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- there may be changes in government regulations or administrative actions;
- our product candidates may have undesirable adverse effects or other unexpected characteristics;
- we may not be able to demonstrate that a produce candidate's clinical and other benefits outweigh its safety risks;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care of future competitive therapies in development;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

We may also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, by the FDA, EMA or other regulatory agencies. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory agencies resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In particular, while we currently expect to report top-line data in the first half of 2020 for our Phase 3 clinical trial comparing transplantation with omidubicel versus standard cord blood, no assurance can be given that we will be able to maintain that timing.

Further, conducting clinical trials in countries outside of the United States and European Union, as we plan to do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with jurisdiction-specific regulatory schemes, as well as political and economic risks relevant to such jurisdictions.

If we experience delays in carrying out or completing any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.

Results from preclinical studies or early stage clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. For example, based on the results of our Phase 1/2 clinical trials of omidubicel for the treatment of hematologic malignancies, we received Breakthrough Therapy Designation for omidubicel in the United States from the FDA, and we are conducting the Phase 3 clinical trial with the same eligibility criteria and endpoints as our Phase 1/2 trials to confirm the superiority of omidubicel over standard umbilical cord blood. However, our Phase 3 clinical trial may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical and early clinical studies. This failure would cause us to abandon further development of omidubicel in this indication, which is currently our most advanced product candidate.

There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, including conclusions about relapse rates in connection with use of omidubicel or other product candidates that are based on small sample sizes of data, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In addition, successful results in one or a few patients may not be indicative of the final results after completion of treatment of all patients in a clinical trial. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

The success of our NAM-based platform and our product candidates is substantially dependent on developments within the emerging field of cellular therapies, some of which are beyond our control.

Our NAM-based cell expansion technology and our product candidates are designed to increase the therapeutic functionality of cell therapy products, which represents a novel development within the field of cellular therapeutics. Stem cell therapies in turn represent a relatively new therapeutic area that presents a number of scientific, clinical, regulatory and ethical challenges. Any adverse developments in the field of stem cell therapies generally, and in the practice of hematopoietic stem cell transplant in particular, will negatively impact our ability to develop and commercialize our product candidates. In particular, we currently anticipate that omidubicel and any additional product candidates that we develop from our NAM-based cell expansion technology would be adopted into the current standard of care for HSCT procedures. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the development and commercialization of therapies targeted at the underlying cause of diseases addressed by omidubicel obviate the need for patients to undergo HSCT procedures, our business prospects will be significantly harmed.

Because our product candidates are based on novel technologies, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of these product candidates and obtain the necessary regulatory approvals for commercialization.

Our product candidates are based on our novel NAM-based cell expansion technology, and unexpected problems related to this new technology may arise that can cause us to delay, suspend or terminate our development efforts. Regulatory approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. Stem cell therapies represent a relatively new therapeutic area, and the FDA has cautioned consumers about potential safety risks associated with these therapies. To date, there are relatively few approved stem cell products.

Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In addition, adverse developments in clinical trials of potential stem cell therapies conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. These regulatory authorities and advisory groups and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products will likely be reviewed by the FDA's advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenue to maintain our business.

As an organization, we have never completed pivotal clinical trials, and we may be unable to do so for any product candidates we may develop, including completing our pivotal Phase 3 clinical trial for omidubicel.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market omidubicel or any of our other product candidates. Carrying out later-stage clinical trials and the submission of a successful BLA is a complicated process. As an organization, we have not previously completed any later stage or pivotal clinical trials and have limited experience in preparing, submitting and prosecuting regulatory filings. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of omidubicel. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing omidubicel.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent us from proceeding with clinical trials.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any drugs that may be approved for the

indications we are investigating, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will drop out of the trials before completion. For example, patients may prefer to undergo treatment with stem cell transplantation with cells sourced from matched related donors, matched unrelated donors or haploidentical donors, as opposed to being treated with omidubicel, which would adversely affect the enrollment of our clinical trials.

We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, the proximity and availability of clinical study sites for prospective patients and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products will be delayed.

Our product candidates and the administration process may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any, and result in costly and damaging product liability claims against us.

Undesirable side effects, including toxicology, caused by our product candidates, or the drugs encapsulated by our product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other regulatory agencies. Results of our studies could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical studies could be suspended or terminated, and the FDA, EMA or other regulatory agencies could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. Moreover, during the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions.

Drug-related, drug-product related, formulation-related and administration-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical study or result in potential product liability claims, which could exceed our clinical trial insurance coverage. We are in the process of obtaining clinical trial insurance policies with respect to all our clinical studies. The insurance policies are in accordance with the local regulations applicable in the jurisdictions where the studies are performed outside of clinical trials.

Further, patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. Infusion reactions have also been reported in approximately 3% of patients treated with omidubicel. Additional serious adverse events reported as related to omidubicel, which each occurred in 3% of patients, included elevated liver enzymes, hypertension, and low platelets. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. In our Phase 1/2 clinical trial of omidubicel for the treatment of sickle cell disease, or SCD, which is a chronic illness, two of the patients died: one due to chronic graft versus host disease, or GvHD, and the other due to secondary graft failure. In our Phase 1/2 trial of omidubicel for the treatment of hematologic malignancies, approximately 10% of patients who received omidubicel experienced serious GvHD. In our Phase 1 clinical trial of GDA-201, adverse events included one patient who died of *E. coli* sepsis. There was also a low level of sporadic engraftment failures. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts.

Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. For instance, allogeneic bone marrow transplant, the area in which omidubicel is being used, is associated with serious complications, including death. In addition, there are expected toxicities for patients who receive an allogeneic bone marrow transplant, such as infertility. Thus, while not directly associated with omidubicel, there are attendant risks with the space in which our product candidates operate, and any related

investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including, but not limited to:

- · regulatory authorities may suspend or withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to create a REMS, which could include a medication guide outlining the risks of such side
  effects for distribution to patients, a communication plan for healthcare providers and/or other elements to
  assure safe use:
- we may be required to recall a product, change the way a product candidate is administered or conduct additional clinical trials:
- we could be sued and held liable for harm caused to patients:
- the product may become less competitive; and
- · our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

#### **Risks Related to Government Regulation**

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any of our product candidates, and the approval may be for a more narrow indication than we seek or be subject to other limitations or restrictions that limit its commercial profile.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our current or future product candidates meet safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of warnings or a REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of

post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and European Union and requirements of comparable regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and the requirements of additional regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products "off-label" for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- · impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- · suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and

implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We have obtained Breakthrough Therapy Designation for omidubicel for the treatment of hematologic malignancies and may receive it in the future if the clinical data support such a designation for one or more of our other product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our current or future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for omidubicel for the treatment of hematologic malignancies may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for qualification.

We may be unable to maintain the benefits associated with orphan drug designations that we have obtained, including market exclusivity, which may cause our revenue, if any, to be reduced.

We have obtained orphan drug designation for omidubicel from the FDA and the EMA for the treatment of hematologic malignancies, and we may pursue orphan drug designation for certain of our future product candidates. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity the orphan patient population. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This

period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have obtained orphan drug designation for omidubicel from the FDA and the EMA for the treatment of hematologic malignancies, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. Further, orphan drug exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription
  drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these
  entities according to their market share in certain government healthcare programs;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- · a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to
  test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially
  including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, tax legislation enacted on December 22, 2017, titled "an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump

signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA or our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies are subject to changes in healthcare legislation and regulatory initiatives. For example, CMS has developed value-based payment models for a variety of care settings, including the inpatient prospective payment system used for reimbursing inpatient hospital services. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and CMS issued a final rule, effective on July 9, 2019 that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost

disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse, privacy and security and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims
  Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or
  entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for
  payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a
  false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to
  avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical

manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act:

- the Health Insurance Portability and Accountability Act, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf;
- the Food Drug and Cosmetic Act, or the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain
  manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare,
  Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the
  government information related to certain payments and other transfers of value to physicians and teaching
  hospitals, as well as ownership and investment interests held by physicians and their immediate family
  members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to non-U.S. government officials, employees of public international organizations and non-U.S. government owned or affiliated entities, candidates for non-U.S. political office, and non-U.S. political parties or officials thereof; and

 similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- · change in protocol design;
- additional treatment arm (control);
- · recall, replacement, or discontinuance of one or more of our products; and
- · additional recordkeeping.

We face competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from major multinational pharmaceutical companies, established and early-stage biotechnology companies, and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing treatments in the rare disease indications that we are

targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Doctors may recommend that patients undergo stem cell transplantation using cells from matched related donors, matched unrelated donors, haploidentical donors or unmodified umbilical cord blood instead of using omidubicel or our other NAM-derived product candidates. In addition, there are several clinical-stage development programs that seek to improve umbilical cord blood transplantation through the use of ex vivo expansion technologies to increase the quantity of hematopoietic stem cells for use in HSCT or the use of ex vivo differentiation technologies to increase the quantity of hematopoietic progenitor cells for use in HSCT. We are aware of several other companies with product candidates in various stages of development for allogeneic HSCT grafts, including Magenta Therapeutics, Inc., Kiadis Pharma NV, Excellthera and Bellicum Pharmaceuticals Inc., and for NK cells, including AbbVie Inc., Takeda Pharmaceutical Company Limited, Fate Therapeutics, Inc. and Ziopharm Oncology, Inc. In addition, many universities and private and public research institutes may develop technologies of interest to us but license them to our competitors. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than omidubicel or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our preclinical studies and clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to protect, develop and maintain intellectual property rights related to our products;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;
- market perception and acceptance of stem cell therapeutics:
- acceptance of our product candidates by physicians and institutions that perform HSCT procedures;
- the price of our products;
- coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare; and
- our ability to manufacture and sell commercial quantities of any approved products to the market.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. Any inability to successfully compete effectively will adversely impact our business and financial prospects.

Even if we obtain and maintain approval for omidubicel or our other product candidates from the FDA, we may never obtain approval outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by non-U.S. regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA.

However, the failure to obtain approval from the FDA or other regulatory authorities may negatively impact our ability to obtain approval in non-U.S. countries. Sales of omidubicel or our other product candidates outside of the United States will be subject to the regulatory requirements of other jurisdictions governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities in other countries also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product candidates, if approved, is also subject to approval.

We intend to submit a marketing authorization application to the EMA for approval of omidubicel in the European Union, but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the applicable regulatory agency may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for a product candidate may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential omidubicel or our other product candidates will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

We initially intend to seek marketing approval for omidubicel for the treatment of hematologic malignancies. We will train our marketing and sales personnel to not promote our products, if approved, for any other uses outside of any FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. As a result, there may be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved. Furthermore, the use of our products for indications other than those approved by the FDA or any non-U.S. regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA, EMA or any other regulatory body in a jurisdiction in which we operate determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, results of operations and financial condition.

# Risks Related to our Reliance on Third Parties

We rely on third parties to conduct certain elements of our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon, and plan to continue to rely upon, third-party vendors, including CROs, to monitor and manage data for our ongoing preclinical studies and clinical trials. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the vendors and CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with good clinical practice, or GCP, cGMP, the Helsinki Declaration, the International Council for Harmonization Guideline for Good Clinical Practice, applicable European Commission Directives on Clinical Trials, laws and regulations applicable to clinical trials conducted in other territories, good laboratory practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable regulatory authorities for all of our product candidates in clinical development as well as rules and regulations regarding the collection and use of personal data such as the GDPR. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, including GCP and cGMP regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs or vendors terminate, we may not be able to enter into arrangements with alternative CROs or vendors or do so on commercially reasonable terms. In addition, our CROs are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or

terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated, which could adversely affect our results of operations and the commercial prospects for our product candidates, increase our costs and delay our ability to generate revenue.

Replacing or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, we may encounter similar challenges or delays in the future, which could have a material adverse impact on our business, financial condition and prospects.

Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.

We expect to continue to depend on third parties, including independent clinical investigators and CROs, to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers and vendors that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs.

These investigators and CROs will not be our employees and we will not be able to control, other than through contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop.

Investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and an investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as GCP, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with GCP procedures could adversely affect the clinical development of our product candidates and harm our business.

We rely on third parties to supply the raw materials and to provide certain equipment that we and our third-party manufacturer use to create our product candidates. Our business could be harmed if existing and prospective third parties fail to provide us with sufficient quantities of these materials and equipment or fail to do so at acceptable quality levels or prices.

We rely on a limited number of suppliers to provide the raw materials other than cord blood (serum and growth factor) needed to produce our product candidates. We have a relationship with a single supplier, Miltenyi Biotec GmbH, for certain equipment (columns and beads) necessary to create our product candidates. We do not currently have an agreement with Miltenyi Biotec GmbH and there can be no assurance we will be successful in entering into an agreement that would provide for a reliable supply of columns and beads necessary to create our product candidates.

We do not have any control over the availability of these raw materials or pieces of equipment. If we or our providers are unable to purchase these raw materials or equipment on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our

product candidates or any future product candidates, could be delayed or there could be a shortage in supply, which could impair our ability to meet our development objectives for our product candidates or generate revenue from the sale of any approved products.

Even following our establishment of our own planned cGMP-compliant manufacturing capabilities, we intend to continue to rely on third-party suppliers for these raw materials and pieces of equipment, which will expose us to risks including:

- failure of any supplier to become or maintain its status as a cGMP-compliant manufacturer of raw materials, which status is a prerequisite to our attainment of a BLA for omidubicel and our other product candidate;
- termination or nonrenewal of supply or service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the supplier or service provider.

We expect to utilize a third party to conduct our product manufacturing, in whole or in part, for the next three to five years. Therefore, we are subject to the risk that this third party may not perform satisfactorily.

Until such time as we establish a manufacturing facility that has been properly validated to comply with FDA cGMP requirements, we will not be able to independently manufacture sufficient material for our planned clinical programs or commercialization thereof upon receipt of regulatory approval. Although we currently produce omidubicel and our other product candidate at our Jerusalem, Israel, facility, we currently rely on only one third-party manufacturer, Lonza Walkersville, Inc., or Lonza U.S., for a portion of the production of omidubicel for our ongoing clinical trials. In the event that this third-party manufacturer does not successfully carry out its contractual duties, meet expected deadlines or manufacture omidubicel in accordance with regulatory requirements, or if there are disagreements between us and this third-party manufacturer, we may not be able to complete, or may be delayed in completing, the clinical trials required for approval of omidubicel. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, which could cause delay or increased expense prior to the approval of omidubicel and could thereby have a material adverse effect on our business, financial condition and results of operations.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Additionally, our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of product candidates for clinical trials could delay the initiation or completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting commercial manufacturing of our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more

costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our product candidate supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our product candidates and could have a material adverse effect on our business, prospects, financial condition and results of operations.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize omidubicel or our other product candidates if and when regulatory approval is obtained. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of product manufacture.

Our reliance on third parties requires us to share our trade secrets and other intellectual property, which increases the possibility that a competitor will discover them or that our trade secrets and other intellectual property will be misappropriated or disclosed.

Because we rely on third parties to provide us with the materials that we use to develop and manufacture our product candidates, we may, at times, share trade secrets and other intellectual property with such third parties. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets and intellectual property. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Despite our efforts to protect our trade secrets, our competitors or other third parties may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. A competitor's or other third party's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition, results of operations and prospects.

We face a variety of challenges and uncertainties associated with our dependence on the availability of human umbilical cord blood units, or CBUs, at cord blood banks for the manufacture of omidubicel.

CBUs are one of the raw materials for the manufacture of omidubicel. The CBUs currently used in the manufacture of omidubicel are procured directly by the clinical cell processing facilities from cord blood banks, which hold more than 800,000 CBUs that were donated, processed and cryopreserved. However, the availability of CBUs for the manufacture of omidubicel depends on a number of regulatory, political, economic and technical factors outside of our control, including:

- · government policies relating to the regulation of CBUs for clinical use;
- · the availability of government funding for cord blood banks;
- individual cord blood bank policies and practices relating to CBU acquisition and banking;
- the pricing of CBUs;
- the methods used in searching for and matching CBUs to patients, which involve emerging technology related to current and future CBU parameters that guide the selection of an appropriate CBU for transplantation; and
- methods for the procurement and shipment of CBUs and their handling and storage at clinical sites.

Additionally, we do not have control over the supply, availability, price or types of CBUs that these third parties use in the manufacture of omidubicel. We rely heavily on these clinical cell processing

facilities to procure CBUs from cord blood banks that are compliant with government regulations and within the current standard of care. In addition, we may identify specific characteristics of CBUs, such as their volume and red blood cell content that may limit their ability to be used to manufacture omidubicel even though these CBUs may otherwise be suitable for use in allogeneic transplant. As a result, the requirement for CBUs to meet our specifications may limit the potential inventory of CBUs eligible for use in the manufacture of omidubicel. There is a large variability in the tests, methods and equipment utilized by the cord blood banks in the testing of the CBUs before storage. This could be resulted in CBUs that would be found unsuitable for production after their arrival to the manufacturing site.

In the United States, cord blood banks are required to file a BLA and to meet certain continued regulatory requirements, in order to bank and provide CBUs for transplantation. Despite this requirement, most of the cord blood banks in the United States are not licensed. Additionally, CBUs from a cord blood bank that maintains a BLA are considered to be licensed and have a product label describing their intended use only from the time the license was provided by the FDA. While the FDA currently allows unlicensed CBUs to be used for transplantation and we have used unlicensed CBUs in the manufacture of omidubicel for our clinical trials, the FDA may later prohibit the use of unlicensed CBUs for transplantation. Additionally, although CBUs from non-U.S. cord blood banks, which are generally unlicensed, are currently available in the United States for use in transplantation and we have used CBUs from non-U.S. cord blood banks in our clinical trials, changes in U.S. and non-U.S. regulations may prohibit or limit the future use of non-U.S. CBUs in the United States. Any inability to procure adequate supplies of CBUs will adversely impact our ability to develop and commercialize omidubicel.

### **Risks Related to Our Intellectual Property**

If we are unable to obtain, maintain or protect intellectual property rights related to any of our product candidates or any future product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We have sought to protect our proprietary position by filing patent applications in the United States and in other countries, with respect to our novel technologies and product candidates, which are important to our business. Patent prosecution is expensive and time consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development activities before it is too late to obtain patent protection.

Further, the patent position of biopharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsettled. This renders the patent prosecution process particularly expensive and time-consuming. There is no assurance that all potentially relevant prior art relating to our patent applications has been found and that there are no material defects in the form, preparation, or prosecution of our patent applications, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad, which may result in such patents being narrowed, found unenforceable or invalidated. For example, we may be subject to a third party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review, or IPR, or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Furthermore, even if they are unchallenged, our patent applications and any future patents may not adequately protect our intellectual property, provide exclusivity for our product

candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If we cannot obtain and maintain effective patent rights for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

In addition to the protection afforded by any patents that have been or may be granted, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data, trade secrets and intellectual property by maintaining the physical security of our premises and physical and electronic security of our information technology systems. Notwithstanding these measures, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants and other third parties who may be involved in the development of intellectual property for us to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that we have entered into such agreements with all applicable third parties or that all such agreements have been duly executed. Even if we have entered into such agreements, we cannot assure you that our counterparties will comply with the terms of such agreements or that the assignment of intellectual property rights under such agreements is self-executing. We may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We also cannot assure you that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets and intellectual property could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Any of the foregoing could significantly harm our business, results of operations and prospects.

Patent reform legislation and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unsettled, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed new and untested regulations and procedures to

govern the full implementation of the Leahy-Smith Act and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions only became effective in March 2013. Prior to March 2013, in the United States, the first to invent was entitled to the patent. As of March 2013, assuming the other requirements for patentability are met, the first to file a patent application is generally entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. Any inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or that we may obtain in the future. Further, the laws of some countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. Any of the foregoing could significantly harm our business, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidate. Such litigation or licenses could be costly or not available on commercially reasonable terms.

It is inherently difficult to conclusively assess our freedom to operate without infringing on or otherwise violating third-party rights. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our product candidates or elements thereof, or our manufacturing or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or our product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may also be pending patent applications that if they result in issued patents, could be alleged to be infringed by our product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed, we may be forced to cease the development and commercialization of and otherwise abandon our product candidates, or we may need to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing to which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidates or the use of our product candidates. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully defend, settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing of our product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our product candidates that are held to be infringing. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe the third-party intellectual property rights, which may not be commercially feasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and otherwise significantly harm our business, results of operations and prospects.

### Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringing or otherwise violating the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, post grant review, IPR, and reexamination proceedings before the USPTO and corresponding non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties or other intellectual property claims.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of

manufacture, or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any materials formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture, or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares. Any of the foregoing could significantly harm our business, results of operations and prospects.

### We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may require the use of intellectual property or proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, or use these intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions, some of which provide that the applicable institution will own certain rights in any technology developed thereunder. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully

obtain rights to required third-party intellectual property rights, we may have to abandon development of that program and our business and financial condition could suffer.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our intellectual property or that of our licensors that we may acquire in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post grant review, inter partes review, or IPR, and equivalent proceedings in non-U.S. jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares. Any of the foregoing could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in

defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could significantly harm our business, results of operations and prospects.

#### We may be subject to claims challenging the inventorship of our intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in or right to compensation with respect to our current patent and patent applications, future patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. To the extent that our employees have not effectively waived the right to compensation with respect to inventions that they helped create, they may be able to assert claims for compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful which in turn could impact our future profitability, business, results of operations and prospects.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patent Law). Although we generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or third-party service providers to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals

to help us comply. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

### We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant non-U.S. markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

# Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited.

Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including biosimilar and generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

### Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to invent the inventions covered by our patents or the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

#### **Risks Related to Our Business Operations**

Our future success depends in part on our ability to retain our senior management team and to attract, retain and motivate other qualified personnel.

We are highly dependent on the members of our senior management team. The loss of their services without a proper replacement may adversely impact the achievement of our objectives. Our employees may leave our employment at any time. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled personnel in our industry, which is likely to continue for the foreseeable future. This is particularly the case in Israel and Boston, Massachusetts, where our operations are focused. As a result, competition for skilled personnel is intense, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of any members of our senior management team without proper replacement, may impede the progress of our research, development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and legal personnel. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenue.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. For instance, we made the decision to prioritize the development of omidubicel for the treatment of hematologic malignancies over SCD because omidubicel is at a more advanced stage of development, while our sickle cell program remains exploratory. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected.

We may not be successful in our efforts to identify, discover or license additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of omidubicel, the success of our business also depends upon our ability

to identify, discover or license additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that such product may become unprofitable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

# Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, non-U.S. governments, extra-state actors and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our drug candidates could be delayed.

We incur significant increased costs as a result of operating as a public company in the United States, and our management is required to devote substantial time to new compliance initiatives.

As a public company whose ordinary shares are listed in the United States, we are subject to an extensive regulatory regime, requiring us, among other things, to maintain various internal controls and

facilities and to prepare and file periodic and current reports and statements, including reports on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. Complying with these requirements is costly and time consuming. In the event that we are unable to demonstrate compliance with our obligations as a public company in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission, or the SEC, or The Nasdaq Global Market, and investors may lose confidence in our operating results and the price of our ordinary shares could decline.

Our independent registered public accounting firm is not engaged to perform an audit of our internal control over financial reporting, and as long as we remain an emerging growth company, as such term is defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will be exempt from the requirement to have an independent registered public accounting firm perform such audit. Accordingly, no such opinion was expressed or will be expressed any during any such period. Once we cease to qualify as an emerging growth company our independent registered public accounting firm will be required to attest to our management's annual assessment of the effectiveness of our internal controls over financial reporting, which will entail additional costs and expenses.

Furthermore, we are only in the early stages of determining formally whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. These controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

In addition, we intend to organize significant management functions in Boston, Massachusetts, where business expenses and salaries may exceed the level of our business expenses in Israel.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States or Israel.

Other than our headquarters and other operations which are located in Israel (as further described below), we currently have limited international operations, but our business strategy incorporates potentially significant international expansion, particularly in anticipation of approval of our product candidates. We plan to retain sales representatives and third-party distributors and conduct physician, infectious disease specialist, hospital pharmacist and patient association outreach activities, as well as clinical trials, outside of the United States, EU and Israel. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits, and licenses;
- failure by us to obtain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent or other intellectual property rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- · difficulties in staffing and managing international operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, prince controls or patient self-pay systems;
- · limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

### We may be subject to extensive environmental, health and safety, and other laws and regulations in multiple jurisdictions.

Our business involves the controlled use, directly or indirectly through our service providers, of hazardous materials, various biological compounds and chemicals; therefore, we, our agents and our service providers may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or non-U.S. laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits or licenses required pursuant to such laws and regulations. For instance, we have undergone inspections and obtained approvals from various governmental agencies. We hold a general business license from the City of Jerusalem that is valid until December 31, 2022. We also hold a toxic substances permit from the Ministry of Environmental Protection (the Hazardous Material Division) and a Certificate of GMP Compliance of a Manufacturer from the Israeli Ministry of Health – Pharmaceutical Administration. Failure to renew any of the foregoing licenses and permits may harm our on-going and future operations. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of our business license or, required environmental or other permits or consents.

## Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees and independent contractors. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, including individually identifiable information, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates. If our operations are found to be in violation of any of these laws, we may be subject to significant penalties, including civil, criminal and administrative

penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Under current Israeli law, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We generally enter into non-competition agreements with our key employees, in most cases within the framework of their employment agreements. These agreements prohibit our key employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under applicable Israeli law, we may be unable to enforce these agreements or any part thereof. If we cannot enforce our non-competition agreements with our employees, then we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

#### Risks Related to Commercialization of Our Product Candidates

We do not have experience producing our product candidates at commercial levels or establishing a cGMP manufacturing facility and may not obtain the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.

We do not currently have the experience or ability to manufacture our product candidates at commercial levels. We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. We also have not completed all of the characterization and validation activities necessary for commercialization and regulatory approvals. If we do not conduct all such necessary activities, our commercialization efforts will be delayed or halted.

We also may encounter problems hiring and retaining the experienced specialist scientific, quality control and manufacturing personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies, which could limit our access to additional attractive development programs. Problems in our manufacturing process or facilities also could restrict our ability to meet market demand for our product candidates.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Our projections of the number of people who have the potential to benefit from treatment with our product candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics or market research, and may prove to be incorrect. Our target patient population may be lower than expected, may not be otherwise amenable to treatment with our product candidate or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. In addition, medical advances may reduce our target markets. For example, new processes and advances in oral antibiotic medications or new operative procedures may limit the need for localized

delivery systems like our product candidates. Further, advances in treatments in the fields in which we are conducting research programs that reduce side effects and have better deliverability to target organs may limit the market for our future product candidates.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any product revenue.

Although we recently hired a chief commercialization officer to lead our efforts to commercialize omidubicel should it receive regulatory approval, we currently have no sales and marketing organization, and we have no experience selling and marketing our product candidates. To successfully commercialize any product candidates that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization independently or by utilizing experienced third parties with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets, all of which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our ability to commercialize our product candidates.

Further, given our lack of prior experience in marketing and selling pharmaceutical products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire sales representatives and third-party distributors to adequately support the commercialization of our product candidates, or we may incur excess costs if we hire more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. We also may enter into collaborations with large pharmaceutical companies to develop and commercialize product candidates. If our future collaborators do not commit sufficient resources to develop and commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We may compete with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community, including physicians, hospital pharmacists and infectious disease specialists, and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If any of our product candidates are approved, but fail to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenue from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Delays in establishing and obtaining regulatory approval of our manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

We intend to establish our own cGMP compliant manufacturing facility. Building our own manufacturing facility will require additional investment, will be time-consuming and may be subject to delays, including because of shortage of labor or compliance with regulatory requirements. In addition, building a manufacturing facility may cost more than we currently anticipate. Delays or problems in the build out of our manufacturing facility may adversely impact our ability to provide supply for the development and commercialization of omidubicel as well as our financial condition.

Before we can begin to commercially manufacture omidubicel or any product candidate, whether in a third-party facility or in our own facility, once established, we must obtain regulatory approval from FDA for our manufacturing process and facility. A manufacturing authorization must also be obtained from the appropriate regulatory authorities in the European Union, Israel and worldwide. In addition, we must pass a pre-approval inspection of our manufacturing facility by the FDA before omidubicel or any product

candidate can obtain marketing approval. In order to obtain approval, we will need to ensure that all of our processes. methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. For example, a recent cGMP audit by the Israeli Ministry of Health, or MOH, of the manufacturing process in the facility of our contract manufacturer of omidubicel resulted in certain critical observations, which we have been working with our contract manufacturer to address. There can be no guarantee, however, that future inspections by regulatory authorities of our manufacturing facilities or those of our contract manufacturers will result in MOH's agreement that these critical observations have been resolved or that similar inspectional observations will not be identified. If we do not demonstrate to the satisfaction of the applicable regulator that our manufacturing facilities, or those of our contract manufacturers, are in compliance with applicable requirements, we may be materially delayed in the development of our product candidates, which would materially harm our business. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

If we receive marketing approval for our product candidates, sales will be limited unless the product achieves broad market acceptance by physicians, patients, third-party payors, hospital pharmacists, infectious disease specialists and others in the medical community.

The commercial success of our product candidates will depend upon the acceptance of the product by the medical community, including physicians, patients, healthcare payors, hospital pharmacists and infectious disease specialists. The degree of market acceptance of any approved product will depend on a number of factors, including:

- the demonstration of clinical safety and efficacy of our product candidates in clinical trials;
- the efficacy, potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the prevalence and severity of any adverse side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- distribution and use restrictions imposed by the FDA or agreed to by us as part of a mandatory or voluntary risk management plan;
- our ability to obtain third-party payor coverage and adequate reimbursement for procedures utilizing our products;
- · the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage;
- the demonstration of the effectiveness of our product candidates in reducing the cost of treatment;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of products and their ability to meet market demand; and
- publicity concerning our product candidates or competing products and treatments.

There are a number of alternatives to our NAM based product candidates, including stem cell transplantation using cells from matched related donors, matched unrelated donors, haploidentical donors or unmodified umbilical cord blood. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients, healthcare payors, hospital pharmacists and

infectious disease specialists, we may not generate sufficient revenue from the product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

It may be difficult for us to profitably sell our product candidates if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures that may affect reimbursement, market acceptance and sales of our product candidates, if approved, will depend on, in part, the extent to which the procedures utilizing our product candidates, performed by health care providers, will be covered by third-party payors, such as government health care programs, commercial insurance and managed care organizations. Our product candidates will be purchased or provided by health care providers for utilization in certain surgical procedures. In the event health care providers and patients accept our product candidates as medically useful, cost effective and safe, there is uncertainty regarding whether our product candidates will be directly reimbursed, reimbursed through a bundled payment or if the product candidates will be included in another type of value-based reimbursement program. Third-party payors determine the extent to which new products will be covered as a benefit under their plans and the level of reimbursement for any covered product or procedure that may utilize a covered product. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

A primary trend in the U.S. healthcare industry and elsewhere has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Third-party payors decide which products and procedures they will pay for and establish reimbursement and co-payment levels. Government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. We cannot be sure that coverage will be available for our product candidates, if approved, or, if coverage is available, the level of direct or indirect reimbursement.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit or part of a covered benefit under its health plan;
- safe, effective and medically necessary;
- · appropriate for the specific patient;
- · cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement are typically made by The Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent products, and the procedures that utilize such products, will be covered and reimbursed under Medicare. Private payors may follow CMS, but have their own methods and approval processes for determining reimbursement for new

products and the procedures that utilize such products. It is difficult to predict what CMS as well as other payors will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

In addition, under current Medicare hospital inpatient reimbursement policies CMS offers a process whereby manufacturers may apply for the temporary add-on payment program, or NTAP, for a new medical technology when the applicable Diagnosis-Related Group, or DRG, based inpatient prospective payment rate is inadequate to cover the cost of a new product. As part of our commercialization efforts, we intend to apply for omidubicel to be eligible under the NTAP program. To obtain add-on payment, a technology must be considered "new," represent an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries, and data reflecting the cost of the new technology must not yet be available in the data used to recalibrate the DRGs and the sponsor much show that admissions involving the furnishing of the technology exceed cost thresholds established by CMS for each applicable DRG. If an application is approved, new technology add-on payments are made to hospitals for no less than two years and no more than three years. We must demonstrate the safety and effectiveness of our technology to the FDA in addition to meeting CMS's requirements for the NTAP program before add-on payments can be made, and we cannot assure that CMS will agree to provide such incremental payments for omidubicel or any of our other product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States. Similarly, health care providers enter into participation agreements with third-party payors wherein reimbursement rates are negotiated. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, we cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved or procedures utilizing such products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material effect on our business, financial condition, results of operations or prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our share price. We do not currently have product liability insurance and do not anticipate obtaining product liability insurance until such time as we have received FDA or other comparable authority approval for a product and there is a product that is being provided to patients outside of clinical trials. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business.

### Risks Related to this Offering and Ownership of Our Ordinary Shares

### Our executive officers, directors and principal shareholders will maintain the ability to exert significant control over matters submitted to our shareholders for approval.

Assuming the sale by us of 4,040,000 ordinary shares in this offering (or 4,646,000 shares if the underwriters exercise their option to purchase additional shares in full), our executive officers, directors and principal shareholders who owned more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own as of June 4, 2019, shares representing approximately 75.5% (or 73.9% if the underwriters exercise their option to purchase additional shares in full) of our share capital. As a result, if these shareholders were to act together, they would be able to control all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in management of our company that our public shareholders disagree with.

# If you purchase our ordinary shares in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The public offering price of our ordinary shares will be substantially higher than the net tangible book value per share of our ordinary shares. Therefore, if you purchase ordinary shares in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding options and warrants are exercised, you will incur further dilution. Based on an assumed public offering price of \$7.47 per share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, you will experience immediate dilution of \$6.07 per share, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the assumed public offering price. In addition, purchasers of ordinary shares in this offering will have contributed approximately 13.7% of the aggregate price paid by all purchasers of our shares but will own only approximately 13.8% of our ordinary shares outstanding after this offering.

## The market price of our ordinary shares has been and may continue to be highly volatile, which could result in substantial losses for purchasers of our ordinary shares in this offering.

The trading price of our ordinary shares is likely to be volatile. The stock market in general, and the market for pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to resell your ordinary shares at or above the public offering price. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our ordinary shares:

- inability to obtain the approvals necessary to commence further clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approvals or the failure to obtain them, or specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to any candidate product in any of our platforms:
- any adverse changes to our relationship with manufacturers or suppliers, especially manufacturers of candidate products;
- any intellectual property infringement, misappropriation or other actions in which we may become involved;

- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of, or involvement in, litigation;
- any changes in our board of directors or management; and
- legislation relating to the sale or pricing of pharmaceuticals in jurisdictions in which we market, or intend to market, our products.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our shares to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

## Sales of a substantial number of shares of our ordinary shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of shares of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ordinary shares. All of the shares owned by our directors and officers are subject to lock-up agreements with the underwriters of this offering that restrict such shareholders' ability to transfer our ordinary shares for at least 90 days from the date of this prospectus. All of our outstanding shares held by our directors and officers will become eligible for unrestricted sale upon expiration of the lockup period, as described in the section of this prospectus entitled "Underwriting." Sales of shares by these shareholders could have a material adverse effect on the trading price of our ordinary shares. Moreover, as of June 4, 2019, holders of an aggregate of 17,792,090 ordinary shares have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in the "Underwriting" section of this prospectus.

# Our management will have broad discretion in the use of the net proceeds from this offering and may allocate the net proceeds from this offering in ways that you and other shareholders may not approve.

Our management will have broad discretion in the use of the net proceeds, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure of our management to use these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities and depositary institutions. These investments may not yield a favorable return to our shareholders.

## If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment

company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business. Based upon the value of our assets, including any goodwill, and the nature and composition of our income and assets, we do not believe that we were classified as a PFIC for the taxable year ended December 31, 2018 and we do not believe that we will be classified as a PFIC for the taxable year ending December 31, 2019 or in the immediately foreseeable future. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ended December 31, 2018, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

The tax consequences that would apply if we are classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

# If a United States person is treated as owning at least 10% of our shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes one or more U.S. subsidiaries, certain of our current or future non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are or are not treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of the controlled foreign corporation's "Subpart F income", "global intangible low-taxed income" and investments in U.S. property, whether or not such controlled foreign corporation makes any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. A failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our current or future non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult their own advisors regarding the potential application of these rules to its investment in the shares.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. For example, the Tax Act introduced a comprehensive set of tax reforms. We continue to assess the impact of such tax reform legislation on our business and may determine that changes to our structure, practice or tax positions are necessary in light of the Tax Act. Certain impacts of this legislation have been taken into account in our financial statements, including the reduction of the U.S. corporate income tax rate from the previous top marginal rate of 35 percent to a flat rate of 21 percent. The Tax Act in conjunction with the tax laws of other jurisdictions in which we operate, however, may require consideration of changes to our structure and the manner in which we conduct our business. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

If tax authorities in any of the countries in which we operate were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

The tax benefits that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, once we begin to produce revenue. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is set at 23% in 2018 and thereafter. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we will receive, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Preferred Enterprise" is entitled to may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we will pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our ordinary shares will be investors' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes.

If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could decline.

The trading market for our ordinary shares is influenced by the research and reports that industry or securities analysts publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will continue to cover us or provide favorable coverage. If any of the analysts who cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of otherwise applicable Nasdaq requirements, and we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports.

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of those otherwise required by the Nasdaq Stock Market for domestic U.S. issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The Nasdaq Global Market may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers.

As a foreign private issuer, we are exempt from the rules and regulations under the Securities Exchange Act of 1934, or the Exchange Act, related to the furnishing and content of proxy statements, including the applicable compensation disclosure requirements. Nevertheless, pursuant to regulations promulgated under the Israeli Companies Law, 5759-1999, or the Israeli Companies Law or the Companies Law, we are required to disclose the annual compensation of our five most highly compensated office holders on an individual basis. Such disclosure is not as extensive as that required of a U.S. domestic issuer. Our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our shares are owned by U.S. residents and a majority of our directors or executive officers are U.S. citizens or residents or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not emerging growth companies.

For as long as we remain an emerging growth company we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited condensed consolidated interim financial statements, with correspondingly
- not being required to comply with the auditor attestation requirements in the assessment of our internal control
  over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting
  Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing
  additional information about the audit and the financial statements;
- · reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (1) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (2) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (3) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide holders of our ordinary shares may be different than the information you might receive from other public companies in which you hold equity. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. However, given that we currently report and expect to continue to report under IFRS as issued by the IASB, the extended transition period available to emerging growth companies that report under GAAP is inapplicable to us.

When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We must meet the Nasdaq Global Market's continued listing requirements and comply with the other Nasdaq rules, or we may risk delisting. Delisting could negatively affect the price of our ordinary shares, which could make it more difficult for us to sell securities in a financing and for you to sell your ordinary shares.

We are required to meet the continued listing requirements of the Nasdaq Global Market and comply with the other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum shareholders' equity, minimum share price and certain other corporate governance requirements. If we do not meet these continued listing requirements, our ordinary shares could be delisted. Delisting of our ordinary shares from the Nasdaq Global Market would cause us to pursue eligibility for trading on other markets or exchanges, or on the pink sheets. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, our ordinary shares would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our ordinary shares, if delisted from the Nasdaq Global Market in the future, would be listed on a national securities exchange or quoted on a national quotation service, the OTCBB or the pink sheets. Delisting from the Nasdaq Global Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our ordinary shares, reduce security analysts' coverage of us and diminish investor.

supplier and employee confidence. In addition, as a consequence of any such delisting, our share price could be negatively affected and our shareholders would likely find it more difficult to sell, or to obtain accurate quotations as to the prices of, our ordinary shares.

### Risks Related to Israeli Law and Our Operations in Israel

Our headquarters and other significant operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military conditions in Israel.

Our executive offices are located in Jerusalem, Israel. Also, it is expected that all of our manufacturing operations will be located at Israel. In addition, a number of our officers and directors are residents of Israel, Accordingly, political. economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, as well as terrorist acts committed within Israel by hostile elements. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. During November 2012 and from July through August 2014, Israel was engaged in an armed conflict with a militia group and political party who controls the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. In December 2008 and January 2009 there was an escalation in violence among Israel, Hamas, the Palestinian Authority and other groups, as well as extensive hostilities along Israel's border with the Gaza Strip, which resulted in missiles being fired from the Gaza Strip into Southern Israel. Similar hostilities accompanied by missiles being fired from the Gaza Strip into Southern Israel, as well at areas more centrally located near Tel Aviv and at areas surrounding Jerusalem, occurred during November 2012 and July through August 2014. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula following the resignation of Hosni Mubarak as president. This included protests throughout Egypt, and the appointment of a military regime in his stead, followed by the elections to parliament which brought groups affiliated with the Muslim Brotherhood (which had been previously outlawed by Egypt), and the subsequent overthrow of this elected government by a military regime. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria, which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated, and chemical weapons have been used in the region. Foreign actors have and continue to intervene in Syria. This instability and any intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries and may have the potential for additional conflicts in the region. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran also has a strong influence among extremist groups in the region, including Hamas in Gaza, Hezbollah in Lebanon and various rebel militia groups in Syria. These situations have escalated at various points in recent years and may escalate in the future to more violent events, which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot

assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could also adversely impact our business.

## Our operations may be disrupted as a result of the obligation of management or key personnel or consultants to perform military service.

Many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, financial condition and results of operations.

## Because we incur a portion of our expenses in currencies other than the U.S. dollar, our financial condition and results of operations may be harmed by currency fluctuations and inflation.

While our reporting and functional currency is the U.S. dollar, we pay a meaningful portion of our expenses in NIS, Euros and other currencies. All of the salaries of our employees, our general and administrative expenses (including rent for our real property facility in Israel), and the fees that we pay to certain of our partners, are denominated in NIS. Certain of our suppliers are located in Europe and are paid in Euros. As a result, we are exposed to the currency fluctuation risks relating to the denomination of our future expenses in U.S. dollars. More specifically, if the U.S. dollar becomes devalued against the NIS or the Euro, our NIS- or Euro- denominated expenses will be greater than anticipated when reported in U.S. dollars. Inflation in Israel compounds the adverse impact of such devaluation by further increasing the amount of our Israeli expenses. Israeli inflation may also (in the future) outweigh the positive effect of any appreciation of the U.S. dollar relative to the NIS, if, and to the extent that, it outpaces such appreciation or precedes such appreciation. The Israeli rate of inflation has not had a material adverse effect on our financial condition during 2016, 2017 or 2018. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS or the Euro and other non-U.S. currencies in relation to the U.S. dollar (and/or from inflation of such non-U.S. currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or in Europe or the rate of devaluation (if any) of the U.S. dollar against the NIS or the Euro.

# Provisions of Israeli law and our amended and restated articles of association may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Certain provisions of Israeli law and our amended and restated articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, our amended and restated articles of association provide that our directors are elected on a staggered basis, such that a potential acquirer cannot readily replace our entire board of directors at a single annual general shareholder meeting. In addition, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a company are purchased. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to certain mergers, Israeli tax law may impose certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger.

Furthermore, under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations and guidelines promulgated thereunder, or the Innovation Law, to which we are subject due to our receipt of grants from the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS), a recipient of IIA grants such as us must report to IIA regarding any change of control of our company or regarding any change in the holding of the means of control of our company which results in any non-Israeli citizen or resident becoming an "interested party", as defined in the Innovation Law, in our company, and in the latter event, the non-Israeli citizen or resident will be required to execute an undertaking in favor of IIA, in a form prescribed by IIA, acknowledging the restrictions imposed by such law and agreeing to abide by its terms.

Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws against us, or our executive officers and directors or asserting U.S. securities laws claims in Israel.

Not all of our directors or officers are residents of the United States and most of their and our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us or our non-U.S. our directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our non-U.S. officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors.

Moreover, among other reasons, including but not limited to, fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

Your liabilities and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the U.S. law that governs the liabilities and responsibilities of shareholders of U.S. corporations.

We are incorporated under Israeli law. The rights and responsibilities of holders of our ordinary shares are governed by our amended and restated articles of association and the Companies Law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S. corporations. In particular, pursuant to the Companies Law each shareholder of an Israeli company has to act in good faith in exercising his or her rights and fulfilling his or her obligations toward the Company and other shareholders and to refrain from abusing his or her power in the Company, including, among other things, in voting at the general meeting of shareholders and class meetings, on amendments to a company's articles of association, increases in a company's authorized share capital, mergers, and transactions requiring shareholders' approval under the Companies Law. In addition, a controlling shareholder of an Israeli company or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or who has the power to appoint or prevent the appointment of a director or officer in the Company, or has other powers toward the Company has a duty of fairness toward the Company. However, Israeli law does not define the substance of this duty of fairness. Because Israeli corporate law has undergone extensive revision in recent years, there is little case law available to assist in understanding the implications of these provisions that govern shareholder behavior.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

All statements other than present and historical facts and conditions contained in this prospectus, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. The words "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "might," "ongoing," "objective," "plan," "potential," "predict," "should," "will" and "would," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the timing and conduct of our clinical trials of omidubicel, GDA-201 and our other product candidates, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of omidubicel, GDA-201 and our other product candidates;
- our plans regarding utilization of regulatory pathways that would allow for accelerated marketing approval in the United States, the European Union and other jurisdictions;
- our expectations regarding timing for application for and receipt of regulatory approval for any of our product candidates;
- our recurring losses from operations, which raised substantial doubt regarding our ability to continue as a going concern absent access to sources of liquidity;
- · our ongoing and planned discovery and development of product candidates;
- our expectations regarding future growth, including our ability to develop, and obtain regulatory approval for, new product candidates;
- our expectations regarding when certain patents may be issued and the protection and enforcement of our intellectual property rights;
- our plans to develop and commercialize our product candidates;
- our estimates regarding the market opportunity for our product candidates;
- · our ability to maintain relationships with certain third parties;
- · our estimates regarding anticipated capital requirements and our needs for additional financing;
- our planned level of capital expenditures;
- our expectations regarding licensing, acquisitions and strategic partnering;
- · our expectations regarding the maintenance of our foreign private issuer status;
- the impact of government laws and regulations; and
- our expectations regarding the use of proceeds from this offering.

As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward- looking statements by these cautionary statements.

This prospectus may contain market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date the statements were made, and while we believed such information formed a reasonable basis for such statements at the time they were made, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

### **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of ordinary shares in this offering will be approximately \$27.7 million, after deducting the estimated underwriting discount and estimated offering expenses payable by us, based on an assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019. If the underwriters exercise their option to purchase up to an additional 606,000 ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately \$31.9 million, after deducting the estimated underwriting discount and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed public offering price of \$7.47 per ordinary share would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discount and estimated offering expenses payable by us, by \$3.80/(3.80) million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of ordinary shares we are offering. An increase (decrease) of 1.0 million in the number of ordinary shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discount and estimated offering expenses payable by us, by \$7.02/(7.02) million, assuming the assumed public offering price stays the same.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, available for sale and short-term deposits, as follows:

- approximately \$15.0 million to \$20.0 million to fund further clinical development of our product candidates, including the completion of our pivotal Phase 3 clinical trial of our lead product candidate, omidubicel, and the preparation of a Biologics Licensing Application for omidubicel for the treatment of hematologic malignancies;
- approximately \$5.0 million to \$10.0 million to expand our commercial manufacturing capabilities; and
- the balance for other general corporate purposes, including general and administrative expenses and working capital.

We may also use a portion of the net proceeds from this offering to acquire or invest in complementary products, technologies or businesses, although we have no present agreements or commitments to do so.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. Due to the uncertainties inherent in the clinical development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for any of the above purposes on a stand-alone basis. Amounts and timing of our actual expenditures will depend upon a number of factors, including our sales, marketing and commercialization efforts, regulatory approval and demand for our product candidates, operating costs and other factors described under "Risk Factors" in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Pending our application of the net proceeds from this offering, we plan to invest such proceeds in short-term, investment-grade, interest-bearing securities and depositary institutions.

### **DIVIDEND POLICY**

We have never declared or paid any cash dividends to our shareholders of our ordinary shares, and we do not anticipate or intend to pay cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors in compliance with applicable legal requirements and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

The Israeli Companies Law imposes further restrictions on our ability to declare and pay dividends. See "Description of Share Capital — Dividend and Liquidation Rights" for additional information.

Payment of dividends may be subject to Israeli withholding taxes. See "Taxation — Material Israeli Tax Considerations" for additional information.

### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents, available-for-sale financial assets and short-term deposits and capitalization as of March 31, 2019, on:

- · an actual basis; and
- an as adjusted basis to give further effect to the sale of 4,040,000 ordinary shares in this offering at the assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, after deducting the underwriting discounts and commissions and estimated offering expenses payable to us.

The as adjusted data included in the table below is also unaudited. You should read this information together with our condensed consolidated financial statements appearing elsewhere in this prospectus and the information set forth under the headings "Selected Financial Data," "Use of Proceeds" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of March 31, 2019			
	Actual		As Adjusted	
	(unaudited) (in thousands)			
Cash and cash equivalents, available-for-sale financial assets and short-term deposits $^{(1)}$	\$	50,406	\$	78,074
Shareholders' equity:				
Ordinary shares of NIS 0.01 par value: 100,000,000 shares authorized, actual; 100,000,000 shares authorized as adjusted; 25,140,048 shares issued and		60		70
outstanding, actual; 29,180,048 shares issued and outstanding, as adjusted <sup>(1)</sup>		68		79
Share premium		197,967		225,624
Capital reserve due to actuarial gains		(160)		(160)
Available for sale reserve		(10)		(10)
Accumulated deficit		(184,720)		(184,720)
Total shareholders' equity <sup>(1)</sup>		13,145		40,813
Total capitalization <sup>(1)</sup>	\$	13,145	\$	40,813

<sup>(1)</sup> Data presented on an as adjusted basis to give effect to the sale of 4,040,000 ordinary shares in this offering at the assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares as The Nasdaq Global Market on June 20, 2019, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The number of ordinary shares issued and outstanding, actual and as adjusted shown in the foregoing table and calculations excludes:

- 3,742,416 ordinary shares reserved for issuance upon the exercise of outstanding options as of March 31, 2019, at a weighted average exercise price of \$4.21 per share;
- 456,344 ordinary shares reserved for future issuance under our 2017 Share Incentive Plan, as of March 31, 2019, as well as any automatic increases in the number of common shares reserved for future issuance under this plan;
- 466,375 ordinary shares issued upon the exercise of options after March 31, 2019; and
- 3,313,512 ordinary shares issuable upon the exercise of outstanding warrants to purchase ordinary shares, at a weighted average exercise price of \$6.72 per share, which warrants are expected to remain outstanding at the consummation of this offering.

#### **DILUTION**

If you invest in our ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the public offering price per ordinary share in this offering and the as adjusted net tangible book value per ordinary share after this offering. Dilution results from the fact that the public offering price per ordinary share is substantially in excess of the net tangible book value per ordinary share. As of March 31, 2019, we had a historical net tangible book value of \$13.1 million, or \$0.52 per ordinary share. Our net tangible book value per share represents total tangible assets less total liabilities, divided by the number of ordinary shares outstanding on March 31, 2019.

After giving effect to the sale of ordinary shares in this offering at an assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, after deducting the estimated underwriting discount and estimated offering expenses, our as adjusted net tangible book value at March 31, 2019 would have been \$1.40 per share. This represents an immediate increase in as adjusted net tangible book value of \$0.88 per share to existing shareholders and immediate dilution of \$6.07 per ordinary share to new investors.

The following table illustrates this dilution per ordinary share:

Assumed public offering price per ordinary share		\$ 7.47
Historical net tangible book value per ordinary share as of March 31, 2019	\$ 0.52	
Increase in as adjusted net tangible book value per ordinary share attributable to this offering	\$ 0.88	
As adjusted net tangible book value per ordinary share after this offering		\$ 1.40
Dilution per ordinary share to new investors participating in this offering		\$ 6.07

A \$1.00 increase (decrease) in the assumed public offering price of \$7.47 per ordinary share, which was the last reported sale price of our ordinary shares on The Nasdaq Global Market on June 20, 2019, would increase (decrease) our as adjusted net tangible book value as of March 31, 2019 after this offering by approximately \$0.13/(0.13) per ordinary share, and would increase (decrease) dilution to investors in this offering by \$0.87/(0.87) per ordinary share, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discount and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. The as adjusted information is illustrative only, and we will adjust this information based on the actual public offering price and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase additional ordinary shares, the as adjusted net tangible book value will increase to \$1.51 per ordinary share, representing an immediate increase in as adjusted net tangible book value to existing shareholders of \$0.99 per ordinary share and an immediate dilution of \$5.96 per ordinary share to new investors participating in this offering.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our equity holders.

The tables and discussion above shown are based on 25,140,048 ordinary shares outstanding as of March 31, 2019, and exclude:

- 3,742,416 ordinary shares reserved for issuance upon the exercise of outstanding options as of March 31, 2019, at a weighted average exercise price of \$4.21 per share;
- 456,344 ordinary shares reserved for future issuance under our 2017 Share Incentive Plan, as of March 31, 2019, as well as any automatic increases in the number of common shares reserved for future issuance under this plan;
- 466,375 ordinary shares issued upon the exercise of options after March 31, 2019; and
- 3,313,512 ordinary shares issuable upon the exercise of outstanding warrants to purchase ordinary shares at a weighted average exercise price of \$6.72 per share, which warrants are expected to remain outstanding at the consummation of this offering.

# SELECTED CONSOLIDATED FINANCIAL DATA

The following tables summarize our financial data. We have derived the following statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus, which have been prepared in accordance with IFRS. The selected consolidated balance sheet data as of December 31, 2016 has been derived from our audited consolidated financial statements, which do not appear in this prospectus. The following statements of operations data for the three months ended March 31, 2019 and 2018 and the balance sheet data as of March 31, 2019 have been derived from our unaudited condensed interim consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period. The following selected financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year ended December 31,			Three months ended March 33				March 31,		
	2018		2017	_	2016		2019		_	2018
							•	audi	,	
Statements of Operations Data	(1	n th	ousands, ex	kcel	ot share and	per	snare amou	ınts)		
Statements of Operations Data:	Ф 22.045	ф	15 010	ф	10.005	ф	7.0	00	Φ.	г осо
Research and development expenses, net	\$ 22,045	\$	15,018	\$	19,095	\$	7,2		\$	5,060
General and administrative expenses	11,599	_	4,472	_	4,614		3,8			1,653
Operating loss	33,644		19,490		23,709		11,0	96		6,713
Financial expenses	20,259		718		155		4,7	34		974
Financial income	(1,042)		(1,197)		(1,193)		(3	49)		(296)
Loss before taxes on income	52,861		19,011		22,671		15,4	81		7,391
Taxes on income	70							26		
Net Loss	52,931		19,011		22,671		15,5	07		7,391
Basic and diluted net loss per ordinary share	\$ 10.53	\$	27.56	\$	32.86	\$	0.	62	\$	10.78
Weighted average number of ordinary shares, basic and diluted	5,025,213		689,898		689,898		25,038,2	61		689,898
				As	of Decembe	r 31,		Α	s of	March 31,
			2018		2017		2016		2	2019
									(una	udited)
					(i	n tho	usands)			
Balance Sheet Data:										
Cash and cash equivalents, available-for-sale and short-term deposits	financial assets	i	\$ 60.68	0	\$ 41.083	3 \$	18.059	\$		50,406
·					. ,		-,	Φ		•
Working capital <sup>(1)</sup>			55,48		39,046		16,538			43,124
Total assets			65,16		44,922		19,179			61,047
Total shareholders' equity			24,68	6/	22,956	)	10,963			13,145

<sup>(1)</sup> Working capital is defined as total current assets minus total current liabilities.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

#### Overview

We are a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure cancer and rare, serious hematologic diseases. While cell therapies have the potential to address a variety of diseases, they are limited by availability of donor cells, matching a donor to the patient, and the decline in donor cell functionality when expanding the cells to achieve a therapeutic dose. We have leveraged our nicotinamide-based, or NAM-based, cell expansion technology to develop a pipeline of products designed to address the limitations of cell therapies. Our proprietary technology allows for the proliferation of donor cells while maintaining the cells' functional therapeutic characteristics, providing a treatment alternative for patients.

Our most advanced product candidate, omidubicel, is an investigational advanced cell therapy designed to expand the life-saving benefits of hematopoietic stem cell (bone marrow) transplant, or HSCT. The Company is currently enrolling patients in a pivotal Phase 3 clinical trial in 120 patients with various hematologic malignancies. We anticipate reporting top-line data from this trial in the first half of 2020. In our Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. Data from the Phase 1/2 clinical study were published in the *Journal of Clinical Oncology* in December 2018. Based on the results of our Phase 1/2 clinical trials, we received Breakthrough Therapy Designation for omidubicel in the United States from the U.S. Food and Drug Administration, or the FDA. Furthermore, we received orphan drug designation from both the FDA and the European Medicines Agency.

We are also developing omidubicel for the treatment of other rare, life-threatening hematologic diseases, including severe aplastic anemia, a bone marrow failure disease, which is currently being investigated in a Phase 1/2 trial sponsored by the National Institutes of Health, or NIH. In addition, we have applied our NAM-based cell expansion technology to natural killer, or NK, cells, to develop our product candidate, GDA-201, an investigational, NK cell-based cancer immunotherapy, now being evaluated in a Phase 1 investigator-sponsored trial for the treatment of relapsed or refractory non-Hodgkin lymphoma, or NHL, and multiple myeloma, or MM.

We have incurred significant net losses since our formation in 1998. Our net losses were \$15.5 million and \$7.4 million for the three months ended March 31, 2019 and 2018, respectively, and \$52.9 million, \$19.0 million and \$22.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of March 31, 2019, our accumulated deficit was \$184.7 million. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We expect that our expenses will increase substantially in connection with our ongoing activities as we:

- conduct our international, multicenter, randomized, pivotal Phase 3 clinical trial;
- · continue the preclinical development of our other product candidates;
- file a Biologics License Application seeking regulatory approval for any of our product candidates;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we obtain regulatory approval;

- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development and commercialization efforts:
- · hire additional clinical development, regulatory, commercial, quality control and manufacturing personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization.

We will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Adequate funding may not be available to us on acceptable terms, or at all.

To continue to fund our operations, we expect to raise capital in addition to the net proceeds of this offering. We may obtain additional financing in the future through the issuance of our ordinary shares, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering and our existing funds will be sufficient to fund our operations through March 2020. However, our ability to successfully transition to profitability will be dependent upon achieving a level of revenue adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

## **Components of Results of Operations**

#### Revenue

We do not currently have any products approved for sale and, to date, we have not recognized any revenue. In the future, we may generate revenue from a combination of product sales, reimbursements, up-front payments and future collaborations. If we fail to achieve clinical success or obtain regulatory approval of any of our product candidates in a timely manner, our ability to generate future revenue will be impaired.

# Research and development expenses, net

The largest component of our total operating expenses has historically been, and we expect will continue to be, research and development. Our research and development expenses, net of grants from the Israel Innovation Authority, or IIA, consist primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- expenses incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants, preclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture preclinical study and clinical trial materials; and
- facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs.

Research expenditures are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if we can demonstrate: the technical feasibility of completing the intangible asset so that it will be available for use or sale; our intention to complete the intangible asset and use or sell it; our ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and our ability to measure reliably the expenditure attributable to the intangible asset during its development. Since our

development projects are subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not satisfied and, therefore, development expenditures are recognized in profit or loss when incurred.

Through March 31, 2019, we have received grants of approximately \$29.3 million in the aggregate from the IIA for research and development funding. Pursuant to the terms of the grants, we are obligated to pay the IIA royalties, at the rate of between 3% to 4% on all our revenue, up to a limit of 100% of the amounts of the U.S. dollar-linked grants received, plus annual interest calculated at a rate based on 12-month LIBOR. We have not paid any royalties to the IIA to date.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, which will also continue to apply to us following the repayment in full of the amounts due to the IIA. The Innovation Law restricts our ability to manufacture products and transfer technologies outside of Israel and may impair our ability to enter into agreements that involve IIA-funded products or know-how without the approval of the IIA. Any approval, if given, will generally be subject to additional financial obligations by us. Failure to comply with the requirements under the Innovation Law may subject us to mandatory repayment of grants received by us, together with interest and penalties as well as expose us to criminal proceedings.

In June 2017, new rules, or the Licensing Rules, were published by the IIA allowing a grant recipient to enter into licensing arrangements or grant other rights in know-how developed under IIA programs outside of Israel, subject to the prior consent of the IIA and payment of license fees, calculated in accordance with the Licensing Rules. The amount of the license fees is based on various factors, including the consideration received by the licensor in connection with the license, and shall not exceed six times the amount of the grants received by the grants recipient (plus accrued interest) for the applicable know-how being licensed. In certain cases, such as when the license consideration includes nonmonetary compensation or when a "special relationship" exists between the licensor and licensee (e.g., when a party controls the other party or is the other party's exclusive distributor), or when the agreed upon consideration does not reflect, in the IIA's opinion, the market value of the license, the IIA may base the value of the transaction on an economic assessment that it obtains for such purpose. See "Taxation – Material Israeli Tax Considerations" for more information.

Government grants received from the IIA are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing revenue. If no such economic benefits are expected, the grants are recognized as a reduction of the related research and development expenses.

We are currently focused on advancing our product candidates, and our future research and development expenses will depend on their clinical success. Research and development expenses will continue to be significant and will increase over at least the next several years as we continue to develop our product candidates and conduct preclinical studies and clinical trials of our product candidates.

These research and development costs include share-based compensation and other employment costs, regulatory, quality assurance and intellectual property costs. The costs incurred in research and development expenses are to advance the development of our product candidates and preclinical research and development programs. A substantial majority of our research and development expenses are related to the development of omidubicel.

We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

#### General and administrative expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, finance, and administrative functions, facility costs and external professional service costs, including legal, accounting and audit services and other consulting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our administrative headcount and infrastructure to support our continued research and development programs and the potential approval and commercialization of our product candidates. We also anticipate that we will incur increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance premiums, executive compensation, and other customary costs associated with being a public company.

# Finance income (expenses), net

Finance income (expenses), net, is calculated by subtracting our financing expense from our financing income, and adding or subtracting the gain or loss, as applicable, that we have realized due to revaluation at fair value of warrants and the IIA royalty-bearing grants liability, offset by interest income from deposits and marketable securities.

#### Income taxes

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$120.5 million (including capital losses of \$0.5 million) as of December 31, 2018. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the unused tax losses can be utilized. As of March 31, 2019, we did not recognize deferred tax assets for carryforward losses because their utilization in the foreseeable future is not probable.

# **Analysis of Results of Operations**

# Comparison of the three months ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

Three months anded

	March 31,		naea
	 2019		2018
	 (unaudited, ii	n thou	ısands)
Operating Expenses:			
Research and development expenses, net <sup>(1)</sup>	\$ 7,283	\$	5,060
General and administrative expenses <sup>(1)</sup>	3,813		1,653
Operating loss	11,096		6,713
Financial expenses, net	4,385		678
Loss before taxes on income	15,481		7,391
Taxes on income	26		_
Net loss	\$ 15,507	\$	7,391

<sup>(1)</sup> Includes share-based compensation expense as follows:

	 Three mon March		ded
	 2019		2018
	 unaudited, in	thous	ands)
Research and development, net	\$ 229	\$	482
General and administrative expenses	862		362
Total share-based compensation	\$ 1,091	\$	844

#### Research and development expenses

Research and development expenses increased by approximately \$2.2 million to \$7.3 million in the three months ended March 31, 2019 from \$5.1 million in the three months ended March 31, 2018. The increase was attributable mainly to a \$1.2 million increase in clinical activities relating to advancing our Phase 3 clinical program and initiation of the GDA-201 clinical program, an increase of \$0.2 million in salaries and benefits, consisting primarily of additional headcount focused on clinical development, a decrease of \$0.5 million in royalty-bearing grants from the IIA, and an increase of \$0.3 million in rent and other expenses.

## General and administrative expenses

General and administrative expenses increased by approximately \$2.1 million to \$3.8 million in the three months ended March 31, 2019, from \$1.7 million in the three months ended March 31, 2018. The increase was attributable mainly to a \$1.0 million increase in salaries and benefits as a result of hiring key C-level executives and establishing our US headquarters, an increase of \$0.5 million in non-cash stock-based compensation expenses, a \$0.4 million increase in professional services expenses, insurance, board fee, legal and other expenses incurred as a result of becoming a public company and a \$0.2 million increase in rent and other expenses.

# Finance expenses, net

Finance expenses, net, increased by approximately \$3.7 million to \$4.4 million of expenses in the three months ended March 31, 2019, from \$0.7 million of expenses in the three months ended March 31, 2018, primarily due to non-cash expenses resulting from revaluation of warrants and the revaluation of IIA royalty-bearing grant liability.

# Comparison of the years ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

Year ended

	 December 31,		
	 2018		2017
	(in tho	usano	ds)
Operating Expenses:			
Research and development expenses, net <sup>(1)</sup>	\$ 22,045	\$	15,018
General and administrative expenses <sup>(1)</sup>	11,599		4,472
Operating loss	33,644		19,490
Financial expenses (income), net	19,217		(479)
Loss before taxes on income	52,861		19,011
Taxes on income	70		_
Net loss	\$ 52,931	\$	19,011

(1) Includes share-based compensation expense as follows:

		ended mber 3	
	2018		2017
	 (in the	ousand	is)
Research and development, net	\$ 705	\$	1,362
General and administrative expenses	2,870		846
Total share-based compensation	\$ 3,575	\$	2,208

# Research and development expenses

Research and development expenses increased by approximately \$7.0 million to \$22.0 million in the year ended December 31, 2018 from \$15.0 million in the year ended December 31, 2017. The increase was attributable mainly to a \$5.4 million increase in clinical activities relating to advancing our Phase 3 clinical program and initiation of the GDA-201 clinical program, an increase of \$0.6 million in salaries and benefits, consisting primarily of additional headcount focused on clinical development, a decrease of \$0.5 million in royalty-bearing grants from the IIA, and an increase of \$0.5 million in rent and other expenses.

#### General and administrative expenses

General and administrative expenses increased by approximately \$7.1 million to \$11.6 million in the year ended December 31, 2018, from \$4.5 million in the year ended December 31, 2017. The increase was attributable mainly to a \$2.9 million increase in salaries and benefits as a result of hiring key C-level executives and establishing our US headquarters, an increase of \$2.0 million in non-cash stock-based compensation expenses, a \$1.4 million increase in professional services expenses incurred during our initial public offering and as a result of becoming a public company and a \$0.8 million increase in rent and other expenses.

## Finance expenses, net

Finance expenses, net, increased by approximately \$19.7 million to \$19.2 million of expenses in the year ended December 31, 2018, from \$0.5 million of income in the year ended December 31, 2017, primarily due to non-cash expenses resulting from revaluation of warrants and the revaluation of IIA royalty-bearing grant liability.

#### **Liquidity and Capital Resources**

# Sources of Liquidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the three months ended March 31, 2019 and the year ended December 31, 2018, we incurred net losses of \$15.5 million and \$52.9 million respectively, and net cash used of \$9.5 million and \$26.4 million respectively, was used in our operating activities. As of March 31, 2019 and December 31, 2018 we had working capital of \$43.1 million and \$55.5 million, respectively, and an accumulated deficit of \$184.7 million and \$169.2 million respectively. Our principal sources of liquidity as of March 31, 2019 and December 31, 2018 consisted of cash and cash equivalents, available-for-sale financial assets and short-term deposits of \$50.4 million and \$60.8 million respectively.

### Capital resources

#### Overview

Through March 31, 2019, we have financed our operations primarily through private placements of equity securities and through the grants received from the IIA. Since November 2018, we have also financed our operations through the proceeds of our initial public offering.

# Cash flows

The following table summarizes our statement of cash flows for the three months ended March 31, 2019 and 2018, and the years ended December 31, 2018 and 2017:

	Three months ended March 31,		Year ended De	cember 31,		
		2019	2019 2018		2017	
		(unaudited, in thou	usands)	(in thousands)		
Net cash provided by (used in)						
Operating activities	\$	(9,450) \$	(6,799) \$	(26,426) \$	(16,549)	
Investing activities		13,543	9,753	(2,751)	(20,222)	
Financing activities		(678)	1,652	48,093	40,037	

## Net cash used in operating activities

The cash used in operating activities during the aforementioned periods resulted primarily from our net losses incurred during such periods, as adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net losses for non-cash items mainly consisted of fair value adjustment of warrants, revaluation of the liability to the IIA and share-based compensation.

Net cash used in operating activities was \$9.5 million during the three months ended March 31, 2019, compared to \$6.8 million used in operating activities during the three months ended March 31, 2018.

The \$2.7 million increase in cash used was attributable primarily due to an increase in our net loss to \$15.5 million during the three months ended March 31, 2019, from \$7.4 million during the three months ended March 31, 2018 offset, in part, by certain non cash expenses related to revaluation of financial derivatives and to IIA.

## Net cash used in investing activities

Net cash used in investing activities was \$13.5 million during the three months ended March 31, 2019, compared to \$9.8 million used in investing activities during the three months ended March 31, 2018. The \$3.7 million increase is primarily related to sale of available for sale assets and transition of bank deposits to cash and cash equivalents.

# Net cash used in financing activities

Net cash used in financing activities was \$0.7 million during the three months ended March 31, 2019, compared to \$1.7 million provided by financing activites during the three months ended March 31, 2018. The decrease is primarily related to \$1.7 million in IIA grants, lease liabilities resulting from implementation of IFRS 16 and expenses from our initial public offering.

#### **Funding Requirements**

We believe that our existing funds, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through March 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our present and future funding requirements will depend on many factors, including, among other things:

- the progress, timing and completion of our pivotal Phase 3 clinical trial for omidubicel;
- the progress, timing and completion of preclinical studies and clinical trials for omidubicel or any of our other product candidates;
- the costs related to obtaining regulatory approval for omidubicel and any of our other product candidates, and
  any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect
  to any of these product candidates;
- selling, marketing and patent-related activities undertaken in connection with the commercialization of
  omidubicel and any of our other product candidates, and costs involved in the development of an effective
  sales and marketing organization;
- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents
  or defending against claims or infringements raised by third parties, and license royalties or other amounts we
  may be required to pay to obtain rights to third-party intellectual property rights; and
- establishing a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we obtain regulatory approval.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

For more information as to the risks associated with our future funding needs, see "Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—Even if this offering is successful, we will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations."

# Contractual obligations and commitments

Our known contractual obligations as of December 31, 2018 are summarized in the following table. The obligations detailed below do not include grants received from the IIA pursuant to which we will owe royalties upon commercialization of our product candidates. As of December 31, 2018, the royalty amount payable under these funding arrangements is \$34.2 million, including interest of \$4.9 million.

	Payments Due By Period							
		s Than Year		2 to 5 Years		to 10 Years		Total
				(in thous	and	s)		
Operating lease obligations <sup>(1)</sup>	\$	1,803	\$	2,522	\$	2,395	\$	6,720

<sup>(1)</sup> Operating lease obligations consist of our real estate lease agreements, which consist of the office building in Jerusalem, Israel, a planned production plant in Kiryat Gat, Israel, a production area in Hadassah, Israel, an office in Boston, Massachusetts and leased cars.

# **Off-balance Sheet Arrangements**

As of the date of this prospectus and during the periods presented, we do not and did not, respectively, have any off-balance sheet arrangements.

# Quantitative and Qualitative Disclosure about Market Risk

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows.

# Foreign currency exchange risk

The U.S. dollar is our functional and reporting currency. However, a material portion of our operating expenses are incurred in NIS. As a result, we are exposed to the risk that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation, if any, of the NIS against the dollar. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. We have a similar issue to a lesser extent with certain Euro-denominated expenses in connection with our material costs. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We do not currently engage in currency hedging activities in order to reduce this currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material currency fluctuations.

#### Liquidity risk

We monitor forecasts of our liquidity reserve (comprising cash and cash equivalents available-for-sale financial assets and short-term deposits). We generally carry this out based on our expected cash flows in accordance with practice and limits set by our management. We are in the clinical stage and we are therefore exposed to liquidity risk. However, we believe that our existing funds, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through March 2020.

# **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the accounting policies discussed below are critical to our financial results and to the understanding of our past and future performance, as these policies relate to the more significant areas involving management's estimates and assumptions. We consider an accounting estimate to be critical if: (i) it requires us to make assumptions because information was not available at the time or it included matters that were highly uncertain at the time we were making our estimate; and (ii) changes in the estimate could have a material impact on our financial condition or results of operations.

# Government Grants from the Israeli Innovation Authority (formerly the Office of the Chief Scientist)

Research and development grants received from the IIA are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing revenue. The amount of the liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest that reflects the appropriate degree of risks inherent in our business. The difference between the amount of the grant received and the fair value of the liability is accounted for as a government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37, "Provisions, Contingent Liabilities and Contingent Assets."

At the end of each reporting period, we evaluate whether there is reasonable assurance that the liability recognized will be repaid based on our best estimate of future sales and, if not, the appropriate amount of the liability is derecognized against a corresponding reduction in research and development expenses. See note 2—"Government Investment Grants" of the accompanying audited consolidated financial statements.

# Share-Based Compensation

We account for our equity-based compensation for employees in accordance with the provisions of IFRS 2 "Share-based Payment," which requires us to measure the cost of equity-based compensation based on the fair value of the award on the grant date.

For option grants prior to our initial public offering, or IPO, we selected the binominal pricing model as the most appropriate method for determining the estimated fair value of our equity-based awards. The resulting cost of an equity incentive award is recognized as an expense over the requisite service period of the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the accelerated method pursuant to which each vesting tranche is treated as a separate amortization period from grant date to vest date and classify these amounts in our consolidated financial statements based on the department to which the related employee reports.

Our determinations of the grant date fair value of options using the binomial model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the fair value of our share price as of the grant date, the expected volatility of our share price over the expected term of the options (estimated using historical data of comparable companies), share option exercise and cancellation behaviors, risk-free interest rates, expected dividend yields (assumed to be zero as we have historically not paid and do not intend to pay dividends on our ordinary shares).

Grant Date	Amount Granted	Type of Shares
March 14, 2019	454,800	Ordinary Shares
January 7, 2019	90,000	Ordinary Shares
October 30, 2018	65,000	Ordinary Shares
July 23, 2018	90,000	Ordinary Shares
July 20, 2018	195,056	Ordinary Shares
May 14, 2018	401,921	Ordinary Shares
December 28, 2017	606,574	Ordinary Shares
November 16, 2017	416,574	Ordinary Shares
March 2, 2017	134,800	Ordinary Shares
March 2, 2017	178,067	Ordinary C Shares <sup>(1)</sup>

(1) The Ordinary C shares were automatically converted into Ordinary Shares immediately prior to the closing of our initial public offering.

Prior to our IPO, the fair value of our ordinary shares was determined by our management with the assistance of an appraiser and was determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the AICPA Practice Aid. For options granted after our IPO, the fair value of our ordinary shares is determined as the closing price of our ordinary shares as reported on The Nasdaq Global Market on the grant date. The assumptions used in our valuation model are based on future expectations combined with management's judgment, and considered a number of objective, complex and subjective factors to determine the best estimate of the fair value of our ordinary shares, including contemporaneous and retrospective valuations of our ordinary shares performed by an unrelated valuation specialist, valuations of comparable peer companies, operating and financial performance, the lack of liquidity of our share capital, and general and industry specific economic outlook. Based on the fair value of our ordinary shares as of March 31, 2019 and December 31, 2018, the intrinsic value of the awards outstanding as of March 31, 2019 and December 31, 2018 was \$26.5 million and \$22.0 million, respectively.

The dates of our valuations historically did not always coincide with the dates of our share-based compensation grants. In such instances, management's estimates were based on the most recent valuation of our ordinary shares. For grants occurring between valuation dates, for financial reporting purposes, we used the closest valuation date before the grant, as we believed that the ordinary share valuation represented the valuation at the date of grant. The following table lists the valuation dates of our ordinary shares:

		Fair Va	alue per Share
Valuation Date	Type of Shares	<u>i</u>	n Dollars
June 30, 2018	Ordinary Shares	\$	6.90
December 31, 2017	Ordinary Shares	\$	4.90
March 31, 2017	Ordinary Shares	\$	5.40
March 31, 2017	Ordinary C Shares <sup>(1)</sup>	\$	6.20

(1) The Ordinary C shares were automatically converted into Ordinary Shares immediately prior to the closing of our IPO.

We determined our ordinary share value as of March 31, 2019 and December 31, 2018 using the income approach. The income approach estimates the aggregate enterprise value of our company based on the present value of future estimated cash flows. Cash flows are estimated for future periods based on projected revenue and costs. These future cash flows are discounted to their present values using an appropriate discount rate. The discounted projected cash flows are summed together to arrive at an indicated aggregate enterprise value under the income approach. In applying the income approach, we derived the discount rate from an analysis of the weighted-average cost of capital based on company industry peers as of each valuation date and adjusted it to reflect the risks inherent in our business cash flows. In estimating our projected revenues, we used data from bone marrow registries such as the European Society for Blood and Marrow Transplantation and from the Center for International Blood and Marrow Transplant Research.

We then allocated the estimated enterprise value among different classes of our equity by applying the Probability Weighted Expected Return method, which was based on potential exit events from a strategic acquirer or public offering. The Probability Weighted Expected Return method requires significant assumptions, including, in particular, the probability that such exit scenarios will occur, the time until investors in our company would experience an exit event, and the volatility of our shares (which we determine based on public companies with business and financial risks comparable to our own).

We applied a discount to the resulting valuation due to the lack of marketability of our ordinary shares. We calculated this using an Asian put option model. The significant assumptions involved were the same as described above. Since our initial public offering, the fair value of our ordinary shares has been determined based on the closing price of our ordinary shares on the Nasdaq Global Market.

# Liability Related to Certain Warrants

We issued certain warrants to investors in connection with our financings to date. We accounted for these warrants according to the provisions of IAS 32, "Financial instruments – presentation," based on the anti-dilution protections provisions and cashless exercise mechanism contained in the warrants agreements. We classified the warrants as non-current liabilities, measured at fair value each reporting period until they will be exercised or expired, with changes in the fair values being recognized in our statement of comprehensive loss as financial income or expense.

As of March 31, 2019 and December 31, 2018, we estimated the fair value of these warrants using a Black-Scholes option pricing model, which is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables are estimated as follows:

- Risk-free Interest Rate. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with a term equivalent to the contractual life of the warrants.
- *Volatility.* The expected share price volatility was based on the historical equity volatility of the ordinary shares of comparable companies that are publicly traded with adjustments to reflect our capital structure.
- Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

# **Recent Accounting Pronouncements**

See note 4 of the accompanying audited consolidated financial statements for the year ended December 31, 2018.

#### **Internal Control Over Financial Reporting**

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our ordinary shares. Pursuant to Section 404 and the related rules adopted by the SEC and the Public

Company Accounting Oversight Board, starting with the second annual report that we file with the SEC following the consummation of our initial public offering, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above, our independent registered public accounting firm will also need to attest to the effectiveness of our internal control over financial reporting under Section 404. We have not yet commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. In addition, we cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective control over financial reporting. The determination and any remedial actions required could result in our incurring additional costs that we did not anticipate. Regardless of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

#### **JOBS Act**

As an "emerging growth company," as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

#### **BUSINESS**

We are a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure cancer and rare, serious hematologic diseases. While cell therapies have the potential to address a variety of diseases, they are limited by availability of donor cells, matching a donor to the patient, and the decline in donor cell functionality when expanding the cells to achieve a therapeutic dose. We have leveraged our nicotinamide-based, or NAM-based, cell expansion technology to develop a pipeline of products designed to address the limitations of cell therapies. Our proprietary technology is designed to allow for the proliferation of donor cells while maintaining the cells' functional therapeutic characteristics, which, if approved, will provide a treatment alternative for patients.

Our most advanced product candidate, omidubicel, is an investigational advanced cell therapy designed to expand the life-saving benefits of hematopoietic stem cell (bone marrow) transplant, or HSCT. The Company is currently enrolling patients in a pivotal Phase 3 clinical trial in approximately 120 patients with various hematologic malignancies, including high risk leukemias such as acute myeloid leukemia, or AML, acute lymphocytic leukemia, or ALL, chronic myeloid leukemia, or CML, myelodysplastic syndrome, or MDS and lymphomas. We anticipate reporting top-line data from this trial in the first half of 2020. In our Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. Data from the Phase 1/2 clinical study were published in the Journal of Clinical Oncology in December 2018. Based on the results of our Phase 1/2 clinical trials, we received Breakthrough Therapy Designation for omidubicel in the United States from the U.S. Food and Drug Administration, or the FDA. Furthermore, we received orphan drug designation from both the FDA and the European Medicines Agency, or the EMA.

We are also developing omidubicel for the treatment of other rare, life-threatening hematologic diseases, including severe aplastic anemia, a bone marrow failure disease, which is currently being investigated in a Phase 1/2 trial sponsored by the National Institutes of Health, or NIH. In addition, we have applied our NAM-based cell expansion technology to natural killer, or NK, cells, to develop our product candidate, GDA-201, an investigational, NK cell-based cancer immunotherapy, now being evaluated in a Phase 1 investigator-sponsored trial for the treatment of relapsed or refractory non-Hodgkin lymphoma, or NHL, and multiple myeloma, or MM.

Cell therapies involve the delivery of human cells to replace or repair damaged tissue or cells in order to treat a variety of cancers and other diseases. Hematopoietic stem cell transplantation with donor cells, or allogeneic HSCT, also called bone marrow transplantation, is the most frequently used cell therapy and is used to treat a variety of hematologic malignancies and other serious conditions. HSCT involves reconstituting a patient's bone marrow from a seed population of stem cells obtained from a donor whose blood-forming and immune-system-forming cells are both cancer-free and effective at carrying out their functions.

There are multiple sources of donor cells. The best source for donor cells is a sibling who is a matched related donor, or MRD, but the chances of having a sibling match in the United States are only 25% to 30%. The majority of patients rely on alternate sources of donor cells, including matched unrelated donor, or MUD, haploidentical, or "half-matched" donors, and umbilical cord blood. However, due to disease progression and other complications during the time needed to find a suitable donor, more than 40% of all patients who are candidates for HSCT do not receive a transplant.

Notwithstanding the various potential sources of donor cells, HSCT is subject to a number of significant limitations, including: (i) delays in finding a suitable match, during which disease progression may make patients ineligible for transplant; (ii) an insufficient number or delayed engraftment of donor cells, leaving patients without a functioning immune system and leading to potentially life-threatening immune deficiency following transplant; and (iii) a lack of long-term compatibility between the donor cells and the patient's own cells, resulting in potentially fatal graft versus host disease, or GvHD.

Umbilical cord blood offers promise as a readily available source of stem cells for patients who need HSCT and do not have a MRD source. It is easier to find a match when using stem cells derived from cord blood, since a full match is not required for a successful transplant using cord blood. This broadens the pool of potential donors and shortens the process of finding a suitable match. However, on average, a typical cord blood graft contains approximately one-tenth the number of stem and progenitor cells

compared to stem cell grafts from adult bone marrow or peripheral blood donors. This lower number of cells may delay engraftment of the donor cells and reconstitution of the immune system. This, in turn, increases both time in the hospital and the likelihood that a patient might contract a life-threatening infection.

Omidubicel, our lead product candidate, is designed to address the limitations of HSCT. Omidubicel is composed of cord blood that has been manufactured using our proprietary NAM-based cell expansion technology, which increases engraftment efficiency in HSCT and enables rapid engraftment and immune system reconstitution. This reduces the risk of infections and other complications after transplant. In addition, the donor T cells in cord blood are naïve, meaning that they have not matured and may more readily adapt to the recipient. This results in greater immunologic compatibility, or the matching of the donor cells with the recipient's cells, reducing the frequency and severity of GvHD, a medical complication following the receipt of transplanted tissue from a genetically different person, when compared to HSCT with MUD. In light of these advantages, omidubicel, if approved, may serve as a universal, readily available, reliable and effective alternative to existing sources of donor cells for HSCT.

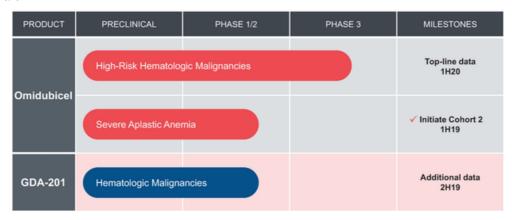
Omidubicel has the potential to be a universal stem cell graft in two broad patient groups: (i) patients with high-risk leukemias and lymphomas who require HSCTs but who lack access to genetically matched donors; and (ii) patients with severe hematologic disorders such as severe aplastic anemia. In the first patient population, we are currently enrolling an international, multicenter, randomized, pivotal Phase 3 clinical trial with top-line data expected in the first half of 2020. In our company-sponsored, Phase 1/2 clinical trial in hematologic malignancies, omidubicel was observed to help patients achieve rapid neutrophil and platelet engraftment. Neutrophil engraftment is defined as achieving a minimum neutrophil count of at least  $0.5 \times 10^9$  per liter on three consecutive measurements on different days. Platelet engraftment is defined as achieving a platelet count of at least  $20 \times 10^9$  per liter on three consecutive measurements on different days, with no platelet transfusion in the preceding seven days. Based on these promising clinical results, believe omidubicel has curative potential for hematologic malignancies initially, and eventually other rare hematologic conditions such as severe aplastic anemia. In the second patient population, we are currently conducting a Phase 1/2 clinical trial of omidubicel sponsored by the NIH, under an Investigational New Drug, or IND, application for omidubicel. In February 2019, we reported preliminary data from three patients at the Transplantation and Cellular Therapy Meeting, or TCT Meeting. All three patients in the first cohort were successfully transplanted and engrafted. The second cohort is currently open for patient enrollment.

We are also applying our technology to develop GDA-201 for innate immunotherapy of expanded natural killer, or NK, cells for application in additional cancer indications when combined with standard-of-care antibody therapies. NK cells are highly potent cytotoxic lymphoid cells that can kill tumor cells in the absence of prior sensitization by other components of the immune system. By expanding NK cells with our NAM technology, we have the potential to increase the number and functionality of therapeutic NK cells targeting tumors. When GDA-201 is combined with targeted antibodies, we have shown that there is enhanced antibody-dependent cellular toxicity, or ADCC. GDA-201 is currently being evaluated in an ongoing investigator-sponsored Phase 1 clinical trial projected to enroll 24 patients with NHL and MM in combination with rituximab or elotuzumab, respectively. In February 2019, we reported preliminary data at the TCT Meeting. The data from the first 14 patients demonstrated that GDA-201 was clinically active and generally well tolerated. Among the 12 patients evaluable for activity, six NHL patients, three patients achieved a complete response, one patient achieved a partial response and two patients experienced progressive disease. Two of the patients who achieved a complete response subsequently underwent a bone marrow transplant. Among the six MM patients evaluable for activity, one patient achieved a complete response, two patients experienced stable disease and three patients experienced progressive disease. Activity was observed at all three dose levels evaluated.

In addition, on February 12, 2019, Gamida Cell and Editas Medicine, Inc., or Editas Medicine entered into an agreement to evaluate the potential use of Editas Medicine's CRISPR technology to edit GDA-201 cells. The two companies will engage in joint research to evaluate unnamed targets by combining our proprietary NAM-based cell expansion technology with Editas Medicine's CRISPR technology. The research initiative is focused on exploring the potential to edit GDA-201 cells to further optimize their tumor-killing properties.

We are led by an experienced management team with extensive expertise in developing oncology therapies and manufacturing cell therapies and other complex biologics. Our director and chief executive officer, Julian Adams, played a central role in the discovery and development of bortezomib, or Velcade®, a widely used therapy for MM and other blood cancers approved by the FDA in 2003. Dr. Adams also led research and development, or R&D, efforts at Infinity Pharmaceuticals, Inc., which helped lead to the 2018 FDA approval of duvelisib, also known as Copiktra®, for the treatment of certain leukemias and lymphomas.

#### Pipeline chart



# Strategy

Our goal is to deliver curative cell therapies to patients with serious and life-threatening medical conditions. The key strategies to achieve our goal are the following:

- Complete Phase 3 clinical development and obtain regulatory approval for omidubicel in hematologic malignancies. We have initiated an international, multicenter, randomized, pivotal Phase 3 clinical trial evaluating transplantation with omidubicel compared to standard umbilical cord blood in approximately 120 patients with various hematological malignancies, including acute lymphocytic leukemia, or ALL, acute myeloid leukemia, or AML, myelodysplastic syndrome, or MDS, chronic myeloid leukemia, or CML, and lymphoma. In this trial, we are evaluating time to neutrophil engraftment as the primary endpoint. We expect to report top-line data in the first half of 2020. Assuming positive results from the Phase 3 clinical trial, we plan to seek regulatory approval for omidubicel in the United States, the European Union and other geographies.
- Advance omidubicel for the treatment of severe aplastic anemia in an ongoing Phase 1/2 clinical trial.
   In addition to hematologic malignancies, we are pursuing omidubicel in severe aplastic anemia. Omidubicel is currently being evaluated in a NIH-sponsored, Phase 1/2 clinical trial in patients with severe aplastic anemia. In February 2019, we reported preliminary data at the TCT Annual Meeting. In this initial cohort of three patients, all successfully underwent a stem cell transplant consisting of omidubicel plus a haploidentical stem cell graft. The rapid engraftment, sustained hematopoiesis and accelerated immune recovery observed in these patients enabled the initiation of a second cohort of patients to be treated with omidubicel as a stand-alone graft in the first half of 2019.
- Investigate the potential of GDA-201 in conjunction with therapeutic antibodies in additional cancer indications. We have applied our NAM-based technology platform for expanded cell products to develop a second product candidate, GDA-201, which has potential application in boosting the innate immune response to cancer. GDA-201 is currently being evaluated in an investigator-sponsored, Phase 1 clinical trial in patients with NHL or MM, in combination with rituximab or elotuzumab, respectively. In February 2019, we reported preliminary data at the TCT Meeting. The data from the first 14 patients demonstrated that

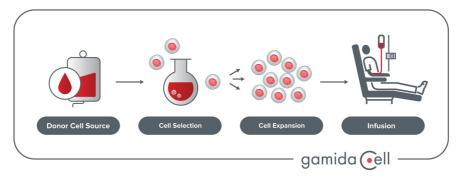
GDA-201 was highly active and generally well tolerated. Among the six NHL patients evaluable for activity, three patients achieved a complete response, one patient achieved a partial response, and two patients experienced progressive disease. Two of the patients who achieved a complete response subsequently received a bone marrow transplant. Among the six MM patients evaluable for activity, one patient underwent a complete response, two patients experienced stable disease, and three patients experienced progressive disease. Activity was observed at all three dose levels evaluated. Based on these data, the Company expects to initiate a multicenter Phase 1/2 clinical trial of GDA-201 in 2020.

- Maximize commercial value of our product candidates. If omidubicel is approved for stem cell
  transplantation, we intend to independently pursue the commercialization of omidubicel in the United States,
  where we plan to build a sales force focused on the approximately 200 domestic stem cell transplant centers.
  Outside of the United States, we may pursue the approval and commercialization of omidubicel in collaboration
  with strategic partners, particularly in Europe, Japan, Taiwan, Korea and other geographies which are more
  effectively managed by companies with local expertise.
- Centralize manufacturing capabilities to deliver a pharmaceutical grade product to meet commercial demand. We have devoted significant resources to optimizing and standardizing process development and manufacturing, which are key components to successfully delivering cell therapies. We have limited in-house GMP manufacturing capabilities and we are working to build additional manufacturing infrastructure at an identified site to diversify production of omidubicel and in preparation for commercialization. Our cryopreservation capabilities enable us to deliver our cell therapies globally, ready for infusion. We believe that these efforts will lead to an efficient production cycle and improved access for patients seeking suitable donor solutions. Our goal is to carefully manage our fixed cost structure, maximize efficiency and scale, and reduce the cost of manufacturing our products.
- Demonstrate omidubicel's value through Health Economics Outcomes Research. We believe that a favorable outcome of our ongoing Health Economics Outcomes Research analysis will inform price, reimbursement and adoption. Additionally, we are developing a reimbursement strategy modeled upon recently approved cell therapies in oncology through the New Technology Add-on Payment program.
- Expand our pipeline of cell therapy product candidates by leveraging our cell expansion technology. We plan to continue to leverage our platform technology in the effort to discover additional product candidates and expand into new therapeutic areas, to address the significant unmet needs of patients with serious medical conditions. We believe our technology can be applied to other cells with therapeutic potential. To accomplish this, we plan to continue to invest in our research and development activities.

#### **NAM-Based Cell Expansion Technology**

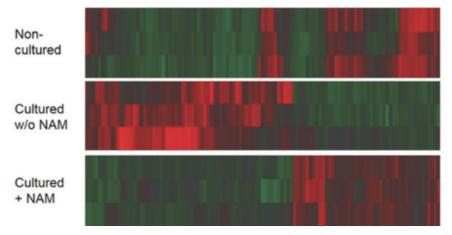
While cell-based therapies have the potential to address a variety of medical conditions, one of the key technical challenges for developing treatments with this approach is the expansion of therapeutically functional cells. In order for cell therapies to be clinically effective, there must be a sufficient quantity of therapeutically active cells for treatment, which requires the donor cells to be expanded in artificial culture conditions. While this may increase the number of cells, the functionality of those cells often diverges from the therapeutic functionality of the original donor cells. This shortcoming in the cells used for treatment can result in suboptimal clinical outcomes.

Our NAM-based epigenetic technology for expanded cell products addresses this challenge by leveraging the biochemical properties of the small molecule nicotinamide in our manufacturing process. We expand the number of donor cells while maintaining their functional therapeutic characteristics through the proprietary combination of NAM, intended to maintain silencing of cell differentiation and preservation of gene expression, and particular cytokines which promote cell growth. Our optimized manufacturing process results in robust and replicable batch production, enabling the generation of standardized donor-derived cell products, potentially resulting in better clinical outcomes.



The first application of the NAM-based technology is in umbilical cord blood cells. Our lead product candidate, omidubicel, contains standard umbilical cord blood-derived stem cells that are expanded to obtain a critical number of effective cells for HSCT. A typical umbilical cord sample has a relatively low number of stem and progenitor cells, which currently limits the use of cord blood in HSCT, and hence, would ideally be increased for more successful treatment purposes.

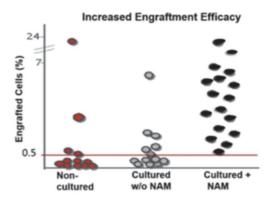
A key component of our cell expanded product candidates is NAM, which is a naturally occurring substance that regulates multiple processes including cellular stress, cellular energy, mitochondrial functions and gene expression. We have successfully demonstrated the effectiveness of NAM-based technology in cord blood expansion cultures. We incubated two cultures of cord blood cells, one treated with NAM and one untreated, for three weeks with cytokines known to induce numerical expansion of cord blood cells. The NAM-treated umbilical cord blood cell cultures had 30 times more stem cells than NAM-untreated umbilical cell cultures, as measured by the abundance of stem-cell-related surface markers. Furthermore, when examining the gene expression pattern of NAM-treated proliferating cord blood stem cells, we observed a high degree of resemblance with the gene expression pattern of original stem cell populations inoculated in expansion cultures. In contrast, the gene expression pattern of cells incubated for three weeks without NAM was very different than that of the original stem cells. This confirms that NAM has the ability to preserve the characteristics of the original stem cell population.



Gene expression of cord blood CD34+ cells before culturing or after three weeks of culture with or without NAM. The levels of expression of clusters of thousands of genes are represented by the density of vertical bars. Three independent samples are shown as individual rows for each condition.

In line with demonstrating the ability of our proprietary cell expansion technology to increase the quantity while maintaining the quality of the therapeutic cells, we have also been able to demonstrate that this could translate to clinical benefit. In pre-clinical models, NAM-treated cord blood cells demonstrated a 7.6-fold improved ability to establish stable grafts versus cord blood cells expanded without NAM. This resulted in a nine-fold increase in the number of engraftable cells over a cord blood unit before expansion.

While test subjects receiving the same number of stem cells cultured without NAM had a low number of engrafted cells, NAM-treated stem cells exhibited a significant increase in the level of engraftment. Thus, not only do NAM-treated stem cells appear to be more stem-like, but they also retain stem cell-like functions and improve the ability to establish stable grafts.



# Cord blood cells cultured with NAM result in a significantly higher number of engrafted cells in a preclinical model.

\* A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value = 0.001 means that there is a 0.1% or less probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant, and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA and EMA, do not rely on strict statistical significance thresholds as criteria for marketing approval and maintain the flexibility to evaluate the overall risks and benefits of a treatment.

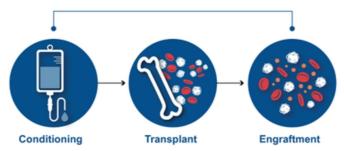
Based on the preclinical results, we advanced omidubicel into the clinic. We have also applied NAM-based technology for our second product candidate, GDA-201, and plan to explore this technology for other cells with therapeutic potential.

#### Allogeneic HSCT

#### Overview

Allogeneic hematopoietic stem cell transplantation, or HSCT, is the transplantation of hematopoietic stem cells, derived from a donor's bone marrow, peripheral blood or standard umbilical cord blood. HSCT involves reconstituting a person's entire blood and bone marrow from a seed population of cells. In some clinical settings, autologous HSCT may be performed, in which cells are derived from the patient and reinfused at a later date. In leukemia and other hematologic malignancies, it is more appropriate to use allogeneic HSCT obtained from a donor, which ensures that the graft does not contain the patient's malignant cells and leverages the ability of donor cells to fight against a patient's cancer, which is known as the "graft versus leukemia" effect.

In an HSCT procedure, a patient is treated with chemotherapy and/or radiation to destroy the residual cancerous or defective cells that reside in the bone marrow. This procedure, called myeloablation, also destroys the hematopoietic stem cells that are responsible for forming red blood cells, platelets and white blood cells. Stem cells from a donor are then infused into a patient who is now in remission, migrate and home to the bone marrow and begin to proliferate and differentiate into various types of blood cells, eventually leading to a full reconstitution of the bone marrow and immune system.



Bone marrow transplant process

The intent of HSCT is to cure patients of their hematologic malignancies. As of 2016, more than 500,000 allogeneic HSCT procedures have been performed worldwide over the past 50 years with over 30,000 being performed per year, of which 8,500 are in the United States. Approximately half of such patients are cured of their hematologic malignancies. From 2006 to 2016, the number of patients receiving an allogeneic HSCT procedure increased by approximately 5% per year in the United States due to multiple factors, including an aging population and new transplant modalities. Approximately 90% of HSCT procedures performed in the United States are for patients with various hematologic malignancies.

Although the number of allogeneic HSCT procedures performed is growing and there are new modalities for the procedure, HSCT continues to have a number of limitations. There are two major areas of unmet need. First, of those who receive a transplant, there is concomitant morbidity and mortality associated with the treatment. Second, a significant number of patients who are candidates for transplant do not receive one in a timely fashion. We believe that omidubicel can address significant limitations.

#### Current Sources of Donor Cells for Allogeneic HSCT

There are multiple potential sources of donor cells for transplants. For each donor, there are various baseline requirements including age and overall health. In general, younger donors produce more and better cells for HSCT than older donors. The optimal source of donor cells is a sibling who is a MRD, but the chances of having a sibling match are only 25% to 30%. An alternate source of donor cells is a MUD, but only 30% of patients requiring a transplant have a good to intermediate probability of finding a MUD. Furthermore, it takes approximately four months on average to identify an appropriate MUD who is medically suitable and willing to donate. During this lengthy time period, there is a risk of disease recurrence. Over time, the patient may also become ineligible due to other health complications. Moreover, prolonged donor searches heighten anxiety for patients and their families. The ability to find a match through this process is particularly challenging for individuals of ethnic backgrounds that are not well represented in donor databases.

Donor matching is determined by human leukocyte antigens, or HLA, which are proteins present on most cells and inherited genetically. HLA are recognized by the immune system, and "foreign" or nonmatching HLA may be rejected. Therefore, matching of HLA between bone marrow donor and recipient is needed for a successful transplant outcome. There are rules for the minimum, or lowest, HLA match needed between a donor and recipient. In general, patients have better transplant outcomes with a closely matched donor. Research has found that a donor must match a minimum of six HLA markers. In some centers, eight markers are tested. In transplantation with a matched related donor or matched unrelated donor, there must be a six of six or eight of eight HLA match with the recipient.

If a matched donor cell source is not identified, there are two alternatives for transplant candidates: haploidentical donors and umbilical cord donors. Haploidentical, or "half-matched" donors, are only partially compatible with the recipient. Because of the immune incompatibility in a haploidentical transplant, there is a high risk of GvHD, infection and other complications. There are two types of GvHD. Acute GvHD primarily affects the skin, the liver and the gastrointestinal tract (stomach, intestines and colon). Chronic GvHD begins later after transplant and lasts longer. It can be associated with damage to the liver, joints, skin and lungs. An approach to reduce these complications is to reduce the number of immune cells by giving cyclophosphamide after the transplant. However, this treatment modality may be associated with a decreased graft versus leukemia effect resulting in a higher rate of relapse, delayed time to engraftment associated with increased risk of infections and other complications.

Alternatively, donor cells can be obtained from umbilical cord blood. There are over a million publicly available cord blood units, making this a readily available source of cells. In contrast to matched unrelated donor transplants, which require a greater degree of matching, cord blood transplantation can be performed successfully with a match of four of six, five of six, or six of six HLA. Because cord blood requires a less stringent degree of genetic matching than other graft sources, it is suitable in approximately 95% of all patients. This obviates the need to go through a prolonged search process with uncertain outcomes in order to find a donor and arrange for the collection of donor cells. Because the donor T cells in cord blood are naïve, meaning that they have not matured, they readily adapt to the recipient and are associated with a low risk of a patient developing GvHD, in particular chronic GvHD. Furthermore, transplantation with cord blood reduces the risk of potential transmission of infections from the donor.

# Limitations of Allogeneic HSCT

There are three critical limitations to successful HSCT:

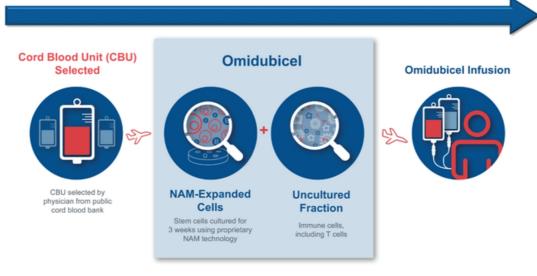
- delays in finding a suitable match, during which disease progression may make patients ineligible for a transplant;
- insufficient number or delayed engraftment of donor cells, leaving patients without a functioning immune system and leading to potentially life-threatening immune deficiency following transplant; and
- lack of long-term compatibility between the donor cells and the patient's own cells, resulting in potentially fatal GvHD.

## Omidubicel is Designed to Address the Limitations of HSCT

Omidubicel is designed to address the limitations of allogeneic HSCT. Omidubicel utilizes the NAM-based cell expansion technology, to expand the number of donor cord blood stem cells while maintaining the cells' functional therapeutic characteristics.

Omidubicel consists of two fractions of a unit of cord blood separated based on the expression of a marker on the surface of individual cells known as CD133. A cell's CD133 status reflects its "stem cell" properties. Those cells that express CD133 represent a pool of stem or progenitor cells, cells that are capable of generating blood cells that can differentiate into a variety of cell subtypes. The CD133-positive stem or progenitor cells are also capable of reproducing themselves. Once we have isolated cells bearing this marker, we then culture them using our proprietary technology to expand their number while maintaining their regenerative properties. After approximately three weeks, we harvest and cryopreserve these cultured cells. The United States Adopted Names Council selected omidubicel as the name for these cells.

Those cells that do not express CD133 represent other types of more mature, differentiated cells, including essential components of the immune system such as T cells. These mature cells cannot engraft but can provide immunological support until T cells derived from the stem cell graft recover. We cryopreserve the CD133-negative cells at the outset of manufacturing and retain them for use as the second component of omidubicel. Gamida Cell refers to the two components collectively as "omidubicel."



# Manufacturing and treatment process for omidubicel

The cryopreserved omidubicel product is shipped cryogenically to transplant centers where both components are thawed and infused to patients on the day of transplantation. The thawing process occurs in a closed system and can also be performed at the patient's bedside for ease of administration. Our cryopreserved product resulted in engraftment results similar to those obtained with non-cryopreserved product in the pilot study at Duke University.

Omidubicel is designed to address the limitations of the current standard of care for HSCT. The NAM-expanded portion is designed to provide a therapeutically effective dose of stem cells to drive rapid engraftment, reconstitution of the entire immune system and long-term graft survival while the CD133-negative portion provides an immediate immune system benefit by supplying T cells.

- Omidubicel is a universal stem cell graft, intended to reduce problems with donor matching. If approved, this will provide a pharmaceutical grade option for the patients who have lengthy searches to find a suitable match and the 40% of patients who are candidates for HSCT and never receive one.
- Omidubicel is designed to deliver a therapeutic dose of stem cells which leads to rapid engraftment and immune reconstitution.
- Omidubicel provides a compatible graft, observed to reduce morbidities including GvHD and infections.

Given these characteristics, omidubicel may serve as a reliable alternative to existing sources of donor cells as well as expand the transplant market for those who are unable to find a match.

# **Omidubicel for HSCT and Hematologic Malignancies**

Omidubicel is in an international, multicenter, randomized, pivotal Phase 3 clinical trial in 120 patients for the treatment of hematologic malignancies. We anticipate reporting top-line data from this trial in the first half of 2020. In our completed Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. Based on these results, we received Breakthrough Therapy Designation from the FDA for omidubicel. In addition, we received orphan drug designation from both the FDA and the EMA.

# Overview: Hematologic Malignancies

Hematologic malignancies are characterized by an abnormal and excessive proliferation of malignant blood cells that replace normal blood cells in the bone marrow and the circulation. In some patients, these cancerous cells proliferate rapidly, requiring urgent treatment. Patients are initially treated with chemotherapy in order to

destroy the malignant cells in a rapid manner. However, in most patients, remission is temporary, and the disease will return after initial treatment. One of the most effective treatment options for these patients is HSCT, where the blood forming cells in the patient are destroyed using chemotherapy, radiation or a combination of both. These patients then receive new bone marrow stem cells from a healthy donor.

# Omidubicel: Phase 1/2 Clinical Trial Results

After an initial safety evaluation of omidubicel in a pilot study at Duke University, an international, multi-center openlabel study was conducted. The results of this single-arm Phase 1/2 trial of omidubicel were published in the *Journal of Clinical Oncology* on December 4, 2018. The study enrolled 36 adolescent and adult patients with hematologic malignancies who did not have a suitably matched donor. All patients in the trial had been previously treated for various hematologic malignancies, including ALL, AML, MDS, CML and lymphoma. These patients were deemed to be in remission and at high risk of subsequent relapse.

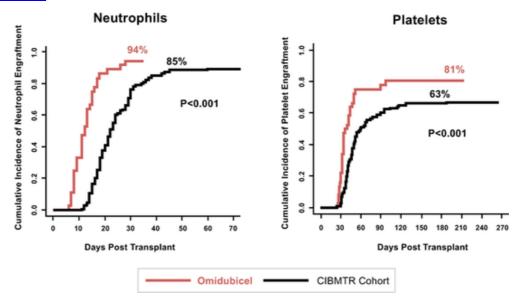
The main objective of the study was to evaluate the safety and efficacy of omidubicel treatment in patients with hematologic malignancies following myeloablative conditioning therapy. Myeloablative conditioning therapy is a combination of chemotherapy agents, and in some cases radiotherapy, that is expected to produce low blood counts and is administered in order to reduce the tumor burden, suppress the patient's immune system, and allow engraftment of donor stem cells. The study compared outcomes against a group of historic controls that were identified from data collected by the Center for International Blood and Marrow Transplant Research, or CIBMTR, which tracks all allogeneic transplants conducted in the United States. From the CIBMTR database, we identified 146 age and disease matched patients who received standard cord blood transplants and served as historic controls.

In this study, omidubicel was administered via central venous catheter after thawing and reconstitution of the two infusion bags, the first containing the omidubicel-cultured fraction and the second the noncultured fraction. The omidubicel-cultured fraction contains at least  $8.0 \times 108$  total nucleated cells, or TNC, while the non-cultured fraction contains at least  $4.0 \times 10^8$  TNC. The final volume of the omidubicel-cultured fraction is 100 milliliters and the final volume of the non-cultured fraction is 50 milliliters.

The study's primary endpoint was time to neutrophil engraftment, and was met based on recovery of neutrophils. Patients treated with omidubicel recovered their neutrophils (500 cells per microliter) with a median recovery of 11.5 days after transplantation, which is significantly shorter than the 21 days observed in the historic controls (p<0.001). Platelet counts recovered within a median time period of 34 days in the omidubicel treated patients, compared to 46 days in the historic controls (p<0.001). For both neutrophils and platelets, the percentage of patients who achieved engraftment was higher than in the historic controls. The age-adjusted cumulative incidence of neutrophil engraftment at 42 days following transplantation was 94% for omidubicel recipients and 85% for the CIBMTR comparator cohort.

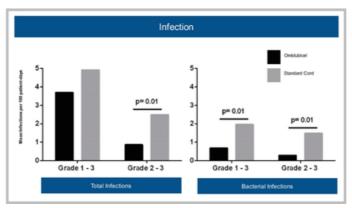
Neutrophils are infection-fighting white blood cells circulating in healthy individuals. A minimum neutrophil count, or ANC, of  $0.5 \times 10^9$  cells per liter is necessary to prevent life-threatening infections. In all omidubicel clinical trials, neutrophil engraftment is defined as achieving an ANC >  $0.5 \times 10^9$  per liter on three consecutive measurements on different days. The day of neutrophil engraftment is designated as the first of the three consecutive measurements and must occur on or before 42 days post-transplant.

Platelets are required for normal blood clotting. Low platelet counts are associated with life-threatening hemorrhage. Platelet counts of  $>20 \times 10^9$  per liter are the minimum needed for the prevention of serious bleeding. Patients who have platelet counts lower than  $20 \times 10^9$  per liter are usually given platelet transfusions in order to maintain their blood clotting function. In all omidubicel clinical trials, platelet engraftment is defined as achieving a platelet count  $>20 \times 10^9$  per liter on three consecutive measurements on different days, with no platelet transfusions in the preceding seven days. The first day of the three measurements is designated the day of platelet engraftment.



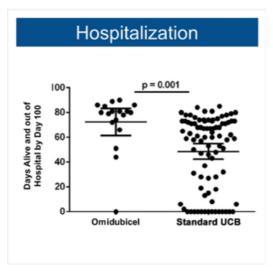
Additional endpoints included rates of acute GvHD, chronic GvHD, infections, hospitalization and overall survival. In the Phase 1/2 trial of omidubicel, rates of high grade acute GvHD were 11% in patients treated with omidubicel and 27% in the CIBMTR cohort (p=0.09 by Fine-Gray analysis). For chronic GVHD, the cumulative incidence of all grades (including mild, moderate, and severe) was 40% for omidubicel recipients and 30% for the CIBMTR comparator cohort (p = 0.1 by Fine-Gray analysis). Rates of the most clinically serious grades of chronic GVHD, moderate and severe, were 10% in both the omidubicel and CIBMTR groups. The two-year estimates of disease-free survival, or DFS, were 43% in the omidubicel group and 45% in the CIBMTR group, while overall survival rates, or OS, were 48% and 51%, respectively; neither DFS or OS were significantly different between the two groups. Other serious adverse events attributed to omidubicel were hypertension (3%), infusion reaction (3%), thrombocytopenia, or low platelets (3%), and transaminitis, or elevated liver enzymes (3%). Of the 16 patients who died, eight deaths (50%) were attributed to relapsed disease, five (31%) to infection, two (13%) to GvHD, and one (6%) to organ failure.

The clinical impact associated with rapid engraftment was assessed in 18 patients treated with omidubicel at Duke University. The patients who received omidubicel had a decreased frequency of infections compared to 86 patients who received a standard cord blood transplant at the same institution. In particular, serious, Grade 2 and Grade 3 infections were significantly reduced (p<0.01).



Omidubicel treated patients have significantly lower rates of serious infections than standard cord blood controls.

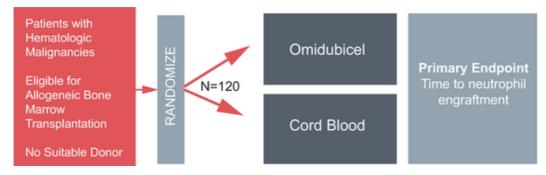
The speed and robustness of the immune system reconstitution also likely contributed to an observed reduction of 20 days in the number of days, post-transplant, that patients were hospitalized when compared to the length of hospital stays for similar patients treated with standard cord blood also at Duke University.



Patients with hematologic malignancies treated with omidubicel had significantly fewer days of hospitalization than comparable patients receiving standard umbilical cord blood.

# Omidubicel: Ongoing Phase 3 Clinical Trial for Hematologic Malignancies

Based on the results of our Phase 1/2 trials, we received Breakthrough Therapy Designation from the FDA for omidubicel; and we are currently enrolling an international, multicenter, randomized, pivotal Phase 3 clinical trial of transplantation of omidubicel versus transplantation of one or two standard cord blood units in approximately 120 patients with ALL, AML, MDS, CML or lymphoma. We are conducting the Phase 3 clinical trial with the same eligibility criteria and endpoints as our Phase 1/2 trials to confirm the superiority of using omidubicel in HSCT over standard cord blood. All patients enrolled in this trial are candidates for allogeneic HSCT who do not have a suitable matched donor. The primary endpoint of this trial is time to neutrophil engraftment. We anticipate completing enrollment by the end of 2019, and we anticipate reporting top-line data from this trial in the first half of 2020. Additional endpoints include platelet engraftment, and rates of acute and chronic GvHD, infections, hospitalization and overall survival.



Ongoing Phase 3 trial of omidubicel for HSCT in patients with hematologic malignancies.

# Omidubicel: Health Economic Implications

The potential clinical advantages of omidubicel could lead to societal benefits such as enabling patients to return to work, spend time with loved ones and enjoy improved quality of life. Omidubicel may also reduce the costs to the healthcare system versus standard cord HSCT due to potentially shortened

isolation and intensive care hospital stays, reduced re-admission rates and decreased severity and rates of infections and GvHD. In the ongoing Phase 3 clinical trial, we are collecting data to assess these endpoints. In parallel, we are conducting a "real world" outcomes data study that is a prospective observational study designed to capture clinical and economic endpoints for haploidentical, mismatched unrelated, and matched unrelated transplant. The data we collect from these efforts will inform a Health Economics Outcomes Research study that will be used to inform pricing and reimbursement.

In 2019 Gamida began providing payors with certain information regarding omidubicel and the indication sought in order to assist the payors to plan and budget for future coverage and reimbursement decisions. We expect commercial payors to cover omidubicel and we plan to apply to commercial payors for an add-on reimbursement code for omidubicel in HSCT. Further, we believe omidubicel will be covered by Medicare in the same way and subject to the same Centers for Medicare & Medicaid Services, or CMS, rules as all new oncology treatments administered within the in-patient hospital setting. We also plan to pursue reimbursement from CMS for omidubicel under the new technology add-on payment, or NTAP, program. CMS now uses the NTAP program to ensure adequate reimbursement for new medical services and technologies provided to Medicare patients treated in the in-patient hospital setting. Notably, two companies who are commercializing advanced cell therapy products for the treatment of hematologic malignancies – Gilead (Yescarta©) and Novartis (Kymriah©) – recently received NTAP status.

# Omidubicel for the Treatment of Other Hematologic Disorders

In addition to hematologic malignancies, we are pursuing the development of omidubicel for the treatment of bone marrow failure disorders. The goal in treating these diseases is to replace defective bone marrow cells with cells derived from cord blood donors. Omidubicel is currently being evaluated in a Phase 1/2 NIH-sponsored clinical trial. In this trial, omidubicel is administered in combination with a reduced conditioning preparative protocol, which is designed to minimize toxicity, in up to 62 patients with severe aplastic anemia or hypoplastic myelodysplastic syndrome, another bone marrow failure disease. This research protocol is designed to evaluate the safety and effectiveness of transplantation with omidubicel to overcome the high incidence of graft rejection associated with standard cord blood HSCT in severe aplastic anemia patients, where graft rejection occurs in up to 50% of subjects. In February 2019, we reported preliminary data at the TCT Annual Meeting.

#### Overview of Severe Aplastic Anemia

Severe aplastic anemia is a rare disease, with an estimated incidence in the United States of 600-900 patients per year. Underlying causes include autoimmune disease, certain medications or toxic substances, and inherited conditions. However, the cause is unknown in approximately half of all cases of severe aplastic anemia. The disease is characterized by stem cells in the bone marrow that are damaged and unable to produce enough new blood cells. This leads to extremely low blood cell counts and platelet levels, and often requires patients to be immediately hospitalized for treatment.

Allogeneic HSCT is the treatment of choice for patients with severe aplastic anemia who have an available matched sibling donor. Among the 2,471 patients with severe aplastic anemia receiving HSCT with a matched sibling donor between 2005 and 2015, the three-year probability of survival was 91% for those younger than 18 years, and 78% for patients 18 years of age or older. Among the 1,751 recipients of HSCT with a MUD during the same period, the probabilities of survival were 78% and 68% for severe aplastic anemia patients under 18 years and greater than or equal to18 years, respectively. Unfortunately, because of the severity of the disease, some patients cannot wait to find an ideal match and use haploidentical matches that have a lower survival rate. Among those who are able to find a matched donor in a timely manner, the survival rates are very good. We believe omidubicel may be able to provide a treatment option for those patients who are unable to locate such a donor in time.

# GDA-201: Our Immuno-Oncology Product Candidate

GDA-201 is our cell therapy product candidate generated by the expansion of NK cells using the NAM-based technology platform. GDA-201 addresses a key limitation in the therapeutic potential of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs of NK cells expanded in culture conditions. GDA-201 is currently in an investigator-sponsored Phase 1 trial for the treatment of MM and NHL. We believe that GDA-201 may have broad potential in both hematologic and solid tumors.

#### Limitations of Therapeutic Antibodies in Cancer Treatment

NHL is the most common malignancy of B cells. An estimated 74,680 new cases of NHL were diagnosed in the United States in 2018. The five-year survival rate for those with NHL is approximately 70%. The combination of an antibody such as rituximab and chemotherapy is the standard of care for patients with NHL. However, many patients develop resistance to rituximab, and when used as monotherapy, only 15% of patients respond. One mechanism that contributes to this resistance is the inability of patient or autologous NK cells to locate and kill tumor cells that rituximab has bound to. Treatment with donor-derived NK cells may overcome this resistance.

MM is a hematologic malignancy characterized by the proliferation of monoclonal plasma cells in the bone marrow. It is more common in elderly patients, with a median age at diagnosis of 65 to 74 years. The National Cancer Institute estimates that there were approximately 30,770 new cases of myeloma diagnosed in the United States in 2018. The preferred treatment for myeloma is an autologous stem cell transplant, but due to other pre-existing conditions, not all patients are eligible for this. These, and the majority of patients who relapse following initial treatment, are then treated with various chemotherapy and antibody-based therapies that have significant anti-cancer activity when used in combination. However, there is still a large unmet clinical need as the five-year survival rate for patients with myeloma is approximately 50%.

#### NK Cells: Broad Anti-Cancer Potential

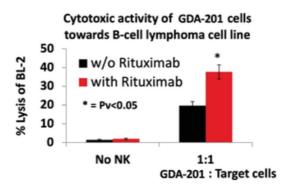
Extensive research efforts are ongoing to generate cellular products for the treatment of cancer patients. There is much interest in the field in the potential of NK cells because they have potent anti-tumor properties. In contrast to other immune cell therapies, NK cells can be used independently from genetic matching, potentially enabling NK cells to serve as a universal donor-based therapy when combined with certain antibodies.

NK cells' tumor killing activity is greatly enhanced by antibodies that recognize tumor cells, which trigger antibody-dependent cellular toxicity, or ADCC. In ADCC, the binding of an antibody to a cell marks it for destruction by NK cells. A number of antibody products have been approved by the FDA as therapeutics in oncology, each of which has limited efficacy as monotherapy. The effectiveness of these antibodies can potentially be enhanced through co-administration with NK cells. A key limitation in the application of NK cells in cell therapy has been the traditionally challenging task of generating sufficient numbers of highly functional NK cells in culture.

#### **Our Solution: GDA-201**

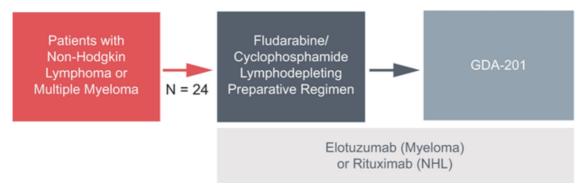
We have developed GDA-201, a cell therapy product candidate generated by expansion of NK cells using our NAM-based technology. We believe that GDA-201 has potential application in boosting the innate immune response to cancer. Functional studies have shown that our GDA-201 cells expanded in culture with our NAM technology and the cytokine IL-15 display increased tumor killing activity over NK cells expanded with IL-15 but without NAM. Our preclinical studies have demonstrated the potential of GDA-201 product to eradicate tumor cells to increase survival rates.

Further, we have demonstrated that GDA-201 cells can kill B cell lymphoma in culture. The efficacy of this killing is further enhanced by the addition of rituximab, which drives ADCC. In a cell lysis experiment, GDA-201 cell-dependent killing of B cells was enhanced by rituximab. No killing was obtained in the groups treated with rituximab and without NK cells.



# Rituximab enhanced lysis of lymphoma by GDA-201

An investigator-sponsored Phase 1 trial of GDA-201 cells in up to 24 patients with MM or NHL was launched in 2017 at the University of Minnesota. These patients have relapsed or refractory NHL or MM, meaning that their disease has come back after standard therapy and/or they are not responding to standard therapy for their disease. In combination with GDA-201 cells, these patients also receive therapeutic antibodies, which, in the case of NHL, includes rituximab, and in the case of MM, elotuzumab. In February 2019, we reported preliminary data at the TCT Meeting. The data reported from the first 14 patients demonstrated that GDA-201 was highly active and generally well tolerated. Among the six NHL patients evaluable for activity, three patients achieved a complete response, one patient achieved a partial response and two patients experienced progressive disease. Two of the patients who achieved a complete response subsequently underwent a bone marrow transplant. Among the six MM patients evaluable for activity, one patient achieved a complete response, two patients experienced stable disease and three patients experienced progressive disease. Activity was observed at all three dose levels evaluated. All 14 patients were evaluable for safety. and data from these patients showed that GDA-201 was generally well tolerated, with no GvHD, no tumor lysis syndrome and no neurotoxicity syndrome observed. Grade 3 (n = 3) and Grade 4 (n = 1) hematologic adverse events were observed. Non-hematologic adverse events were mostly Grade 1 and Grade 2. There was one case of Grade 3 cytokine release syndrome in a patient who later died due to sepsis. Based on these data, the Company expects to initiate a multicenter Phase 1/2 clinical trial of GDA-201 in 2020.



#### Phase 1 trial of GDA-201 in patients with MM or NHL

The results of this study will provide the basis for further exploration in solid tumors.

# **Omidubicel for the Treatment of Non-Malignant Disorders**

Omidubicel has also been tested in patients with sickle cell disease, or SCD, for which HSCT is currently the only clinically established cure. In Phase 1/2 clinical trials, 14 patients with SCD were treated with a standard unit of cord blood followed by omidubicel, administered via central venous catheter after thawing and reconstitution of the infusion bags. The standard cord blood unit was infused first, with the dose consisting of the entire unit, or one infusion bag. The omidubicel infusion consisted of two infusion bags, the first containing the omidubicel cultured fraction and the second, the non-cultured fraction. The omidubicel-cultured fraction contained at least  $8.0 \times 10^8$  TNC, while the non-cultured fraction contained at least  $4.0 \times 10^8$  TNC. The final volume of the omidubicel-cultured fraction was 100 milliliters and the final volume of the non-cultured fraction was 50 milliliters. All patients initially engrafted at a median of seven days. Twelve patients had long-term engraftment and were disease free after 22 months. Two of the patients died, one due to chronic GvHD and the other due to secondary graft failure. There were no other serious adverse events attributed to omidubicel in patients with SCD. These results are favorable when compared to those from a study of 29 patients with SCD who underwent HSCT with cells from a MUD donor. In that study, 27 of the patients had neutrophil engraftment, and the median time to engraftment was 12 days. There were eight deaths, seven due to GvHD and one due to graft rejection; 19 of 29 were disease-free at two years. The SCD trial is currently closed to further enrollment, and data will be analyzed when patient follow-up is completed in the second half of 2019.

We believe that omidubicel has potential to replace other allogeneic HSCT procedures in other hematologic diseases and some metabolic disorders. The following table illustrates the annual incidence of certain non-malignant diseases in the United States, according to the U.S. National Marrow Donor Program.

Bone Marrow Diseases	Annual Incidence (US)
Severe aplastic anemia	600 - 900
Franconi anemia	50
Paroxsymal nocturnal hemoglobinuria (PNH)	350
Inherited Immune System Disorders	
Severe combined immunodeficiency (SCID)	100
Wiskott-Aldrich syndrome (WAS)	25
Hemoglobinopathies	
Beta thalassemia major	3,000
Sickle cell disease (SCD)	1 in 365 African American births
Inherited Metabolic Disorders	
Krabbe disease (GLD)	40
Hurier syndrome (MPS-IH)	40
Adrenoleukodystrophy (ALD)	200
Metachromatic leukodystrophy (MLD)	10

# Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology platform, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We anticipate intensifying competition in the field of cell therapies as new therapies are approved and advanced technologies become available. Many of our competitors will have substantially greater

financial, technical and human resources. Competitors may also have more experience developing, obtaining approval for, and marketing novel treatments in the indications we are pursuing. These factors could give our competitors an advantage over us in recruiting and retaining qualified personnel, completing clinical development, and commercializing their products. Competitors that are able to obtain FDA or other regulatory approval for their products more rapidly than we can for our products may also establish a stronger market position, diminishing our commercial opportunity. Key considerations that would impact our capacity to effectively compete include the efficacy, safety, ease of use, as well as pricing and reimbursement of our products.

There are several clinical-stage development programs that seek to improve human umbilical cord blood transplantation through the use of an allogeneic HSCT graft. In addition, there are clinical-stage development programs that focus on natural killer cells. Companies active in these areas include, but are not limited to:

Allogeneic HSCT Graft: Magenta Therapeutics, Inc., Fate Therapeutics, Inc., ExCellThera Inc., Aldagen, Inc., a wholly-owned subsidiary of Cytomedix, Inc., Angiocrine Bioscience Inc., Medipost Co., Ltd., Kiadis Pharma NV, MolMed S.p.A., Bellicum Pharmaceuticals, Inc.; and

Natural Killer Cell product: AbbVie Inc., Affimed N.V., Innate Pharma SA, Agilent Technologies Inc., Altor Bioscience Corp., Bayer HealthCare Pharmaceuticals LLC, Bellicum Pharmaceuticals, Inc., Bristol-Myers Squibb, Celgene Corporation, Celularity Inc., Fortress Biotech, Inc., Fate Therapeutics, Inc., Genexine Inc., Sanofi Genzyme, Glycostem Therapeutics B.V., Green Cross Lab Cell Corporation, Incyte Corporation, Ivy Life Sciences, Co., Ltd., Takeda Pharmaceutical Company Limited, Miltenyi Biotec GmbH, multimmune GmbH, NantKwest, Inc., Nkarta Therapeutics, Inc., NKBio Co., Ltd., PersonGen BioTherapeutics Suzhou Co. Ltd., United Therapeutics Corporation, Y-mAbs Therapeutics, Inc., Ziopharm Oncology, Inc.

# Manufacturing

Our product candidates are currently manufactured at our Jerusalem, Israel facility using a scalable self-assembly process with well-defined unit operations. This highly specialized and precisely controlled manufacturing process enables us to manufacture product candidates reproducibly and efficiently for clinical and commercial applications.

We currently rely on third-party clinical cell processing facilities and contract manufacturers for all of our required raw materials, active ingredients and finished products for our pre-clinical research and clinical trials. We currently rely on a third party, Lonza Walkersville, Inc., or Lonza U.S., to conduct a material portion of our product manufacturing for omidubicel and intend to do so at Lonza U.S. or a Lonza U.S. affiliate, at least until our manufacturing facility is expected to be completed. In February 2016, and as amended, we entered into a Manufacturing Services Agreement, or the Manufacturing Agreement, with Lonza U.S. for the production of products containing human cells intended for therapeutic use in humans. Under the terms of the Manufacturing Agreement, Lonza U.S. manufactures, packages, ships, and handles quality assurance and control products, based on statements of work, which we submit with respect to each development of a process or product and as may be further be amended by change orders. Each statement of work describes the activities to be performed by the parties and is subject to the terms of the Manufacturing Agreement unless the parties have agreed otherwise. In February 2016, we signed a statement of work, or SOW, for technology transfer and clinical manufacturing of omidubicel for a period ended December 2018. In February 2019, the SOW was extended and is effective until November 30, 2019. An additional SOW was executed with Lonza Netherlands B.V., or Lonza, and Lonza U.S., extending the term until December 2020.

The term of the Manufacturing Agreement is five years, unless terminated earlier pursuant to its terms. The Manufacturing Agreement may be terminated in the event of an uncured material breach by one of the parties. In addition, the Manufacturing Agreement or any statement of work thereunder may be terminated by us by providing six months prior written notice or by Lonza U.S. by providing 12 months prior written notice. In addition, the Manufacturing Agreement may be terminated if omidubicel, which is being produced thereunder, has been or will be suspended or terminated by the FDA due to the failure of the product candidate, by providing two months prior written notice. Further, the Manufacturing Agreement may be terminated by either party upon notice in the event of dissolution, termination of existence,

liquidation or business failure of the other party, the uncured appointment of a custodian or receiver to the other party or un-dismissed institution of insolvency, reorganization or bankruptcy proceedings.

In June 2019, we entered into a Manufacturing Services Agreement, or the Services Agreement, with Lonza, which provides for the future commercial production after potential FDA approval of omidubicel. Under the Services Agreement, Lonza will construct and dedicate production suites prior to anticipated commercial launch. Additionally, the agreement enables us to increase the number of Lonza's dedicated production suites over time to ensure commercial supply of omidubicel.

The term of the Services Agreement is the shorter of seven years from the date of execution or five years from the date of the first FDA approval of omidubicel. The Services Agreement may be terminated in the event of an uncured material breach by one of the parties. If we do not receive FDA approval of omidubicel by December 31, 2021, we will have the right to terminate the Services Agreement upon 30 days' written notice. Either party may terminate without cause after the referenced time periods, but only after the Initial Term, which is the third anniversary of the Effective Date (June 10, 2019). Further, the Manufacturing Agreement may be terminated by either party upon notice in the event of dissolution, termination of existence, liquidation or business failure of the other party, the uncured appointment of a custodian or receiver to the other party or un-dismissed institution of insolvency, reorganization or bankruptcy proceedings.

As of March 31, 2019, we have paid Lonza U.S. an aggregate of approximately \$9.7 million pursuant to the Manufacturing Agreement.

# Marketing, Sales and Distribution

Given our stage of development, we do not currently have any internal sales, marketing or distribution infrastructure or capabilities. We have a wholly-owned U.S. subsidiary, Gamida Cell Inc., which supports our U.S. development and potential commercialization efforts.

In the event that we receive regulatory approvals for our products in markets outside of the United States, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market or sell our products through their well-developed sales, marketing and distribution organizations in such countries, and we may also build Gamida Cell's internal sales and marketing organization and capabilities.

#### **Intellectual Property**

We strive to protect and enhance the proprietary technologies, inventions, products and product candidates, methods of manufacture, methods of using our products and product candidates, and improvements thereof that are commercially important to our business. We protect our proprietary intellectual property by, among other things, filing patent applications in the United States and in jurisdictions outside of the United States covering our proprietary technologies, inventions, products and product candidates, methods, and improvements that are important to the development and implementation of our business.

As of June 10, 2019, we own 38 issued patents and 16 pending patent applications worldwide, including 9 U.S. issued patents, two pending U.S. non-provisional patent applications, two pending U.S. provisional patent applications and three pending PCT applications. We own two issued patents in the United States and 16 issued foreign patents related to our omidubicel product candidate. The patents that we own outside of the United States are granted in Australia, Canada, Europe, Hong Kong, Israel, Japan, Singapore, and South Africa. In addition, we own one pending U.S. non-provisional patent application and two pending PCT applications related to our omidubicel product candidate. These patents and pending patent applications contain composition-of-matter claims to our omidubicel product candidate, and claims to methods of producing and methods of treatment using omidubicel. Not accounting for any patent term adjustment, regulatory extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely, these patents, and if granted, these patent applications, will expire from 2023 to 2038. In particular, U.S. Patent No. 7,955,852, EP Patent No. 1576089, EP Patent No. 2206773, JP Patent No. 4738738, and IL Patent No. 163180, which relate to methods of expanding a population of

hematopoietic stem cells by culturing the cells with nicotinamide or nicotinamide analogs, and transplantable cell populations produced by these methods, expire in 2023, not accounting for any patent term adjustment, regulatory extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely and U.S. Patent No. 8,846,393, EP Patent No. 1974012, JP Patent No. 5102773 and IL Patent No. 191669, which relate to methods of enhancing cell homing and engraftment potential of hematopoietic stem cells by expansion in the presence of nicotinamide, expire in 2026, not accounting for any patent term adjustment, regulatory extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely.

We own six issued foreign patents related to GDA-201. The patents that we own outside of the United States are granted in Australia, Europe, Hong Kong, Israel, and Japan. In addition, we own one pending U.S. non-provisional patent application, one pending U.S. provisional patent application, one pending PCT application and six pending foreign patent applications related to our GDA-201 product candidate. These patents and pending patent applications contain composition-of-matter claims to our GDA-201 product candidate, and claims to methods of producing and methods of treatment using our GDA-201 product candidate. Not accounting for any patent term adjustment, regulatory extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely, these patents, and if granted, these patent applications, will expire from 2030 to 2040. In particular, EP Patent No. 2519239, JP Patent No. 5943843, JP Patent No. 6215394 and IL Patent No. 220660, which relate to methods of expanding a population of natural killer cells by culturing the cells with nicotinamide or nicotinamide analogs, and transplantable cell populations produced by these methods, expire in 2030, not accounting for any patent term adjustment, regulatory extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely.

In addition, we filed for and obtained trademark registration in the United States, China, Europe, Hong Kong and Israel for "NiCord". We also rely upon trade secrets, know-how and continuing technological innovation to develop, strengthen and maintain our competitive position.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, if and when our product candidates receive approval from the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents we may obtain in the future covering those products, depending upon the length of the clinical trials for each product and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications.

As with other biotechnology and pharmaceutical companies, our ability to establish and maintain our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. There can be no assurance that

any of our current or future patent applications will result in the issuance of patents or that any of our current or future issued patents will provide any meaningful protection of our product candidates or technology. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property".

#### **Research Grants**

# Grants under the Innovation Law

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, and the provisions of the applicable regulations, rules, procedures and benefit tracks, (collectively, the "Innovation Law"), research and development programs that meet specified criteria and are approved by a committee of the IIA are eligible for grants. The grants awarded are typically up to 50% of the project's expenditures, as determined by the research committee and subject to the benefit track under which the grant was awarded. A company that receives a grant from the IIA, or a grant recipient, is typically required to pay royalties to the IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products), until 100% of the U.S. dollars-linked grant plus annual LIBOR interest is repaid. The rate of royalties to be paid may vary between different benefits tracks, as shall be determined by the IIA. Under the regular benefits tracks the rate of royalties varies between 3% to 5% of the income generated from the IIA-supported products. The obligation to pay royalties is contingent on actual income generated from such products and services. In the absence of such income, no payment of such royalties is required.

The terms of the grants under the Innovation Law also generally require that the products developed as part of the programs under which the grants were given be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless a prior written approval is received from the IIA (such approval is not required for the transfer of a portion of the manufacturing capacity which does not exceed, in the aggregate, 10% of the portion declared to be manufactured outside of Israel in the applications for funding, in which case only notification is required) and additional payments are required to be made to the IIA. It should be noted, that this does not restrict the export of products that incorporate the funded know-how. See "Risk Factors—Risks Related to Israeli Law and Our Operations in Israel" for additional information.

Since our incorporation, we have received grants from the IIA relating to various projects. No royalties have been paid to the IIA in respect of any grant. Our total outstanding obligation to the IIA, respectively, including the interest accrued through March 31, 2019, amounts to approximately \$34.3 million including interest amounts of approximately \$5.0 million.

# **Government Regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in non-U.S. countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be
  updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;

- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the
  proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and
  controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected
  clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

## Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the
  target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption,
  metabolism and distribution of the investigational product in humans, the side effects associated with
  increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently

producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### **BLA Submission and Review**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained

or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

# Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

#### **Breakthrough Therapy Designation**

A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may

demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation allows more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

# Other Healthcare Regulations

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all facts and circumstances. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, amended the intent requirement of the federal Anti-Kickback Statute, and other healthcare criminal fraud statutes, so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute. The PPACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil and criminal false claims laws, including the federal civil False Claims Act, or FCA, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the U.S. federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged impermissible promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, the PPACA amended the intent requirement of some of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the PPACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation of both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities subject to the law, such as health plans, healthcare clearinghouses, and certain healthcare providers, and their business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Among other things, HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties and HIPAA's security standards directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require the registration of pharmaceutical sales representatives, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, and/or state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which

could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

# Coverage and Reimbursement

Our ability to successfully commercialize any products for which we receive approval will depend in part on the extent to which coverage and adequate reimbursement for the procedures utilizing our products will be available to health care providers from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which procedures, and the products utilized in such procedures, they will cover and establish reimbursement levels. Assuming coverage is obtained for procedures utilizing a given product, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who undergo procedures for the treatment of their conditions, and their treating physicians, generally rely on third-party payors to reimburse all or part of the costs associated with the procedures which utilize our products. Treating physicians are unlikely to use and order our products unless coverage is provided and the reimbursement is adequate to cover all or a significant portion of the cost of the procedures which utilize our products. Therefore, coverage and adequate reimbursement for procedures, which utilize new products, is critical to the acceptance of such new products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Increasingly, government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which may utilize such newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance

There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product, or the procedures which utilize such product, will be paid for in all cases or at a rate which the health care providers who purchase those products will find cost effective.

# Healthcare Reform Measures

The United States and some non-U.S. jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the pharmaceutical industry in the United States has been affected by the passage of PPACA, which, among other things: imposed new fees on entities that manufacture or import certain branded prescription drugs; expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs; implemented a licensure framework for follow-on biologic

products; expanded health care fraud and abuse laws; revised the methodology by which rebates owed by manufacturers to the state and federal government under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including products that are inhaled, infused, instilled, implanted or injected; imposed an additional rebate similar to an inflation penalty on new formulations of drugs; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2.0% per fiscal year, which went into effect in April 2013, and due to subsequent legislative amendments, including the BBA, will remain in effect through 2027, unless additional U.S. Congressional action is taken. In addition, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional changes that may affect our business include new quality and payment programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of prescription drugs under Medicare and reform government program reimbursement methodologies for pharmaceutical products. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate

cost sharing for generic drugs for low-income patients. Further, the Trump administration released a blueprint to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and CMS issued a final rule, effective on July 9, 2019 that requires direct-toconsumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. In addition, individual states in the United States have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of products.

### The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any non-U.S. official, political party or candidate for the purpose of influencing any act or decision of the non-U.S. entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

# Non-U.S. Government Regulation

To the extent that any of our product candidates, once approved, are sold in a country outside of the United States, we may be subject to similar non-U.S. laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

In order to market our future products in the EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein) and many other jurisdictions, we must obtain regulatory approvals from such jurisdictions. More precisely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the

mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

# Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial authorization of the reference product in the European Union. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

# Pediatric Investigation Plan

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

# **Orphan Drug Designation**

In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the member state competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed PIP.

This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinical superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant are eligible for incentives made available by the European Union and its Member States to support research into, and the development and availability of, orphan drugs.

# **Employees**

As of December 31, 2018, we had 70 full-time employees and three part-time employees, 61 of whom are based in Israel and 12 of whom are based in the United States. Of these employees, 68 are primarily engaged in research and development activities and 15 are primarily engaged in general and administrative matters. A total of 7 employees have an M.D. or Ph.D. degree. None of our employees is represented by a labor union. We have never experienced any employment-related work stoppages and believe our relationships with our employees are good.

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israeli Ministry of Economy and Industry. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums.

#### **Facilities**

Our principal executive offices are located at 5 Nahum Heftsadie Street, Givaat Shaul, Jerusalem 91340, Israel, where we lease an approximately 1,300 square foot facility. This facility houses our administrative headquarters, research and development laboratories and pilot manufacturing facility. We also maintain an office at 673 Boylston Street, Boston, Massachusetts which serves as the executive headquarters for our U.S. subsidiary. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

We have also entered into a lease agreement for an approximately 52,000 square foot facility in Kiryat Gat, Israel, where we intend to build a commercial-grade cGMP manufacturing facility.

# Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily Israel, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations use chemicals and produce waste materials and sewage and require permits from various governmental authorities including, local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or

criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations. In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities that were previously permitted.

# **Legal Proceedings**

From time to time, we may become party to litigation or other legal proceedings that we consider to be part of the ordinary course of business. We are not currently party to any material legal proceedings.

### **MANAGEMENT**

# **Executive Officers and Directors**

The following table sets forth information concerning our executive officers and directors, including their ages, as of June 4, 2019. The business address for each of our executive officers and directors is c/o 5 Nahum Heftsadie Street, Givaat Shaul. Jerusalem 91340. Israel.

Name	Age	Position
Dr. Julian Adams	64	Director and Chief Executive Officer
Shai Lankry	42	Chief Financial Officer
Joshua Hamermesh	46	Chief Business Officer
Tzvi Palash	62	Chief Operating Officer
Dr. Tracey Lodie	49	Chief Scientific Officer
Tony Peled	65	Chief Technology Officer and Vice President of Research & Development
Dr. Ronit Simantov	54	Chief Medical Officer
Thomas Klima	47	Chief Commercial Officer
Robert I. Blum*	56	Chairman of the Board of Directors
Ofer Gonen*	45	Director
Kenneth I. Moch*	64	Director
Dr. Michael S. Perry*	60	Director
Nurit Benjamini*	52	Director
Shawn C. Tomasello*	60	Director
Stephen T. Wills*	62	Director

Non-management director

### **Executive Officers**

Julian Adams, Ph.D., joined our board of directors in August 2016 and has served as our Chief Executive Officer since November 2017. Dr. Adams has more than 35 years of experience in drug discovery and development. From 2003 to 2016, Dr. Adams held roles of increasing responsibility at Infinity Pharmaceuticals, Inc., where he built and led the company's R&D efforts which ultimately led to the approval of duvelisib, also known as Copiktra®, for the treatment of certain leukemias and lymphomas. Prior to joining Infinity, Dr. Adams served as a Senior Vice President at Millenium Pharmaceuticals from 1999 to 2003, where he led the development of bortezomib, also known as Velcade®, for the treatment of multiple myeloma. He has served on the boards of directors of numerous biotechnology companies, and currently serves as the Chairman of the board of directors of Elicio Therapeutics. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

Shai Lankry has served as our Chief Financial Officer since April 2018. Mr. Lankry has more than 15 years of senior management experience in finance. Prior to joining Gamida Cell, from 2016 to 2018, Mr. Lankry served as a Finance Director at West Pharmaceutical Services Inc., leading the R&D and operations financials for the Israeli subsidiary. Previously, from 2013 to 2017, Mr. Lankry was the Chief Financial Officer and Israeli Site Manager of Macrocure Ltd. where he played an integral role in the company's 2014 U.S. initial public offering and 2017 acquisition by Leap Therapeutics Inc. Before joining Macrocure, from 2006 to 2013, Mr. Lankry held senior finance positions at Ethicon Biosurgery, a Johnson & Johnson company, where in his most recent position, he was the Biologics Cluster Finance Director, managing the Biologics finance organization at multiple sites worldwide. Mr. Lankry is a licensed Israeli CPA and earned an M.B.A. in Finance from Tel-Aviv University.

*Joshua Hamermesh* has served as our Chief Business Officer since April 2018. Mr. Hamermesh has more than two decades of experience in corporate strategy and commercialization for pharmaceutical and biotechnology companies. Mr. Hamermesh is currently a director of Neurohealing Pharmaceuticals, a biopharmaceutical company. He earned his undergraduate degree from Amherst College and received an M.B.A. from Harvard Business School.

Tzvi Palash has served as our Chief Operating Officer since July 2018. Mr. Palash has more than 30 years of expertise in commercial operations in the healthcare industry. Prior to joining Gamida Cell, Mr. Palash served as chief operating officer at Protalix Biotherapeutics, Inc., as a general manager at ColBar LifeScience Ltd, as a member of the Global Aesthetic Management Team within the Consumer Group of Johnson & Johnson and held operational roles at Teva Pharmaceutical Industries and Interpham Laboratories. Mr. Palash holds a B.Sc. from Tel Aviv University and an M.Sc. in biochemistry from Hebrew University of Jerusalem.

Tracey Lodie, Ph.D. has served as our Chief Scientific Officer since June 2019. Dr. Lodie is an immunologist with over 16 years of drug discovery experience in the areas of autoimmunity, transplant biology and immuno-oncology. Prior to joining Gamida Cell, Dr. Lodie served as senior vice president, translational immunology at BlueRock Therapeutics and has also served as vice president of immunology at Syros Pharmaceuticals. Prior to Syros Pharmaceuticals, Dr. Lodie spent over 14 years at Sanofi-Genzyme, where she held roles of increasing responsibility. While at Sanofi-Genzyme, Dr. Lodie's research led to the approval of Mozobil® and her group was responsible for data that supported the approval and post-approval safety requirements of Lemtrada®. Dr. Lodie has experience as an academic instructor and has served in various industry related and non-profit leadership roles, including scientific advisory boards. Dr. Lodie holds a Ph.D. in immunology and pathology from Boston University School of Medicine and a B.S. in biology from Fairfield University.

Tony Peled is the co-founder of the Company and the researcher whose discoveries have led to Gamida Cell's key clinical achievements. Ms. Peled has served as our Chief Technology Officer and Vice President of Research & Development since June 2019 and previously served as our Chief Scientific Officer and Vice President of Research & Development since 2000. Prior to founding Gamida Cell, Ms. Peled was a scientist in the hematology department at Hadassah University Hospital, and she has more than 30 years of experience in hematopoiesis and stem cell research. She received her undergraduate degree from Hebrew University of Jerusalem.

Ronit Simantov, M.D., has served as our Chief Medical Officer since June 2017. Dr. Simantov has more than 20 years of experience in in hematology and oncology research, development, registration and product launch. Prior to joining Gamida Cell, from 2011 to 2017, Dr. Simantov served as head of oncology global medical affairs at Pfizer, where she was responsible for multiple programs including Sutent® (sunitinib), Inlyta® (axitinib), Ibrance® (palbociclib), Bosulif® (bosutinib), and Xalkori® (crizotinib). From 2010 to 2011, Dr. Simantov led Phase 1 through Phase 3 studies as Vice President of Clinical Research at OSI Pharmaceuticals. Dr. Simantov also led development of small molecules and antibody-drug conjugates at CuraGen Corporation (acquired by Celldex) from 2007-2009, where she served as Chief Medical Officer. Prior to joining industry, Dr. Simantov spent seven years on the academic faculty at Weill Medical College of Cornell University, where she directed the fellowship program and conducted angiogenesis and vascular biology research. She has authored over 40 peer-reviewed manuscripts. Dr. Simantov earned a B.A. from Johns Hopkins University and an M.D. from New York University School of Medicine. She completed a residency in internal medicine at New York Presbyterian Hospital and a fellowship in hematology and oncology at Weill Cornell Medicine.

Thomas Klima, has served as our Chief Commercial Officer since January 2019. Before joining Gamida Cell, Mr. Klima served as the Head of Global Commercial Planning and Operations at Atara Biotherapeutics Inc. from January 2018 to January 2019. From 2015 to 2018, Mr. Klima was a Senior Vice President and Chief Commercial Officer at Navidea Biopharmaceuticals Inc. Mr. Klima also served as Head of Sales and Commercial Operations at Algeta ASA from 2012 to 2015 and led the successful commercial build-out and launch of Xofigo<sup>®</sup>. Before Algeta, he held various commercial leadership positions at Dendreon. Mr. Klima began his pharmaceutical career at Eli Lilly where he held several positions of increasing responsibility and participated in the global launch of Cymbalta<sup>®</sup>. Mr. Klima holds a B.A. in Business Administration and Marketing from Western State College, Colorado.

# Non-Employee Directors

Robert I. Blum joined our board of directors as Chairman in September 2018. Mr. Blum has served as the President and Chief Executive Officer of Cytokinetics, Inc. since January 2007. Previously, Mr. Blum held other positions of increasing responsibility following his participation in the founding of Cytokinetics.

Prior to Cytokinetics, Mr. Blum served in senior business development and marketing positions at COR Therapeutics, Inc. and in various commercial and business planning roles at Marion Laboratories, Inc. and Syntex Corporation. Mr. Blum received B.A. degrees in Human Biology and Economics from Stanford University and an M.B.A. from Harvard Business School.

Michael S. Perry, Ph.D., has served on our board of directors since May 2017. Dr. Perry has served as the Chief Executive Officer of Avita Medical Ltd since June 2017, and as a member of its board of directors since February 2013. He also served as a Managing Director of Bioscience Managers Pty Ltd. since April 2017. Prior to joining Avita Medical as Chief Executive Officer, Dr. Perry held a variety of executive roles in large pharma and biotech companies and venture capital, including as Chief Scientific Officer of Novartis Pharma A.G.'s Cell and Gene Therapy Unit and Global Head of Cellular Therapy from 2012 to 2017, Global Head of R&D at Baxter International from 2000 to 2002, and as a venture partner at Bay City Capital LLC From 2004 to 2012. He has also served as a director of Arrowhead Pharmaceuticals since December 2011 and as a director of Ampliphi Biosciences Corporation since 2005. Dr. Perry earned a Doctor of Veterinary Medicine (DVM), a Ph.D. in Biomedical Science-pharmacology and a B.Sc. in physics, all from the University of Guelph, and is also a graduate of the Harvard Business School International Management Program.

Ofer Gonen has served on our board of directors since January 2015. Mr. Gonen has served as the Chief Executive Officer of Clal Biotechnology Industries since 2016 and as a member of its board of directors since 2003. He has served as a director of MediWound since 2013. Previously, Mr. Gonen served as the general manager of Biomedical Investments and as an Academic Aide to the Governor of the Bank of Israel. Mr. Gonen holds a B.Sc. in Physics, Mathematics and Chemistry from the Hebrew University of Jerusalem and an M.A. in Economics and Finance from Tel Aviv University.

Kenneth I. Moch has served on our board since July 2016. Mr. Moch serves as the President and Chief Executive Officer of Cognition Therapeutics. He has served as a director of Zynerba Pharmaceuticals and as a director of the Biotechnology Innovation Association. Mr. Moch more than 30 years of experience in building private and public life science companies. He holds an A.B. in biochemistry from Princeton University and an M.B.A. from the Stanford University Graduate School of Business.

*Nurit Benjamini* has served on our board of directors since January 2019. Ms. Benjamini serves as Chief Financial Officer of TabTale Ltd., a company that creates fresh mobile content since December 2013. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wix.com; from 2007 to 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd., now Sigma Designs Israel Ltd., a subsidiary of Sigma Designs Inc. and from 2000 to 2007, she served as the Chief Financial Officer of Compugen Ltd. Ms. Benjamini currently serves as the chairperson of the audit committee, and on the board of directors of RedHill Biopharma Ltd., as an external director of BiolineRx Ltd., and as the chairperson of its audit committee, and on the board of directors of Allot Communications Ltd. Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

Shawn C. Tomasello has served on our board of directors since March 2019. Prior to joining Gamida Cell, Ms. Tomasello served as chief commercial officer of Kite Pharma, now part of Gilead Sciences. Ms. Tomasello previously served as chief commercial officer of commercial and medical affairs at Pharmacyclics, now part of AbbVie. Ms. Tomasello currently serves on the boards of Mesoblast Limited, UroGen Pharma, Diplomat Pharmacy, Centrexion Therapeutics and Oxford BioTherapeutics. Ms. Tomasello holds a B.S. in marketing from the University of Cincinnati and an M.B.A. from Murray State University.

Stephen T. Wills has served on our board of directors since March 2019. Mr. Wills currently serves as chief financial officer, chief operating officer and executive vice president of Palatin Technologies. Prior to joining Palatin, Mr. Wills was the executive chairman and interim principal executive officer of Derma Sciences, now part of Integra LifeSciences. Mr. Wills currently serves as chairman of the boards of directors of MediWound Ltd. and Caliper Corporation. Mr. Wills is a certified public accountant. He holds a B.S. in accounting from West Chester University and a M.S. in taxation from Temple University.

# Compensation of Executive Officers and Directors as a Group

The aggregate compensation paid by us to our executive officers and directors for the year ended December 31, 2018, was approximately \$4.6 million, including share-based compensation expenses of approximately \$2.5 million. This amount includes approximately \$0.3 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel.

We do not have any written agreements with any director providing for benefits upon the termination of such director's relationship with our company, other than our employment agreement with our Chief Executive Officer.

Our board of directors approved the payment of a bonus to certain of our executive officers upon the completion of the initial public offering and subject to the discretion of our Compensation Committee. The bonus in the amount of \$62,500 was paid during March 2019, to each of our chief executive officer, chief business officer, chief medical officer and chief financial officer.

Our office holders are also employed under the terms and conditions prescribed in personal contracts. These personal contracts provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain acceleration provisions upon material events such as a change of control or entry into a material agreement, customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition and assignment of inventions provisions may be limited under applicable law. See "Risk Factors—Risks Related to Our Business Operations—." Under current Israeli law, we may not be able to enforce office holders' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former officer holders.

Our employees are employed under the terms prescribed in their respective personal contracts, in accordance with the decisions of our management. Under these employment contracts, the employees are entitled to the social benefits prescribed by law and as otherwise provided in their personal contracts. Each of these employment contracts contains provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. Under current applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. See "Risk Factors—Risks Related to Our Business Operations—"for a further description of the enforceability of non-competition clauses. We also provide certain of our employees with a company car, which is leased from a leasing company.

# Foreign Private Issuer

Under the Companies Law, companies incorporated under the laws of the State of Israel whose shares are publicly traded, including companies with shares listed on The Nasdaq Global Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to matters such as external directors, the audit committee, the compensation committee and an internal auditor. This is the case even if our shares are not listed on a stock exchange in Israel. These requirements are in addition to the corporate governance requirements imposed by the Listing Rules of the Nasdaq Stock Market and other applicable provisions of U.S. securities laws to which we are subject (as a foreign private issuer).

We are a "foreign private issuer" under the U.S. securities laws and the Nasdaq corporate governance rules. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Also, we are not required to comply with Regulation FD,

which restricts the selective disclosure of material information. However, we are required to file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and to submit to the SEC from time to time, on Form 6-K, reports of information that would likely be material to an investment decision in our ordinary shares.

As a foreign private issuer, we are permitted to follow certain Israeli corporate governance practices instead of the Nasdaq corporate governance rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. Pursuant to the "foreign private issuer exemption":

- we established a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 25% of our voting rights and if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of shareholders, instead of 25% of our voting rights;
- we adopted and approved material changes to equity incentive plans in accordance with the Companies Law, which does not impose a requirement of shareholder approval for such actions. In addition, we follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval prior to an issuance of securities in connection with equity-based compensation of officers, directors, employees or consultants;
- with the exception of directors elected by our board of directors, our directors are elected by an annual meeting
  of our shareholders to hold office until the next annual meeting following one year from his or her election. The
  nominations for directors, which are presented to our shareholders by our board of directors, are generally
  made by the board of directors itself, in accordance with the provisions of our amended and restated articles of
  association and the Companies Law. Nominations need not be made by a nominating committee of our board
  of directors consisting solely of independent directors, as required under the Nasdaq Marketplace Rules;
- as opposed to making periodic reports to shareholders and proxy solicitation materials available to shareholders in the manner specified by the Nasdaq corporate governance rules, the Companies Law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. We will only mail such reports to shareholders upon request; and
- we follow Israeli corporate governance practice instead of Nasdaq requirements to obtain shareholder approval
  for certain dilutive events (such as issuances that will result in a change of control, certain transactions other
  than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock
  or assets of another company).

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on The Nasdaq Global Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. We also comply with Israeli corporate governance requirements under the Companies Law applicable to public companies.

# **Board Practices**

Our amended and restated articles of association provide that we may have between 5 and 11 directors. Our board of directors currently consists of seven directors. Our directors are divided into three classes with staggered three-year terms. Each class of directors consists, as nearly as possible, of one-third of the total number of directors constituting the entire board of directors. At each annual general meeting of our shareholders, the election or re-election of directors following the expiration of the term of office of the directors of that class of directors will be for a term of office that expires on the third annual general meeting following such election or re-election, such that from 2019 and after, at each annual general meeting the term of office of only one class of directors will expire. Each director will hold office

until the annual general meeting of our shareholders in which his or her term expires, unless they are removed by a vote of 60% of the total voting power of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Israeli Companies Law and our amended and restated articles of association.

Our directors are divided among the three classes as follows:

- the Class I directors are Kenneth I. Moch, Dr. Michael S. Perry and Nurit Benjamini, and their terms will expire
  at the annual general meeting of the shareholders to be held in 2020 and when their successors are elected
  and qualified;
- (ii) the Class II directors are Robert I. Blum, Dr. Julian Adams and Ofer Gonen, and their terms will expire at the annual general meeting of the shareholders to be held in 2021 and when their successors are elected and qualified; and
- (iii) the Class III directors are Shawn C. Tomasello and Stephen T. Willis, and their terms will expire at the annual general meeting of the shareholders to be held in 2022 and when their successors are elected and qualified.

Because our ordinary shares do not have cumulative voting rights in the election of directors, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors up for election or re-election.

In addition, if a director's office becomes vacant, the remaining serving directors may continue to act in any manner, provided that their number is of the minimal number specified in our amended and restated articles of association. If the number of serving directors is lower than five, then our board of directors may only act in an emergency or to fill the office of director which has become vacant up to a number equal to the minimum number provided for pursuant to our amended and restated articles of association, or in order to call a general meeting of the Company's shareholders for the purpose of electing directors to fill any of our vacancies. In addition, the directors may appoint, immediately or of a future date, additional director(s) to serve until the subsequent annual general meeting of our shareholders, provided that the total number of directors in office shall not exceed directors.

Pursuant to the Companies Law and our amended and restated articles of association, a resolution proposed at any meeting of our board of directors at which a quorum is present is adopted if approved by a vote of a majority of the directors present and eligible to vote. A quorum of the board of directors requires at least a majority of the directors then in office who are lawfully entitled to participate in the meeting.

In addition, under the Companies Law, our board of directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the listed company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that we require at least one director with the requisite financial and accounting expertise. Robert Blum has such financial and accounting expertise.

Each of our non-executive directors is entitled to the following payments, which are paid in arrears, in quarterly installments: (i) an annual fee of \$40,000 plus VAT, if applicable, (ii) for each committee membership, other than the nominating and corporate governance committee, an additional annual fee of \$10,000 plus VAT, if applicable, and an additional annual fee of \$4,000 plus VAT, if applicable for the nominating and corporate governance committee, (iii) for chairmanship of the board of directors an additional annual fee of \$20,000 plus VAT, if applicable, and (iv) for each chairmanship of a committee of the board of directors, other than the nominating and corporate governance committee, an additional annual fee of \$5,000 plus VAT, if applicable, and an additional annual fee of \$3,500 plus VAT, if applicable, for the nominating and corporate governance committee. In addition, each of our non-executive directors, other than the chairman of the board of directors, is entitled to receive a grant of options to purchase

18,000 ordinary shares of the Company upon his or her initial appointment or election and thereafter an annual grant of options to purchase 12,000 ordinary shares of the Company, and the chairman of the board of directors is entitled to receive an annual grant of options to purchase 15,000 ordinary shares of the Company.

#### Alternate directors

Our amended and restated articles of association provide, as allowed by the Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. The alternate director will be regarded as a director. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors as long as he or she is not already serving as a member of such committee. The term of appointment of an alternate director may be for one meeting of the board of directors or until notice is given of the cancellation of the appointment.

### **External directors**

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," including companies with shares listed on The Nasdaq Global Market, are required to appoint at least two external directors.

Pursuant to regulations promulgated under the Companies Law, companies with shares traded on a U.S. stock exchange, including The Nasdaq Global Market, may, subject to certain conditions, "opt out" from the Companies Law requirements to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors. In accordance with these regulations, we elected to "opt out" from the Companies Law requirement to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors.

Under these regulations, the exemptions from such Companies Law requirements will continue to be available to us so long as: (i) we do not have a "controlling shareholder" (as such term is defined under the Companies Law), (ii) our shares are traded on a U.S. stock exchange, including The Nasdaq Global Market, and (iii) we comply with the director independence requirements, the audit committee and the compensation committee composition requirements, under U.S. laws (including applicable Nasdaq Rules) applicable to U.S. domestic issuers.

## **Audit committee**

Under the Companies Law, the board of directors of any public company must appoint an audit committee, comprised of at least three directors.

# Nasdaq requirements

Under the Nasdaq Rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

Our audit committee consists of Nurit Benjamini, Stephen T. Wills and Kenneth I. Moch. Ms. Benjamini serves as Chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq corporate governance rules and are independent directors under such rules. Our board of directors has determined that Ms. Benjamini is an "audit committee financial expert" as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq Rules. Our board of directors has determined that each member of our audit committee is independent as such term is defined in Rule 10A-3 under the Exchange Act, and that each member of our audit committee satisfies the additional requirements applicable under the Nasdaq Rules to members of audit committees.

# Approval of transactions with related parties

Under the Companies Law, the approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See "Management—Board Practices—Fiduciary duties and approval of specified related party transactions under Israeli law." The term "controlling shareholder" means any shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its chief executive officer. For the purpose of approving transactions with controlling shareholders, the term "controlling shareholder" also includes any shareholder that holds 25% or more of the voting rights of the company if no other shareholder holds more than 50% of the voting rights in the company. For purposes of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders. As of the date of this prospectus, we do not have a controlling shareholder as defined under the Companies Law.

### **Audit committee role**

Our board of directors has adopted an audit committee charter setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq Rules, which include, among others:

- retaining and terminating our independent auditors, subject to the ratification of the board of directors, and in the case of retention, to that of the shareholders;
- pre-approving of audit and non-audit services and related fees and terms, to be provided by the independent
  auditors; overseeing the accounting and financial reporting processes of our company and audits of our
  financial statements, the effectiveness of our internal control over financial reporting and making such reports
  as may be required of an audit committee under the rules and regulations promulgated under the Exchange
  Act:
- reviewing with management and our independent auditor our annual and quarterly financial statements prior to publication or filing (or submission, as the case may be) to the SEC;
- recommending to the board of directors the retention and termination of the internal auditor, and the internal auditor's engagement fees and terms, in accordance with the Companies Law as well as approving the yearly or periodic work plan proposed by the internal auditor;
- reviewing with our general counsel and/or external counsel, as deem necessary, legal and regulatory matters
  that could have a material impact on the financial statements;
- identifying irregularities in our business administration, inter alia, by consulting with the internal auditor or with the independent auditor, and suggesting corrective measures to the board of directors; and
- reviewing policies and procedures with respect to transactions (other than transactions related to the
  compensation or terms of services) between the company and officers and directors, or affiliates of officers or
  directors, or transactions that are not in the ordinary course of the Company's business and deciding whether
  to approve such acts and transactions if so required under the Companies Law.

# Compensation committee

Under the Companies Law, the board of directors of any public company must appoint a compensation committee. Our compensation committee, which consists of Ofer Gonen, Dr. Michael S. Perry, Kenneth I. Moch and Shawn C. Tomasello, assists our board of directors in determining compensation for our directors and officers. Mr. Moch serves as Chairman of the committee. Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Rules, including the additional independence requirements applicable to the members of a compensation committee.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- making recommendations to the board of directors with respect to the approval of the compensation policy for
  office holders and, once every three years, regarding any extensions to a compensation policy that was
  adopted for a period of more than three years;
- reviewing the implementation of the compensation policy and periodically making recommendations to the board of directors with respect to any amendments or updates to the compensation policy;
- resolving whether or not to approve arrangements with respect to the terms of office and employment of office holders; and
- exempting, under certain circumstances, a transaction with our chief executive officer from the approval of the general meeting of our shareholders.

Our board of directors has adopted a compensation committee charter setting forth the responsibilities of the committee consistent with the Nasdag Rules, which include among others:

- recommending a compensation policy to our board of directors for its approval, in accordance with the
  requirements of the Companies Law, as well as making recommendations to the board of directors with respect
  to other compensation policies, incentive-based compensation plans and equity-based compensation plans,
  overseeing the development and implementation of such policies and recommending to our board of directors
  any amendments or modifications that the committee deems appropriate, including as required under the
  Companies Law;
- reviewing and approving the granting of options and other incentive awards to the chief executive officer and
  other executive officers, including reviewing and approving corporate goals and objectives relevant to the
  compensation of our chief executive officer and other executive officers, and evaluating their performance in
  light of such goals and objectives;
- approving and exempting certain transactions regarding office holders' compensation pursuant to the Companies Law; and
- administering our equity-based compensation plans, including without limitation, approving the adoption of such plans, amending and interpreting such plans and the awards and agreements issued pursuant thereto, and making awards to eligible persons under the plans and determining the terms of such awards.

In general, under the Companies Law, a public company must have a compensation policy approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, our compensation policy must be approved at least once every three years, first, by our board of directors, upon recommendation of our compensation committee, and second, by a simple majority of the ordinary shares present, in person or by proxy, and voting at a shareholders meeting, provided that either:

- such majority includes at least a majority of the shares held by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such compensation arrangement and who are present and voting (excluding abstentions); or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement, does not exceed 2% of the company's aggregate voting rights.

We refer to this as the Special Approval for Compensation. Under the Companies Law, subject to certain conditions, the board of directors may ratify the compensation policy even if it is not ratified by the shareholders.

Pursuant to the Companies Law, under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed grounds and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the shareholders, is for the benefit of the company.

If a company that initially offers its securities to the public adopts a compensation policy in advance of its initial public offering and describes it in its prospectus for such offering, as in the case of our company, then such compensation policy shall be deemed a validly adopted policy in accordance with the Companies Law requirements described above. Furthermore, if the compensation policy is established in accordance with the aforementioned relief, then it will remain in effect for term of five years from the date such company becomes a public company. We have adopted our compensation policy pursuant to the foregoing relief.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must be determined and later reevaluated according to certain factors, including: the advancement of the company's objectives, business plan and long-term strategy; the creation of appropriate incentives for office holders, while considering, among other things, the company's size, the nature of its operations and risk management policy; and, with respect to variable compensation, the contribution of the office holder towards the achievement of the company's long-term goals and the maximization of its profits, all with a long-term objective and according to the position of the office holder. The compensation policy must furthermore consider the following additional factors:

- the education, skills, experience, expertise and accomplishments of the relevant office holder;
- the office holder's position, responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the employment of
  other employees of the company, including employees employed through contractors who provide services to
  the company, in particular the ratio between such cost to the average and median salary of such employees of
  the company, as well as the impact of disparities between them on the work relationships in the company;
- if the terms of employment include variable components—the possibility of reducing variable components at the discretion of the board of directors and the possibility of setting a limit on the value of non-cash variable equity-based components; and
- if the terms of employment include severance compensation—the term of employment or office of the office holder, the terms of his or her compensation during such period, the company's performance during the such period, his or her individual contribution to the achievement of the company goals and the maximization of its profits and the circumstances under which he or she is leaving the company.

The compensation policy must also include, among others, with regards to variable components:

- with the exception of office holders who report directly to the chief executive officer, determining the variable
  components on long-term performance basis and on measurable criteria; however, the company may
  determine that an immaterial part of the variable components of an office holder's compensation package shall
  be awarded based on non-measurable criteria, if such amount is not higher than three months' salary per
  annum, while taking into account such office holder's contribution to the company;
- the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their payment, or in the case of equity-based compensation, at the time of grant;

- a condition under which the office holder will return to the company, according to conditions to be set forth in
  the compensation policy, any amounts paid as part of his or her terms of employment, if such amounts were
  paid based on information later to be discovered to be wrong, and such information was restated in the
  company's financial statements;
- the minimum holding or vesting period of variable equity-based components to be set in the terms of office or employment, as applicable, while taking into consideration long-term incentives; and
- a limit to retirement grants.

Our compensation policy, which became effective immediately after the pricing of our initial public offering, is designed to promote retention and motivation of directors and executive officers, incentivize individual excellence, align the interests of our directors and executive officers with our long-term performance and provide a risk management tool. To that end, a portion of an executive officer compensation package is targeted to reflect our short and long-term goals, as well as the executive officer's individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer's incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officers' individual characteristics (such as their respective positions, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers, and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses and other cash bonuses (such as a signing bonus and special bonuses with respect to any special achievements, such as outstanding personal achievement, outstanding personal effort or outstanding company performance), equity-based compensation, benefits, retirement and termination of service arrangements. All cash bonuses are limited to a maximum amount linked to the executive officer's base salary. In addition, the total variable compensation components (cash bonuses and equity-based compensation) may not exceed 90% of each executive officer's total compensation package with respect to any given calendar year.

An annual cash bonus may be awarded to executive officers upon the attainment of pre-set periodic objectives and individual targets. The annual cash bonus that may be granted to our executive officers other than our chief executive officer will be based on performance objectives and a discretionary evaluation of the executive officer's overall performance by our chief executive officer and subject to minimum thresholds. The annual cash bonus that may be granted to executive officers other than our chief executive officer may be based entirely on a discretionary evaluation. Furthermore, our chief executive officer will be entitled to recommend performance objectives, and such performance objectives will be approved by our compensation committee (and, if required by law, by our board of directors).

The measurable performance objectives of our chief executive officer will be determined annually by our compensation committee and board of directors, will include the weight to be assigned to each achievement in the overall evaluation. A non-material portion of the chief executive officer's annual cash bonus may be based on a discretionary evaluation of the chief executive officer's overall performance by the compensation committee and the board of directors based on quantitative and qualitative criteria.

The equity-based compensation under our compensation policy for our executive officers (including members of our board of directors) is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the executive officers' interests with our long-term interests and those of our shareholders and to strengthen the retention and the motivation of executive officers in the long term. Our compensation policy provides for executive officer compensation in the form of share options or other equity-based awards, such as restricted shares and restricted share units, in accordance with our share incentive plan then in place. All equity-based incentives granted to executive officers shall be subject to vesting periods in order to promote long-term retention of the awarded executive officers. The

equity-based compensation shall be granted from time to time and shall be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and personal responsibilities of each executive officer.

In addition, our compensation policy contains compensation recovery provisions which allow us under certain conditions to recover bonuses paid in excess, enables our chief executive officer to approve an immaterial change in the terms of employment of an executive officer who reports directly to the chief executive officer (provided that the changes of the terms of employment are in accordance with our compensation policy) and allows us to exculpate, indemnify and insure our executive officers and directors to the maximum extent permitted by Israeli law, subject to certain limitations set forth therein.

Our compensation policy also provides for compensation to the members of our board of directors either (i) in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time, or (ii) in accordance with the amounts determined in our compensation policy.

### Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Robert Blum, Dr. Julian Adams and Ofer Gonen. The function of the nominating and corporate governance committee is described in the approved charter of the committee, and includes responsibility for identifying individuals qualified to become board members and recommending that the board of directors consider the director nominees for election at the general meeting of shareholders. The nominating and corporate governance committee is also responsible for developing and recommending to the board of directors a set of corporate governance guidelines applicable to the company, periodically reviewing such guidelines and recommending any changes thereto.

### Internal auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor cannot be an interested party or an office holder or a relative of an interested party or an office holder, nor may the internal auditor be the company's independent auditor or its representative. An "interested party" is defined in the Companies Law as: (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. Our internal auditor is Yisrael Gewirtz, who serves as a partner at Fahn Kanne Control Management Ltd.

# Fiduciary duties and approval of specified related party transactions under Israeli law Fiduciary duties of office holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company.

The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version), 5728-1968. The duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among others, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to these actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes, among others, the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal benefit for himself or herself or for others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above that would otherwise constitute a breach of the duty of loyalty of an office holder, provided, that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest, including any related material information or document, a sufficient time before the approval of such act. Any such approval is subject to the terms of the Companies Law, setting forth, among other things, the stakeholders of the company entitled to provide such approval, and the methods of obtaining such approval.

### Disclosure of personal interests of an office holder and approval of acts and transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to make such disclosure if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

Under the Companies Law, once an office holder has complied with the above disclosure requirements, a company may approve a transaction between the company and the office holder or a third-party in which the office holder has a personal interest, or approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty; however, a company may not approve a transaction or action that is not performed by the office holder in good faith or unless it is in the company's interest.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or a transaction with a third party in which the office holder has a personal interest and an action of an office holder that would otherwise be deemed a breach of duty of loyalty, which is not an extraordinary transaction, requires approval of the board of directors. Our amended and restated articles of association do not provide otherwise.

Under the Companies Law, an extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors. The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy or if the office holder is the chief executive officer (subject to a number of exceptions), then such arrangement is subject to a Special Approval for Compensation. Arrangements regarding the compensation, indemnification or insurance of a director or the chief executive officer of the company require the approval of the compensation committee, board of directors and, subject to certain exceptions, shareholders by an ordinary majority, in that order, and in the case of the chief executive officer or under certain circumstances, a Special Approval for Compensation.

A director who has a personal interest in a matter that is considered at a meeting of the board of directors or the audit committee may generally not be present at the meeting or vote on the matter unless a majority of the directors or members of the audit committee have a personal interest in the matter, or

unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present to present the transaction that is subject to approval. If a majority of the directors have a personal interest in the matter, such matter also requires approval of the shareholders of the company.

Under the Companies Law, the definition of a "personal interest" includes the personal interest of a person in an action or a transaction of a company, including the personal interest of such person's relative or the interest of any corporation in which the person and/or such person's relative is a director or chief executive officer, a 5% or more shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the chief executive officer, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave the proxy to another person to vote on his or her behalf, regardless of whether the proxy holder has discretion how to vote on the matter.

Under the Companies Law, an "extraordinary transaction" which requires approval is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

An extraordinary transaction in which an office holder has a personal interest requires approval of the company's audit committee followed by the approval of the board of directors.

### Compensation of Executive Officers

The table below reflects the compensation granted to our five most highly compensated office holders (as defined in the Companies Law) during or with respect to the year ended December 31, 2018. We refer to the five individuals for whom disclosure is provided herein as our "Covered Executives." For purposes of the table below, "compensation" includes amounts accrued or paid in connection with salary cost, consultancy fees, bonuses, share-based compensation, retirement or termination payments, benefits and perquisites such as car, phone and social benefits and any undertaking to provide such compensation. All amounts reported in the table are in terms of cost to the Company, as recognized in our consolidated financial statements for the year ended December 31, 2018, plus compensation paid to such Covered Executives following the end of the year in respect of services provided during the year. Each of the Covered Executives was covered by our director and officer liability insurance policy and was entitled to indemnification and exculpation in accordance with applicable law and our articles of association.

# Individual Covered Executive Compensation

Name and Principal Position <sup>(1)</sup>		Salary <sup>(2)</sup>		nus	Share-based Compensation <sup>(3)</sup> In thousands US		All other compensation <sup>(4)</sup>	Total
Dr. Julian Adams - Director and Chief Executive Officer	\$	575	\$	_	\$	1,083	\$ 5	\$1,663
Dr. Yael Margolin - Former Director and Chief Executive Officer		376		_		539	17	932
Dr. Ronit Simantov - Chief Medical Officer		372		50		411	14	847
Shai Lankry - Chief Financial Officer		193		_		411	7	611
Joshua Hamermesh - Chief Business Officer		274		_		317	ć	600

<sup>(1)</sup> All Covered Executives were employed on a full time (100%) basis during their term of employment in 2018.

<sup>(2)</sup> Salary includes the Covered Executive's gross salary plus payment of social benefits made by us on behalf of such Covered Executive. Such benefits may include, to the extent applicable to the Covered Executive, payments, contributions and/or allocations for savings funds (e.g., managers' life insurance policy), education funds (referred to in Hebrew as "keren hishtalmut"), pension, severance, risk insurances (e.g., life, or work disability insurance), payments for social security and tax gross-up payments, vacation, medical insurance and benefits, convalescence or recreation pay and other benefits and perquisites consistent with our policies.

- (3) Represents the share-based compensation expenses recorded in the Company's consolidated financial statements for the year ended December 31, 2018, based on the option's fair value, calculated in accordance with accounting guidance for share-based compensation. For a discussion of the assumptions used in reaching this valuation, see Note 11 to our consolidated financial statements.
- (4) Including leased car expenses.

# Letter Agreement with Dr. Julian Adams

We entered into a letter agreement with Dr. Julian Adams, our director and chief executive officer, dated November 20, 2017.

Under the terms of the letter agreement, as amended, Dr. Adams is entitled to a gross monthly salary of \$43,167, which is equivalent to a gross salary of \$518,000 on an annualized basis, or the Base Salary, reimbursement of business expenses, disability coverage and health insurance coverage in accordance with the Company's health care plan. In addition, Dr. Adams is eligible to receive a cash incentive target gross bonus equal to 40% of the annual Base Salary, or the Incentive Bonus. The Incentive Bonus is based on the attainment of performance goals and milestones as will be determined by the board of directors of the Company.

Upon termination of his employment (other than for cause), Dr. Adams is entitled to receive, during up to eight months following the date on which his employment is terminated, the annual Incentive Bonus, pro-rated for the portion of that year until the last day of employment, a monthly payment equal to the Base Salary, the cost of health insurance premium and disability benefit premiums as in effect on the date of termination of his employment.

In the event of a change of control of the Company, if Dr. Adams' employment is terminated by the Company without cause, or if he resigns on account of good reason, each within 12 months following the change of control, then Dr. Adams will be entitled to a bonus payment equal to his target annual bonus as well as full acceleration of any options granted to him until the date of the change of control.

In June 2019, the general meeting of the Company's shareholders approved an aggregate grant to Dr. Adams of options to purchase 138,000 ordinary shares of the Company, with an exercise price per share of \$11.01 (the closing price of the Company's ordinary shares on Nasdaq on the date of approval by our board of directors). The options will vest and become exercisable under the following schedule: twenty-five percent (25%) of the options, on the first anniversary of the grant date, and six and one-quarter percent (6.25%) of the options, at the end of each subsequent three-month period thereafter over the course of the following three (3) years, subject to an acceleration in the event of certain terminations of employment within a certain period of time after a change of control; provided that Dr. Adams remains continuously as an employee or service provider of the Company or its subsidiary throughout such vesting dates. The term of the options will be 10 years, unless they expire earlier in accordance with the terms of the 2017 Plan.

# Disclosure of personal interests of a controlling shareholder and approval of transactions

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See "Management—Board Practices — Audit committee—Approval of transactions with related parties" for a definition of controlling shareholder. Unless exempted under the Companies Law, extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, which includes transactions for the provision of services by a controlling shareholder or his or her relative, whether directly or indirectly, including through a company controlled by such controlling shareholder, and if such controlling shareholder or relative thereof is an office holder in the company, any transactions regarding his or her terms of office, require the approval of the audit committee, the board of directors and a majority of the shares voted by the shareholders of the company participating and voting on the matter in a shareholders' meeting. In addition, the shareholder approval must fulfill one of the following requirements, which we refer to as a Special Majority:

 at least a majority of the shares held by shareholders who do not have a personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

• the shares voted by shareholders who do not have a personal interest in the transaction who vote against the transaction represent no more than two percent (2%) of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires approval once every three years, unless, with respect to certain transactions that are not related to provision of services or terms of office, the audit committee determines that the longer duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Companies Law, certain transactions and arrangements with a controlling shareholder or his or her relative, or with directors or office holders, which would otherwise require approval of a company's shareholders, may be exempt from shareholder approval under certain conditions.

### Compensation of Directors and Executive Officers

*Directors*. Under the Companies Law, the compensation of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. If the compensation of our directors is inconsistent with our stated compensation policy, then, those provisions that must be included in the compensation policy according to the Companies Law must have been considered by the compensation committee and board of directors, and shareholder approval will also be required, provided that:

- at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such matter, present and voting at such meeting, are voted in favor of the compensation package, excluding abstentions; or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed two percent (2%) of the aggregate voting rights in the company.

Executive officers other than the chief executive officer. The Companies Law requires the approval of the compensation of a public company's executive officers (other than the chief executive officer) in the following order: (i) the compensation committee, (ii) the company's board of directors, and (iii) if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision.

An amendment to an existing arrangement with an office holder who is not the chief executive officer or a director requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. However, according to regulations promulgated under the Israeli Companies Law, an amendment to an existing arrangement with an office holder who is subordinate to the chief executive officer (and who is not a director) shall not require the approval of the compensation committee, if (i) the amendment is approved by the chief executive officer and the company's compensation policy determines that a non-material amendment to the terms of service of an office holder (other than the chief executive officer) may be approved by the chief executive officer and (ii) the engagement terms are consistent with the company's compensation policy.

Chief executive officer. Under the Companies Law, the compensation of a public company's chief executive officer is required to be approved by: (i) the company's compensation committee; (ii) the company's board of directors, and (iii) the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed report for their decision. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). In addition, the compensation committee may waive the shareholder approval requirement with regards to the approval of the engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

### **Duties of shareholders**

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at general meetings of shareholders on the following matters:

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above mentioned shareholder duties, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or any other power with respect to the company, has a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

# Approval of private placements

Under the Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in special circumstances, such as a private placement completed in lieu of a special tender offer or a private placement which qualifies as a related party transaction (see "Management—Board Practices—Fiduciary duties and approval of specified related party transactions under Israeli law"), approval at a general meeting of the shareholders of a company is required.

### **Exculpation, Insurance and Indemnification of Office Holders**

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. A company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of the duty of care but only if a provision

authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. An Israeli company may not exculpate a director from liability arising out of a breach of the duty of care with respect to a dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738—1968, or the Securities Law, a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- a monetary liability incurred by or imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such undertaking must be limited to certain events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the foreseen events and described above amount or criteria;
- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder as (1) a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; or (2) in connection with a monetary sanction; a monetary liability imposed on him or her in favor of an injured party at an Administrative Procedure (as defined below) pursuant to Section 52(54)(a)(1)(a) of the Securities Law;
- expenses incurred by an office holder or certain compensation payments made to an injured party that were
  instituted against an office holder in connection with an Administrative Procedure under the Securities Law,
  including reasonable litigation expenses and reasonable attorneys' fees; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in
  proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with
  criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that
  does not require proof of criminal intent.

"Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a breach of duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure instituted against him or her, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the
  company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the
  act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See "Management—Board Practices—Fiduciary duties and approval of specified related party transactions under Israeli law."

Our amended and restated articles of association permit us to, exculpate, indemnify and insure our office holders as permitted under the Companies Law. Our office holders are currently covered by a directors and officers' liability insurance policy. As of the date of this registration statement, no claims for directors' and officers' liability insurance have been filed under this policy, we are not aware of any pending or threatened litigation or proceeding involving any of our directors or officers in which indemnification is sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

We have entered into agreements with each of our directors and executive officers exculpating them, to the fullest extent permitted by law, from liability to us for damages caused to us as a result of a breach of duty of care, and undertaking to indemnify them to the fullest extent permitted by law. The insurance is subject to our discretion depending on its availability, effectiveness and cost. Effective as October 30, 2018, the maximum amount set forth in such agreements is (1) with respect to indemnification in connection with a public offering of our securities, the gross proceeds raised by us and/or any selling shareholder in such public offering, and (2) with respect to all permitted indemnification, the greater of (i) an amount equal to 25% of our shareholders' equity on a consolidated basis, based on our most recent financial statements made publicly available before the date on which the indemnity payment is made and (ii) \$40 million. In the opinion of the SEC, indemnification of directors and executive officers for liabilities arising under the Securities Act however, is against public policy and therefore unenforceable.

## **Equity Compensation Plans**

# Employee Share and Option Plan (1998)

In 1998, our board of directors adopted our Employee Share and Option Plan (1998), or the 1998 Plan. There are currently no options outstanding or options available for issuance under the 1998 Plan. There are currently 152,809 ordinary shares, which resulted from the exercise of certain options granted under the 1998 Plan, held in trust in favor of the employees who exercised such options. The 1998 Plan remains in effect in order to allow our employees to enjoy certain tax benefits under Israeli tax law.

# Stock Option Plan (1999)

In 1999, our board of directors adopted our Stock Option Plan (1999), or the 1999 Plan. There are currently no options outstanding or options available for issuance under the 1999 Plan. There are currently 3,300 ordinary shares, which resulted from the exercise of certain options granted under the 1999 Plan, held in trust in favor of the employees who exercised such options. The 1999 Plan remains in effect in order to allow our employees to enjoy certain tax benefits under Israeli tax law.

# 2003 Israeli Share Option Plan

In July 2003, our board of directors adopted our 2003 Israeli Share Option Plan, or the 2003 Plan. There are currently no options outstanding or options available for issuance under the 2003 Plan. There

are currently 73,888 ordinary shares, which resulted from the exercise of certain options granted under the 2003 Plan, held in trust in favor of the employees who exercised such options. The 2003 Plan remains in effect in order to allow our employees to enjoy certain tax benefits under Israeli tax law.

### 2014 Israeli Share Incentive Plan

In November 2014 and December 2014, respectively, our board of directors adopted and our shareholders approved our 2014 Israeli Share Incentive Plan, or the 2014 Plan. The 2014 Plan replaced our 2003 Plan. We are no longer granting options under the 2014 Plan because it was superseded by our 2017 Share Incentive Plan, or the 2017 Plan, although previously granted awards remain outstanding. As of December 31, 2018, following the conversion of the Ordinary C shares into ordinary shares in connection with our initial public offering, we had options to purchase 1,112,250 Ordinary Shares outstanding under the 2014 Plan with a weighted-average exercise price of \$0.25.

The 2014 Plan provides for the grant of options to the Company's and affiliates' directors, employees, officers, consultants, advisors and service providers, and any other person whose services are considered valuable to us or our affiliates, to encourage a sense of proprietorship of such persons, and to stimulate the active interest of such persons in the development and financial success of the Company by providing them with opportunities to purchase shares in the Company.

The 2014 Plan is administered by our board of directors directly or upon recommendation of a committee designated by the board of directors, which determines, subject to Israeli law, the grantees of awards and the terms of the grant, including, exercise prices, vesting schedules, acceleration of vesting and the other matters necessary in the administration of the 2014 Plan. The 2014 Plan enables us to issue awards under various tax regimes, including, without limitation, pursuant to Section 102 of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance, and under Section 3(i) of the Ordinance.

Section 102 of the Ordinance allows employees, directors and officers, who are not controlling shareholders, to receive favorable tax treatment for compensation in the form of shares or options. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, which provides the most favorable tax treatment for grantees, permits the issuance to a trustee under the "capital gain track." Note however, that according to Section 102(b)(3) of the Ordinance, if the company granting the shares or options is a publicly traded company or is listed for trading on any stock exchange within a period of 90 days from the date of grant, any difference between the exercise price of the Awards (if any) and the average closing price of the company's shares at the 30 trading days preceding the grant date (when the company is listed on a stock exchange) or 30 trading days following the listing of the company, as applicable, will be taxed as "ordinary income" at the grantee's marginal tax rate. In order to comply with the terms of the capital gain track, all securities granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such securities and other shares received following any realization of rights with respect to such securities, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant grantee. The trustee may not release these securities to the relevant grantee before 24 months from the date of grant and deposit of such securities with the trustee. However, under this track, we are not allowed to deduct an expense with respect to the issuance of the options or shares.

The 2014 Plan provides that options granted to our employees, directors and officers who are not controlling shareholders and who are considered Israeli residents may be intended to qualify for special tax treatment under the "capital gain track" provisions of Section 102(b) of the Ordinance as detailed above. Our Israeli non-employee service providers and controlling shareholders may only be granted options under Section 3(i) of the Ordinance, which does not provide for similar tax benefits.

The options granted under the 2014 Plan are currently fully vested.

Options expiry is determined by the specific option agreement or at the end of an extended period following the termination of the grantee's employment or service. In the event of the death of a grantee

while employed by or performing service for us or a subsidiary, or in the event of termination of a grantee's employment or services for reasons of disability, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within the twelve (12) month period from the date of disability or death. If a grantee's employment or service is terminated by reason of retirement in accordance with applicable law, the grantee may exercise his or her vested options within the twelve (12) month period after the date of such retirement. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested options will expire on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may generally exercise his or her vested options within 90 days of the date of termination.

Options may not be assigned, transferred or given as collateral nor may any right with respect to the options be given to a third party. As long as options and/or shares are held by the Section 102 trustee, all rights of the grantee over the shares may not be transferred, assigned, pledged or mortgaged, except by will or the laws of descent and distribution.

In the event of a merger, acquisition or reorganization of our company, or a sale of all, or substantially all, of our shares or assets or other transaction having a similar effect on us, then without the consent of the option holder, our board of directors or its designated committee, as applicable, may but is not required to (i) cause any outstanding options to be assumed or an equivalent award to be substituted by such successor corporation, or (ii) in case the successor corporation does not assume or substitute the award (a) if provided for in the relevant option agreement – all unvested options of the applicable grantee shall become vested and such grantee shall have the right to exercise such options in connection with such transaction or (b) cancel the options and substitute for any other type of asset or property determined by the board of directors or the committee as fair under the circumstances.

### 2017 Share Incentive Plan

In January 2017 and February 2017, respectively, our board of directors adopted and our shareholders approved our 2017 Plan. The 2017 Plan replaced our 2014 Plan. We are no longer granting options under the 2014 Plan because it was superseded by the 2017 Plan, although previously granted awards remain outstanding. As of December 31, 2018, we had options to purchase 2,085,366 ordinary shares outstanding under the 2017 Plan with a weighted-average exercise price of \$4.57.

As of December 31, 2018, our 2017 Plan, as amended, has up to 787,933 ordinary shares reserved for issuance to plan beneficiaries. The 2017 Plan, as amended, also contains an "evergreen" provision, which provides for an automatic allotment of ordinary shares to be added every year to the pool of ordinary shares available for grant under the 2017 Plan. Under the evergreen provision, on January 1 of each year (beginning January 1, 2020), the number of ordinary shares available under the 2017 Plan automatically increases by the lesser of the following: (i) three and one-half percent (3.5%) of our outstanding ordinary shares on the last day of the immediately preceding year; and (ii) an amount determined in advance of January 1 by the board.

The 2017 Plan provides for the grant of awards, including options, restricted shares and RSUs, to the Company's and affiliates' directors, employees, officers, consultants, advisors, and any other person whose services are considered valuable to us or our affiliates, to increase their efforts on our and our affiliates' behalf, and to promote the success of the Company's business by providing them with opportunities to acquire a proprietary interest in the Company.

The 2017 Plan is administered by a committee designated by the board of directors, which determines, subject to Israeli law, the grantees of awards and the terms of the grant, including, exercise prices, vesting schedules, acceleration of vesting and conditions and restrictions applicable to an award, as well other matters necessary in the administration of the 2017 Plan. In the event that the Board does not appoint or establish a committee, the 2017 Plan shall be administered by the Board. The 2017 Plan enables us to issue awards under various tax regimes, including, without limitation, pursuant to Section 102 of the Ordinance as discussed under "2014 Israeli Share Option Plan" above, and under Section 3(i) of the Ordinance and Section 422 of the United States Internal Revenue Code of 1986, as amended, or the Code.

The 2017 Plan provides that awards granted to our employees, directors and officers who are not controlling shareholders and who are considered Israeli residents are intended to qualify for special tax

treatment under the "capital gain track" provisions of Section 102(b) of the Ordinance as detailed above. Our Israeli nonemployee service providers and controlling shareholders may only be granted awards under Section 3(i) of the Ordinance, which does not provide for similar tax benefits.

Awards granted under the 2017 Plan to U.S. residents may qualify as "incentive stock options" within the meaning of Section 422 of the Code, or may be non-qualified. The exercise price for "incentive stock options" must not be less than the fair market value on the date on which an option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

The vesting schedule of options granted under the 2017 Plan is set forth in each grantee's grant letter.

Awards terminate upon the date set out in the grantee's specific award agreement or at the end of an extended period following the termination of the grantee's employment or service. In the event of the death of a grantee while employed by or performing service for us or an affiliate, or within the three (3) month period after the termination, or in the event of termination of a grantee's employment or services for reasons of disability, the grantee (or his or her estate or legal successor (in the case of death) or the person who acquired legal rights to exercise such awards (in the case of death or disability)), may exercise awards that have vested prior to termination within a period of one (1) year from the date of disability or death but in any event no later than the expiration date of the awards. If a grantee's employment or service is terminated by reason of retirement in accordance with applicable law, the grantee may exercise his or her vested awards within the three (3) month period after the date of such retirement. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested awards will expire on the date of termination. If a grantee's employment or service is terminated for any other reason, all unvested awards shall expire and the grantee may exercise his or her vested awards within three (3) months after the date of termination. Any expired or unvested awards return to the pool and become available for reissuance.

Options may not be assigned or transferred other than by will or laws of descent, unless otherwise determined by the committee.

In the event of a merger or consolidation of our company, or a sale of all, or substantially all, of our shares or assets or other transaction having a similar effect on us, or liquidation or dissolution, or such other transaction or circumstances that the Board determines to be a relevant transaction, then without the consent of the grantee, our board of directors or its designated committee, as applicable, may but is not required to (i) cause any outstanding award to be assumed or substituted by such successor corporation, or (ii) regardless of whether or not the successor corporation assumes or substitutes the award (a) provide the grantee with the option to exercise the award as to all or part of the shares, and may provide for an acceleration of vesting of unvested awards, or (b) cancel the award and pay in cash, shares of the company, the acquirer or other corporation which is a party to such transaction or other property as determined by the board of directors or the committee as fair in the circumstances. Notwithstanding the foregoing, our board of directors or its designated committee may upon such event amend, modify or terminate the terms of any award as the board of directors or the committee shall deem, in good faith, appropriate.

As of December 31, 2018, outstanding awards under our Equity Incentive Plans totaled 3,197,616 ordinary shares and an additional 723,872 awards were available for grant. Of the 3,197,616 outstanding options, options to purchase 1,705,256 ordinary shares were vested as of December 31, 2018, with a weighted average exercise price of \$1.20 per share, and will expire between January 18, 2020 and October 29, 2028.

# PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of June 4, 2019 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- · each of our directors and executive officers; and
- all of our directors and executive officers as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days of June 4, 2019 to be outstanding and to be beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

As of June 4, 2019 and based on their reported registered office, 3 of our record holders were U.S. persons, holding in aggregate approximately 0.6% of our outstanding ordinary shares immediately prior to this offering. These do not include outstanding ordinary shares held in street name. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

A description of any material relationship that our principal shareholders have had with us or any of our predecessors or affiliates within the past three years is included under "Certain Relationships and Related Party Transactions."

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o Gamida Cell Ltd., 5 Nahum Heftsadie St., Givaat Shaul, Jerusalem 91340, Israel.

	No. of Shares Beneficially Owned Prior to this Offering <sup>(1)</sup>	Percentage Owned Before this Offering	Percentage Owned After this Offering
Holders of more than 5% of our voting securities:			
Access Industries <sup>(2)</sup>	6,792,489	26.4%	22.8%
Novartis Pharma AG <sup>(3)</sup>	5,194,054	19.6%	17.0%
Smartmix Limited <sup>(4)</sup>	2,857,331	10.7%	9.3%
Elbit Cord Blood Limited Partnership <sup>(5)</sup>	2,685,590	10.5%	9.1%
Shavit Capital Funds <sup>(6)</sup>	2,575,801	9.9%	8.6%
Israel HealthCare Ventures 2 LP Incorporated (IHCV II) <sup>(7)</sup>	1,915,508	7.4%	6.4%
Directors and executive officers who are not 5% holders:			
Dr. Julian Adams	*	*	*
Shai Lankry	*	*	*
Josh Hamermesh	*	*	*
Tzvi Palash	*	*	*
Tony Peled <sup>(8)</sup>	332,499	1.3%	1.1%
Dr. Tracey Lodie	*	*	*
Dr. Ronit Simantov	*	*	*
Thomas Klima	*	*	*
Robert I. Blum	*	*	*
Ofer Gonen	*	*	*
Kenneth I. Moch	*	*	*
Michael S. Perry	*	*	*
Nurit Benjamini	*	*	*
Shawn C. Tomasello	*	*	*
Stephen T. Wills	*	*	*
All directors and executive officers as a group (15 persons) <sup>(9)</sup>	644,891	2.5%	2.2%

<sup>\*</sup> Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

<sup>(1)</sup> The percentages shown are based on 25,606,423 ordinary shares issued and outstanding as of June 4, 2019.

<sup>(2)</sup> Consists of: (i) 1,507,369 ordinary shares and 160,743 ordinary shares issuable upon exercise of outstanding warrants held by Clal Biotechnology Industries Ltd., or CBI; (ii) 1,374,377 ordinary shares held by Bio Medical Investment (1997) Ltd., or Bio Medical, a wholly owned subsidiary of CBI; and (iii) 3,750,000 ordinary shares by Al Gamida Holdings LLC. Clal Industries Ltd. owns 47% of the outstanding shares of, and controls, CBI. Clal Industries Ltd. is wholly owned by Access Al Ltd., which is owned by Al Diversified Holdings S.à r.l., which is owned by Al Diversified Parent S.à r.l., which is owned by Al Diversified Holdings LLC, or AIDH Limited. AIDH Limited is controlled by Al SMS L.P., or Al SMS. Access Industries Holdings LLC, or AIH, owns a majority of the equity of Al SMS, and Access Industries, LLC, or LLC, holds a majority of the outstanding voting interests in AIH. Access Industries Management, LLC, or AIM, controls LLC and AIH, and Len Blavatnik controls AIM. The address of each of Clal Industries Ltd., CBI and Bio Medical is the Triangular Tower, 3 Azrieli Center, Tel Aviv 6701101, Israel and the address of each of foregoing other than Clal Industries Ltd., CBI and Bio Medical is 730 Fifth Avenue, 20th Floor, New York, NY 10019.

<sup>(3)</sup> Consists of 4,336,759 ordinary shares and 857,295 ordinary shares issuable upon exercise of outstanding warrants. The principal address of Novartis A.G. is Lichtstrasse 35 4056 Basel, Switzerland.

<sup>(4)</sup> Consists of 1,785,714 ordinary shares and 1,071,617 ordinary shares issuable upon exercise of outstanding warrants held by SMARTMIX LIMITED. The controlling shareholder of SMARTMIX LIMITED is VMS Investment Fund II, L.P. VMS Investment Fund II, L.P. is managed by VMS Investment Management GP II Limited in its capacity as the general partner. The controlling shareholder of VMS Investment Management Management Inc. The controlling shareholder of VMS Investment Management Inc. is VMS Financial Services Group Limited. The controlling shareholder of VMS Holdings Limited. The controlling shareholder of VMS Holdings Limited is MAK Siu Hang Viola. The address of each of foregoing other than VMS Investment Fund II, L.P., VMS Investment Management GP II Limited and MAK Siu Hang Viola is Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin

- Islands. The address of each of VMS Investment Fund II, L.P. and VMS Investment Management GP II Limited is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands. The address of MAK Siu Hang Viola is 4/F, No. 24 Belleview Drive, Repulse Bay Garden, Hong Kong.
- (5) Consists of 2,685,590 ordinary shares held by Elbit Cord Blood Limited Partnership, or ECB. The controlling interest holder of ECB is Elbit Medical Technologies Ltd. The controlling shareholder of Elbit Medical Technologies Ltd. is Elbit Imaging Ltd. The principal address of each of the foregoing is 3 Shimshon, Olympia A Tower, Petach Tikva 4952701, Israel.
- (6) Consists of (i) 1,124,574 ordinary shares and 206,971 ordinary shares issuable upon exercise of outstanding warrants held by Shavit Capital Fund III (US), L.P. (ii) 156,401 ordinary shares and 28,784 ordinary shares issuable upon exercise of outstanding warrants held by Shavit Capital Fund 3 (Israel), L.P., (iii) 556,082 ordinary shares and 102,343 ordinary shares issuable upon exercise of outstanding warrants held by Shavit Capital Fund IV (US), L.P., (iv) 297,900 ordinary shares and 54,827 ordinary shares issuable upon exercise of outstanding warrants held by Shavit Capital Fund 4 (Israel), L.P., and (v) 21,723 ordinary shares and 26,196 ordinary shares issuable upon exercise of outstanding warrants held by Mr. Gary Leibler. Gabriel Capital Management Ltd. ("GCM") is the management company to Shavit Capital Fund III (US), L.P. Shavit Capital Fund 3 (Israel), L.P., Shavit Capital Fund IV (US), L.P. and Shavit Capital Fund 4 (Israel), L.P. and Gary Leibler is the sole shareholder of GCM. The address of each of the foregoing is Jerusalem Technology Park, Building 1B, Box 70, Malha, Jerusalem, 96951 Israel.
- (7) Consists of 1,808,347 ordinary shares and 107,161 ordinary shares issuable upon exercise of outstanding warrants held by Israel HealthCare Ventures 2 LP Incorporated (IHCV II), or IHCV 2. The general partner of IHCV2 is IHCV2 General Partner Limited, which is controlled by its directors Fort Limited and Elton Limited. The controlling shareholder of Fort Limited and Elton Limited is Fort Management Services Limited. The controlling shareholder of Fort Management Services Limited is Jos Ensink. The address of each of the foregoing is Bordage House, Le Bordage, St Peter Port, Guernsey, GY1 1BU.
- (8) Consists of 23,600 ordinary shares and options to purchase 308,899 ordinary shares, which are currently exercisable or will become exercisable within 60 days of June 4, 2019.
- (9) In addition to the shares and options described in footnote (8), includes options to purchase 312,392 ordinary shares, which are currently exercisable or will become exercisable within 60 days of June 4, 2019.

### **Record Holders**

As of June 4, 2019, there were 90 holders of record of our ordinary shares (not including CEDE & Co.).

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Our policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred. The following is a description of material transactions, or series of related material transactions since January 1, 2016, to which we were or will be a party and in which the other parties included or will include our directors, executive officers, holders of more than 5% of our voting securities or any member of the immediate family of any of the foregoing persons.

### **Agreements with Shareholders**

# Amended and Restated Investors' Rights Agreement

We are party to an investors' rights agreement, dated July 3, 2017, or the Investors' Rights Agreement, with certain of our shareholders. As of June 4, 2019, the holders of a total of 17,792,090 ordinary shares have the right to require us to register these shares under the Securities Act under specified circumstances.

# Series F-1 Preferred Share Purchase Agreements

In June 2017, pursuant to that certain Series F Preferred Share Purchase Agreement, we issued to investors a total of 4,274,363 Series F-1 Preferred Shares and warrants to purchase up to 2,564,619 Series F-2 Preferred Shares for an aggregate investment amount of \$40,350,000. Under the Series F Preferred Share Purchase Agreement, we issued (i) Novartis a total of 847,458 Series F-1 Preferred Shares and warrants to purchase 508,475 Series F-2 Preferred Shares for an aggregate investment amount of \$8,000,000, (ii) Israel HealthCare Ventures 2 LP Incorporated a total of 105,898 Series F-1 Preferred Shares and warrants to purchase 63,559 Series F-2 Preferred Shares for an aggregate investment amount of \$1,000,000, (iii) Smartmix Limited, a total of 1,059,322 Series F-1 Preferred Shares and warrants to purchase 635,593 Series F-2 Preferred Shares for an aggregate investment amount of \$10,000,000, (iv) Shavit Capital Funds a total of 1,059,321 Series F-1 Preferred Shares and warrants to purchase 635,593 Series F-2 Preferred Shares for an aggregate investment amount of \$10,000,000, and (v) Clal Biotechnology Industries Ltd. a total of 158,898 Series F-1 Preferred Shares and warrants to purchase 95,339 Series F-2 Preferred Shares for an aggregate investment amount of \$1,500,000. In connection with the completion of our initial public offering, all Series F Preferred shares were converted to ordinary shares and all of the warrants to purchase Series F-2 Preferred Shares have been converted to warrants to purchase ordinary shares. As part of the Series F Preferred Share Purchase Agreement, each of Shavit Capital Funds and Smartmix Limited had the right to appoint an non-voting observer to our board of directors. On February 4, 2019, we entered into the Second Amendment to Series F Preferred Share Purchase Agreement, pursuant to which the board observer rights of each of Shavit Capital Funds and Smartmix Limited were terminated.

# **Information Rights Agreements**

As part of our initial public offering and effective as of its closing, we entered into information rights agreements with certain of our principal shareholders, Clal Biotechnology Industries Ltd. and Elbit Cord Blood Limited Partnership, respectively. The information rights agreements provide the respective counterparty with rights to receive our annual and quarterly financial statements, auditor consent letters and valuation reports, and other information reasonably required by such counterparty to enable it to prepare its financial statements. The information rights agreements also require that the Company provide the respective counterparty with information material to the Company and mandated to be disclosed by the requirements applicable to such counterparty, as well as certain other material information of the Company. The information rights agreements contain customary confidentiality provisions and terminate when the respective counterparty, and any company that controls such counterparty, is no longer required to issue public reports pursuant to the Israeli Securities Law or the Securities Exchange Act of 1934, as amended.

### **Novartis Investment Agreements**

In October 2015, following the execution of an investment agreement, we issued a total of 286,369 Series C Preferred Shares to Novartis for an aggregate investment amount of \$5,000,000. In addition, pursuant to the agreement, we granted Novartis the right to appoint a non-voting observer to our board of directors subject to Novartis holding at least four percent (4%) of the issued and outstanding share capital of the Company.

# Agreements and Arrangements with Directors and Executive Officers

# Chairman Letter Agreement

In connection with our initial public offering, we entered into a chairman letter agreement with Mr. Robert I. Blum, the chairman of our board of directors, dated September 13, 2018. This agreement sets forth Mr. Blum's entitlement to receive an annual fixed cash fee of \$50,000 plus value-added tax, or VAT, if applicable, an initial grant of 30,000 options to purchase ordinary shares of the Company upon the closing of our initial public offering or the four-month anniversary of the agreement and annual grants thereafter of 15,000 options to purchase ordinary shares of the Company. The agreement also contains customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition provisions may be limited under applicable law.

### **Director Letter Agreements**

In connection with our initial public offering or at the later date when each was appointed or elected, we have entered into written board member letter agreements with each of our directors. These agreements set forth the directors entitlement to receive an annual fixed cash fee equal to \$50,000 plus value added tax, if applicable, and annual grants of equity-based compensation. These agreements also contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law.

As of October 30, 2018, each of the Company's non-executive directors shall be entitled to the following payments, which shall be paid in arrears, in quarterly installments: (i) an annual fee of \$40,000 plus VAT, if applicable, (ii) for each committee membership an additional annual fee of \$10,000 plus VAT, if applicable, (iii) for chairmanship of the board of directors an additional annual fee of \$10,000 plus VAT, if applicable, and (iv) for each chairmanship of a committee of the board of directors an additional annual fee of \$5,000 plus VAT, if applicable. In addition, each of the Company's non-executive directors, other than the chairman of the board of directors, shall be entitled to receive an annual grant of options to purchase 10,000 ordinary shares of the Company.

# **Executive Officers Employment Agreements**

We have entered into written employment agreements with each of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits (except for the accrual of vacation days). These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition provisions may be limited under applicable law.

# **Options**

Since our inception we have granted options to purchase our ordinary shares and Ordinary C shares to our officers and certain of our directors. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. We describe our option plans under "Business—Equity Compensation Plans". If the relationship between us and an executive officer or a director is terminated, except for cause (as defined in the option plans), all options that are vested will generally remain exercisable for ninety days after such termination.

# **Indemnification Agreements**

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by Israeli law. In connection with our initial public offering or at the later date when each was appointed or elected, we entered into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from a public offering of our shares, to the extent that these liabilities are not covered by insurance. We have also obtained directors and officers insurance for each of our executive officers and directors. For further information, see "Management—Board Practices—Exculpation, Insurance and Indemnification of Directors and Officers."

## **DESCRIPTION OF SHARE CAPITAL**

The following description of our share capital and provisions of our amended and restated articles of association are summaries and do not purport to be complete.

#### General

Our authorized share capital consists of 100,000,000 ordinary shares, par value NIS 0.01 per share, of which 25,606,423 shares are issued and outstanding as of June 4, 2019.

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

# **Registration Number and Purposes of the Company**

We are registered with the Israeli Registrar of Companies. Our registration number is 51-260120-4. Our purpose, as set forth in our amended and restated articles of association, is to engage in any lawful act or activity.

## **Voting Rights**

All ordinary shares have identical voting and other rights in all respects.

#### Transfer of shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

#### **Election of directors**

Under our amended and restated articles of association, our board of directors must consist of not less than 5 but no more than 11 directors. Pursuant to our amended and restated articles of association, each of our directors will be appointed by a simple majority vote of holders of our voting shares, participating and voting at an annual general meeting of our shareholders. In addition, our directors are divided into three classes, one class being elected each year at the annual general meeting of our shareholders, and serve on our board of directors until they are removed by a vote of 60% of the total voting power of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Israeli Companies Law and our amended and restated articles of association. In addition, our amended and restated articles of association allow our board of directors to fill vacancies on the board of directors or to appoint new directors up to the maximum number of directors permitted under our amended and restated articles of association. Such directors serve for a term of office equal to the remaining period of the term of office of the directors(s) whose office(s) have been vacated or in the case of new directors, for a term of office according to the class to which such director was assigned upon appointment.

## **Dividend and Liquidation Rights**

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Israeli Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the end of the period to which the financial statements relate is

not more than six months prior to the date of the distribution. If we do not meet such criteria, then we may distribute dividends only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

## **Exchange Controls**

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

## **Shareholder meetings**

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as special general meetings. Our board of directors may call special general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law provides that our board of directors is required to convene a special general meeting upon the written request of (i) any two or more of our directors or one-quarter or more of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power.

Subject to the provisions of the Israeli Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may generally be between four and 21 days prior to the date of the meeting, and in certain circumstances, between four and 40 days prior to the date of the meeting. Furthermore, the Israeli Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- · appointment or termination of our auditors;
- appointment of external directors;
- · approval of certain related party transactions;
- increases or reductions of our authorized share capital:
- · a merger; and
- the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Israeli Companies Law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting. Under the Israeli Companies Law and our amended and restated articles of association, shareholders are not permitted to take action by way of written consent in lieu of a meeting.

## **Voting rights**

#### Quorum

Pursuant to our amended and restated articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights. A meeting adjourned for lack of a quorum shall be adjourned either to the same day in the next week, at the same time and place, to such day and at such time and place as indicated in the notice to such meeting, or to such day and at such time and place as the chairperson of the meeting shall determine. At the reconvened meeting, any number of shareholders present in person or by proxy shall constitute a quorum, unless a meeting was called pursuant to a request by our shareholders, in which case the quorum required is one or more shareholders, present in person or by proxy and holding the number of shares required to call the meeting as described under "—Shareholder Meetings."

#### Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law or by our amended and restated articles of association. Under the Israeli Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder, (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if such terms are not extraordinary) requires the approval described above under "Management-Fiduciary duties and approval of specified related party transactions under Israeli law-Disclosure of personal interests of a controlling shareholder and approval of transactions" and (iii) approval of certain compensationrelated matters require the approval described above under "-Board of directors and officers-Compensation Committee." Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. Our amended and restated articles of association also provide that the removal of any director from office or the amendment of the provisions relating to our staggered board requires the vote of 60% of the total voting power of our shareholders. Another exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Israeli Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting and voting on the resolution.

## Access to corporate records

Under the Companies Law, all shareholders generally have the right to review minutes of our general meetings, our shareholder register, including with respect to material shareholders, our articles of association, our financial statements, other documents as provided in the Companies Law, and any document we are required by law to file publicly with the Israeli Companies Registrar or the Israeli Securities Authority. Any shareholder who specifies the purpose of its request may request to review any document in our possession that relates to any action or transaction with a related party which requires shareholder approval under the Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise impair our interests.

# **Registration Rights**

We have entered into the Investors' Rights Agreement with certain of our shareholders, pursuant to which as of June 4, 2019, the holders of a total of 17,792,090 ordinary shares have the right to require us to register these shares under the Securities Act under specified circumstances and have incidental registration rights as described below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act.

## **Demand Registration Rights**

Beginning 180 days after the effective date of our initial public offering, or IPO, registration statement, subject to any lock-up agreement entered into with the underwriters of this offering, (1) holders of a majority of the registrable securities under the Investors' Rights Agreement or (2) holders of registrable securities then outstanding and constituting the Special F Majority, as defined under the articles of association in effect immediately prior to our IPO, may request, subject to certain exceptions, that we file a registration statement on Form F-1. Upon receipt of such registration request, we are obligated to use our reasonable commercial efforts to file the registration statement as soon as practicable, and in any event within sixty (60) days after the date such request is given by the initiating shareholders.

We have the right not to effect such filing during the period that is within 180 days after we have filed another such registration statement or completed certain other registered offerings or if we intend to file a registration statement for our own account within 90 days. We are not obligated to file more than three registration statements on Form F-1 pursuant to these demand provisions. Any other holder of registrable securities has the right to include its registrable securities in an underwritten registration pursuant to a demand registration.

## Shelf Registration Rights

If we become eligible to register any of our shares on Form F-3, (1) holders of at least 25% of the registrable securities under the Investors' Rights Agreement or (2) holders of registrable securities then outstanding and constituting the Special F Majority, as defined under the articles of association in effect immediately prior to this offering, may, subject to certain limitation, request that we file a shelf registration statement for an offering to be made on a delayed or continuous basis pursuant to Rule 415 under the Securities Act registering the resale from time to time by holders of registrable securities. In such event, we are required to give written notice of such request to all holders of registrable securities, who may elect to join in such request. Subsequently, upon receipt of such registration request, we are obligated to use our reasonable commercial efforts to file the registration statement as soon as practicable, and in any event within 45 days after the date such request is given. We are required to effect only one shelf registration statement. We are not required to effect any underwritten offering within 90 days of another underwritten offering.

## Acquisitions under Israeli law

#### Full tender offer

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's issued and outstanding share capital or that of a certain class of shares is required by the Companies Law to make a tender offer to all of the company's shareholders or the shareholders who holds shares of the same class for the purchase of all of the issued and outstanding shares of the company or of the same class, as applicable.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved it, which condition shall not apply if offerees holding less than 2% of the company's issued and outstanding share capital failed to approve such tender offer).

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether the shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court unless the acquirer stipulated that a shareholder that accepts the offer may not seek appraisal rights. If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, or the shareholders who did not

accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

#### Special tender offer

The Companies Law provides that an acquisition of shares of a public Israeli company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private placement, provided that the general meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company, (ii) was from a shareholder holding at least 25% of the voting rights in the company, or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer, excluding the votes of a holder of control in the offeror, a person who has personal interest in acceptance of the special tender offer, holders of 25% or more of the voting rights in the company or anyone on their behalf, including their relatives and entities controlled by them.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer, or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention. In addition, the board of directors must disclose any personal interest each member of the board of directors has in the offer or stems therefrom. An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his or her acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special tender offer or had objected to the offer may accept the offer within four days of the last day set for the acceptance of the offer.

In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity shall refrain from making a subsequent tender offer for the purchase of shares of the target company and cannot execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

## Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting. The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, such determination taking into account the financial status of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, vote against the merger. In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders. Pursuant to the Companies Law, if a merger is with a company's controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described above under "Board Practices — Fiduciary duties and approval of specified related party transactions under Israeli law.").

Under the Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger pursuant to regulations promulgated under the Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations the target company. The court may further give instructions to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

## Anti-takeover measures

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. We have no preferred shares authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israeli Companies Law as described above in "—Voting Rights." In addition, as disclosed under "—Election of directors" we will have a classified board structure upon completion of this offering, which will effectively limit the ability of any investor or potential investor or group of investors or potential investors to gain control of our board of directors.

## **Borrowing Powers**

Pursuant to the Israeli Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

## **Changes in Capital**

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to Israeli law and must be approved by a resolution duly passed by our shareholders at a general meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares is Broadridge Corporate Issuer Solutions, Inc. Its address is 1717 Arch St., Suite 1300, Philadelphia, Pennsylvania 19103, and its telephone number is (215) 553-5400.

## Listing

Our ordinary shares are listed on The Nasdaq Global Market under the symbol "GMDA."

#### **TAXATION**

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences in your particular situation, as well as any tax consequences that may arise under the laws of any taxing jurisdiction.

## **Material Israeli Tax Considerations**

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on a new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY NON-U.S., STATE OR LOCAL TAXES.

## **General Corporate Tax Structure in Israel**

Israeli resident companies are generally subject to corporate tax on their taxable income at the rate of 23% in 2018 and thereafter. However, the effective tax rate payable by a company that derives income from a Preferred Enterprise or a Technology Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

## Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law, provides certain tax benefits for an "Industrial Company". The Industry Encouragement Law defines an "Industrial Company" as an Israeli resident company incorporated in Israel, of which 90% or more of its income in any tax year, other than income from certain government loans, is derived from an "Industrial Enterprise" owned by it and located in Israel or in the "Area", in accordance with the definition in the section 3a of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance. An "Industrial Enterprise" is defined as an enterprise which is held by an Industrial Company whose principal activity in any given tax year is industrial production.

The following tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of patents and rights to use a patent and know-how that were purchased in good faith and are used for the development or advancement of the Industrial Enterprise, commencing from the tax year where the Industrial Enterprise began to use them;
- under certain conditions, the right to elect to file consolidated tax returns with Israeli Industrial Companies controlled by it; and
- expenses related to a public offering are deductible in equal amounts over three years commencing on the vear of this offering.

We believe that we qualify as an "Industrial Company" within the meaning of the Industry Encouragement Law. There can be no assurance that we will continue to qualify as an Industrial Company or that the benefits described above will be available to us in the future.

#### Tax Benefits under the Law for the Encouragement of Capital Investments, 1959

The Law for the Encouragement of Capital Investments, 1959, generally referred to as the "Investment Law", provides certain incentives for capital investments in production facilities (or other eligible assets).

The Investment Law was significantly amended several times over the recent years, with the three most significant changes effective as of April 1, 2005, referred to in this prospectus as the 2005 Amendment, as of January 1, 2011, referred to in this prospectus as the 2011 Amendment, and as of January 1, 2017, referred to in this prospectus as the 2017 Amendment. Pursuant to the 2005 Amendment, tax benefits granted in accordance with the provisions of the Investment Law prior to its revision by the 2005 Amendment remain in force but any benefits granted subsequently are subject to the provisions of the amended Investment Law. Similarly, the 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment. However, companies entitled to benefits under the Investment Law as in effect prior to January 1, 2011 were entitled to choose to continue to enjoy such benefits, provided that certain conditions are met, or elect instead, irrevocably, to forego such benefits and have the benefits of the 2011 Amendment apply. The 2017 Amendment introduces new benefits for Technological Enterprises, alongside the existing tax benefits. We did not utilize any of the benefits for which we were eligible under the Investment Law prior to the 2011 Amendment, and starting in the 2017 tax year we elected to apply for the new benefits under the 2011 Amendment.

#### Tax benefits under the 2011 Amendment

On December 29, 2010, the Israeli Parliament approved the 2011 Amendment. The 2011 Amendment significantly revised the tax incentive regime in Israel and commenced on January 1, 2011.

The 2011 Amendment canceled the availability of the tax benefits granted under the Investment Law prior to 2011 and, instead, introduced new tax benefits for income generated by a "Preferred Company" through its "Preferred Enterprise" (as such terms are defined in the Investment Law) as of January 1, 2011. The definition of a Preferred Company includes a company incorporated in Israel that is not fully owned by a governmental entity, and that has, among other things, Preferred Enterprise status and is controlled and managed from Israel.

A Preferred Company is entitled to a reduced corporate tax rate with respect to the income attributed to the Preferred Enterprise, at the following rates:

Tax Year	Development Region "A"	Other Areas within Israel
2011-2012	10%	15%
2013	7%	12.5%
2014-2016	9%	16%
2017 onwards <sup>(1)</sup>	7.5%	16%

(1) In December 2016, the Israeli Parliament (the Knesset) approved an amendment to the Investments Law pursuant to which the tax rate applicable to Preferred Enterprises in Development Region "A" would be reduced to 7.5% as of January 1, 2017.

The classification of income generated from the provision of usage rights in know-how or software that were developed in the Preferred Enterprise, as well as royalty income received with respect to such usage, as Preferred Enterprise income is subject to the issuance if a pre-ruling from the Israel Tax Authority stipulates that such income is associated with the productive activity of the Preferred Enterprise in Israel.

Dividends distributed from income which is attributed to a "Preferred Enterprise" will be subject to withholding tax at source at the following rates: (i) Israeli resident corporations – 0%, (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate)) (ii) Israeli resident individuals – 20% (iii) non-Israeli residents (individuals and corporations) - 20%, subject to a reduced tax rate under the provisions of an applicable double tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate).

The 2011 Amendment also revised the grant track to apply only to the approved programs located in Development Region "A" and shall provide not only cash grants (as prior to the 2011 Amendment) but also the granting of loans. The rates for grants and loans shall not be fixed but up to 20% of the amount of the approved investment (may be increased with additional 4%). In addition, a company owning a Preferred Enterprise under the grant track may be entitled also to the tax benefits which are prescribed for a Preferred Enterprise.

#### New Tax benefits under the 2017 Amendment that became effective on January 1, 2017.

The 2017 Amendment was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017. The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in Development Region "A". These corporate tax rates shall apply only with respect to the portion of intellectual property developed in Israel. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from IIA.

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by an Israeli company or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from IIA. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. If such dividends are distributed to a foreign company and other conditions are met, the withholding tax rate will be 4% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). We are examining the impact of the 2017 Amendment and the degree to which we will qualify as a Preferred Technology Enterprise or Special Preferred Technology Enterprise, and the amount of Preferred Technology Income that we may have, or other benefits that we may receive from the 2017 Amendment.

## **Taxation of the Company Shareholders**

# **Capital Gains**

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident, and on the disposal of such assets by a non-Israel resident if those assets are either (i) located in Israel, (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless a tax treaty between Israel and the seller's country of residence provides otherwise. The Ordinance distinguishes between "Real Capital Gain" and the "Inflationary Surplus". Real Capital Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli CPI between the date of purchase and the date of disposal.

The Real Capital Gain accrued by individuals on the sale of our ordinary shares (that were purchased after January 1, 2012, whether listed on a stock exchange or not) will be taxed at the rate of 25%. However, if such shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with such person's relative or another person who collaborates with such person on a permanent basis, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding twelve (12) months period and/or claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares, such gain will be taxed at the rate of 30%.

The Real Capital Gain derived by corporations will be generally subject to the ordinary corporate tax 23% in 2018 and thereafter.

Individual shareholder dealing in securities, or to whom such income is otherwise taxable as ordinary business income are taxed in Israel at their marginal tax rates applicable to business income (up to 50% in 2018, including Excess Tax as detailed below).

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli resident (whether an individual or a corporation) shareholder may be exempt under the Ordinance from Israeli taxation provided that such shareholders did not acquire their shares prior to January 1, 2009 or acquired their shares after the Company was listed for trading on Nasdaq provided, among other things, that (i) such gains were not derived from a permanent business or business activity that the non-Israeli resident maintains in Israel, and (ii) such shareholders are not subject to the Israeli Income Tax Law (Inflationary Adjustments) 5745-1985. These provisions dealing with capital gain are not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be business income. However, non-Israeli corporations will not be entitled to the foregoing exemptions if an Israeli resident (i) has a controlling interest of more than 25% in such non-Israeli corporation or (ii) is the beneficiary of or is entitled to 25% or more of the revenue or profits of such non-Israeli corporation, whether directly or indirectly.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for an exemption). For example, the U.S.-Israel Double Tax Treaty exempts U.S. resident holding the shares as a capital asset and is entitled to claim the benefits afforded to such a resident by the U.S.-Israel Double Tax Treaty, or a Treaty U.S. Resident, from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12 month period preceding such sale, subject to certain conditions; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days in the aggregate at the taxable year; (iii) the capital gain from the sale, exchange or disposition was not derived through a permanent establishment that the U.S. resident maintains in Israel, (iv) the capital gains arising from such sale, exchange or disposition is not attributed to real estate located in Israel; or (v) the capital gains arising from such sale, exchange or disposition is not attributed to royalties. If any such case occurs, the sale, exchange or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable. However, under the U.S.-Israel Tax Treaty, such Treaty U.S. Resident would be permitted to claim a credit for such taxes against U.S. federal income tax imposed on any gain from such sale, exchange or disposition, under the circumstances and subject to the limitations specified in the U.S.-Israel Double Tax Treaty.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale. Specifically, in transactions involving a sale of all of the shares of an Israeli resident company, in the form of a merger or otherwise, the Israel Tax Authority may require from shareholders who are not liable for Israeli tax to sign declarations in forms specified by this authority or obtain a specific exemption from the Israel Tax Authority to confirm their status as non-Israeli resident, and, in the absence of such declarations or exemptions, may require the purchaser of the shares to withhold taxes at source.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities on the amount of the consideration paid upon the sale of the securities at the rate of 25% in respect of an individual, or at a rate of corporate tax, in respect of a corporation 23% in 2018 and thereafter.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

## **Dividends**

A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12 months period.

Distribution of dividends from income attributed to a Preferred Enterprise is generally subject to a tax at a rate of 20%. However, if such dividends are distributed to an Israeli company, no tax is imposed (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for an exemption) will apply). If the dividend is attributable partly to income derived from a Preferred Enterprise, and partly from other sources of income, the income tax rate will be a blended rate reflecting the relative portions of the types of income. We cannot assure you that we will designate the profits that we may distribute in a way that will reduce shareholders' tax liability.

If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Ordinance generally provides that a non-Israeli resident (either individual or corporation) is subject to an Israeli income tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12 months period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate).

For example, under the U.S.-Israel Double Tax Treaty the following rates will apply in respect of dividends distributed by an Israeli resident company to a Treaty U.S. Resident: (i) if the Treaty U.S. Resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting shares of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends – the maximum tax rate of withholding is 12.5%, and (ii) in all other cases, the tax rate is 25%, or the domestic rate (if such is lower). The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment that the Treaty U.S. Resident maintains in Israel. U.S. residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for United States federal income tax purposes in the amount of the taxes withheld, subject to detailed rules contained in U.S. tax legislation.

A non-Israeli resident who receives dividend income derived from or accrued from Israel, from which the full amount of tax was withheld at source, is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer, (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed and (iii) the taxpayer is not obliged to pay excess tax (as further explained below).

Payors of dividends on our shares, including the Israeli shareholder effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemption, reduced tax rates and the demonstration of a shareholder of his, her or its foreign residency, to withhold taxes upon the distribution of dividends at a rate of 25%, provided that the shares are registered with a Nominee Company (for corporations and individuals).

## Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% in 2017 and thereafter, on annual income exceeding a certain threshold (NIS 640,000 for 2017 which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to income derived from dividends, interest and capital gains.

## Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

## Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

#### Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our ordinary shares by U.S. Holders (as defined below). This discussion applies to U.S. Holders that purchase ordinary shares pursuant to this offering and hold such ordinary shares as capital assets within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain former citizens or residents of the United States, persons who hold ordinary shares as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment, persons who received their ordinary shares as compensatory payments, persons that have a "functional currency" other than the U.S. dollar, persons that own directly, indirectly or through attribution 10% or more of our shares by vote or value, persons who are subject to Section 451(b) of the Code, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities and arrangements that are classified as partnerships for U.S. federal income tax purposes, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of ordinary shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax consequences relating to an investment in the ordinary shares will depend in part upon the status and activities of such entity or arrangement and the particular partner. Any such entity or arrangement should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of ordinary shares.

Persons considering an investment in ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

## **Passive Foreign Investment Company Consequences**

In general, a corporation organized outside the United States will be treated as a passive foreign investment company, or PFIC, for any taxable year in which either (1) at least 75% of its gross income is "passive income", the PFIC income test, or (2) on average at least 50% of its assets, determined on a quarterly basis, are assets that produce passive income or are held for the production of passive income, the PFIC asset test. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities, and other assets that may produce passive income. Generally, in determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value being determined in large part by reference to the market value of our common shares, which may be volatile). Based upon the value of our assets, including any goodwill and the nature and composition of our income and assets, we do not believe that we were classified as a PFIC for the taxable year ended December 31, 2018, and we do not believe that we will be classified as a PFIC for the taxable year ending December 31, 2019 or in the immediately foreseeable future. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Our status as a PFIC is a fact-intensive determination made on an annual basis after the end of each taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ended December 31, 2018, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

If we are a PFIC in any taxable year during which a U.S. Holder owns ordinary shares, the U.S. Holder could be liable for additional taxes and interest charges under the "PFIC excess distribution regime" upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the ordinary shares, and (2) any gain recognized on a sale, exchange or other disposition, including a pledge, of the ordinary shares, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder's holding period for ordinary shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax.

If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to the ordinary shares. If the election is made, the U.S. Holder will be deemed to sell the ordinary shares it holds at their fair market value on the last day of

the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's ordinary shares would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds ordinary shares and one of our non-U.S. corporate subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to our non-U.S. subsidiaries.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on ordinary shares if such U.S. Holder makes a valid "mark-to-market" election for our ordinary shares. A mark-to-market election is available to a U.S. Holder only for "marketable stock." Our ordinary shares will be marketable stock as long as they remain listed on The Nasdaq Global Market and are regularly traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. If a mark-to-market election is in effect, a U.S. Holder generally would take into account, as ordinary income for each taxable year of the U.S. holder, the excess of the fair market value of ordinary shares held at the end of such taxable year over the adjusted tax basis of such ordinary shares. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in ordinary shares would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of ordinary shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss.

A mark-to-market election will not apply to ordinary shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any non-U.S. subsidiaries that we may organize or acquire in the future. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs that we may organize or acquire in the future notwithstanding the U.S. Holder's mark-to-market election for the ordinary shares.

The tax consequences that would apply if we are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

Each U.S. person that is an investor of a PFIC is generally required to file an annual information return on IRS Form 8621 containing such information as the U.S. Treasury Department may require. The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of PFIC status on the purchase, ownership and disposition of ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to the ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares of a PFIC.

## **Distributions**

As described in the section entitled "— Dividend Policy," we do not anticipate declaring or paying dividends to holders of our ordinary shares in the foreseeable future. However, if we make a distribution contrary to the expectation, subject to the discussion above under "— Passive Foreign Investment Company Consequences," a U.S. Holder that receives a distribution with respect to ordinary shares generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's ordinary shares. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's ordinary shares, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends.

Distributions on ordinary shares that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. Subject to certain complex conditions and limitations, Israeli taxes withheld on any distributions on ordinary shares may be eligible for credit against a U.S. Holder's federal income tax liability. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit in their particular circumstances and the possibility of claiming an itemized deduction (in lieu of the foreign tax credit) for any foreign taxes paid or withheld.

Distributions on ordinary shares that are treated as dividends generally will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation" are eligible for taxation to non-corporate U.S. Holders at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain requirements are met. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on shares that are readily tradable on an established securities market in the United States. Our ordinary shares will generally be considered to be readily tradable on an established securities market in the United States for so long as they are listed on The Nasdaq Global Market. We believe that we qualify as a resident of Israel for purposes of, and are eligible for the benefits of, the U.S.-Israel Double Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-Israel Double Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange of information provision. Therefore, subject to the discussion above under "- Passive Foreign Investment Company Consequences," if the U.S.-Israel Double Tax Treaty is applicable, or if our ordinary shares are readily tradable on an established securities market in the United States, such dividends will generally be "qualified dividend income" in the hands of individual U.S. Holders, provided that certain conditions are met, including holding period and the absence of certain risk reduction transaction requirements. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

## Sale, Exchange or Other Disposition of Ordinary Shares

Subject to the discussion above under "— Passive Foreign Investment Company Consequences," a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of ordinary shares in an amount equal to the difference, if any, between the amount realized (i.e., the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ordinary shares. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for

non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ordinary shares were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of ordinary shares will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

#### **Medicare Tax**

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ordinary shares. If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your investment in ordinary shares.

## Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in ordinary shares, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Passive Foreign Investment Company Consequences", each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than US\$100,000 for ordinary shares may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of ordinary shares may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate United States taxpayer identification number or otherwise establish a basis for exemption (usually on IRS Form W-9), or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

## **UNDERWRITING**

We and the underwriters named below have entered into an underwriting agreement, dated the date of this prospectus, with respect to our ordinary shares (the "shares") being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the respective number of shares shown opposite its name in the following table. RBC Capital Markets, LLC, which is located at 200 Vesey Street, New York, New York 10281, and JMP Securities LLC, which is located at 450 Park Avenue, New York, New York 10022, are the representatives of the underwriters (the "representatives").

Underwriters	Number of Shares
RBC Capital Markets, LLC	
JMP Securities LLC	
Oppenheimer & Co. Inc.	
Total	4,040,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until that option is exercised. If an underwriter fails or refuses to purchase any of its committed shares, the purchase commitments of the non-defaulting underwriters may be increased or this offering may be terminated.

The underwriters have an option to buy up to an additional 606,000 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise this option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above, and the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriters propose to offer the shares directly to the public at the public offering price set forth on the cover of this prospectus and to certain dealers at such offering price less a concession not in excess of \$ per share. After the public offering of the shares, the offering price and the selling concession may be changed by the underwriters.

The following table shows the per share and the total underwriting discount to be paid by us to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discount, will be approximately \$0.7 million, all of which will be paid by us. We have agreed to reimburse the underwriters for up to \$20,000 of their expenses incurred in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc. and up to \$35,000 of their travel and other expenses incurred in connection with the potential marketing of this offering.

The expenses set forth above include a commission of approximately \$200,000 payable by us to Israeli broker-dealer Apex Issuances Ltd., for services it is providing to us in connection with this offering, including identifying potential investors in Israel. Apex Issuances Ltd. is not a U.S. registered broker-dealer. All sales of our ordinary shares in the United States will be made by U.S. registered broker-dealers.

We and our officers and directors have agreed with the underwriters that, for a period of 90 days after the date of this prospectus (the "lock-up period"), subject to certain exceptions, we and they will not (1) offer, sell, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of), directly or indirectly, including the filing (or participation in the filing) with the SEC of a registration

statement under the Securities Act to register, any of our shares or any securities convertible into or exercisable or exchangeable for our shares or warrants or other rights to acquire shares of which such officer, director or holder is now, or may in the future become, the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act), or (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic benefits or risks of ownership of such shares, securities, warrants or other rights to acquire shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of our shares or other securities, in cash or otherwise, or (3) publicly disclose the intention to enter into any transaction described in clause (1) or (2) above, except with the prior written consent of the representatives.

The restrictions above do not apply to the following:

- transfers of securities as a bona fide gift;
- transfers or dispositions of securities to any trust for the direct or indirect benefit of the lock-up signatory or any
  member of the immediate family of the lock-up signatory;
- transfers or dispositions of securities to affiliates (within the meaning set forth in Rule 405 under the Securities Act):
- transfers of securities by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the lock-up signatory;
- transfers or dispositions of securities to satisfy tax withholding obligations upon exercise or vesting of options or equity awards;
- transfers of securities made by operation of law (including pursuant to divorce settlements);
- the exercise of options, warrants, restricted share or restricted share units granted pursuant to our equity incentive plans and outstanding on the date of this prospectus;
- transfers of securities made in connection with a bona fide third-party tender offer;
- entry into any trading plan established pursuant to Rule 10b5-1 under the Exchange Act;
- transfers of securities to us in connection with the termination of the employment (or other service relationship) of the lock-up signatory; or
- transfers of securities to by the lock-up signatory to its investment manager or advisor with discretionary authority over the lock-up signatory's investments;

#### provided, however, that

- in the case of transfers or distributions made pursuant to the first, second, third, fourth, sixth, and tenth bullets above, it will be a condition of such transfer or disposition that the transferee agrees to be bound in writing by the restrictions set forth above;
- in the case of transfers or dispositions made pursuant to the first, second, third, fourth, sixth, eighth and ninth bullets above, such transfer shall not involve a disposition for value;
- in the case of transfers or distributions made pursuant to the first, second, third, fourth, fifth, seventh, and ninth bullets above, no filing by any party under the Exchange Act or other public announcement shall be required or made voluntarily during the lock-up period, other than (x) filings made on a Form 5 made after the expiration of the lock-up period, and (y) a required filing on Schedule 13A, 13G or Form 13F if the lock-up signatory is not a director or officer of the Company, so long as such required filing includes a reasonably detailed explanation of such transfer or disposition: and
- in the case of transfers or dispositions made pursuant to the ninth bullet above, such trading plan does not provide for any sales or other dispositions of securities subject to the foregoing restrictions during the lock-up period, and no public announcement or filing under the Exchange Act or otherwise is made by or on behalf of the lock-up signatory or the Company regarding the establishment of, or sales under, such plan during the lock-up period, other than a required filing

on Schedule 13D, Schedule 13G or Form 13F under the Exchange Act, if the lock-up signatory is not an officer or director of the Company, so long as such required filing includes a statement to the effect that no transfers will be made during the lock-up period.

Our shares are listed on The Nasdaq Global Market under the symbol "GMDA."

In connection with this offering, the underwriters may purchase and sell our shares in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of our shares than they are required to purchase in this offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things. the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares made by the underwriters in the open market prior to the completion of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our ordinary shares, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the shares. As a result, the price of our shares may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on The Nasdag Global Market, in the over-the-counter market or otherwise.

In connection with this offering, the underwriters may engage in passive market making transactions in the shares on The Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of shares and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our shares to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and may end passive market making activities at any time.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act and to contribute to payments that the underwriters may be required to make for these liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may

agree to allocate a number of our shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

#### Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the shares offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### Australia

No prospectus or other disclosure document, as defined in the Corporations Act 2001 ("Cth") of Australia, or Corporations Act, in relation to our shares has been or will be lodged with the Australian Securities & Investments Commission ( the "ASIC"). This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- (a) you confirm and warrant that you are either:
  - (i) a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
  - (ii) a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
  - (iii) a person associated with the company under section 708(12) of the Corporations Act; or
  - (iv) a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act, any offer made to you under this document is void and incapable of acceptance; and
- (b) you warrant and agree that you will not offer any of our shares for resale in Australia within 12 months of that security being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## Canada

The shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* ("NI 33-105"), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### China

The information in this document does not constitute a public offer of the shares, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The shares may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

## **European Economic Area**

The shares are not intended to be offered, sold or otherwise made available to and should not be offered, sold or otherwise made available to any retail investor in the European Economic Area ("EEA"). For these purposes, a retail investor means a person who is one (or more) of: (i) a retail client as defined in point (11) of Article 4(1) of Directive 2014/65/EU (or as amended, "MiFID II"), or (ii) a customer within the meaning of Directive 2002/92/EC, where that customer would not qualify as a professional client as defined in point (10) of Article 4(1) of MiFID II, or (iii) not a qualified investor as defined in Directive 2003/71/EC (as amended, the "Prospectus Directive"). Consequently no key information document required by Regulation (EU) No 1286/2014 (as amended, the "PRIIPs Regulation") for offering or selling the shares or otherwise making them available to retail investors in the EEA has been prepared and therefore offering or selling the shares or otherwise making them available to any retail investor in the EEA may be unlawful under the PRIIPs Regulation. This prospectus has been prepared on the basis that any offer of the shares in any Member State of the EEA will be made pursuant to an exemption under the PRIIPs Regulation. This prospectus has been prepared on the basis that any offer of the shares in any Member State of the EEA will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of the shares. This prospectus is not a prospectus for the purposes of the Prospectus Directive.

## MiFID II Product Governance

Any person offering, selling or recommending the shares (a "distributor") should take into consideration the manufacturers' target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the shares (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels.

# **Hong Kong**

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the

Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

#### Israe

The shares offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the "ISA"), nor have such shares been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the shares being offered.

This document does not constitute a prospectus under the Israeli Securities Law and has not been filed with or approved by the ISA. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the ordinary shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

## Japan

The shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

#### **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of
which is to hold investments and the entire share capital of which is owned by one or more individuals, each of
whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:
  - to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such securities of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
  - · where no consideration is or will be given for the transfer; or
  - · where the transfer is by operation of law.

#### **Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the shares may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority ("FINMA").

This document is personal to the recipient only and not for general circulation in Switzerland.

## **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of Section 85 of the Financial Services and Markets Act 2000, as amended (the "FSMA")) has been published or is intended to be published in respect of the shares. This document is issued on a confidential basis to "qualified investors" (within the meaning of Section 86(7) of FSMA) in the United Kingdom, and the shares may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances that do not require the publication of a prospectus pursuant to Section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) received in connection with the issue or sale of the shares have only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which Section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (the "FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a United Kingdom relevant person should not act or rely on this document or any of its contents.

# **EXPENSES OF THIS OFFERING**

The following table sets forth the costs and expenses, other than the underwriting discount, payable by us in connection with the sale of our ordinary shares being registered. All amounts are estimates except for the SEC registration fee and the FINRA filing fee.

Item	Amount o be Paid
SEC registration fee	\$ 4,209
FINRA filing fee	5,675
Printing and engraving expenses	50,000
Legal fees and expenses	300,000
Accounting fees and expenses	90,000
Miscellaneous expenses	250,116
Total	\$ 700,000

## **LEGAL MATTERS**

The validity of the issuance of our ordinary shares offered in this prospectus and certain other matters of Israeli law will be passed upon for us by Meitar Liquornik Geva Leshem Tal, Ramat Gan, Israel. Certain matters of U.S. federal law will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, New York, New York with respect to U.S. federal law

## **EXPERTS**

The consolidated financial statements as of December 31, 2018 and 2017 and for each of the three years in the period ended December 31, 2018 appearing in this Prospectus and Registration Statement have been audited by Kost, Forer, Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, as set forth in their report thereon (which contain an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1d to the Consolidated Financial Statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The address of Kost, Forer, Gabbay & Kasierer is Menachem Begin 144, Tel Aviv, Israel.

## **ENFORCEABILITY OF CIVIL LIABILITIES**

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have irrevocably appointed Gamida Cell Inc. as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. The address of our agent is 673 Boylston Street, Boston, Massachusetts.

We have been informed by our legal counsel in Israel, Meitar Liquornik Geva Leshem Tal, that it may be difficult to initiate an action with respect to U.S. securities law in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to hear such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses which can be a time-consuming and costly process. Certain matters of procedure may also be governed by Israeli law.

Subject to certain time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and
- the judgment is executory in the state in which it was given.

Even if these conditions are met, an Israeli court will not declare a foreign civil judgment enforceable if:

- the judgment was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases);
- · the enforcement of the judgment is likely to prejudice the sovereignty or security of the State of Israel;
- · the judgment was obtained by fraud;
- the opportunity given to the defendant to bring its arguments and evidence before the court was not reasonable in the opinion of the Israeli court;
- the judgment was rendered by a court not competent to render it according to the laws of private international law as they apply in Israel;
- the judgment is contradictory to another judgment that was given in the same matter between the same parties and that is still valid; or
- at the time the action was brought in the foreign court, a lawsuit in the same matter and between the same parties was pending before a court or tribunal in Israel.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

We are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, pursuant to which we file reports with the SEC. These other reports or other information may be inspected without charge on the SEC's web site at http://www.sec.gov. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act, although we intend to report our results of operations voluntarily on a quarterly basis.

We maintain a corporate website at http://www.gamida-cell.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.

# **GAMIDA CELL LTD. AND ITS SUBSIDIARY**

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

# U.S. DOLLARS IN THOUSANDS

	Page
Audited Consolidated Financial Statements	
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	<u>F-2</u>
Consolidated Statements of Financial Position as of December 31, 2018 and 2017	<u>F-3</u>
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2018, 2017 and	
<u>2016</u>	<u>F-4</u>
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2018, 2017 and 2016	<u>F-5</u>
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018, 2017 and 2016	<u>F-6</u>
Notes to Consolidated Financial Statements	<u>F-8</u>



# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM To the Shareholders and Board of Directors of GAMIDA CELL LTD.

## **Opinion on the Financial Statements**

We have audited the accompanying consolidated statements of financial position of Gamida Cell Ltd. (the "Company") and its subsidiary as of December 31, 2018 and 2017, the related consolidated statements of comprehensive loss, changes in equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and its subsidiary at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

## The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1d to the consolidated financial statements, the Company has recurring losses from operations, negative cash flows from operating activities, has a net capital deficiency and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1d. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

## **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

<u>/s/ Kost Forer Gabbay & Kasierer</u>
KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global
We have served as the Company's auditor since 2000.
Tel-Aviv, Israel
February 25, 2019

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands		_		
		2018	nber	31, 2017
ASSETS				
CURRENT ASSETS:	_	40.070	_	04.005
Cash and cash equivalents	\$	40,272	\$	21,325
Available-for-sale financial assets		20,417		14,758
Short term deposits				5,000
Prepaid expenses and other current assets		1,502		2,539
Total current assets		62,191		43,622
NON-CURRENT ASSETS:				
Property and equipment, net		2,311		940
Other assets		662		360
Total non-current assets		2,973		1,300
Total assets	\$	65,164	\$	44,922
	Ť	00,101	Ť	11,022
LIABILITIES AND SHAREHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Trade payables	\$	1,985	\$	2,390
Employees and payroll accruals	•	2,888	•	1,517
Accrued expenses and other payables		1,832		669
/ tool and of policinos and out of payables		6,705	_	4,576
				<u> </u>
NON-CURRENT LIABILITIES:				
Liabilities presented at fair value		24,049		10,300
Employee benefit liabilities, net		183		200
Liability to Israel Innovation Authority (IIA)		9,540		6,890
		33,772		17,390
CONTINGENT LIABILITIES AND COMMITMENTS				
SHAREHOLDERS' EQUITY:				
Share capital -				
Ordinary shares of NIS 0.01 par value - Authorized: 100,000,000 and 23,277,000 shares at December 31, 2018 and 2017, respectively; Issued and outstanding: 24,930,736 and 689,898 shares at December 31, 2018 and				
2017, respectively		67		2
Preferred shares of NIS 0.01 par value - Authorized: 0 and 16,723,000 shares at December 31, 2018 and 2017, respectively; Issued and outstanding: 0 and 14,154,743 shares at December 31, 2018 and 2017, respectively		_		38
Share premium		193,953		139,311
Capital reserve due to actuarial loss		(77)		(79)
Available for sale reserve		(43)		(34)
Accumulated deficit		(169,213)		(116,282)
Total shareholders' equity		24,687		22,956
Total liabilities and shareholders' equity	\$	65,164	\$	44,922

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

# U.S. dollars in thousands (except share and per share data)

, , , , ,			ar ended ember 31,		
		2018	2017		2016
Operating expenses:					
Research and development expenses, net	\$	22,045	\$ 15,018	\$	19,095
General and administrative expenses		11,599	 4,472		4,614
Operating loss	_	33,644	 19,490		23,709
Financial expenses		20,259	718		155
Financial income		(1,042)	(1,197)		(1,193)
Loss before taxes on income		52,861	19,011		
Taxes on income		70			
Net Loss		52,931	19,011		22,671
Other comprehensive loss:					
Items that will be reclassified subsequently to profit or loss:					
Actuarial net loss of defined benefit plans		(2)	35		20
Changes in the fair value of available for sale financial assets		9	34	_	
Total comprehensive loss	\$	52,938	\$ 19,080	\$	22,691
Net loss per share:					
Basic and diluted net loss per share	\$	10.53	\$ 27.56	\$	32.86
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	_	5,025,213	689,898		689,898

# **CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

# U.S. dollars in thousands (except share and per share data)

	Ordinary shares Preferred sl		shares		Available for sale	Capital reserve due			
	Number	Amount	Number	Amount	Share Premium	reserve Amount	to actuarial losses	Accumulated deficit	Total equity
Balance as of January 1, 2016	689,898	\$ 2	9,880,380	\$ 26	\$102,408	\$ —	\$ (24)	\$ (74,600)	\$ 27,812
Net loss	_	_	_	_	_	_	_	(22,671)	(22,671)
Other comprehensive loss							(20)		(20)
Total comprehensive loss	_	_	_	_	_	_	(20)	(22,671)	(22,691)
Share-based compensation					5,842				5,842
Balance as of December 31, 2016	689,898	2	9,880,380	26	108,250	_	(44)	(97,271)	10,963
Net loss	_	_	_	_	_	_	_	(19,011)	(19,011)
Other comprehensive loss						(34)	(35)		(69)
Total									
Total comprehensive loss	_	_	_	_	_	(34)	(35)	(19,011)	(19,080)
Issuance of series F-1 preferred shares, net of issuance costs	_	_	4,274,363	12	28,853	_	_	_	28,865
Share-based			4,274,000	12	,				
compensation					2,208				2,208
Balance as of December 31, 2017	689,898	2	14,154,743	38	139,311	(34)	(79)	(116,282)	22,956
Net loss	_	_	_	_	_	_	_	(52,931)	(52,931)
Other comprehensive loss						<u>(9)</u>	2		(7)
Total comprehensive loss	_	_	_	_	_	(9)	2	(52,931)	(52,938)
Issuance of additional preferred shares following Anti-dilution					(0)				
Protection Exercise of options	9,692	_	3,134,546	8	(8)	_	_	_	_ 2
Conversion of									_
preferred shares Issuance of ordinary shares in initial public offering, net of issuance expenses in	17,289,289	46	(17,289,289)	(46)	_	_	_	_	_
an amount of \$5,947	6,648,368	18	_	_	47,223	_	_	_	47,241
Exercise of warrants Share-based compensation	293,489 	1			3,850 3,575				3,851
				_	_	_	_	_	
Balance as of December 31, 2018	24,930,736	\$ 67		<u> </u>	\$193,953	\$ (43)	\$ (77)	\$ (169,213)	\$ 24,687

# CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands						
		Year ended December 31,				
	20	18		2017		2016
Cash flows from operating activities:						
Net loss	\$ (5)	2,931)	\$	(19,011)	\$	(22,671)
Adjustments to reconcile net loss to net cash used in operating activities:						
Adjustments to the profit or loss items:						
Adjustments to the profit or loss items:						
Depreciation		269		162		124
Financial income, net		(858)		(330)		92
Cost of share-based compensation		3,575		2,208		5,842
Change in employee benefit liabilities, net		(15)		26		28
Amortization of premium on available-for-sale financial assets		272		28		_
Revaluation of financial derivatives	1	7,600		(1,061)		(805)
Revaluation of liability to IIA	:	2,037		631		_
Other						37
	2	2,880		1,664		5,318
Changes in asset and liability items:						
Decrease (Increase) in other receivables, prepaid expenses and other		0.40		(2.210)		10
Current assets		942		(2,210) 1,464		13 297
(Decrease) Increase in trade payables  Decrease in related parties		(405)		1,404		148
Change in liability to IIA						4,030
Increase in accrued expenses and other payables and employees and payroll						4,000
accruals	:	2,296		1,214		131
	:	2,833		468		4,619
Cash received during the year for:						
Interest received		792		330		144
Net cash used in operating activities	(2	6,426)		(16,549)		(12,590)
Cash flows from investing activities:						
D. observation of control of the Control		1 0 15)		(400)		(00.4)
Purchase of property and equipment		1,645)		(402)		(284)
Purchase of available-for-sale financial assets		0,905) 5,000		(14,820)		_
Proceeds from (investment in) bank deposits  Investment in restricted bank deposits	,	(150)		(5,000)		_
Proceed from sale of available-for-sale financial assets		4,949				
Proceeds from liquidation of joint venture and other assets		-,5-5				<u> </u>
r rocceus nom nquiuation of joint venture and other assets			_		_	555
Net cash (used in) provided by investing activities	ľ	2,751)		(20,222)		311
Tot sach (asset in) provided by investing delivines		_,. <u>-,</u> ,	_	(,)		<u> </u>

# **CONSOLIDATED STATEMENTS OF CASH FLOWS**

1	15	dol	lars	in	th	ΛI	102	nde	•
·	J. 3.	uoi	IAI 5	111		UU	24	HU:	•

	Year ended December 31,					
		2018		2017		2016
Cash flows from financing activities:						
Receipt of grants from the IIA		612		272		1,688
Proceeds from issuance of financial derivatives		_		10,900		_
Proceeds from initial public offering, net		47,479		_		_
Exercise of options		2		_		_
Proceeds from issuance of shares, net		_		28,865		_
	<u></u>			_		
Net cash provided by financing activities		48,093		40,037		1,688
, , , , , , , , , , , , , , , , , , ,	· ·	,				
Exchange differences on balances of cash and cash equivalents		31		_		(92)
Increase (decrease) in cash and cash equivalents		18,947		3,266		(10,683)
Cash and cash equivalents at beginning of year		21,325		18,059		28,742
, ,						
Cash and cash equivalents at end of year	\$	40,272	\$	21,325	\$	18,059
,			=			
Significant non-cash transactions:						
<u>organicant non saon transactions.</u>						
IIA liability for grants to be received	\$	_	\$	269	\$	_
in that inty for grants to be received	<u> </u>		Ť		<u> </u>	
Exercise of warrants liabilities to equity	\$	3,851	\$	_	\$	_
Exercise of Warranto habilities to equity		0,001	<u> </u>		<u>*</u>	
Issuance expenses on credit	\$	238	\$		\$	_
issuance expenses on creuit	Ψ	230	Ψ		Ψ	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## U.S. dollars in thousands except share and per share data

#### NOTE 1:- GENERAL

- a. Gamida Cell Ltd. (the "Company"), founded in 1998, is a clinical-stage biopharmaceutical company that develops novel curative treatments for orphan indications, including hematological malignancies and rare genetic diseases using stem cells and natural killer (NK) cells.
- b. On October 30, 2018, the Company closed an Initial Public Offering ("IPO") of its ordinary shares on the Nasdaq, under the symbol "GMDA" which resulted in the sale of 6,250,000 ordinary shares at a public offering price of \$8 per share, before underwriting discounts. The underwriters purchased 398,368 additional shares at a public offering price of \$8 per share. The Company received net proceeds from the IPO of approximately \$47,241 (net of issuance costs and underwriting discounts of approximately \$5,947). Upon the closing of the IPO, all of the Company's outstanding preferred shares automatically converted into 17,289,289 ordinary shares.
- c. The Company uses its proprietary platform NAM technology to expand in culture, highly functional cells derived from umbilical cord blood or peripheral blood, while enhancing the potential therapeutic efficacy of these cells.

The Company's lead product candidate, omidubicel®, is currently being developed in a pivotal Phase 3 clinical study to treat patients with various hematologic malignancies, such as leukemias and lymphomas, who are indicated to receive a donor-derived hematopoietic stem cell transplant (bone marrow transplant). Bone marrow transplantation with a graft derived from a matched donor is currently the standard-of-care treatment for many of these patients, but there is a significant unmet need for patients who cannot find a fully matched donor. Omidubicel is designed as a universal graft that addresses the limitations found in other sources of donor cells.

Omidubicel was granted Breakthrough Therapy designation from the FDA and Orphan Drug designation in the US and in Europe.

At the 2017 American Society of Hematology meeting, the Company presented final results from the Phase 1/2 trial evaluating omidubicel. The study met its primary endpoint, demonstrating rapid neutrophil engraftment with manageable side effects.

In addition to hematologic malignancies, the Company is pursuing the development of omidubicel for the treatment of bone marrow failure disorders. Omidubicel is currently being evaluated in a Phase 1/2 clinical trial sponsored by the National Institutes of Health in patients with severe aplastic anemia, a rare, life-threatening hematological disorder.

Beyond omidubicel, the Company develops another product candidate, GDA-201, for innate immunotherapy of expanded NK cells, to be used in combination with standard-of-care therapeutic antibodies. NK cells have potent anti-tumor properties and have the advantage over other oncology cell therapies of not requiring genetic matching, potentially enabling NK cells to serve as a universal donor-based therapy when combined with certain antibodies. A Phase 1 investigator-initiated study to treat patients with B-cell lymphoma and multiple myeloma is enrolling patients.

d. The Company is devoting substantially all of its efforts toward research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated deficits as of December 31, 2018 amounted to \$169,213 and negative cash flows from operating activities for year ended December 31, 2018 amounted to \$26,426. The Company requires additional financing in order to continue to fund its current operations and pay existing and future liabilities.

## U.S. dollars in thousands (except share and per share data)

## NOTE 1:- GENERAL (Cont.)

These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern.

#### e. Definitions:

In these financial statements:

The Company - Gamida Cell Ltd. and its Subsidiary

Subsidiary - Gamida Cell Inc. Incorporated in 2000 and intended to focus on sales and marketing

upon product approval

Related Parties - As defined in IAS 24

Dollar - U.S. dollar

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the financial statements for all periods presented, unless otherwise stated.

a. Basis of presentation of the financial statements:

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The consolidated financial statements have been prepared on a cost basis, except for available-for-sale financial assets and financial liabilities that have been measured at fair value through profit or loss. The Company has elected to present profit or loss items using the function of expense method.

- b. The operating cycle of the Company is one year.
- c. Consolidated financial statements:

The consolidated financial statements comprise the financial statements of the Company and its Subsidiary.

The financial statements of the Company and its Subsidiary are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all companies in the group. Significant intra-group balances, transactions and gains or losses resulting from intra-group are eliminated in full in the consolidated financial statements.

- d. Functional currency, presentation currency and foreign currency:
  - 1. Functional currency and presentation currency:

The presentation currency of the financial statements is the U.S. dollar.

The functional currency is the currency that best reflects the economic environment in which the Company and its Subsidiary operate and conduct their transactions. Most of

U.S. dollars in thousands (except share and per share data)

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

the Company costs are incurred in U.S. dollars. In addition, the Company's financing activities are incurred in U.S. dollars. The Company's management believes that the functional currency of the Company is the U.S. dollar.

2. Transactions, assets and liabilities in foreign currency:

Transactions denominated in foreign currency are recorded upon initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange rate differences are recognized in profit or loss. Non-monetary assets and liabilities measured at cost in foreign currency are translated at the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

# e. Cash equivalents:

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of investment or with a maturity of more than three months, but which are redeemable on demand without penalty and which form part of the Company's cash management.

f. Short-term deposits and restricted deposits:

Short-term bank deposits are deposits with an original maturity of more than three months from the date of investment and which do not meet the definition of cash equivalents. The deposits are presented according to their terms of deposit.

Restricted deposit is primarily invested in highly liquid deposits. Restricted deposit amounted to \$150 and \$0 as of December 31, 2018 and 2017, respectvley and is included in prepaid expenses and other current assets on the statements of financial position.

## g. Property and equipment:

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation, accumulated impairment losses and any related investment grants and excluding day-to-day servicing expenses.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	90
Machinery	15
Office furniture and equipment	6 - 33
Leasehold improvements	(*)

(\*) Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

The useful life, depreciation method and residual value of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate.

U.S. dollars in thousands (except share and per share data)

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

An item of property and equipment is derecognized upon disposal or when no future economic benefits are expected from its use or disposal.

## h. Research and development costs:

Research expenditures are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate: the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Since the Company's development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and, therefore, development expenditures are recognized in profit or loss when incurred.

## i. Impairment of non-financial assets:

The Company evaluates the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years, and its recoverable amount.

During the years ended December 31, 2018, 2017 and 2016, the Company did not recognize any impairment of non-financial assets.

# j. Government investment grants:

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with the related conditions.

Government grants received from Israel Innovation Authority ("IIA") (formerly, the Office of the Chief Scientist in Israel ("OCS")) are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. If no such economic benefits are expected, the grants are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as contingent liability in accordance with IAS 37.

At the end of each reporting period, the Company evaluates, based on its best estimate of future sales, whether there is reasonable assurance that the liability recognized, in whole or

U.S. dollars in thousands (except share and per share data)

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

in part, will not be repaid (since the Company will not be required to pay royalties). If there is such reasonable assurance, the appropriate amount of the liability is derecognized and recorded in profit or loss as a revaluation of research and development expenses.

If the estimate of future sales indicates that there is no such reasonable assurance, the appropriate amount of the liability that reflects expected future royalty payments is recognized with a corresponding adjustment to financial expenses or income. As of December 31, 2018 and 2017, the Company determined that future economic benefits are expected from its research and development project and recorded a liability for its entire contingent obligation to IIA.

Grants received from the IIA which are recognized as a liability are accounted for as forgivable loans, in accordance with IAS 20 (Revised). Accordingly, when the liability for the loan is first recognized, it is measured at fair value using a discount rate that reflects a market rate of interest, which in the Company's case was determined to be 28% and 25% for 2018 and 2017, respectively. The difference between the amount of the grants received and the fair value of the liability is accounted for upon recognition of the liability as a government grant and recognized as a reduction of research and development expenses.

For the years ended December 31, 2018, 2017 and 2016 no royalties were paid with respect to grants received from the IIA. Payments will be treated as a reduction of the liability.

Grants in the amount of \$2,425, \$2,948 and \$4,264 were approved during 2018, 2017 and 2016, respectively. Grant receivable amounted to \$0 and \$1,578 as of December 31, 2018 and 2017, respectively, and is included in prepaid expenses and other current assets on the statements of financial position.

## k. Provisions:

A provision in accordance with IAS 37 is recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

# I. Operating leases:

Lease agreements are classified as an operating lease if they do not transfer substantially all the risks and benefits incidental to ownership of the leased asset. Operating lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term.

# m. Share-based payment transactions:

The Company's employees and other service providers are entitled to remuneration in the form of equity-settled share-based payment transactions.

## Equity-settled transactions:

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value is determined using an acceptable option pricing model.

U.S. dollars in thousands (except share and per share data)

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

With respect to other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments. In cases where the fair value of the goods or services received as consideration of equity instruments cannot be measured, it is measured by reference to the fair value of the equity instruments granted.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period which the performance and/or service conditions are to be satisfied, ending on the date on which the relevant employee becomes fully entitled to the award.

No expense is recognized for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition, which are treated as vested irrespective of whether the market condition is satisfied, provided that all other vesting conditions are satisfied.

## n. Deferred tax:

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax assets are recognized for all deductible temporary differences. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and unused tax losses can be utilized.

Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

# o. Employee benefit liabilities:

The Company has several employee benefit plans:

# Short-term employee benefits:

Short-term employee benefits are benefits that are expected to be settled entirely before twelve months after the end of the annual reporting period in which the employees render the related services. These benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered.

# 2. Post-employment benefits:

The plans are normally financed by contributions to insurance companies and classified as defined benefit plans.

The Company operates a defined benefit plan in respect of severance pay pursuant to the Severance Pay Law, 1963 (the "Law"). According to the Law, employees are entitled to severance pay upon dismissal or retirement. The liability for termination of employment is measured using the projected unit credit method. The amounts are presented based on discounted expected future cash flows using a discount rate determined by reference to yields on Government bonds.

U.S. dollars in thousands (except share and per share data)

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

In respect of its severance pay obligation to certain of its employees, the Company makes current deposits in pension funds and insurance companies (the "Plan Assets"). Plan Assets comprise assets held by a long-term employee benefit fund or qualifying insurance policies. Plan Assets are not available to the Company's own creditors and cannot be returned directly to the Company.

Actuarial gains and losses are recognized in other comprehensive income or (loss) retrospectively in the period in which they occur.

# p. Initial adoption of IFRS 9, "Financial Instruments":

In July 2014, the IASB issued the final and complete version of IFRS 9, "Financial Instruments" ("the new Standard"), which replaces IAS 39, "Financial Instruments: Recognition and Measurement". The new Standard mainly focuses on the classification and measurement of financial assets and it applies to all assets within the scope of IAS 39.

The new Standard has been applied for the first time in these financial statements retrospectively without restatement of comparative data.

There is no material effect of the initial adoption of the new Standard on the Company's financial statements.

# q. Financial instruments:

As described in Note 2p regarding the initial adoption of IFRS 9, "Financial Instruments" ("the Standard"), the Company elected to adopt the provisions of the Standard retrospectively without restatement of comparative data.

The accounting policy for financial instruments applied until December 31, 2017, is as follows:

#### Investment in marketable securities:

Financial assets within the scope of IAS 39 are initially recognized at fair value plus directly attributable transaction costs, except for financial assets measured at fair value through profit or loss in respect of which transaction costs are recorded in profit or loss.

After initial recognition, the accounting treatment of financial assets is based on their classification as follows:

- a) Financial assets at fair value through profit or loss
- b) Held-to-maturity investments
- c) Loans and receivables
- d) Available-for-sale financial assets

The Company classifies all of its marketable securities as available-for-sale. Available-for-sale financial assets are (non-derivative) financial assets that are designated as available for sale or are not classified in any of the three preceding categories. After initial recognition, available-for-sale financial assets are measured at fair value. Gains or losses from fair value adjustments, except for interest, exchange rate differences that relate to debt instruments and dividends from an equity instrument, are recognized in other comprehensive income. When the investment is disposed of or in case of impairment, the other comprehensive income (loss) is transferred to profit or loss.

## U.S. dollars in thousands (except share and per share data)

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Marketable securities as of December 31, 2017 and 2018 includes corporate and government debentures with no significant premium or discount. The investment in marketable securities which are classified as available-for-sale is considered Level 2 measurement.

#### 2. Financial liabilities:

Financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables net of directly attribute transaction costs. The Company's financial liabilities include trade and other payables and warrants to shareholders.

Warrants to shareholders can be excercied into a variable number of shares and therefore such warrants are recorded as a financial liability and are measured at each balance sheet date at their fair value. Gains or losses are recognized in profit or loss.

# a) Derecognition:

A financial liability is derecognized when the obligation under the liability is discharged or cancelled, or expires.

## b) Offsetting of financial instruments:

Financial assets and financial liabilities are offset and the net amount is reported in the statements of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, to realize the assets and settle the liabilities simultaneously.

#### 3. Fair value:

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy.

The carrying amounts of cash and cash equivalents, available-for-sale financial assets, other receivables, short-term deposits, and other current assets, trade payables and accrued expenses and other payables approximate their fair value due to the short-term maturity of such instruments. Regarding fair value of the liability to IIA, refer to note 2j above.

U.S. dollars in thousands (except share and per share data)

# NOTE 3:- SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

The key assumptions made in the financial statements concerning uncertainties at the end of the reporting period and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Government grants:

Government grants received from the IIA at the Ministry of Industry, Trade and Labor are recognized as a liability if future economic benefits are expected from the research and development activity that will result in royalty-bearing sales. There is uncertainty regarding the estimated future cash flows and the estimated discount rate used to measure the amortized cost of the liability.

Determining the fair value of an unquoted financial liabilities:

The fair value of unquoted financial liabilities in Level 3 of the fair value hierarchy is determined using valuation techniques including projected cash flows discounted at current rates applicable for items with similar terms and risk characteristics. Changes in estimated projected cash flows and estimated discount rates, after consideration of risk factors such as liquidity risk, credit risk and volatility, are liable to affect the fair value of these liabilities.

# NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

IFRS 16. "Leases":

In January 2016, the IASB issued IFRS 16, "Leases" ("the new Lease Standard"). According to the new Lease Standard, a lease is a contract, or part of a contract, that conveys the right to use an asset for a period of time in exchange for consideration.

The effects of the adoption of the new Lease Standard are as follows:

- According to the new Lease Standard, lessees are required to recognize all leases in the statement of
  financial position (excluding certain exceptions, see below). Lessees will recognize a liability for lease
  payments with a corresponding right-of-use asset, similar to the accounting treatment for finance
  leases under the existing standard, IAS 17, "Leases". Lessees will also recognize interest expense
  and depreciation expense separately.
- Variable lease payments that are not dependent on changes in the Consumer Price Index ("CPI") or interest rates, but are based on performance or use are recognized as an expense by the lessees as incurred and recognized as income by the lessors as earned.
- In the event of a change in variable lease payments that are CPI-linked, lessees are required to remeasure the lease liability and record the effect of the remeasurement as an adjustment to the carrying amount of the right-of-use asset.
- The accounting treatment by lessors remains substantially unchanged from the existing standard, namely classification of a lease as a finance lease or an operating lease.
- The new Lease Standard includes two exceptions which allow lessees to account for leases based on the existing accounting treatment for operating leases - leases for which the underlying asset is of low financial value and short-term leases (up to one year).

U.S. dollars in thousands (except share and per share data)

# NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Cont.)

The new Lease Standard is effective for annual periods beginning on or after January 1, 2019.

The Company will apply the modified retrospective approach upon the initial adoption of the new Lease Standard by measuring the right-of-use asset at an amount equal to the lease liability, as measured on the transition date.

The Company has a number of lease contracts, mainly leases of an office building and a production plant (see also Note 9). In assessing the impact of the new Lease Standard on the financial statements, the Company evaluated the following matters:

- Options to extend the lease according to the new Lease Standard, the non-cancellable period of a lease includes periods that are covered by options to extend the lease if the lessee is reasonably certain to exercise the option.
- Separation of lease components according to the new Lease Standard, all lease components within
  a contract should be accounted for separately from non-lease components. A lessee is allowed a
  practical expedient according to which it can elect, by class of underlying asset, not to separate nonlease components from lease components, and instead account for them as a single lease
  component.
- Incremental interest rate the Company estimates the incremental interest rate to be used for measuring the lease liability and right-of-use asset on the date of initial adoption of the new Lease Standard, based on the lease term and nature of the leased asset.

The Company estimated that the effect of the initial adoption of the new Lease Standard as of January 1, 2019, is expected to result in an increase in the Company's total assets and liabilities in the amount to \$7,523 and no impact on equity.

Moreover, the effect of the initial adoption of the new Lease Standard in 2019 is expected to result in a decrease in the Company's lease expenses of \$1,940 and an increase in the Company's depreciation and finance expenses of \$1,928 and \$94, respectively. The total effect of the initial adoption of the new Lease Standard in 2019 is expected to result in a decrease of \$12 in operating loss and an increase of \$82 in loss before income taxes.

## NOTE 5:- CASH AND CASH EQUIVALENTS

	 December 31,			
	 2018	2017		
Cash for immediate withdrawal	\$ 3,289	\$	3,316	
Cash equivalents - short-term deposits(1)	 36,983		18,009	
	\$ 40,272	\$	21,325	

(1) The cash equivalents are short-term bank deposits denominated in dollars and bear interest at an average annual rate of 2.05% and 1.050% as of December 31, 2018 and 2017, respectively.

U.S. dollars in thousands (except share and per share data)

# NOTE 6:- PROPERTY AND EQUIPMENT, NET

Composition and movement:

2018:

			furi	ffice niture ınd	Lease		į	oject in	
	Ma	chinery	equi	pment	improve	ments	pro	cess	Total
Cost:									
Balance at January 1, 2018	\$	2,181	\$	396	\$	992	\$	47	\$ 3,616
Additions		973		139		107		421	1,640
Balance at December 31, 2018		3,154		535		1,099		468	5,256
Accumulated depreciation:									
Balance at January 1, 2018		1,558		308		810		_	2,676
Depreciation		195		37		37		_	269
_ op. co		-			-	•			-
Balance at December 31, 2018		1,753		345		847		_	2,945
Dalarios at Bosombol 61, 2016		_,,			-		-		
Property and equipment, net at									
December 31, 2018	\$	1,401	\$	190	\$	252	\$	468	\$ 2,311
2 3 3 3 3 2 , 2 3 2 3	Ė						=		

# 2017:

_Ma	chinery_	furni ar	ture id			iń			otal_
\$	1,902	\$	369	\$	943	\$	_	\$ 3	3,214
	279		27		49		47		402
	2,181		396		992		47	3	3,616
	1,433		292		789		_	2	2,514
	125		16		21		_		162
		_	,						
	1,558		308		810		_	2	2,676
			,						
\$	623	\$	88	\$	182	\$	47	\$	940
	\$	279 2,181  1,433 125  1,558	\$ 1,902 \$ 279 2,181 1,433 125 1,558	\$ 1,902 \$ 369 279 27 2,181 396 1,433 292 125 16 1,558 308	Machinery         furniture and equipment         Leaseh improven           \$ 1,902         \$ 369         \$ 279           279         27         27           2,181         396         396           1,433         292         125           125         16         1,558           308         308	Machinery         furniture and equipment         Leasehold improvements           \$ 1,902         \$ 369         \$ 943           279         27         49           2,181         396         992           1,433         292         789           125         16         21           1,558         308         810	Machinery         furniture and equipment         Leasehold improvements         Projin processor           \$ 1,902         \$ 369         \$ 943         \$ 279         27         49         27         49	Machinery         furniture and equipment         Leasehold improvements         Project in process           \$ 1,902         \$ 369         \$ 943         \$ — 279           279         27         49         47           2,181         396         992         47           1,433         292         789         — 2125           125         16         21         — 21           1,558         308         810         — 21	Machinery         furniture and equipment         Leasehold improvements         Project in process         T           \$ 1,902         \$ 369         \$ 943         \$ — \$ 3           279         27         49         47           2,181         396         992         47         3           1,433         292         789         — 2         2           125         16         21         —         2           1,558         308         810         — 2         2

# NOTE 7:- ACCRUED EXPENSES AND OTHER PAYABLES

	 December 31,			
	2018		2017	
Subcontractors accruals	\$ 1,096	\$	468	
Legal and consulting accruals	479		201	
Other	 257		_	
	\$ 1,832	\$	669	

U.S. dollars in thousands (except share and per share data)

# NOTE 8:- LIABILITIES PRESENTED AT FAIR VALUE

a. Warrants to purchase Preferred F-2 shares:

On June 18, 2017 the Company signed a Series F Preferred Share Purchase Agreement ("SPA") with existing and new investors. According to the SPA and upon the closing that occurred on July 9, 2017 the Company issued 4,274,363 Preferred F-1 shares, nominal value NIS 0.01 each, at \$9.44 per share, accompanied by the issuance of warrants to purchase 2,564,619 Preferred F-2 shares, nominal value NIS 0.01, with an exercise price of \$11.33 per share, in exchange for an aggregate proceeds of \$40,350. The issuance costs in the amount of \$585 associated with the equity transaction have been charged directly to the consolidated statements of changes in equity and the issuance costs associated with the issuance of the warrants in the amount of \$216 have been charged directly to the statement of comprehensive loss.

According to the SPA, the warrants to purchase Preferred F-2 Shares are subject to conversion ratio to be adjusted as defined in the SPA and to non-standard anti-dilution protection provisions and cashless exercise mechanism and therefore accounted for as a financial liability which was measured at fair value through profit or loss.

Upon the closing of the IPO as described in note 1b, 2,564,619 warrants to purchase Preferred F-2 shares were automatically converted into warrants to purchase 4,323,978 ordinary shares, nominal value NIS 0.01, with an exercise price of \$6.72 per share with an expiration until earlier of July 3, 2022 or a Deemed Liquidation event as described in the Company's articles of association (the "AOA").

In December 2018, the Company issued a total of 293,489 ordinary shares pursuant to the cashless exercise of 607,044 warrants.

The Company measured the fair value of the warrants by using Black and Shoultz simulation model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected time until liquidation. Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected time until liquidation is the period in which liquidation event will occurred subject to the Company's expectations. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

b. Warrants to purchase Company's shares:

	Decer	nber 31,
	2018	2017
	Ordinary shares	Preferred F-2 shares
Risk-free interest rate	2.5%	1.5%
Expected volatility	80%	90%
Expected life (in years)	3.5	4.5
Expected dividend yield	0	0

U.S. dollars in thousands (except share and per share data)

# NOTE 8:- LIABILITIES PRESENTED AT FAIR VALUE (Cont.)

c. Changes in the fair value of warrants classified as Level 3 in the fair value hierarchy:

	Fair value of warrants E-2	Fair value of Warrants to purchase Ordinary shares	Total warrants presented at fair value
Balance at January 1, 2016	\$ 1,266	\$ —	\$ 1,266
Revaluation of financial derivatives	(805)	=	(805)
Balance at December 31, 2016	461	_	461
Proceeds from issue of financial derivatives	_	10,900	10,900
Revaluation of financial derivatives	(461)	(600)	(1,061)
Balance at December 31, 2017		10,300	10,300
Exercise of warrants	_	(3,851)	(3,851)
Revaluation of financial derivatives	=	17,600	17,600
Balance at December 31, 2018	<u> </u>	\$ 24,049	\$ 24,049

d. Description of significant unobservable inputs to valuation:

		December 31,			
	20	)18	2017		
		erred hares	Preferred F-2 shares		
Sensitivity to changes in inputs:					
Gain (loss) from change:					
10% increase in volatility	\$	— \$	720		
10% decrease in volatility	\$	— \$	(750)		
Gain (loss) from change:					
1% increase in discount rate	\$	— \$	(1,040)		
1% decrease in discount rate	\$	— \$	(1,290)		

U.S. dollars in thousands (except share and per share data)

# NOTE 9:- CONTINGENT LIABILITIES AND COMMITMENTS

a. The Company has entered into commercial real estate lease agreements which consist of the office building and production plant. The leases are under non-cancellable terms and mature over 1-9 years. In December 2017, the Company signed a lease agreement for a production plant which will be effective upon fulfillment of the suspending condition as described in the lease agreement.

The future minimum lease fees payable as of December 31, 2018 are as follows:

First year	\$ 1,803
Second through fifth years	2,522
After fifth year	 2,395
	\$ 6,720

- b. The Company rents vehicles under an operating lease agreement, for a fixed monthly fee of \$13. The leases are under non-cancellable terms and mature over 1-3 years.
- c. The Company is obligated to pay royalties to the Government of Israel through the IIA at the rates of 3% to 4% on sales proceeds from products developed through the grants received from the IIA. The maximum amount of royalties payable to the Government of Israel is limited to 100% of the grants received, linked to the dollar and bearing interest at the LIBOR rate. The obligation to pay these royalties is contingent on actual sales of the products and in the absence of such sales, no payment is required. The Company expects to incur sales that will trigger payments of royalties starting in 2020. As of December 31, 2018, the Company's aggregate contingent obligations for payments to the IIA, based on royalty-bearing participation received or accrued amounted to \$34,197 (including interest of \$4,916).

# NOTE 10:- SHAREHOLDERS' EQUITY

a. Composition of share capital:

	December 31,					
	201	8	201	17		
	Authorized	Issued and outstanding	Authorized	Issued and outstanding		
	Number of shares					
Ordinary share of NIS 0.01 par value	100,000,000	24,930,736	22,007,000	549,990		
Ordinary B share of NIS 0.01 par value	_	_	140,000	139,908		
Ordinary C share of NIS 0.01 par value			1,130,000			
	100,000,000	24,930,736	23,277,000	689,898		

U.S. dollars in thousands (except share and per share data)

# NOTE 10:- SHAREHOLDERS' EQUITY (Cont.)

	December 31,					
	20:	18	20	17		
	Authorized	Issued and outstanding	Authorized	Issued and outstanding		
		Number	of shares			
Series Preferred A share of NIS						
0.01 par value	_	_	600,000	600,000		
Series Preferred B share of NIS						
0.01 par value	_	_	1,454,000	1,453,846		
Series Preferred C share of NIS						
0.01 par value	_	_	2,828,000	2,827,430		
Series Preferred D share of NIS						
0.01 par value	_	_	3,405,000	3,404,314		
Series Preferred E1 share of NIS						
0.01 par value	_	_	572,000	571,478		
Series Preferred E2 share of NIS						
0.01 par value	_	_	1,024,000	1,023,312		
Series Preferred F1 share of NIS						
0.01 par value	_	_	4,275,000	4,274,363		
Series Preferred F2 share of NIS						
0.01 par value	<u></u>		2,565,000			
			16,723,000	14,154,743		

# b. Rights attached to the shares:

1. Ordinary shares:

Subject to our current AOA, the holders of ordinary shares have the right to receive notices to attend and vote in general meetings of the Company's shareholders, and the right to share in dividends and other distributions and upon liquidation.

2. Preferred shares:

All issued and outstanding preferred shares were converted to ordinary shares upon the IPO.

# NOTE 11:- SHARE-BASED PAYMENT

a. On November 23, 2014, the Company's Board of Directors approved, subject to the approval of the shareholders, the creation of a new class of shares of the Company, Ordinary C shares, nominal value NIS 0.01 each and to classify 1,500,000 ordinary shares for such class, 1,152,044 out of which for allocation to the Company's employees under the new amended 2014 Israel Share Option Plan ("2014 Plan"). The exercise price of the options granted under the plans may not be less than the nominal value of the shares into which the options are exercised. The options vest primarily over three years. Any options, which are forfeited or not exercised before expiration, become available for future grants.

There are no cash settlement alternatives. On December 29, 2014, the Company's shareholders meeting ratified and approved the aforesaid decisions.

On January 23, 2017 the Company's Board of Directors approved the Company's 2017 Share Incentive Plan (the "2017 Plan"), and the subsequent grant of options to the Company's employees, officers and directors. Pursuant to the Plan, the Company initially

U.S. dollars in thousands (except share and per share data)

# NOTE 11:- SHARE-BASED PAYMENT (Cont.)

reserved for issuance 312,867 ordinary shares, nominal value NIS 0.01 each. Contemporaneously, the Company's Board of Directors approved the termination of the Company's 2014 Plan and the extension of the exercise period of the outstanding options to Ordinary C shares to expire on January 2020 instead of January 2018. There was no material impact on the financial statements, with respect to the Company's 2014 plan extension. On February 28, 2017 the Company's shareholders approved the 2017 Plan.

On June 26, 2017 and on December 28, 2017 the Company's Board of Directors approved the reservation of additional 463,384 and 559,764 ordinary shares, respectively, for issuance under the 2017 Plan (totaling, including previous plans, an aggregate of 1,338,015 ordinary shares).

The Company estimates the fair value of stock options granted using the Binominal option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term.

Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected term of the options granted is derived from output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan for years 2018, 2017 and 2016:

	Year ended December 31,			
	2018	2017	2016	
Dividend yield (%)	0	0	0	
Expected volatility of the share prices (%)	93%-95%	89%-94%	71%-94%	
Risk-free interest rate (%)	2.63-2.88	1.76-2.4	0.3	
Share price	\$8.00	\$5.00	\$13.4	

Based on the above inputs, the fair value of the options was determined at \$3.64-\$5.85 at the grant date.

U.S. dollars in thousands (except share and per share data)

# NOTE 11:- SHARE-BASED PAYMENT (Cont.)

b. Movement during the year:

	201	8	201	L <b>7</b>		
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price USD		
Outstanding at beginning of year	2.467.023	2.28	1,129,008	0.25		
Granted during the year	751,977	5.60	1,338,015	3.99		
Expired during the period	2,000	6.00	· · · —	_		
Exercised during the period	9,692	0.25	_	_		
Forfeited during the year	9,692	0.25				
Share options outstanding at end of year	3,197,616	3.07	2,467,023	2.28		
Share options exercisable at end of year	1,705,256	1.21	1,379,075	0.60		

c. As of December 31, 2018, there are \$4,103 of total unrecognized company cost related to non-vested share based compensation that are expected to be recognized over a period of up to 4 years.

# NOTE 12:- TAXES ON INCOME

- a. Tax rates applicable to the income of the Company:
  - 1) Corporate Tax rates:

Taxable income of the Israeli parent is subject to the Israeli corporate tax at the rate of 25% in 2016, 24% in 2017 and 23% in 2018.

Non-Israeli subsidiaries are taxed according to the tax laws in their respective countries of residence.

Income subject to tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"):

The Investment Law provides tax benefits for Israeli companies meeting certain requirements and criteria. The Investment Law has undergone certain amendments and reforms in recent years.

The Israeli parliament enacted a reform to the Investment Law, effective January 2011. According to the reform, a flat rate tax applies to companies eligible for the "Preferred Enterprise" status. In order to be eligible for Preferred Enterprise status, a company must meet minimum requirements to establish that it contributes to the country's economic growth and is a competitive factor for the gross domestic product.

The Company's Israeli operations elected "Preferred Enterprise" status, starting in 2017.

## U.S. dollars in thousands (except share and per share data)

# NOTE 12:- TAXES ON INCOME (Cont.)

Benefits granted to a Preferred Enterprise include reduced tax rates. In peripheral regions (Development Area A) the reduced tax rate was 9% in 2016. As part of Economic Efficiency Law (Legislative Amendments for Accomplishment of Budgetary Targets for Budget Years 2017-2018), 5777-2016, the tax rate for Area A will be 7.5% in 2017 onwards. In other regions the tax rate is 16%. Preferred Enterprises in peripheral regions will be eligible for Investment Center grants, as well as the applicable reduced tax rates.

b. The Law for the Encouragement of Industry (Taxation), 1969:

The Company has the status of an "industrial company", under this law. According to this status and by virtue of regulations published thereunder, the Company is entitled to claim a deduction of accelerated depreciation on equipment used in industrial activities, as determined in the regulations issued under the Inflationary Law. The Company is also entitled to amortize a patent or a patent or knowhow usage right that are used in the enterprise's development or promotion, to deduct listed share issuance expenses and to file consolidated financial statements under certain conditions.

c. Net operating losses carryforward:

The Company has net operating losses and capital loss for tax purposes as of December 31, 2018, in the amount of \$120,000 and \$500, respectively, which may be carried forward and offset against taxable income in the future for an indefinite period.

d. Final tax assessments:

The Company's tax assessments through the 2012 tax year are considered final.

e. Deferred taxes:

The Company did not recognize deferred tax assets in the Company's consolidated financial statements for the years ended December 31, 2018 and 2017 for carryforward losses and other temporary differences because their utilization in the foreseeable future is not probable.

## NOTE 13:- SELECTED STATEMENTS OF COMPREHENSIVE INCOME DATA

a. Research and development expenses, net:

	 Year	end	ed Decemb	er 3	1,
	2018		2017		2016
Salaries and social benefits	\$ 5,016	\$	3,795	\$	2,774
Share-based payment	705		1,362		3,195
Subcontractors	12,695		9,617		8,150
Materials	3,610		1,677		2,232
Rent and maintenance	758		486		364
Travel and trade shows	728		346		507
Depreciation	195		142		124
Other	239		_		61
Less royalty bearing grants	(1,901)		(2,407)		(4,030)
Reversal of grants received in prior years to related liability					5,718
Total research and development expenses, net	\$ 22,045	\$	15,018	\$	19,095

U.S. dollars in thousands (except share and per share data)

# NOTE 13:- SELECTED STATEMENTS OF COMPREHENSIVE INCOME DATA (Cont.)

b. General and administrative expenses:

	 Year	end	ed Decemb	er 3	1,
	 2018		2017		2016
Salaries and social benefits	\$ 4,788	\$	1,870	\$	924
Share-based payment	2,870		846		2,647
Professional services	2,818		1,467		843
Rent and maintenance	1,065		83		138
Other	58		206		62
Total general and administrative expenses	\$ 11,599	\$	4,472	\$	4,614

c. Finance expenses:

	Year en	ded De	ecembe	er 31,	
	 2018	20	17		2016
Revaluation of IIA liability	\$ 2,037	\$	631	\$	_
Revaluation of liabilities at fair value	17,600		_		_
Bank charges, interest expense and other fees	68		54		23
Foreign currency translation adjustments	 554		33		132
Total finance expenses	\$ 20,259	\$	718	\$	155

d. Finance income:

		Year ended December 31,						
	_	2018	2017			2016		
Interest income	\$	877	\$	330	\$	163		
Revaluation of liabilities at fair value		_		845		805		
Foreign currency translation adjustments	<u>\$</u>	165		22		225		
Total finance income	<u>\$</u>	1,042	\$	1,197	\$	1,193		

# NOTE 14:- RELATED PARTY TRANSACTIONS

Benefits to key executive personnel:

		December 31,					
	2018			2017		2016	
Short-term benefits	\$ 1,9	21	\$	1,578	\$	987	
Other long-term benefits		63		569		61	
Share-based payment	2,3	342		1,689		4,842	
	\$ 4,3	326	\$	3,836	\$	5,890	

# **GAMIDA CELL LTD. AND ITS SUBSIDIARY**

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

# U.S. DOLLARS IN THOUSANDS

	Page
Unaudited Interim Consolidated Financial Statements	
Interim Consolidated Statements of Financial Position as of March 31, 2019 and 2018	FF-2
Interim Consolidated Statements of Comprehensive Loss for the Three Month Periods Ended March 31, 2019 and 2018	<u>FF-3</u>
Interim Consolidated Statements of Changes in Equity for the Three Month Periods Ended March 31, 2019 and 2018	<u>FF-4</u>
Interim Consolidated Statements of Cash Flows for the Three Month Periods Ended March 31, 2019 and 2018	<u>FF-5</u>
Notes to Interim Consolidated Financial Statements	FF-7

# INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands								
		Marc	March 31,			December 31,		
		2019	_	2018		2018		
		Unau	dite	d				
ASSETS								
CURRENT ASSETS:								
Cash and cash equivalents	\$	43,749	\$	25,931	\$	40,272		
Available-for-sale financial assets		6,507	Ť	9,679		20,417		
Prepaid expenses and other current assets		684		887		1,502		
Total current assets		50,940		36,497		62,191		
NON-CURRENT ASSETS:								
Property and equipment, net		2,782		1,122		2,311		
Right-of-use assets		6,668		_,				
Other assets		657		355		662		
Total non-current assets		10,107		1,477		2,973		
Total assets	\$	61,047	\$	37,974	\$	65,164		
LIABILITIES AND EQUITY								
CURRENT LIABILITIES:								
Trade payables	\$	1,341	\$	852	\$	1,985		
Employees and payroll accruals		2,580		_		2,888		
Current maturities of lease liabilities		2,156		_		_		
Accrued expenses and other payables		1,739		2,446		1,832		
Total current liabilities		7,816	_	3,298		6,705		
NON-CURRENT LIABILITIES:								
Liabilities presented at fair value		25,031		10,700		24,049		
Employee benefit liabilities, net		276		184		183		
Lease Liabilities		4,671		_		_		
Liability to Israel Innovation Authority (IIA)		10,108		7,432		9,540		
Total non-current liabilities		40,086		18,316		33,772		
SHAREHOLDERS' EQUITY:								
Share capital -								
Ordinary shares of NIS 0.01 par value - Authorized: 100,000,000 shares at March 31, 2019 (unaudited) and December 31, 2018 and 23,277,000 shares at March 31,2018 (unaudited); Issued and outstanding: 25,140,048 and 24,930,736 share at March 31, 2019 (unaudited) and December 31, 2018 respectively, and 689,89								
shares at March 31, 2018 (unaudited);		68		2		67		
Preferred shares of NIS 0.01 par value - Authorized: 0 shares at March 31, 2019 (unaudited) and December 31, 2018 and 16,723,000 shares at March 31, 2018 (unaudited); Issued and outstanding: 0 shares at March 31, 2019 (unaudited) an December 31, 2018 and 14,154,743 shares at March 31, 2018 (unaudited);	d	_		38		_		
Share premium		197,967		140.155		193.953		
Capital reserve due to actuarial gains		(160)		(79)		(77)		
Available-for-sale reserve		(10)		(83)		(43)		
Accumulated deficit		(184,720)		(123,673)		(169,213)		
Total shareholders' equity		13,145		16,360		24,687		
Total liabilities and shareholders' equity	\$	61,047	\$	37,974	\$	65,164		
May 6, 2019	<u> </u>	, 1	Ť	2.,0.1	Ź	50,231		
Date of approval of the financial statements  Julian Adams				Shai Lanl	(r)/			
Director and CEO			Ch	ief Financia		cer		

# INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

# U.S. dollars in thousands (except share and per share data)

	March	31,	December 31,		
	2019	2018	2018		
Operating evaposes	Unaudi	ted			
Operating expenses:	\$ 7.283	ф F 060	\$ 22.045		
Research and development, net	. ,	\$ 5,060	,-		
General and administrative	3,813	1,653	11,599		
Operating loss	11,096	6,713	33,644		
Finance expenses	4,734	974	20,259		
Finance income	(349)	(296)	(1,042)		
Loss before taxes on income	15,481	7,391	52,861		
Taxes on income	26	_	70		
Net loss	15,507	7,391	52,931		
Other comprehensive loss:					
Items that will be reclassified subsequently to profit or loss:					
Actuarial net loss of defined benefit plans	83	_	(2)		
Changes in the fair value of available for sale financial assets	(33)	49	9		
Total comprehensive loss	15,557	7,440	52,938		
Net less yet share					
Net loss per share:	0.00	40.70	40.50		
Basic and diluted net loss per share	0.62	10.78	10.53		
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	25,038,261	689,898	5,025,213		

# INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)

# U.S. dollars in thousands (except share and per share data)

	Ordinary :	share	es	Preferred s	share	es	-	ilable sale	Capital reserve due				
	Number	Am	ount	Number	Am	ount	Share Premium	erve ount		actuarial osses	Ac	cumulated deficit	Total equity
Balance as of January 1, 2019	24,930,736	\$	67	_	\$	_	\$193,953	\$ (43)	\$	(77)	\$	(169,213)	\$ 24,687
Net loss	_		_	_		_	_	_		_		(15,507)	(15,507)
Other comprehensive loss								 33		(83)			(50)
Total comprehensive loss	_		_	_		_	_	33		(83)		(15,507)	(15,557)
Exercise of warrants	209,312		1	_		_	2,923	_				_	2,924
Share-based compensation							1,091			<u> </u>		<u> </u>	1,091
Balance as of March 31, 2019 (unaudited)	25,140,048	\$	68	_	\$	_	\$197,967	\$ (10)	\$	(160)	\$	(184,720)	\$ 13,145
Balance as of January 1, 2018	689,898	\$	2	14,154,743	\$	38	\$139,311	\$ (34)	\$	(79)	\$	(116,282)	\$ 22,956
Net loss	_			_		_	_			_		(7,391)	(7,391)
Other comprehensive loss	_		_	_		_	_	(49)		_		(1,001) —	(49)
Total comprehensive loss	_		_	_		_	_	(49)		_		(7,391)	(7,440)
Share-based compensation							844					<u> </u>	844
Balance as of March 31, 2018 (unaudited)	689,898	\$	2	14,154,743	\$	38	\$140,155	\$ (83)	\$	(79)	\$	(123,673)	16,360
Balance as of January 1, 2018	689,898	\$	2	14,154,743	\$	38	139,311	\$ (34)	\$	(79)	\$	(116,282)	\$ 22,956
Net loss	_			_			_					(52,931)	(52,931)
Other comprehensive												(32,301)	(32,331)
loss								 (9)		2			(7)
Total comprehensive loss	_		_	_		_	_	(9)		2		(52,931)	(52,938)
Issuance of additional preferred shares following Anti-dilution Protection	_		_	3,134,546		8	(8)	_		_		_	_
Exercise of options	9,692		_	· · · -		_	2	_		_		_	2
Conversion of preferred shares	17,289,289		46	(17,289,289)		(46)	_	_		_		_	_
Issuance of ordinary shares in initial public offering, net of issuance expenses in	6 6 40 260		10				47 222						47 241
an amount of \$5,947 Exercise of warrants	6,648,368 293,489		18 1	_			47,223 3,850						47,241 3,851
Share-based compensation							3,575						3,575
Balance as of December 31, 2018	24,930,736	\$	67		\$		193,953	\$ (43)	\$	(77)	\$	(169,213)	\$ 24,687

# INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands	Three n		Year ended		
	2019	arch 3	2018	De	2018
		naudit			2010
Cash flows from operating activities:					
Nether	<b>A</b> (15.5)	<b>17</b> ) (	ф <i>(</i> 7.001)	Φ.	(50,004)
Net loss	\$ (15,50	)/) :	\$ (7,391)	\$	(52,931)
Adjustments to reconcile net loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation of property, plant and equipment and right-of-use assets	54	12	49		269
Financial income, net	(19	91)	_		(858)
Cost of share-based compensation	1,09	91	844		3,575
Change in employee benefit liabilities, net		L2	(16)		(15)
Interest received		_	(13)		_
Amortization of premium on available-for-sale financial assets	į	50	81		272
Revaluation of financial derivatives	3,90	)6	400		17,600
Revaluation of liability to IIA	56	88	412		2,037
	5,9 <sup>-</sup>	78	1,757		22,880
Changes in asset and liability items:					
Increase in prepaid expenses and other current assets and other assets	40	9	100		942
Decrease in trade payables	(84	14)	(1,538)		(405)
Increase - in accrued expenses and other payables		21	260		2,296
	<b>(</b> Δ <sup>.</sup>	L4)	(1,178)		2,833
Cash received during the period for:			(1,110)		2,000
Interest received	52	21	13		792
Interest paid		28)			
Net cash used in operating activities	(9,4	50)	(6,799)		(26,426)
Cook flows from investing activities					
Cash flows from investing activities:					
Purchase of property and equipment	(3!	50)	(231)		(1,645)
Purchase of of available-for-sale financial assets			_		(10,905)
Proceed from sale of available-for-sale financial assets	13,89	93	4,984		4,949
Proceeds from bank deposits		_	5,000		5,000
Investment in restricted bank deposits		= -			(150)
Net cash provided by (used in) investing activities	13,5	13	9,753		(2,751)

# INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands							
	T	Three mon Marc				ear ended cember 31,	
		2019		2018	2018		
		Unau	dite	d			
Cash flows from financing activities:							
Receipt of grants from the IIA		_		1,652		612	
Proceeds from initial public offering, net		(238)		· —		47,479	
Payment of lease liabilities		(440)		_		· —	
Exercise of options	_					2	
Net cash (used in) provided by financing activities		(678)	_	1,652		48,093	
Exchange differences on balances of cash and cash equivalents	_	62				31	
Increase in cash and cash equivalents		3,477		4,606		18,947	
Cash and cash equivalents at beginning of period		40,272	_	21,325		21,325	
Cash and cash equivalents at end of period	\$	43,749	\$	25,931	\$	40,272	
Supplemental disclosure of non-cash financing activities:							
Significant non-cash transactions:							
IIA liability for grants to be received	\$		\$	130	\$	<u> </u>	
Exercise of warrants liabilities to equity	\$	2,924	\$		\$	3,851	
Purchase of property, plant and equipment on credit	\$	199	\$		\$		
Issuance expenses on credit	\$	_	\$	_	\$	238	

## U.S. dollars in thousands

## NOTE 1:- GENERAL

- Gamida Cell Ltd. (the "Company"), founded in 1998, is a clinical-stage biopharmaceutical company that develops novel curative treatments for orphan indications, including hematologicalmalignancies and rare genetic diseases using stem cells and Natural Killer (NK) cells.
- b. The Company uses its proprietary platform NAM technology to expand in culture, highly functional cells derived from umbilical cord blood or peripheral blood, while enhancing the potential therapeutic efficacy of these cells.

The lead product candidate, omidubicel (formally known as NiCord), is currently developed in a pivotal registration phase III clinical study to treat patients with high-risk hematological malignancies (blood cancers) such as leukemia or lymphoma who are indicated to receive a donor derived (allogeneic) bone marrow transplantation. BMT transplantation with a graft derived from bone marrow or peripheral blood cells of a matched donor is currently the standard of care treatment for many of these patients, but there is a significant unmet need for patients who cannot find a fully matched donor. Omidubicel is designed as a universal bone marrow donor graft which can be available to all patients in need.

Omidubicel was granted a Breakthrough Therapy designation from the FDA and an orphan drug designation in the US and in Europe.

In December 2017, the Company presented at the ASH annual meeting final results from the phase I/II trial evaluating omidubicel. The study met its primary endpoint, demonstrating rapid neutrophil engraftment with manageable side effects.

In addition to hematologic malignancies, the Company pursuing the development of omidubicel for the treatment of bone marrow failure disorders. Omidubicel is currently being evaluated in a Phase 1/2 clinical trial sponsored by the National Institutes of Health in patients with severe aplastic anemia, a rare, life-threatening hematological disorder.

Beyond omidubicel, the Company develops another product candidate, GDA-201 (formally known as NAM-NK), for innate immunotherapy of expanded natural killer, or NK, cells, to be used in combination with standard-of-care therapeutic antibodies. NK cells have potent anti-tumor properties and have the advantage over other oncology cell therapies of not requiring genetic matching, potentially enabling NK cells to serve as a universal donor-based therapy when combined with certain antibodies A phase I/II investigator initiated study to treat patients with B cell lymphoma and multiple myeloma is enrolling patients.

c. The Company is devoting substantially all of its efforts toward research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated deficit as of March 31, 2019 is \$184,720 and negative cash flows from operating activities during the period is \$9,450. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The interim consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern. The Company requires additional financing in order to continue to fund its current operations and pay existing and future liabilities.

## U.S. dollars in thousands

d. Definitions:

In these financial statements:

The Company - Gamida Cell Ltd. and its subsidiary

Subsidiary Gamida Cell Inc. Incorporated in 2000 and intended to focus on sales and marketing

upon product approval.

Related Parties - As defined in IAS 24

Dollar - U.S. dollar

# NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. The accompanying unaudited interim consolidated financial statements for the three months periods ended March 31, 2019 and 2018 have been prepared in accordance with IAS 34 "Interim Financial Reporting" for interim financial information.

The interim consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company's annual consolidated financial statements as of December 31, 2018 and their accompanying disclosures.

The interim consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the full year ending December 31, 2019.

- b. The accounting policies adopted in the preparation of the interim consolidated financial statements are consistent with those followed in the preparation of the company's annual consolidated financial statements for the year ended December 31, 2018, except for the adoption of new standards effective as of January 1, 2019. The Company has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.
- c. IFRS 16 Leases:

The Company applies, for the first time, IFRS 16 Leases. As required by IAS 34, the nature and effect of these changes are disclosed below.

The Company adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The Company elected to use the transition practical expedient allowing the standard to be applied only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application. The Company also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option ('short-term leases'), and lease contracts for which the underlying asset is of low value ('low-value assets').

The Company has a number of lease contracts, mainly leases of an office building and a production plant. Before the adoption of IFRS 16, the Company classified each of its leases (as lessee) at the inception date as an operating lease. The leased property was not capitalized and the lease payments were recognized as rent expense in profit or loss on a straight-line basis over the lease term. Any prepaid rent and accrued rent were recognized under prepaid expenses and other current assets and accrued expenses and other payables, respectively.

## U.S. dollars in thousands

Upon adoption of IFRS 16, the Company applied a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The standard provides specific transition requirements and practical expedients, which has been applied by the Company.

The Company recognized right-of-use assets and lease liabilities for those leases previously classified as operating leases, except for short-term leases and leases of low-value assets. The right-of-use assets for most leases were recognised based on the carrying amount as if the standard had always been applied, apart from the use of incremental borrowing rate at the date of initial application. In some leases, the right-of-use assets were recognised based on the amount equal to the lease liabilities, adjusted for any related prepaid and accrued lease payments previously recognized. Lease liabilities were recognized based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application.

Based on the foregoing, as at January 1, 2019:

- Right-of-use assets of \$7,106 were recognized and presented separately in the statement of financial position.
- Additional lease liabilities of \$7,032 were recognized and presented separately in the statement of financial position.
- Prepaid expenses and other current assets of \$256 and accrued expenses and other payables of \$182 related to previous operating leases were derecognized.

Set out below, are the carrying amounts of the Company's right-of-use assets and lease liabilities and the movements during the period:

		Right-of-use assets								
	Offices and labs							Lease liabilities		
As of January 1, 2019	\$ 2,10	4	\$ 291	\$	4,711	\$ 7,106	\$	7,032		
Depreciation expenses	(29	2)	(32)		(140)	(464)		_		
Interest expenses	-	_	_		_	_		237		
Re-measurement	-	_	_		26	26		26		
Payments		_			<u> </u>			(468)		
As of March 31, 2019	\$ 1,81	2	\$ 259	\$	4,597	\$ 6,668	\$	6,827		

The lease liabilities as of January 1, 2019 reconciliation to the operating lease commitments as of December 31, 2018 are as follows:

Operating lease commitments as of December 31, 2018	\$ 7,441
Weighted average incremental borrowing rate as of January 1, 2019 (%)	1.42
Discounted operating lease commitments of January 1, 2019	7,032
Lease liabilities as of January 1, 2019	\$ 7 032

Set out below are the new accounting policies of the Company upon adoption of IFRS 16, which have been applied from the date of initial application:

## a. Right-of-use assets

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities

## U.S. dollars in thousands

recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of- use assets are subject to impairment.

#### b. Lease liabilities

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including insubstance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the Company exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period in which the event or condition that triggers the payment occurs.

## **NOTE 3:- SHARE-BASED PAYMENT**

The total compensation cost related to all of the Company's equity-based awards, recognized during the presented periods was comprised as follows:

	 Three months ended March 31,				Year ended December 31,	
	 2019 2018			2018		
	 Unaud	lited				
Research and development	\$ 229	\$	482	\$	705	
General and administrative	 862		362		2,870	
	\$ 1,091	\$	844	\$	3,575	

The Company estimates the fair value of stock options granted using the Binominal option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term.

Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected term of the options granted is derived from output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan for the following periods:

Based on the above inputs, the fair value of the options was determined at \$10.50 - \$11.01 at the grant dates during 2019.

		Three months ended March 31,		
	2019	2019 2018		
	Unau	Unaudited		
Dividend yield (%)	0	0	0	
Expected volatility of the share prices (%)	76%-80%	88%-94%	93%-95%	
Risk-free interest rate (%)	2.51-2.70	2.17-2.89	2.63-2.88	

## U.S. dollars in thousands

Movement during the periods:

		Three mon Marcl			Year ended December 31,		
	2019	9	2018	3	2018		
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price USD	Number of options	Weighted average exercise price	
Outstanding at beginning of period	3,197,616	3.07	2,467,023	2.28	2,467,023	2.28	
Granted during the period	544,800	10.93	_	_	751,977	5.60	
Expired during the period	_	_	_	_	(2,000)	6.00	
Exercised during the period		_	_	_	(9,692)	0.25	
Forfeited during the period			(9,692)	0.25	(9,692)	0.25	
Share options outstanding at end of period	3,742,416	3.63	2,457,331	2.27	3,197,616	3.07	
Share options exercisable at end of period	1,755,342	1.37	1,428,275	0.74	1,705,256	1.21	

As of March 31, 2019, there are \$7,851 of total unrecognized cost related to non-vested share based compensation that are expected to be recognized over a period of up to 4 years.

# NOTE 4:- LIABILITIES PRESENTED AT FAIR VALUE

a. Warrants to purchase Company's shares:

The Company measured the fair value of the warrants by using Option Pricing Method utilized in a Black-Scholes simulation model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected time until liquidation. Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected time until liquidation is the period in which liquidation event will occurred subject to the Company's expectations. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

	I hree mor Marc	ths ended h 31,	December 31,	
	2019	2018	2018	
	Unau	dited	Audited	
Risk-free interest rate	2.21%	2.3%	2.52%	
Expected volatility	82%	90%	80%	
Expected life (in years)	3.25	2.25-3	3.5	
Expected dividend yield	0	0	0	

# U.S. dollars in thousands

b. Changes in the fair value of warrants classified as Level 3 in the fair value hierarchy:

	_	Fair value of financial derivatives
Balance at December 31, 2018	\$	24,049
Exercise of warrants		(2,924)
Revaluation of financial derivatives		3,906
Balance at March 31, 2019	\$	25,031

# 4,040,000 Ordinary Shares



# Gamida Cell Ltd.

PRELIMINARY PROSPECTUS

# **RBC Capital Markets**

**JMP Securities** 

Oppenheimer & Co.

, 2019

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

# Item 6: Indemnification of Directors, Officers and Employees

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. A company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of the duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. An Israeli company may not exculpate a director from liability arising out of a breach of the duty of care with respect to a dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738—1968, or the Securities Law, a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- a monetary liability incurred by or imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such undertaking must be limited to certain events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the foreseen events and described above amount or criteria;
- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder as (1) a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; or (2) in connection with a monetary sanction; a monetary liability imposed on him or her in favor of an injured party at an Administrative Procedure (as defined below) pursuant to Section 52(54)(a)(1)(a) of the Securities Law;
- expenses incurred by an office holder or certain compensation payments made to an injured party that were
  instituted against an office holder in connection with an Administrative Procedure under the Securities Law,
  including reasonable litigation expenses and reasonable attorneys' fees; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in
  proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with
  criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that
  does not require proof of criminal intent.

"Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a breach of duty of loyalty to the company, provided that the office holder acted in good faith and had a
  reasonable basis to believe that the act would not harm the company;

- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure instituted against him or her, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the
  company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the
  act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See "Management — Board Practices — Fiduciary duties and approval of specified related party transactions under Israeli law."

Our amended and restated articles of association permit us to, exculpate, indemnify and insure our office holders as permitted under the Companies Law. Our office holders are currently covered by a directors and officers' liability insurance policy. As of the date of this registration statement, no claims for directors' and officers' liability insurance have been filed under this policy, we are not aware of any pending or threatened litigation or proceeding involving any of our directors or officers in which indemnification is sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

We have entered into agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, including, with respect to liabilities resulting from this offering, to the extent that these liabilities are not covered by insurance. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our activities. The maximum amount set forth in such agreements is (1) with respect to indemnification in connection with a public offering of our securities, the gross proceeds raised by us and/or any selling shareholder in such public offering, and (2) with respect to all permitted indemnification, the greater of (a) an amount equal to 25% of our shareholders' equity on a consolidated basis, based on our most recent financial statements made publicly available before the date on which the indemnity payment is made and (b) \$40 million. Each office holder who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any. In the opinion of the SEC, however, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

## Item 7. Recent Sales of Unregistered Securities.

Set forth below are the sales of all securities of the registrant sold by the registrant within the past three years (i.e., since January 1, 2016, up to the date of this registration statement) which were not registered under the Securities Act.

• In June 2017, we issued a total of 4,274,363 Preferred F-1 Shares and warrants to purchase up to 2,564,619 Preferred F-2 Shares for an aggregate purchase price of \$40,350,000.

We granted share options to employees, directors and consultants under our 2014 Israeli Share Option Plan
and 2017 Share Incentive Plan, covering an aggregate of 1,129,008 Ordinary C Shares and 1,737,098
Ordinary Shares, with exercise prices ranging from \$0.25 to \$4.90 per share. As of the date of this registration
statement, 9,692 of these options have been forfeited and cancelled without being exercised.

We claimed exemption from registration under the Securities Act for these issuances described above under Section 4(a)(2) or Regulation S promulgated under the Securities Act, as well as, with respect to grants of share options, under Rule 701 of the Securities Act as transactions pursuant to written compensatory plans or pursuant to a written contract relating to compensation.

No underwriters were employed in connection with the securities issuances set forth in this Item 7.

## Item 8. Exhibits and Financial Statement Schedules.

- (a) Exhibits. See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- **(b) Financial Statement Schedules.** Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## Item 9. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective; and
- (2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

# **Exhibit Index**

Exhibit			Incorporated	by Reference		Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
<u>1.1</u>	Form of Underwriting Agreement					X
3.1	Amended and Restated Articles of Association of the Registrant, as currently in effect	6-K	001-38716	3.1	11/1/2018	
3.3	Memorandum of Association of the Registrant (unofficial English translation from Hebrew original), as amended on September 14, 2006	F-1	333-227601	3.4	9/28/2018	
<u>4.1</u>	Warrant to purchase Ordinary Shares	F-1	333-227601	4.1	9/28/2018	
<u>5.1</u>	Opinion of Meitar Liquornik Geva Leshem Tal, Israeli counsel to the Registrant, as to the validity of the ordinary shares					X
<u>10.1</u>	Form of Indemnification Agreement	F-1/A	333-227601	10.1	10/17/2018	
<u>10.2</u>	Employee Share and Option Plan (1998)	F-1	333-227601	10.2	9/28/2018	
10.3	Stock Option Plan (1999)	F-1	333-227601	10.3	9/28/2018	
10.4	2003 Israeli Share Option Plan	F-1	333-227601	10.4	9/28/2018	
10.5	2014 Israeli Share Option Plan	F-1	333-227601	10.5	9/28/2018	
<u>10.6</u>	2017 Share Incentive Plan, as amended					×
10.7	Amended and Restated Investors' Rights Agreement, dated July 3, 2017, among the Registrant and the shareholders named therein	F-1	333-227601	10.7	9/28/2018	
10.8†	Manufacturing Services Agreement, dated February 8, 2016, between the Registrant and Lonza Walkersville, Inc.	F-1	333-227601	10.8	9/28/2018	
10.9	Amendment No. 2 to Manufacturing Services Agreement, dated May 23, 2016, between the Registrant and Lonza Walkersville, Inc.	F-1	333-227601	10.9	9/28/2018	
10.10	Lease Agreement, dated December 13, 2017, by and between the Registrant and Y.D.B. Investments Ltd. (unofficial English translation from Hebrew original)	F-1	333-227601	10.10	9/28/2018	

Exhibit			Incorporated I	y Reference	1	Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
10.11	Lease Agreement, dated March 14, 2000, as amended on June 5, 2000 and May 30, 2010, by and between the Registrant and Traub Group Investments Ltd. (formerly P.P.D. Diamonds Ltd.) (unofficial English translation from Hebrew original)	F-1	333-227601	10.11	9/28/2018	
10.12	Form of Letter Agreement re: Information Rights	F-1/A	333-227601	10.12	10/17/2018	
10.13	Gamida Cell Ltd. Compensation Policy, as amended					Х
10.14†	Manufacturing Services Agreement, dated June 10, 2019, by and between the Registrant and Lonza Netherlands B.V.					X
<u>21.1</u>	Subsidiaries of the Registrant	F-1	333-227601	21.1	9/28/2018	
<u>23.1</u>	Consent of KOST, FORER, GABBAY & KASIERER, a Member of Ernst & Young Global, Independent Registered Accounting Firm					Х
23.2	Consent of Meitar Liquornik Geva Leshem Tal (included in Exhibit 5.1)					X
<u>24.1</u>	Power of Attorney (included in signature pages of Registration Statement)					х

Portions of this exhibit (indicated by bracketed asterisks) have been omitted because the Registrant has determined they are not material and would likely cause competitive harm to the Registrant if publicly disclosed.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Jerusalem, Israel on this 24<sup>th</sup> day of June, 2019.

#### **GAMIDA CELL LTD.**

By: /s/ Julian Adams
Julian Adams, Ph.D.
Director and Chief Executive Officer

#### **POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Julian Adams and Shai Lankry, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Julian Adams Julian Adams, Ph.D.	Director and Chief Executive Officer ( <i>Principal Executive Officer</i> )	June 24, 2019
/s/ Shai Lankry Shai Lankry	Chief Financial Officer ( <i>Principal Financial Officer and Principal Accounting Officer</i> )	June 24, 2019
/s/ Robert I. Blum Robert I. Blum	Chairman	June 24, 2019
/s/ Ofer Gonen Ofer Gonen	Director	June 24, 2019
/s/ Kenneth I. Moch Kenneth I. Moch	Director	June 24, 2019
/s/ Michael S. Perry Michael S. Perry	Director	June 24, 2019
/s/ Nurit Benjamini Nurit Benjamini	Director	June 24, 2019

## TABLE OF CONTENTS

SIGNATURE	TITLE	DATE
/s/ Shawn C. Tomasello Shawn C. Tomasello	_ Director	June 24, 2019
/s/ Stephen T. Wills Stephen T. Wills	_ Director	June 24, 2019
Gamida Cell Inc.		
By: /s/ Julian Adams Julian Adams, Ph.D. Director and Chief Executive Officer	AUTHORIZED U.S. REPRESENTATIVE	June 24, 2019
	II 7	

#### GAMIDA CELL LTD.

#### • SHARES

### ORDINARY SHARES, NOMINAL VALUE NIS 0.01 PER SHARE

### UNDERWRITING AGREEMENT

June [●], 2019

RBC Capital Markets, LLC JMP Securities LLC

As Representatives of the Several Underwriters

c/o RBC Capital Markets, LLC 200 Vesey Street New York, New York 10281

and

c/o JMP Securities LLC 450 Park Avenue New York, New York 10022

Ladies and Gentlemen:

Gamida Cell Ltd., a limited liability company organized under the laws of the State of Israel (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell an aggregate of [●] shares (the "Firm Shares") of the Company's ordinary shares with a nominal value of New Israeli Shekel ("NIS") 0.01 per share (the "Ordinary Shares"), to the several underwriters (collectively, the "Underwriters") named in Schedule I to this agreement (this "Agreement"), for whom RBC Capital Markets, LLC and JMP Securities LLC are acting as representatives (the "Representatives"). The Company has also agreed to grant to the Underwriters an option (the "Option") to purchase up to an additional [●] ordinary shares of the Company (the "Option Shares") on the terms set forth in Section 1(b) hereof. The Firm Shares and the Option Shares are hereinafter collectively referred to as the "Shares."

The Company confirms as follows its agreement with the Representatives and the several other Underwriters:

### 1. Agreement to Sell and Purchase.

(a) *Purchase of Firm Shares*. On the basis of the representations, warranties and agreements of the Company contained herein and subject to all the terms and conditions of this Agreement, the Company agrees to sell to the several Underwriters and each of the several Underwriters, severally and not jointly, agrees to purchase from the Company, at a purchase price per share of \$[●] (the "<u>Purchase Price</u>"), the number of Firm Shares set forth opposite the name of such Underwriter in <u>Schedule I</u>, plus such additional number of Firm Shares which such Underwriter may become obligated to purchase pursuant to Section 88 hereof.

(b) *Purchase of Option Shares*. Subject to all the terms and conditions of this Agreement, the Company grants the Option to the several Underwriters to purchase, severally and not jointly, all or less than all of the Option Shares at the Purchase Price less an amount per share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable on the Option Shares. The Option may be exercised in whole or in part at any time on or before the 30th day after the date of this Agreement, upon written notice (the "Option Shares Notice") by the Representatives to the Company no later than 12:00 noon, New York City time, at least two and no more than five business days before the date specified for closing in the Option Shares Notice (the "Option Closing Date") setting forth the aggregate number of Option Shares to be purchased and the time and date for such purchase. On any Option Closing Date, the Company shall issue and sell to the Underwriters the number of Option Shares set forth in the Option Shares Notice and each Underwriter shall purchase from the Company such percentage of the Option Shares as is equal to the percentage of Firm Shares that such Underwriter is purchasing, as adjusted by the Representatives in such manner as they deem advisable to avoid fractional shares.

# 2. <u>Delivery and Payment</u>.

- (a) Closing. Delivery of the Firm Shares shall be made to the Representatives through the facilities of the Depository Trust Company ("DTC") for the respective accounts of the Underwriters against payment of the Purchase Price by wire transfer of immediately available funds to the Company. Such payment shall be made at 10:00 a.m., New York City time, on the second business day (the third business day, should the offering be priced after 4:00 p.m., Eastern Time) after the date on which the first bona fide offering of the Firm Shares to the public is made by the Underwriters or at such time on such other date, not later than ten business days after such date, as may be agreed upon by the Company and the Representatives (such date is hereinafter referred to as the "Closing Date").
- (b) *Option Closing*. To the extent the Option is exercised, delivery of the Option Shares against payment by the Representatives (in the manner and at the location specified above) shall take place at the time and date (which may be the Closing Date, but not earlier than the Closing Date) specified in the Option Shares Notice.
- (c) *Electronic Transfer.* Electronic transfer of Shares shall be made at the time of purchase in such names and in such denominations as the Representatives shall specify.
- (d) *Stamp Tax*. The Company shall pay, bear and hold the Underwriters harmless against any stamp duty, stamp duty reserve tax, and any other issue, transfer, registration, documentary, value added tax or sales tax or duty in any jurisdiction ("<u>Stamp Tax</u>") which is payable in connection with: (i) the execution, delivery, consummation or enforcement of this Agreement; (ii) the grant, exercise or lapsing of the Option; (iii) the creation, allotment, or issue of any Shares; (iv) the initial entry of the Shares into the facilities of DTC; (v) the acquisition of the Shares by, or crediting or delivery of the Shares to or for the account of, the Underwriters (or any purchasers or subscribers procured by the Underwriters); or (vi) the sale and/or delivery of any Shares by any Underwriter to any initial purchaser in the manner contemplated in this Agreement.

- 3. <u>Representations and Warranties of the Company</u>. The Company represents and warrants to, and covenants with, each Underwriter as follows:
- Compliance with Registration Requirements. A registration statement on Form F-1 (Registration No. 333-(a) [•]) relating to the Shares, including a preliminary prospectus and such amendments to such registration statement as may have been required to the date of this Agreement, has been prepared by the Company under the provisions of the Securities Act of 1933, as amended (the "Act"), and the rules and regulations (collectively referred to as the "Rules and Regulations") of the Securities and Exchange Commission (the "Commission") thereunder, and has been filed with the Commission. Copies of such registration statement and of each amendment thereto, if any, including the related preliminary prospectuses, heretofore filed by the Company with the Commission have been delivered to the Underwriters. The term "Registration Statement" means the registration statement as amended at the time it becomes or became effective, including financial statements and all exhibits and any information deemed to be included therein by Rule 430A, Rule 430B or Rule 430C of the Rules and Regulations, as applicable. If the Company files a registration statement to register a portion of the Shares and relies on Rule 462(b) of the Rules and Regulations for such registration statement to become effective upon filing with the Commission (the "Rule 462 Registration Statement"), then any reference to the "Registration Statement" shall be deemed to include the Rule 462 Registration Statement, as amended from time to time. The term "preliminary prospectus" as used herein means a preliminary prospectus as contemplated by Rule 430, Rule 430A or Rule 430B of the Rules and Regulations included at any time as part of, or deemed to be part of or included in, the registration statement. The term "Prospectus" means the final prospectus in connection with this offering as first filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations or, if no such filing is required, the form of final prospectus included in the Registration Statement at the effective date. The term "Testing-the-Waters Communication" means any oral or written communication with potential investors in reliance on Section 5(d) of the Act. The term "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 of the Rules and Regulations.
- (b) *Effectiveness of Registration*. The Registration Statement, any Rule 462 Registration Statement and any post-effective amendment thereto have been declared effective by the Commission under the Act or have become effective pursuant to Rule 462 of the Rules and Regulations. The Company has responded to all requests, if any, of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462 Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are threatened by the Commission.

- Accuracy of Registration Statement. Each of the Registration Statement, any Rule 462 Registration Statement and any post-effective amendment thereto, at the time it became effective and at all subsequent times, complied and will comply in all material respects with the Act and the Rules and Regulations, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date and at all subsequent times, complied and will comply in all material respects with the Act and the Rules and Regulations, and did not or will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein not misleading, in the light of the circumstances under which they were made. Each preliminary prospectus (including the preliminary prospectus or prospectuses filed as part of the Registration Statement or any amendment thereto) complied when so filed in all material respects with the Rules and Regulations, and each preliminary prospectus and the Prospectus delivered to the Underwriters for use in connection with this offering is identical to the electronically transmitted copies thereof filed with the Commission on EDGAR, except to the extent permitted by Regulation S-T. The foregoing representations and warranties in this Section 3(c) do not apply to any statements or omissions made in reliance on and in conformity with information relating to any Underwriter furnished in writing to the Company by the Representatives specifically for inclusion in the Registration Statement or Prospectus or any amendment or supplement thereto. For all purposes of this Agreement, the only information (the "Underwriters' Information") relating to any Underwriter furnished in writing to the Company by the Representatives specifically for inclusion in the preliminary prospectus, the Registration Statement or the Prospectus is the following information contained under the caption "Underwriting": the amounts of the selling concession set forth in the Prospectus in the first sentence of the fourth paragraph and information regarding stabilization, syndicate covering transactions, penalty bids and passive market making in the first and second sentences of the tenth paragraph, the first sentence of the eleventh paragraph, the first and last sentences of the thirteenth paragraph, and the sixteenth paragraph.
- (d) *Company Not Ineligible Issuer*. (i) At the time of filing the Registration Statement relating to the Shares and (ii) as of the date of the execution and delivery of this Agreement (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an "ineligible issuer" (as defined in Rule 405 of the Rules and Regulations).
- (e) Disclosure at the Time of Sale. As of the Applicable Time (as defined below), neither (i) the Issuer General Use Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time, the most recent preliminary prospectus related to this offering and the information included in Schedule IV hereto, all considered together (collectively, the "General Disclosure Package"), nor (ii) any individual Issuer Limited Use Free Writing Prospectus (as defined below), when considered together with the General Disclosure Package, nor (iii) any Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the General Disclosure Package based upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the Underwriters' Information.

As used in this subsection and elsewhere in this Agreement:

"Applicable Time" means [ $\bullet$ ] p.m. (New York City Time) on [ $\bullet$ ], 2019 or such other time as agreed by the Company and the Representatives.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the Rules and Regulations, relating to the Shares that (i) is required to be filed with the Commission by the Company, (ii) is a "written communication that is a road show" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g); provided, however, that a Written Testing-the-Waters Communication shall be deemed not to be an Issuer Free Writing Prospectus.

"<u>Issuer General Use Free Writing Prospectus</u>" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors, as evidenced by its being specified in <u>Schedule II</u> hereto.

"<u>Issuer Limited Use Free Writing Prospectus</u>" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

- (f) Issuer Free Writing Prospectuses. Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the Prospectus Delivery Period (as defined below), does not include any information that conflicts with the information contained in the Registration Statement. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with the Underwriters' Information. If at any time following the issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement relating to the Shares or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in light of the circumstances prevailing at that subsequent time, not misleading, the Company has promptly notified or will promptly notify the Representatives and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement, or omission. This subsection (f) does not apply to statements in or omissions from any Issuer Free Writing Prospectus in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the Underwriters' Information.
- (g) Distribution of Offering Material by the Company. The Company has not distributed and will not distribute, prior to the later of the Closing Date, any Option Closing Date and the completion of the Underwriters' distribution of the Shares, any offering material in connection with the offering or sale of the Shares, other than any Testing-the-Waters Communication made in compliance with Section 3(vv) hereof, the Registration Statement, the preliminary prospectus, the Permitted Free Writing Prospectuses reviewed and consented to by the Representatives and included in Schedule II hereto, and the Prospectus.

- (h) Due Incorporation; Subsidiaries.
- (i) The Company is, and at the Closing Date will be, a corporation duly organized, validly existing and in good standing under the laws of the State of Israel. The Company has, and at the Closing Date will have, full power and authority to conduct all the activities conducted by it, to own or lease all the assets owned or leased by it and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus. The Company is, and at the Closing Date will be, duly licensed or qualified to do business in and in good standing as a foreign corporation in all jurisdictions in which the nature of the activities conducted by it or the character of the assets owned or leased by it makes such licensing or qualification necessary, except where the failure to be so qualified or in such good standing would not, individually or in the aggregate, (i) have a material adverse effect on the business, properties, assets, management, business prospects, condition (financial or otherwise), results of operations or capitalization of the Company, or (ii) prevent or materially interfere with the consummation of the transactions contemplated hereby or the performance by the Company of its obligations hereunder (any such effect, prevention or interference, a "Material Adverse Effect"). The memorandum and articles of association and other constitutive or organizational documents of the Company comply with the requirements of applicable Israeli law and are in full force and effect.
- (ii) The subsidiary (as used in this Section 3, "subsidiary" has the meaning set forth in Rule 405 of the Rules and Regulations) of the Company has been duly incorporated or organized, is validly existing as a corporation in good standing under the laws of the jurisdiction of its organization, has the corporate power and authority to own its property and to conduct its business as described in the Registration Statement, the General Disclosure Package and Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued share capital or other equity interests of the subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly by the Company, free and clear of all liens, charges, encumbrances, equities, security interests, restrictions on voting or transfer or any other claims. No subsidiary is currently prohibited, directly or indirectly under any agreement or instrument to which it is a party or is subject, from paying any dividends to its shareholders, from repaying the Company or any other subsidiary of the Company any loans or advances to such subsidiary from the Company or such other subsidiary or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary.
- (i) Capitalization. The authorized, issued and outstanding share capital of the Company is as set forth in the Registration Statement, the General Disclosure Package and the Prospectus under the caption "Capitalization." The outstanding Ordinary Shares and any other outstanding share capital of the Company have been, and the Shares will be, duly authorized, validly issued, fully paid and non-assessable and will not be subject to any preemptive, first refusal, or similar right. The description of the Ordinary Shares included in the Registration Statement, the General Disclosure Package and the Prospectus is now, and at the Closing Date will be, complete and accurate in all material respects. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company does not have outstanding, and at the Closing Date and any Option Closing Date will not have outstanding, any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or any contracts or commitments to issue or sell, any securities of the Company or any such warrants, convertible securities or obligations. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, there are no stockholder agreements, voting agreements or other similar agreements with respect to the Company's share capital to which the Company is a party or, to the Company's knowledge, between or among any of the Company's shareholders. Upon the issuance and delivery pursuant to the terms of this Agreement, the Underwriters will acquire good and marketable title to the Shares, free and clear of any lien, charge, claim, encumbrance, pledge, security interest, defect or other restriction or equity of any kind whatsoever.

- Financial Statements. The financial statements of the Company (including the related notes thereto) and schedules included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the financial condition of the Company and its consolidated subsidiary as of the respective dates thereof and their results of operations and cash flows for the respective periods covered thereby, all in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board on a consistent basis throughout the entire period involved. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the financial statements included therein and the books and records of the Company and its subsidiary. The pro forma financial statements, if any, and the other pro forma financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein, have been prepared in accordance with the Commission's rules and guidelines with respect to pro forma financial statements and have been properly computed on the bases described therein. The assumptions used in the preparation of the pro forma financial statements, if any, and other pro forma financial information included in the Registration Statement, the General Disclosure Package and the Prospectus are reasonable and the adjustments used therein are appropriate to give effect to the transactions or circumstances referred to therein. No other financial statements, schedules or reconciliations of "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) of the Company are required by the Act or the Rules and Regulations to be included in the Registration Statement, the General Disclosure Package and the Prospectus.
- (k) *Independent Accountants*. Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global (the "<u>Accountants</u>"), who certified the financial statements and supporting schedules of the Company and its consolidated subsidiary included in the Registration Statement, the General Disclosure Package and the Prospectus, are (i) independent accountants as required by the Act and the Rules and Regulations and by the rules of the Public Company Accounting Oversight Board (United States) (the "<u>PCAOB</u>"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Act, and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

- (l) *No Material Adverse Changes.* Since the respective dates as of which information is given in the Registration Statement and the Prospectus and prior to the Closing Date and any Option Closing Date, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, (i) there has not been a material adverse change, or any development that would be expected to result in a material adverse change, in or affecting the business, properties, assets, management, business prospects, earnings, rights, condition (financial or otherwise), results of operations, capitalization or long-term debt of the Company and its subsidiaries, taken as a whole, arising for any reason whatsoever (a "Material Adverse Change"), (ii) the Company has not incurred, nor will it incur, any material liabilities or obligations, direct or contingent, nor has it entered into, nor will it enter into, any material transactions not in the ordinary course of business, other than pursuant to this Agreement and the transactions referred to herein, (iii) the Company has not and will not have paid, declared, set aside for payment or made any dividends or other distributions of any kind on any class of its share capital and (iv) the Company has not altered its method of accounting.
- (m) *Investment Company*. Each of the Company and its subsidiaries is not, and, after giving effect to the issuance and sale of the Shares and the use of the proceeds therefrom as described in the General Disclosure Package and the Prospectus, will not be, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission promulgated thereunder.
- (n) *Litigation.* Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, there are no actions, suits or proceedings pending, or to the Company's knowledge, threatened against or affecting, the Company or any of its subsidiaries or any of their respective officers in their capacity as such, before or by any foreign, federal or state court, commission, regulatory body, including, but not limited to, the Financial Industry Regulatory Authority, Inc. ("FINRA") and the Nasdaq Stock Market LLC, administrative agency or other governmental body, domestic or foreign, wherein an unfavorable ruling, decision or finding could reasonably be expected to result in a Material Adverse Effect. The Company has not received any written notice of proceedings relating to the revocation or modification of any authorization, approval, order, license, certificate, franchise or permit, where such revocation or modification would reasonably be expected to result in a Material Adverse Effect. There are no pending investigations known to the Company involving the Company by any governmental agency having jurisdiction over the Company or its business or operations that would reasonably be expected to result in a Material Adverse Effect.
- (o) Compliance with Laws and Regulations and Performance of Obligations and Contracts. The Company and its subsidiaries have, and at the Closing Date and any Option Closing Date will have, (i) complied in all material respects with all laws, regulations and orders applicable to it or its business and (ii) performed all obligations required to be performed by it, and is not, and at the Closing Date will not be, in default under any indenture, mortgage, deed of trust, voting trust agreement, loan agreement, bond, debenture, note agreement, lease or other agreement or instrument (individually, a "Contract" and collectively, "Contracts") to which it is a party or by which its property is bound or affected, in any such case which default or event, individually or in the aggregate, would have a Material Adverse Effect. To the knowledge of the Company, no other party under any Contract to which it is a party is in default in any respect thereunder or has given written or oral notice to the Company or any of its officers or directors of such other party's intention to terminate, cancel or refuse to renew any Contract. The Company is not now, and at the Closing Date will not be, in violation of any provision of its certificate of incorporation or by-laws. The disclosures included in the Registration Statement, the General Disclosure Package and the Prospectus concerning the effects of federal, state, local and foreign laws, rules and regulations on the business of the Company as currently conducted and as proposed to be conducted are correct in all material respects.

- (p) No Consent of Governmental Body Needed. No consent, approval, authorization, license, registration, qualification or order of, or any filing or declaration with, any court or arbitrator or governmental or regulatory authority, agency or body is required in connection with the authorization, issuance, transfer, sale or delivery of the Shares by the Company, in connection with the execution, delivery and performance of this Agreement by the Company or in connection with the taking by the Company of any action contemplated hereby, except as have been obtained under the Act and such as may be required under state securities or Blue Sky laws or the by-laws and rules of FINRA and the Nasdaq Stock Market LLC in connection with the purchase and distribution by the Underwriters of the Shares to be sold by the Company except for (a) formal authorization from the Israel Innovation Authority (formerly the Office of the Chief Scientist) of the Israeli Ministry of Economy and Industry, and (b) certain post-closing filings to be filed with the Israeli Registrar of Companies.
- (q) *Agreement Duly Authorized.* The Company has full corporate power and authority to enter into this Agreement. This Agreement has been duly authorized, executed and delivered by the Company.
- (r) *No Conflicts.* The execution and delivery by the Company of this Agreement and the performance of this Agreement, the consummation of the transactions contemplated hereby, and the application of the net proceeds from the offering and sale of the Shares to be sold in the manner set forth in the General Disclosure Package and the Prospectus under "Use of Proceeds" do not and will not (i) violate the memorandum or articles of association of the Company or (ii) result in the creation or imposition of any lien, charge or encumbrance upon any of the assets of the Company or its subsidiaries pursuant to the terms or provisions of, or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or give any other party a right to terminate any of its obligations under, or result in the acceleration of any obligation under any Contract to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries or any of its properties is bound or affected, or violate or conflict with any judgment, ruling, decree, order, law, statute, rule or regulation of any court or other governmental agency or body applicable to the business or properties of the Company or any of its subsidiaries, except, in the case of clause (ii), as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.
- (s) *Title to Real and Personal Property.* The Company and its subsidiaries have good and marketable title to all properties and assets described in the Registration Statement, the General Disclosure Package and the Prospectus as being owned respectively by them, in each case, free and clear of all liens, charges, encumbrances or restrictions, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus or those where the failure to have such title would not have, individually or in the aggregate, a Material Adverse Effect. The Company and its subsidiaries have valid, subsisting and enforceable leases for the properties described in the General Disclosure Package and the Prospectus as leased by them, with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such properties by the Company and its subsidiaries.

- (t) Documents Described in Registration Statement. There is no document or Contract of a character required to be described in the Registration Statement, the General Disclosure Package and the Prospectus or to be filed as an exhibit to the Registration Statement that is not described or filed as required. All such documents and Contracts described in the Registration Statement, General Disclosure Package and the Prospectus or filed as an exhibit to the Registration Statement were duly authorized, executed and delivered by the Company, constitute valid and binding agreements of the Company and are enforceable against the Company in accordance with the terms thereof.
- (u) *No Untrue Statement; Statistical and Market Data.* No statement, representation, warranty or covenant made by the Company in this Agreement or made in any certificate or document required by this Agreement to be delivered to Representatives was or will be, when made, inaccurate, untrue or incorrect. All statistical or market-related data included in the Registration Statement, the General Disclosure Package and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects, and the Company has obtained the written consent to the use of such data from such sources to the extent required.
- (v) *No Price Stabilization or Manipulation.* Neither the Company nor any of its directors, officers or controlling persons has taken, directly or indirectly, any action intended to cause or result in, or which might reasonably be expected to cause or result in, or which has constituted, stabilization or manipulation, under the Act or otherwise, of the price of any security of the Company to facilitate the sale or resale of the Shares.
- (w) *No Registration Rights.* Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, no holder of securities of the Company has rights to register any securities of the Company because of the filing of the Registration Statement, the Prospectus or the offering of the Shares, except for rights that have been duly waived by such holder, have expired or have been fulfilled by registration prior to the date of this Agreement.
- (x) *Stock Exchange Listing.* The Shares have been approved for listing on the Nasdaq Global Market, subject only to official notice of issuance.
- (y) *Labor Matters*. Neither the Company nor any of its subsidiaries is involved in any labor dispute except, where the dispute would not, individually or in the aggregate, have a Material Adverse Effect, nor, to the knowledge of the Company, is any such dispute threatened. The Company is in compliance in all material respects with the labor and employment laws and collective bargaining agreements and extension orders applicable to their employees in the State of Israel, except, where such non-compliance would not, individually or in the aggregate, have a Material Adverse Effect.

- (z) No Unlawful Payments. Neither the Company nor any of its subsidiaries, nor any director or officer of the Company or its subsidiaries, nor, to the knowledge of the Company, any agent, employee or representative of the Company or its subsidiaries, affiliate or other person associated with or acting on behalf of the Company or its subsidiaries, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment of corporate funds or benefit to any foreign or domestic government or regulatory official or employee, including, without limitation, of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offense under any other applicable anti-bribery or anti-corruption laws; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company has instituted, maintained and enforced, and will continue to maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.
- (aa) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of all jurisdictions in which the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental or regulatory agency (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries, nor any director or officer of the Company or its subsidiaries, nor, to the knowledge of the Company, any agent, employee or representative of the Company or its subsidiaries, affiliate or other person associated with or acting on behalf of the Company or its subsidiaries is currently the subject or target of any sanctions administered or enforced by the U.S. government (including, without limitation, the Office of Foreign Assets Control of the U.S. Treasury Department or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority (collectively, "Sanctions"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, Cuba, Iran, North Korea, the Crimean region and Syria (each, a "Sanctioned Country"); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

- (cc) Passive Foreign Investment Company. Subject to the qualifications, limitations, exceptions and assumptions set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company does not expect (i) that it was for the taxable year ended on December 31, 2018, and (ii) to be for the taxable year ending December 31, 2019 or in the immediately foreseeable future, a passive foreign investment company, as defined in Section 1297 of the Internal Revenue Code of 1986, as amended.
- (dd) *Taxes*. The Company and its subsidiaries have filed all federal, state and foreign income and franchise tax returns and have paid all taxes required to be filed or paid by them and, if due and payable, any related or similar assessment, fine or penalty levied against them, except where the failure to file or pay would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 3(j) hereof to the extent required pursuant to IFRS in respect of all material federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been finally determined. The Company and its subsidiaries are not aware of any material claims against them by any taxing authority in relation to the filing of tax returns or the payment of required taxes.
- (ee) *Insurance*. The Company and its subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company believes are adequate for the conduct of their business and the value of their properties and is customary for companies engaged in similar industries, and all such insurance is in full force and effect. The Company has no reason to believe that it and its subsidiaries will not be able to (i) renew their existing insurance coverage as and when such policies expire or (ii) obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct their business as currently conducted or proposed to be conducted and at a cost that would not, individually or in the aggregate, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.
- (ff) Defined Benefit Plans. The Company has not maintained or contributed to a defined benefit plan as defined in Section 3(35) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). No plan maintained or contributed to by the Company that is subject to ERISA (an "ERISA Plan") (or any trust created thereunder) has engaged in a "prohibited transaction" within the meaning of Section 406 of ERISA or Section 4975 of the Internal Revenue Code of 1986, as amended (the "Code") that could subject the Company to any material tax penalty on prohibited transactions and that has not adequately been corrected. Each ERISA Plan is in compliance in all material respects with all reporting, disclosure and other requirements of the Code and ERISA as they relate to such ERISA Plan, except for any noncompliance which would not result in the imposition of a material tax or monetary penalty. With respect to each ERISA Plan that is intended to be "qualified" within the meaning of Section 401(a) of the Code, either (i) a determination letter has been issued by the Internal Revenue Service stating that such ERISA Plan and the attendant trust are qualified thereunder, or (ii) the remedial amendment period under Section 401(b) of the Code with respect to the establishment of such ERISA Plan has not ended and a determination letter application will be filed with respect to such ERISA Plan prior to the end of such remedial amendment period. The Company has never completely or partially withdrawn from a "multiemployer plan," as defined in Section 3(37) of ERISA.

Title to Intellectual Property. Except as set forth in the Registration Statement, the General Disclosure (gg)Package and the Prospectus, the Company and its subsidiaries own, have valid and enforceable licenses for or otherwise have adequate rights to use all technology (including but not limited to inventions and proprietary or confidential information, systems or procedures), designs, processes, licenses, patents, trademarks, service marks, trade secrets, trade names, know how, copyrights and other works of authorship, computer programs, technical data and information and all similar intellectual property or proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing, as applicable) (collectively, "Intellectual Property") that are or would reasonably be expected to be material to their business as currently conducted or as proposed to be conducted or to the development, manufacture, operation and sale of any products and services sold or proposed to be sold by any of the Company or its subsidiaries, except where the failure to own, license or otherwise have rights to such Intellectual Property would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Intellectual Property of the Company and its subsidiaries has not been adjudged by a court or other administrative body of competent jurisdiction to be invalid or unenforceable in whole or in part, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus. (i) there are no third parties who have established or, to the knowledge of the Company, will be able to establish, rights to any Intellectual Property owned by, or licensed to, the Company or its subsidiaries, except for, and to the extent of, the ownership rights of the owners of the Intellectual Property which the Registration Statement, the General Disclosure Package and the Prospectus disclose is licensed to the Company; (ii) to the knowledge of the Company, there is no infringement, misappropriation or other violation by third parties of any Intellectual Property owned by, or licensed to, the Company or its subsidiaries; (iii) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the Company's or any of its subsidiaries' rights in or to any Intellectual Property and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Intellectual Property owned by, or licensed to, the Company and its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (v) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that (nor has the Company or any of its subsidiaries received any claim from a third party that) the Company or its subsidiaries infringe, misappropriate or otherwise violate, or would, upon the commercialization of any product or service described in the Registration Statement, the General Disclosure Package or the Prospectus as under development, infringe, misappropriate or otherwise violate, any Intellectual Property rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (vi) the Company and its subsidiaries have complied with and there has been no material breach or default under the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company and its subsidiaries, and all such agreements are in full force and effect; and (vii) the product candidates described in the Registration Statement, the General Disclosure Package or the Prospectus as under development by the Company and its subsidiaries fall within the scope of the claims of one or more patents owned by, or exclusively licensed to, the Company and its subsidiaries except, in each case of (ii) through (vii), as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company and its subsidiaries are not obligated or under any liability whatsoever to make any material payment by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any Intellectual Property, with respect to the use thereof or in connection with the conduct of their respective businesses or otherwise.

- (hh) Protection of Intellectual Property. The Company and its subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all their Intellectual Property in all material respects, including, but not limited to complying with all duty of disclosure requirements before the U.S. Patent and Trademark Office and any other non-U.S. Patent Offices as appropriate.
- (ii) Related Party Transactions. There are no business relationships or related party transactions involving the Company or any other person required to be described in the General Disclosure Package and the Prospectus that have not been described. Without limiting the generality of the immediately preceding sentence, no relationship, direct or indirect, exists between or among the Company on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company on the other hand, that is required to be described in the General Disclosure Package and the Prospectus and that is not so described. Since inception, the Company has not, directly or indirectly, extended or maintained credit, arranged to extend credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer of the Company, or to or for any family member or affiliate of any director or executive officer of the Company in violation of applicable laws, including Section 13(k) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").
- *Environmental Matters.* (a) (i) Each of the Company and its subsidiaries is and has been in compliance with, and is not subject to any pending, or to the knowledge of the Company, threatened costs or liability under, any and all federal, state, local and non-U.S. statutes, laws, rules, regulations, ordinances, codes, other requirements or rules of law (including common law) and judicial or administrative decisions or orders, relating to pollution, the generation, use, handling, transportation, treatment, storage, discharge, disposal or release of hazardous substances, the protection or restoration of the environment, human health and safety, noise or the protection of natural resources, including wildlife, migratory birds, eagles or endangered or threatened species or habitats (collectively, "Environmental Laws") and to the knowledge of the Company, there are no facts or circumstances that would reasonably be expected to result in such non-compliance, cost or liability, (ii) neither the Company nor any of its subsidiaries owns, occupies, operates, leases or uses any real property contaminated with Hazardous Substances, (iii) neither the Company nor any of its subsidiaries is conducting or funding any investigation, remediation, remedial action or monitoring of actual or suspected Hazardous Substances in the environment, (iv) neither the Company nor any of its subsidiaries is liable or allegedly liable for any release or threatened release of Hazardous Substances, including at any off-site treatment, storage or disposal site, (v) neither the Company nor any of its subsidiaries, nor to the knowledge of the Company, any principal supplier, manufacturer or contractor of the Company or any of its subsidiaries, is subject to any claim, action, suit, order, demand or notice by any governmental agency or governmental body or person relating to Environmental Laws or Hazardous Substances, (vi) the Company and its subsidiaries have received and are in compliance with all, and have no liability under any, permits, licenses, authorizations, identification numbers or other approvals required under applicable Environmental Laws to conduct their respective businesses, and (vii) to the knowledge of the Company, there are no requirements proposed for adoption or implementation under any Environmental Law, except in each case covered by clauses (i) – (vii) such as would not individually or in the aggregate reasonably be expected to result in a Material Adverse Effect; (b) there are no proceedings that are pending, or known to be contemplated, against the Company or any of its subsidiaries pursuant to any Environmental Laws by a governmental authority, other than such proceedings for which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed; and (c) there are no costs or expenditures (including capital expenditures) under or pursuant to Environmental Laws that would reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries. For purposes of this subsection, "Hazardous Substances" means (A) petroleum and petroleum products, by-products or breakdown products, radioactive materials, asbestos-containing materials, polychlorinated biphenyls and mold, and (B) any other chemical, material or substance defined as toxic or hazardous or as a pollutant, contaminant or waste or words of similar import, or regulated or that can form the basis for liability, under Environmental Laws.

### (kk) Controls and Procedures.

- (i) Disclosure Controls and Procedures. The Company has established and maintains disclosure controls and procedures (as such term is defined in Rules 13a-15 and 15d-15 under the Exchange Act) that (A) are designed to ensure that material information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and its principal financial officer by others within those entities; (B) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures, commencing as of the end of the period covered by the Company's most recent annual or quarterly report filed with the Commission; and (C) are effective in all material respects to perform the functions for which they were established.
- (ii) Internal Control Over Financial Reporting and Internal Accounting Controls. The Company maintains (i) effective "internal control over financial reporting" as defined in, and in compliance with, Rules 13a-15 and 15d-15 under the Exchange Act, and (ii) a system of internal accounting controls sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS and to maintain asset accountability; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (E) interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and is prepared in accordance with the Commission's Rules and Regulations.

- (iii) *eXtensible Business Reporting Language*. The interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- (iv) *No Material Weakness in Internal Controls.* Since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness (as defined in Rule 1-02 of Regulation S-X of the Commission) in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of (x) any significant deficiency in the design or operation of its internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in its internal controls, except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year; or (y) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls.
- (ll) Off-Balance Sheet Transactions. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, there are no off-balance sheet transactions (including, without limitation, transactions related to, and the existence of, "variable interest entities" within the meaning of Financial Accounting Standards Board Accounting Standards Codification Topic 810), arrangements, obligations (including contingent obligations), or any other relationships with unconsolidated entities or other persons, that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses.
- (mm) Audit Committee. The Company's Board of Directors has validly appointed an audit committee whose composition satisfies, the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act. Neither the Board of Directors nor the audit committee has been informed, nor is any director of the Company aware, of (i) any significant deficiency in the design or operation of the Company's internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weakness in the Company's internal controls; or (ii) any fraud, whether or not material, that involves management or other employees of the Company who have a significant role in the Company's internal controls.

- (nn) *Sarbanes-Oxley.* The Company is, and after giving effect to the offering and sale of the Shares will be, in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Commission promulgated thereunder that are applicable to the Company as an "emerging growth company" as defined in Section 2(a)(19) of the Act (an "Emerging Growth Company").
- (oo) Accurate Disclosure. The statements included in the Registration Statement, the General Disclosure Package and the Prospectus under the captions "Taxation," "Description of Share Capital," "Shares Eligible for Future Sale," and "Underwriting," and the statements in the Registration Statement under Items 14 and 15 thereof, insofar as such statements contain descriptions of the terms of statutes, rules, regulations or legal or governmental proceedings, or contracts or other documents, are fair and accurate in all material respects.
- Clinical Trials. The pre-clinical studies and clinical trials conducted by or, to the knowledge of the (pp) Company and its subsidiaries, on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries have participated, that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication were and, if still pending, are being conducted in accordance with protocols filed with the appropriate regulatory authorities for each such study or trial, as the case may be, and with standard medical and scientific research standards and procedures, all applicable statutes, all applicable rules and regulations of the United States Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), the Israel Ministry of Health (the "IMH") and other comparable regulatory agencies to which they are subject and Good Clinical Practices and Good Laboratory Practices, except to the extent where failure to conduct in such manner would not have a Material Adverse Effect. Each description of the results of such studies and trials contained in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication is accurate and complete in all material respects and fairly presents the data derived from such studies and trials, and the Company or its subsidiaries have no knowledge of any other studies or trials the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters The Company and its subsidiaries have not received any written notices, correspondence or other communications from the FDA, the EMA, the IMH or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency (collectively, the "Regulatory Agencies") requiring or, to the Company's knowledge, threatening the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication. The Company and its subsidiaries have operated at all times and currently are in compliance in all material respects with all applicable statutes, rules, regulations and policies of the Regulatory Agencies.
- (qq) Regulatory Filings. The Company and its subsidiaries have not failed to file with the Regulatory Agencies any required material filing, declaration, listing, registration, report or submission with respect to any products or product candidates that are described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication or any other filing required by any other applicable Regulatory Agency or governmental authority; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable laws when filed; all such filings, declarations, listings, registrations, reports or submissions were timely, complete, accurate and not misleading on the date filed in all material respects (or were corrected or supplemented by subsequent submission); and no deficiencies regarding compliance with applicable law have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions.

- Licenses and Permits. Except as would not, individually or in the aggregate, have a Material Adverse Effect, (i) the Company and its subsidiaries hold, and are operating in compliance in all material respects with, such permits, licenses, franchises, registrations, exemptions, approvals, authorizations and clearances of any other governmental authorities (including, without limitation, the FDA, the EMA and the IMH) required for the conduct of their business as currently conducted (collectively, the "Permits"), and all such Permits are in full force and effect; and (ii) the Company and its subsidiaries have fulfilled and performed all of their obligations with respect to the Permits, and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the holder of any Permit. All applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for any and all requests for a Permit from the FDA, the EMA, the IMH or other governmental authority relating to the Company or a subsidiary, its business and its products, when submitted to the FDA, the EMA, the IMH or other governmental authority by or on behalf of the Company or a subsidiary, were true, complete and correct in all material respects. Any necessary or required updates, changes, corrections or modification to such applications, notifications, submissions, information, claims, reports and statistics and other data have been submitted to the FDA, the EMA, the IMH or other governmental authority, except as would not, individually or in the aggregate, have a Material Adverse Effect. The Company and its subsidiaries have not received any notification, correspondence or any other written or oral communication, including notification of any pending or, to the Company's knowledge, threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority including, without limitation, the FDA, the EMA, the IMH or the United States Drug Enforcement Administration ("DEA"), of potential or actual material non-compliance by, or material liability of, the Company or a subsidiary under any Permits. To the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to any liability of the Company or a subsidiary under any Permits, except as would not, individually or in the aggregate, have a Material Adverse Effect.
- Compliance with Certain Regulatory Matters. The Company, its subsidiaries, and their respective directors (ss) and officers and, to the Company's knowledge, their respective employees and agents have operated and currently are in compliance in all material respects with applicable statutes and implementing regulations administered or enforced by the FDA, EMA, IMH, DEA or any other federal, state, local, or foreign governmental authority, including, without limitation, the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the federal False Statements Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. §1320a-7a), all criminal laws relating to health care fraud and abuse, including, but not limited, to 18 U.S.C. §§ 286 and 287, the exclusion law (42 U.S.C. § 1320a-7), the statutes, regulations and directives of Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and all other government funded or sponsored healthcare programs, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §17921 et seq.), and all other regulations promulgated pursuant to such laws; and any other similar local, state, federal or foreign law or regulation. Neither the Company nor its subsidiaries are a party to, and do not have any ongoing reporting obligations pursuant to, any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental authority. Neither the Company, its subsidiaries nor, to the knowledge of the Company, any of their respective directors, officers, employees or agents has been debarred, excluded or suspended from participation in or receiving payment from any federal, state or local government health care program or is subject to an audit, investigation, proceeding or other similar action by any governmental authority that could reasonably be expected to result in debarment, suspension or exclusion.

- (tt) Absence of Certain Regulatory Actions. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, or as would not, individually or in the aggregate, have a Material Adverse Effect, the Company has not had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for Company products or product candidates) subject to a governmental authority (including, without limitation, the FDA, the EMA or the IMH) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company products, processes or operations, or similar correspondence or notice from the FDA, EMA, IMH or other governmental authority alleging or asserting material noncompliance with any applicable laws. To the Company's knowledge, none of the FDA, the EMA or IMH nor any other governmental authority have threatened such action. Neither the Company nor its subsidiaries have received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court, arbitrator, Regulatory Agency or other governmental authority or third party alleging that any product operation or activity is in violation of any health care laws, nor to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened, except as would not, individually or in the aggregate, have a Material Adverse Effect.
- (uu) *Emerging Growth Company Status*. From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an Emerging Growth Company.
- (vv) Testing-the-Waters Communications. The Company (i) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. All Testing-the-Waters Communications have been conducted in compliance with all applicable law. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed or approved for distribution any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. Each Written Testing-the-Waters Communication listed on Schedule III hereto did not, as of the Applicable Time, and at all times through the completion of the public offer and sale of the Shares will not, include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the General Disclosure Package or the Prospectus.

- (ww) *Confidential Submission of Registration Statement.* The Company has filed publicly on EDGAR at least 48 hours prior to the date hereof any confidentially submitted registration statement relating to the offer and sale of the Shares.
- (xx) *No Rating*. Neither the Company nor any of its subsidiaries has debt securities or preferred stock that is rated by any "nationally recognized statistical rating organization" (as such term is defined in Section 3(a)(62) of the Exchange Act).
- (yy) *No Broker's Fees.* Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any Underwriter for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.
- (zz) *Insolvency*. No event of insolvency has occurred in relation to the Company or its subsidiaries, nor is there, nor will there be at the Closing Date, any act which has occurred or, to the best of the Company's knowledge, is anticipated to occur which is likely to result in an event of insolvency in relation to the Company or its subsidiaries.
- Cybersecurity. (i)(x) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there has been no security breach or other compromise of or relating to any of the Company's information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, "IT Systems and Data") and (y) the Company has not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems and Data, except as would not, in the case of this clause (i), individually or in the aggregate, have a Material Adverse Effect; (ii) the Company is presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, have a Material Adverse Effect; and (iii) the Company and its subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures and safeguards to maintain and protect their confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data) used in connection with their businesses and the Company has implemented backup and disaster recovery technology consistent with industry standards and practices.

- (bbb) *Foreign Private Issuer*. The Company is a "foreign private issuer" within the meaning of Rule 405 under the Act.
- (ccc) Submission to Jurisdiction. The Company has the power to submit, and pursuant to Section 9(f) of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each United States federal court and New York state court located in the Borough of Manhattan, in the City of New York, New York, U.S.A. (each, a "New York Court"), and the Company has the power to designate, appoint and authorize, and pursuant to Section 9(f) of this Agreement, has legally, validly, effectively and irrevocably designated, appointed and authorized an agent for service of process in any action arising out of or relating to this Agreement or the Shares in any New York Court, and service of process effected on such authorized agent will be effective to confer valid personal jurisdiction over the Company as provided in Section 9(f) hereof.
- (ddd) *Enforceability of Judgement*. Subject to the conditions and qualifications set forth in the Registration Statement, the General Disclosure Package and the Prospectus, any final judgment for a fixed or readily calculable sum of money rendered by a New York Court having jurisdiction under its own domestic laws and recognized by the Israeli courts as having jurisdiction to give such final judgment in respect of any suit, action or proceeding against the Company based upon this Agreement and any instruments or agreements entered into for the consummation of the transactions contemplated herein and therein would be declared enforceable against the Company, without re-examination or review of the merits of the cause of action in respect of which the original judgment was given or re-litigation of the matters adjudicated upon, by the courts of Israel. The Company is not aware of any reason why the enforcement in Israel of such a New York Court judgment would be, as of the date hereof, contrary to public policy of Israel.
- (eee) *No Rights of Immunity*. Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its subsidiaries or their respective properties, assets or revenues has any right of immunity under Israeli, New York or United States law, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any law of Israel, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Agreement. To the extent that the Company, any of its subsidiaries or any of their respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced, the Company waives or will waive such right to the extent permitted by law and has consented to such relief and enforcement as provided in Section 9(f) of this Agreement.

- 4. <u>Agreements of the Company</u>. The Company agrees with each Underwriter as follows:
- (a) Amendments and Supplements to Registration Statement. The Company shall not, either prior to any effective date or thereafter during such period as the Prospectus is required by law to be delivered (whether physically or through compliance with Rule 172 of the Rules and Regulations or any similar rule) (the "Prospectus Delivery Period") in connection with sales of the Shares by an Underwriter or dealer, amend or supplement the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communications, unless a copy of such amendment or supplement thereof shall first have been submitted to the Representatives within a reasonable period of time prior to the filing or, if no filing is required, the use thereof and the Representatives shall not have objected thereto in good faith.
- (b) Amendments and Supplements to the Registration Statement, the General Disclosure Package, and the Prospectus and Other Securities Act Matters. If, during the Prospectus Delivery Period, any event or development shall occur or condition exist as a result of which the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading, or if it shall be necessary to amend or supplement the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication in order to make the statements therein, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading, or if in the opinion of the Representatives it is otherwise necessary to amend or supplement the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication, or to file a new registration statement containing the Prospectus, in order to comply with the Act, the Rules and Regulations, the Exchange Act or the Exchange Act Rules, including in connection with the delivery of the Prospectus, the Company agrees to (i) promptly notify the Representatives of any such event or condition and (ii) promptly prepare (subject to Section 4(a) and 4(f) hereof), file with the Commission (and use its reasonable best efforts to have any amendment to the Registration Statement or any new registration statement to be declared effective) and furnish at its own expense to the Underwriters (and, if applicable, to dealers), amendments or supplements to the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication, or any new registration statement, necessary in order to make the statements in the General Disclosure Package, the Prospectus or the applicable Written Testing-the-Waters Communication as so amended or supplemented, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading or so that the Registration Statement, the General Disclosure Package, the Prospectus or the applicable Written Testing-the-Waters Communication, as amended or supplemented, will comply with the Act, the Rules and Regulations, the Exchange Act or the Exchange Act Rules or any other applicable law.

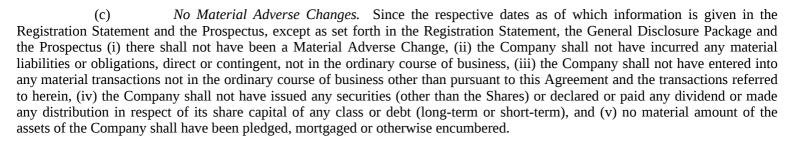
- Notifications to the Representatives. The Company shall use its best efforts to cause the Registration Statement to become effective, and shall notify the Representatives promptly, and shall confirm such advice in writing, (i) when any post-effective amendment to the Registration Statement has become effective and when any post-effective amendment thereto becomes effective, (ii) of any request by the Commission for amendments or supplements to the Registration Statement or the Prospectus or for additional information, (iii) of the commencement by the Commission or by any state securities commission of any proceedings for the suspension of the qualification of any of the Shares for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose, including, without limitation, the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose or the threat thereof, (iv) of the happening of any event during the Prospectus Delivery Period that in the judgment of the Company makes any statement of a material fact made in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication misleading (including by omission) or untrue or that requires the making of any changes in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication in order to make the statements of a material fact therein, in light of the circumstances in which they are made, not misleading, (v) of receipt by the Company or any representative of the Company of any other communication from the Commission relating to the Company, the Registration Statement, any preliminary prospectus, the Prospectus or any Written Testing-the-Waters Communication and (vi) of any distribution of Written Testing-the-Waters Communication by or on behalf of the Company (other than through any Underwriter). If at any time the Commission shall issue any order suspending the effectiveness of the Registration Statement, the Company shall use best efforts to obtain the withdrawal of such order as soon as possible. The Company shall comply with the provisions of and make all requisite filings with the Commission pursuant to Rules 424(b), 430A, 430B, 430C and 462(b) of the Rules and Regulations and notify the Representatives promptly of all such filings.
- (d) Executed Registration Statement. The Company shall furnish to the Representatives, without charge, for transmittal to each of the other Underwriters, two signed copies of the Registration Statement and of any post-effective amendment thereto, including financial statements and schedules, and all exhibits thereto, and shall furnish to the Representatives, without charge, for transmittal to each of the other Underwriters, a copy of the Registration Statement and any post-effective amendment thereto, including financial statements and schedules but without exhibits.
- (e) *Undertakings*. The Company shall comply with all the provisions of any undertakings contained and required to be contained in the Registration Statement.
- (f) *Prospectus*. The Company shall prepare the Prospectus in a form approved by the Representatives and shall file such Prospectus with the Commission pursuant to Rule 424(b) of the Rules and Regulations with a filing date not later than the second business day following the execution and delivery of this Agreement. Promptly after the effective date of the Registration Statement, and thereafter from time to time, the Company shall deliver to each of the Underwriters, without charge, as many copies of the Prospectus and any amendment or supplement thereto as the Representatives may reasonably request. The Company consents to the use of the Prospectus and any amendment or supplement thereto by the Underwriters and by all dealers to whom the Shares may be sold, both in connection with the offering or sale of the Shares and for any period of time thereafter during the Prospectus Delivery Period. If, during the Prospectus Delivery Period any event shall occur that in the judgment of the Company or counsel to the Underwriters should be set forth in the Prospectus in order to make any statement of a material fact therein, in the light of the circumstances under which it was made, not misleading (including by omission), or if it is necessary to supplement or amend the Prospectus to comply with law, the Company shall forthwith prepare and duly file with the Commission an appropriate supplement or amendment thereto, and shall deliver to each of the Underwriters, without charge, such number of copies thereof as the Representatives may reasonably request.

- (g) Permitted Free Writing Prospectuses. The Company represents and agrees that it has not made and, unless it obtains the prior consent of the Representatives, will not make, any offer relating to the Shares that would constitute a "free writing prospectus" as defined in Rule 405 of the Rules and Regulations, required to be filed with the Commission or retained by the Company under Rule 433 of the Rules and Regulations: *provided* that the prior written consent of the Representatives hereto shall be deemed to have been given in respect of the Issuer Free Writing Prospectuses included in Schedule II hereto. Any such free writing prospectus consented to by the Representatives is herein referred to as a "Permitted Free Writing Prospectus." The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, and (ii) has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 of the Act applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping. If at any time following the issuance of an Issuer Free Writing Prospectus there occurs an event or development as a result of which such Issuer Free Writing Prospectus would conflict with the information contained in the Registration Statement relating to the Shares or would include an untrue statement of material fact or would omit to state a material fact necessary in order to make the statements therein, in light of the circumstances prevailing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement, or omission. The Company represents that it has satisfied and agrees that it will satisfy the conditions in Rule 433 to avoid a requirement to file with the Commission any electronic road show.
- (h) Compliance with Blue Sky Laws. Prior to any public offering of the Shares by the Underwriters, the Company shall cooperate with the Representatives and counsel to the Underwriters in connection with the registration or qualification (or the obtaining of exemptions from the application thereof) of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives may request, including, without limitation, the provinces and territories of Canada and other jurisdictions outside the United States; provided, however, that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action which would subject it to general service of process in any jurisdiction where it is not now so subject.
- (i) *Delivery of Financial Statements.* During the period of two years commencing on the effective date of the Registration Statement applicable to the Underwriters, the Company shall furnish to the Representatives and each other Underwriter who may so request copies of such financial statements and other periodic and special reports as the Company may from time to time distribute generally to the holders of any class of its share capital, and will furnish to the Representatives and each other Underwriter who may so request a copy of each annual or other report it shall be required to file with the Commission; *provided, however,* that electronically transmitted copies filed with the Commission pursuant to EDGAR shall satisfy the Company's obligation to furnish copies hereunder.

- (j) Availability of Earnings Statements. The Company shall make generally available to holders of its securities as soon as may be practicable but in no event later than the last day of the fifteenth full calendar month following the calendar quarter in which the most recent effective date occurs in accordance with Rule 158 of the Rules and Regulations, an earnings statement (which need not be audited but shall be in reasonable detail) for a period of 12 months ended commencing after the effective date of the Registration Statement, and satisfying the provisions of Section 11(a) of the Act (including Rule 158 of the Rules and Regulations).
- Payment of Expenses. Whether or not any of the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay or cause to be paid, or reimburse if paid by the Representatives, all costs and expenses incident to the performance of the obligations of the Company under this Agreement, including but not limited to: (i) the costs incident to the authorization, issuance, sale, preparation and delivery of the Shares and any Stamp Tax or other taxes payable in connection therewith, (ii) the costs incident to the preparation, printing and filing under the Act of the Registration Statement and exhibits to it, each preliminary prospectus, each Permitted Free Writing Prospectus, the Prospectus, each Written Testing-the-Waters Communications, if any, and any amendment or supplement to the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication, and the distribution thereof, (iii) the costs of preparing, printing and delivering certificates representing the Shares, (iv) the costs of producing and delivering this Agreement, the Agreement Among Underwriters and any other related documents in connection with the offering, purchase, sale and delivery of the Shares, (v) the costs of furnishing (including costs of shipping, mailing and courier) such copies of the Registration Statement, the Prospectus, any preliminary prospectus, any Permitted Free Writing Prospectus and any Written Testing-the-Waters Communication, and all amendments and supplements thereto, as may be requested for use in connection with the offering and sale of the Shares by the Underwriters or by dealers to whom Shares may be sold, (vi) the costs, fees and expenses of listing the Shares on the Nasdag Global Market, (vii) the filing fees incident to, and the fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Shares, (viii) the fees and expenses incident to the registration or qualification of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions designated pursuant to Section 4(h) hereof and the securities laws of Canada, including the fees, disbursements and other charges of counsel to the Underwriters in connection therewith, and, if requested by the Representatives, the preparation and printing of preliminary, supplemental and final Blue Sky memoranda and a "Canadian wrapper;" provided, however, that the Company shall not be required to pay or reimburse the Underwriters for fees and disbursements of counsel to the Underwriters in excess of \$20,000 in connection with Sections 4(k)(vi), 4(k)(vii) and 4(k)(viii), (ix) the fees and expenses of counsel to the Company, (x) the costs and charges of DTC and the transfer agent for the Shares, (xi) the fees and expenses of the Accountants, (xii) (A) the costs and expenses of the Company and (B) half of the aggregate costs and expenses of the Representatives up to a maximum amount of \$35,000, in each case relating to investor presentations on any "road show" or any Testing-the-Waters Communication undertaken in connection with the marketing of the Shares, including, without limitation, all costs and expenses associated with any electronic road show, travel and lodging expenses of, with respect to the Company, the officers, employees, agents and other representatives of the Company and consultants and, with respect to the Representatives, the Representatives engaged in connection with investor presentations, and (C) one-half of the cost of any aircraft and other transportation chartered in connection with the road show, and the Underwriters shall be responsible for the remaining one-half of such expenses; and (xiii) all fees, costs and expenses for consultants used by the Company in connection with the offering. All payments to be made by the Company hereunder shall be made without withholding or deduction for or on account of any present or future taxes, duties or governmental changes whatsoever unless the Company is compelled by law to deduct or withhold such taxes, duties or charges. In that event, the Company shall pay such additional amounts as may be necessary in order that the net amounts received by the Underwriters after such withholding or deduction shall equal the amounts that would have been received if no withholding or deduction had been made; provided, however, that such additional amounts shall not be paid by the Company to the extent an Underwriter determines, in its sole discretion exercised in good faith, that such amounts subject to withholding are creditable. This paragraph shall not be construed to require the Underwriters to make available their tax returns (or any other information relating to their taxes that they, in their sole discretion, deem confidential) to the Company or any other person. Except as provided in this Section 4(k) and in Section 4(1), the Underwriters shall pay their own costs and expenses, including the costs and expenses of their counsel.

- (l) Reimbursement of Expenses upon Termination of Agreement. If for any reason the Company shall be unable to perform its obligations or to fulfill any conditions hereunder or if the Underwriters shall terminate this Agreement pursuant to Section 7 hereof, the Company shall reimburse the Underwriters for all out-of-pocket expenses (including the fees, disbursements and other charges of counsel to the Underwriters) reasonably incurred by them in connection herewith; *provided*, *however*, that the Company shall not be obligated to reimburse the expenses of any defaulting Underwriter under Section 8 hereof.
- (m) No Stabilization or Manipulation. The Company shall not at any time, directly or indirectly, take any action intended to cause or result in, or which might reasonably be expected to cause or result in, or which will constitute, stabilization or manipulation, under the Act or otherwise, of the price of the Ordinary Shares to facilitate the sale or resale of any of the Shares.
- (n) *Use of Proceeds*. The Company shall apply the net proceeds from the offering and sale of the Shares to be sold in the manner set forth in the General Disclosure Package and the Prospectus under "Use of Proceeds" and shall file such reports with the Commission with respect to the sale of the Shares and the application of the proceeds therefrom as may be required in accordance with Rule 463 under the Act.
- Lock-Up Agreements of Company, Management and Directors. The Company shall not, for a period of 90 days after the date of the Prospectus (the "Lock-Up Period"), without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), (1) offer, sell, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition), directly or indirectly, or file with the Commission a registration statement under the Act to register, any Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares or warrants or other rights to acquire Ordinary Shares or (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic benefits or risks of ownership of such Ordinary Shares, securities, warrants or other rights to acquire Ordinary Shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Ordinary Shares or other securities, in cash or otherwise, or publicly disclose the intention to enter into any transaction described in clause (1) or (2) above. The foregoing sentence shall not apply to (A) the Shares to be sold hereunder, (B) any Ordinary Shares issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, General Disclosure Package and the Prospectus, (C) any Ordinary Shares issued or options to purchase Ordinary Shares granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, General Disclosure Package and the Prospectus, (D) the filing of a registration statement on Form S-8 relating to Ordinary Shares granted pursuant to the Company's equity incentive plans existing as of the Closing Date and disclosed in the General Disclosure Package, and (E) Ordinary Shares or any securities convertible into, or exercisable, or exchangeable for, Ordinary Shares issued, sold or delivered in connection with any acquisition or strategic investment (including any joint venture, strategic alliance or partnership) as long as (x) the aggregate number of Ordinary Shares issued or issuable does not exceed 5% of the number of Ordinary Shares outstanding immediately after the completion of the offering of the Shares contemplated herein, and (y) each recipient of any such shares or other securities executes a lock-up agreement restricting the resale of such securities in the form executed by each of the executive officers and directors of the Company for the remainder of the 90-day restricted period. The Company has caused each of its officers and directors to enter into agreements with the Representatives in the form set forth in Exhibit A.

- (p) *Emerging Growth Company Status*. The Company shall promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the offering or sale of the Shares is not required by the Act to be delivered (whether physically or through compliance with Rule 172 of the Rules and Regulations or any similar rule) and (ii) completion of the Lock-Up Period.
  - (q) *Transfer Agent.* The Company shall maintain, at its expense, a registrar and transfer agent for the Shares.
- 5. <u>Conditions of the Obligations of the Underwriters.</u> The obligation of each Underwriter to purchase the Firm Shares on the Closing Date or any Option Shares on the Option Closing Date, as the case may be, as provided herein is subject to the accuracy of the representations and warranties of the Company, the performance by the Company of its covenants and other obligations hereunder and to the following additional conditions:
- (a) Post Effective Amendments and Prospectus Filings. Notification that the Registration Statement has become effective shall be received by the Representatives not later than 6:00 p.m., New York City time, on the date of this Agreement or at such later date and time as shall be consented to in writing by the Representatives and all filings made pursuant to Rules 424, 430A, 430B or 430C of the Rules and Regulations, as applicable, shall have been made or will be made prior to the Closing Date in accordance with all such applicable rules.
- (b) No Stop Orders, Requests for Information and No Amendments. (i) No stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall be pending or are, to the knowledge of the Company, threatened by the Commission, (ii) no order suspending the qualification or registration of the Shares under the securities or Blue Sky laws of any jurisdiction shall be in effect and no proceeding for such purpose shall be pending before or, to the knowledge of the Company, threatened or contemplated by the authorities of any such jurisdiction, (iii) any request for additional information on the part of the staff of the Commission or any such authorities shall have been complied with to the satisfaction of the staff of the Commission or such authorities and (iv) after the date hereof no amendment or supplement to the Registration Statement or the Prospectus shall have been filed unless a copy thereof was first submitted to the Representatives and the Representatives did not object thereto in good faith, and the Representatives shall have received certificates, dated the Closing Date and any Option Closing Date and signed by the Chief Executive Officer or the Chairman of the Board of Directors and the Chief Financial Officer of the Company (who may, as to proceedings threatened, rely upon the best of their information and belief), to the effect of clauses (i), (ii) and (iii).



- (d) *No Actions, Suits or Proceedings.* Since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package and the Prospectus, there shall have been no actions, suits or proceedings instituted, or to the Company's knowledge, threatened against or affecting, the Company, its subsidiaries or any of their respective officers in their capacity as such, before or by any federal, state or local court, commission, regulatory body, administrative agency or other governmental body, domestic or foreign.
- (e) All Representations True and Correct and All Conditions Fulfilled. Each of the representations and warranties of the Company contained herein shall be true and correct at the Closing Date as if made at the Closing Date and any Option Closing Date, as the case may be, and all covenants and agreements contained herein to be performed by the Company and all conditions contained herein to be fulfilled or complied with by the Company at or prior to the Closing Date and any Option Closing Date, shall have been duly performed, fulfilled or complied with.
- (f) *Opinions of Counsel to the Company.* The Representatives shall have received the opinions and letters, each dated the Closing Date and any Option Closing Date, as the case may be, reasonably satisfactory in form and substance to counsel for the Underwriters, from Cooley LLP, U.S. counsel to the Company, Meitar Liquornik Geva Leshem Tal, Israeli counsel to the Company, and Cooley LLP, intellectual property counsel to the Company.

- (g) Opinion of Counsel to the Underwriters. The Representatives shall have received an opinion, dated the Closing Date and any Option Closing Date, from Davis Polk & Wardwell LLP, counsel to the Underwriters, with respect to the Registration Statement, the Prospectus and this Agreement, which opinion shall be satisfactory in all respects to the Representatives.
- (h) Accountants' Comfort Letter. On the date of the Prospectus, the Representatives shall have received from the Accountants a letter dated the date of its delivery, addressed to the Representatives, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement and the Prospectus. At the Closing Date and any Option Closing Date, as the case may be, the Representatives shall have received from the Accountants a letter dated such date, in form and substance reasonably satisfactory to the Representatives, to the effect that they reaffirm the statements made in the letter furnished by them pursuant to the preceding sentence and have conducted additional procedures with respect to certain financial figures included in the Prospectus, except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the Closing Date or any Option Closing Date, as the case may be.
- (i) *Officers' Certificates*. At the Closing Date and any Option Closing Date, as the case may be, there shall be furnished to the Representatives an accurate certificate, dated the date of its delivery, signed by each of the Chief Executive Officer and the Chief Financial Officer of the Company, in form and substance satisfactory to the Representatives, to the effect that:
  - (i) each signer of such certificate has carefully examined the Registration Statement and the Prospectus;
  - (ii) there has not been a Material Adverse Change;
- (iii) each of the representations and warranties of the Company and its subsidiaries contained in this Agreement are, at the time such certificate is delivered, true and correct; and
- (iv) each of the covenants required herein to be performed by the Company and its subsidiaries on or prior to the date of such certificate has been duly, timely and fully performed and each condition herein required to be complied with by the Company and its subsidiaries on or prior to the delivery of such certificate has been duly, timely and fully complied with.
- (j) *Lock-Up Agreements*. At the date of this Agreement, the Representatives shall have received the executed "lock-up" agreements referred to in Section 4(o) hereof from the Company's officers and directors.

- (k) *Compliance with Blue Sky Laws.* The Shares shall be qualified for sale in such states and jurisdictions as the Representatives may reasonably request, including, without limitation, qualification for exemption from registration or prospectus delivery requirements in the provinces and territories of Canada and other jurisdictions outside the United States, and each such qualification shall be in effect and not subject to any stop order or other proceeding on the Closing Date and any Option Closing Date.
- (l) *Stock Exchange Listing.* The Shares shall have been duly authorized for listing on the Nasdaq Global Market, subject only to notice of issuance.
- (m) Good Standing. At the Closing Date and any Option Closing Date, the Company shall have furnished to the Representatives satisfactory evidence of the good standing of the Company and its subsidiaries in their respective jurisdictions of organization and their good standing as foreign entities in such other jurisdictions as the Representatives may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions. If the applicable jurisdiction does not have a concept of "good standing," the Company will furnish evidence in writing or any standard form of telecommunication from the appropriate governmental authorities that the relevant company remains duly registered in the jurisdiction of its incorporation.
- (n) *Company Certificates.* The Company shall have furnished to the Representatives such certificates, in addition to those specifically mentioned herein, as the Representatives may have reasonably requested as to the accuracy and completeness at the Closing Date and any Option Closing Date of any statement in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication as to the accuracy at the Closing Date and any Option Closing Date of the representations and warranties of the Company herein, as to the performance by the Company of its obligations hereunder, or as to the fulfillment of the conditions concurrent and precedent to the obligations hereunder of the Underwriters.
- (o) *No Objection.* FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Shares.

If any of the conditions hereinabove provided for in this Section 5 shall not have been fulfilled when and as required by this Agreement to be fulfilled, the obligations of the Underwriters hereunder may be terminated by the Representatives by notifying the Company of such termination in writing at or prior to the Closing Date or any Option Closing Date, as the case may be.

### 6. Indemnification.

- *Indemnification of the Underwriters.* The Company shall indemnify and hold harmless each Underwriter, its affiliates, the directors, officers, employees, counsel and agents of each Underwriter and each person, if any, who controls each Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), to which they, or any of them, may become subject under the Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based on (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rules 430A, 430B or 430C, as applicable or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, any preliminary prospectus supplement, any Issuer Free Writing Prospectus, the Prospectus or any Written Testing-the-Waters Communication (or any amendment or supplement to any of the foregoing) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iii) any untrue statement or alleged untrue statement of a material fact contained in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company shall not be liable to the extent that such loss, claim, liability, expense or damage arises from the sale of the Shares in the public offering to any person by an Underwriter and is based on an untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriters' Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.
- (b) *Indemnification of the Company*. Each Underwriter shall, severally and not jointly, indemnify and hold harmless the Company, each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, each director of the Company and each officer of the Company who signs the Registration Statement to the same extent as the foregoing indemnity from the Company to each Underwriter, but only insofar as losses, claims, liabilities, expenses or damages arise out of or are based on any untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriters' Information. This indemnity will be in addition to any liability that each Underwriter might otherwise have.

*Indemnification Procedures.* Any party that proposes to assert the right to be indemnified under this Section 6 shall, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 6, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 6 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (i) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (ii) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (iii) the indemnified party has reasonably concluded that a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iv) the indemnifying party has not in fact employed counsel satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel shall be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges shall be reimbursed by the indemnifying party promptly upon receipt of documented notice thereof. An indemnifying party shall not be liable for any settlement of any action or claim effected without its written consent (which consent will not be unreasonably withheld or delayed). No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 6 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 6 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Underwriters, the Company and the Underwriters shall contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Underwriters, such as persons who control the Company within the meaning of the Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Underwriters may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions which resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Representatives on behalf of the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 6(d) were to be determined by pro rata allocation or by any other method of allocation (even if the Underwriters were treated as one entity for such purpose) which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action in respect thereof, referred to above in this Section 6(d) shall be deemed to include, for purpose of this Section 6(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 6(d), no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by it, and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligation to contribute as provided in this Section 6(d) are several in proportion to their respective underwriting obligations and not joint. For purposes of this Section 6(d), any person who controls a party to this Agreement within the meaning of the Act will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, and each affiliate, director, officer, employee, counsel or agent of any Underwriter will have the same rights to contribution as such Underwriter, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 6(d), will notify any such party or parties from whom contribution may be sought, but the omission so to notify will not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 6(d). No party will be liable for contribution with respect to any action or claim settled without its written consent (which consent will not be unreasonably withheld).

- (e) *Survival*. The indemnity and contribution agreements contained in this Section 6 and the representations and warranties of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of the Underwriters, (ii) acceptance of any of the Shares and payment therefor or (iii) any termination of this Agreement.
- 7. <u>Termination</u>. The obligations of the several Underwriters under this Agreement may be terminated at any time prior to the Closing Date (or, with respect to the Option Shares, on or prior to any Option Closing Date), by notice to the Company from the Representatives, without liability on the part of any Underwriter to the Company, if, prior to delivery and payment for the Firm Shares (or the Option Shares, as the case may be), in the sole judgment of the Representatives, any of the following shall occur:
- (a) trading or quotation in any of the equity securities of the Company shall have been suspended or limited by the Commission or by an exchange or otherwise;
- (b) trading in securities generally on the New York Stock Exchange, the Nasdaq Global Market or the Nasdaq Global Select Market shall have been suspended or limited or minimum or maximum prices shall have been generally established on such exchange, or additional material governmental restrictions, not in force on the date of this Agreement, shall have been imposed upon trading in securities generally by such exchange or by order of the Commission or any court or other governmental authority;
- (c) a general banking moratorium shall have been declared by any of U.S. federal, New York or Israeli authorities;
- (d) the United States or Israel shall have become engaged in new hostilities, there shall have been any outbreak or escalation in hostilities involving the United States or Israel or there shall have been a declaration of a national emergency or war by the United States or Israel or there shall have occurred such a material adverse change in general economic, political or financial conditions, including, without limitation, as a result of terrorist activities after the date hereof (or the effect of international conditions on the financial markets in the United States shall be such), or any other calamity or crisis shall have occurred, the effect of any of which is such as to make it impracticable or inadvisable to market the Shares on the terms and in the manner contemplated by the Prospectus or to enforce contracts for the sale of securities;
- (e) the Company shall have sustained a loss material or substantial to the Company by reason of flood, fire, accident, hurricane, earthquake, theft, sabotage, or other calamity or malicious act, whether or not such loss shall have been insured, the effect of any of which is such as to make it impracticable or inadvisable to market the Shares on the terms and in the manner contemplated by the Prospectus; or
  - (f) there shall have been a Material Adverse Change.

Substitution of Underwriters. If any one or more of the Underwriters shall fail or refuse to purchase any of the Firm Shares which it or they have agreed to purchase hereunder, and the aggregate number of Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of Firm Shares, the other Underwriters shall be obligated, severally, to purchase the Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase, in the proportions which the number of Firm Shares which they have respectively agreed to purchase pursuant to Section 1 hereof bears to the aggregate number of Firm Shares which all such nondefaulting Underwriters have so agreed to purchase, or in such other proportions as the Representatives may specify; provided that in no event shall the maximum number of Firm Shares which any Underwriter has become obligated to purchase pursuant to Section 1 hereof be increased pursuant to this Section 8 by more than one-ninth of the number of Firm Shares agreed to be purchased by such Underwriter without the prior written consent of such Underwriter. If any Underwriter or Underwriters shall fail or refuse to purchase any Firm Shares and the aggregate number of Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase exceeds one-tenth of the aggregate number of the Firm Shares and arrangements satisfactory to the Company and the Representatives for the purchase of such Firm Shares are not made within 48 hours after such default, this Agreement will terminate without liability on the part of any non-defaulting Underwriter, or the Company for the purchase or sale of any Shares under this Agreement. In any such case either the Representatives or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement and in the Prospectus or in any other documents or arrangements may be effected. Any action taken pursuant to this Section 8 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

# 9. <u>Miscellaneous</u>.

- (a) *Notices*. Notice given pursuant to any of the provisions of this Agreement shall be in writing and, unless otherwise specified, shall be mailed, hand delivered or telecopied (a) if to the Company, at the office of the Company, 673 Boylston Street, Boston, Massachusetts, 02116, Attention: Chief Executive Officer, with a copy (which shall not constitute notice) to Cooley LLP, 1114 Avenue of the Americas, New York, New York, 10035, Attention: Joshua A. Kaufman and Daniel I. Goldberg, or (b) if to the Underwriters, c/o RBC Capital Markets, LLC, 200 Vesey Street, 8th Floor, New York, New York 10281, Attention: Equity Syndicate Department (Fax: 212-428-6260) and JMP Securities LLC, 600 Montgomery Street, Suite 1100, San Francisco, California 94111, Attention: Equity Securities (Fax: 415-835-8920), with a copy (which shall not constitute notice) to Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, New York, 10017, Attention: Derek Dostal. Any such notice shall be effective only upon receipt. Any notice under Section 6 hereof may be made by telecopy or telephone, but if so made shall be subsequently confirmed in writing.
- (b) *No Third Party Beneficiaries*. This Agreement has been and is made solely for the benefit of the several Underwriters, the Company and the controlling persons, affiliates, directors, officers, employees, counsel and agents referred to in Section 6 hereof, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" as used in this Agreement shall not include a purchaser of Shares from the Underwriters in his, her or its capacity as such a purchaser.

- (c) *Survival of Representations and Warranties*. All representations, warranties and agreements of the Company contained herein or in certificates or other instruments delivered pursuant hereto shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any of their controlling persons and shall survive delivery of and payment for the Shares hereunder.
- (d) Disclaimer of Fiduciary Relationship. The Company acknowledges and agrees that (i) the purchase and sale of the Shares pursuant to this Agreement, including the determination of the public offering price of the Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters, on the other hand, (ii) in connection with the offering contemplated by this Agreement and the process leading to such transaction, each of the Underwriters is and has been acting solely as a principal and is not the agent or fiduciary of the Company or its securityholders, creditors, employees or any other party, (iii) none of the Underwriters has assumed nor will it assume any advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Shares contemplated by this Agreement or the process leading thereto (irrespective of whether any Underwriter or its affiliates has advised or is currently advising the Company on other matters) and the Underwriters have no obligation to the Company with respect to the offering of the Shares contemplated by this Agreement except the obligations expressly set forth in this Agreement, (iv) each of the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated by this Agreement and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.
- (e) Actions of the Representatives. Any action by the Underwriters hereunder may be taken by the Representatives on behalf of the Underwriters, and any such action taken by the Representatives shall be binding upon the Underwriters.
- THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN (f) Governing Law. ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("Related Proceedings") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "Related Judgment"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum. With respect to any Related Proceeding, each party irrevocably waives, to the fullest extent permitted by applicable law, all immunity (whether on the basis of sovereignty or otherwise) from jurisdiction, service of process, attachment (both before and after judgment) and execution to which it might otherwise be entitled in the Specified Courts, and with respect to any Related Judgment, each party waives any such immunity in the Specified Courts or any other court of competent jurisdiction, and will not raise or claim or cause to be pleaded any such immunity at or in respect of any such Related Proceeding or Related Judgment, including, without limitation, any immunity pursuant to the United States Foreign Sovereign Immunities Act of 1976, as amended.

- (g) Judgement Currency. If for the purposes of obtaining judgment in any court it is necessary to convert a sum due hereunder into any currency other than United States dollars, the parties hereto agree, to the fullest extent permitted by law, that the rate of exchange used shall be the rate at which in accordance with normal banking procedures the Underwriters could purchase United States dollars with such other currency in The City of New York on the business day preceding that on which final judgment is given. The obligation of the Company with respect to any sum due from it to any Underwriter or any person controlling any Underwriter shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first business day following receipt by such Underwriter or controlling person of any sum in such other currency, and only to the extent that such Underwriter or controlling person may in accordance with normal banking procedures purchase United States dollars with such other currency. If the United States dollars so purchased are less than the sum originally due to such Underwriter or controlling person hereunder, the Company agrees as a separate obligation and notwithstanding any such judgment, to indemnify such Underwriter or controlling person against such loss. If the United States dollars so purchased are greater than the sum originally due to such Underwriter or controlling person hereunder, such Underwriter or controlling person agrees to pay to the Company an amount equal to the excess of the dollars so purchased over the sum originally due to such Underwriter or controlling person hereunder.
- (h) Appointment of Agent for Service. The Company hereby appoints Gamida Cell Inc. as its agent for service of process (the "Agent for Service") in any suit, action or proceeding described in the preceding paragraph and agrees that service of process in any such suit, action or proceeding may be made upon it at the office of such agent. The Company waives, to the fullest extent permitted by law, any other requirements of or objections to personal jurisdiction with respect thereto. The Company represents and warrants that such agent has agreed to act as its agent for service of process, and the Company agrees to take any and all action, including the filing of any and all documents and instruments, that may be necessary to continue such appointment in full force and effect; provided, however, that the Company may (and shall, to the extent the Agent for Service ceases to be able to be served on the basis contemplated herein), by written notice of the Representatives, designate such additional or alternative agent for service of process under this Section 9(h) that (i) maintains an office located in the Borough of Manhattan, City of New York, State of New York and (ii) is a corporate service company which acts as agent for service of process for other persons in the ordinary course of its business. Such written notice shall identify the name of such agent for service of process and the address of the office of such agent for service of process in the Borough of Manhattan, City of New York, State of New York.
- (i) *Counterparts*. This Agreement may be signed in two or more counterparts with the same effect as if the signatures thereto and hereto were upon the same instrument.

- (j) Survival of Provisions Upon Invalidity of Any Single Provision. In case any provision in this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- (k) *Waiver of Jury Trial.* The Company and the Underwriters each hereby irrevocably waive any right they may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or the transactions contemplated hereby.
- (l) *Titles and Subtitles.* The titles of the sections and subsections of this Agreement are for convenience and reference only and are not to be considered in construing this Agreement.
- (m) *Entire Agreement*. This Agreement embodies the entire agreement and understanding between the parties hereto and supersedes all prior agreements and understandings relating to the subject matter hereof. This Agreement may not be amended or otherwise modified or any provision hereof waived except by an instrument in writing signed by the Representatives and the Company.

# 10. Recognition of the U.S. Special Resolution Regimes

- (a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
- (b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 10,

"BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

# "Covered Entity" means any of the following:

- (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);
- (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or
- (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

[Signature page follows]

Please confirm that the foregoing correctly sets forth the agreement between the Company and the several Underwriters.		
	Very truly yours,	
	Gamida Cell Ltd.	
	By: Name: Title:	

Confirmed as of the date first above mentioned:	
RBC CAPITAL MARKETS, LLC JMP SECURITIES LLC	
Acting on behalf of themselves and as Representatives of the several Underwriters named in <u>Schedule I</u> hereto	
RBC CAPITAL MARKETS, LLC	
By: Name: Title:	
JMP SECURITIES LLC	
By: Name: Title:	

Schedule I

Underwriter		Number of Firm Shares
RBC Capital Markets, LLC		[•]
JMP Securities LLC		[•]
Oppenheimer & Co. Inc.		[•]
[●]		[•]
Total		[•]
	S-I-1	

[ullet]

WRITTEN TESTING-THE-WATERS COMMUNICATIONS:

[NTD]

S-III-1

# INFORMATION PROVIDED ORALLY BY THE UNDERWRITERS

- 1. The public offering price per Ordinary Share shall be  $\{[\bullet]$ .
- [2. The Company is selling [•] Ordinary Shares.]
- [3. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional  $[\bullet]$  Ordinary Shares.]

S-IV-1

# FORM OF LOCK-UP AGREEMENT

June [●], 2019

RBC Capital Markets, LLC JMP Securities LLC

As Representative of the Several Underwriters

RBC Capital Markets, LLC 00 Vesey Street

New York, New York 10281

and

JMP Securities LLC 450 Park Avenue New York, New York 10022

Ladies and Gentlemen:

In consideration of the agreement of the several underwriters (the "Underwriters"), for which RBC Capital Markets, LLC and JMP Securities LLC intend to act as Representatives (the "Representatives"), to underwrite a proposed public offering (the "Offering") of ordinary shares with a nominal value of New Israeli Shekel 0.01 per share (the "Ordinary Shares"), of Gamida Cell Ltd., a private limited liability company organized under the laws of the State of Israel (the "Company"), the undersigned hereby irrevocably agrees that the undersigned shall not, for a period (the "Lock-Up Period") beginning on the date of this agreement (this "Lock-Up Agreement") and ending 90 days after the date of the final prospectus for the Offering, without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), (1) offer, sell, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of), or require the Company to file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), to register, any Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares or warrants or other rights to acquire Ordinary Shares of which the undersigned is now, or may in the future become, the beneficial owner (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (such shares, securities, warrants or rights collectively, the "Restricted Securities"), (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic benefits or risks of ownership of such Restricted Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Ordinary Shares or other securities, in cash or otherwise, or (3) publicly disclose the intention to enter into any transaction described in clause (1) or (2) above. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of Restricted Securities owned either of record or beneficially by the undersigned except in compliance with the foregoing restrictions. Any securities of the Company acquired by the undersigned in the Offering will also be Restricted Securities subject to this Lock-Up Agreement (the restrictions in this paragraph being referred to as the "Registration Restrictions").

The undersigned further agrees that the Registration Restrictions shall be equally applicable to any issuer-directed Ordinary Shares the undersigned may purchase in the Offering.

The Registration Restrictions shall not apply to: (i) transfers of Restricted Securities as a *bong fide* gift or gifts by the undersigned: (ii) transfers or dispositions of Restricted Securities to any trust for the direct or indirect benefit of the undersigned or any member of the immediate family of the undersigned; (iii) transfers or dispositions of Restricted Securities to any of the undersigned's affiliates (within the meaning set forth in Rule 405 under the Securities Act); (iv) transfers of Restricted Securities by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the undersigned; (v) the surrender or forfeiture of Restricted Securities to the Company to satisfy tax withholding obligations upon exercise or vesting of stock options or equity awards held by the undersigned on the date of the preliminary prospectus for the Offering and granted pursuant to the Company's equity incentive plans as described in the preliminary prospectus for the Offering; (vi) transfer of Restricted Securities made by operation of law, including pursuant to a qualified domestic relations order or in connection with a divorce settlement; (vii) the exercise of any option, warrant or other right to acquire Restricted Securities, the settlement of any stock-settled stock appreciation rights, restricted stock or restricted stock units or the conversion of any convertible security into Restricted Securities outstanding on the date of the preliminary prospectus for the Offering and granted pursuant to the Company's equity incentive plans as described in the preliminary prospectus for the Offering; (viii) transfers of Restricted Securities made upon completion of a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of the then outstanding Ordinary Shares involving a Change of Control of the Company after completion of the Offering, provided that, in the event that such tender offer, merger, consolidation or other similar transaction is not completed, the undersigned's Restricted Securities shall remain subject to the restrictions contained herein (for purposes hereof, "Change of Control" shall mean the transfer, whether by tender offer, merger, consolidation or other similar transaction, in one transaction or a series of related transactions, to a person or group of affiliated persons, of Ordinary Shares, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company or the surviving entity); (ix) entry by the undersigned into any trading plan established pursuant to Rule 10b5-1 under the Exchange Act; (x) the transfer of Restricted Securities to the Company in connection with the termination of the undersigned's employment or other service relationship with the Company, pursuant to agreements under which the Company has the option to repurchase such shares or a right of first refusal with respect to transfers of such shares; or (xi) the transfer to any corporation, partnership, limited liability company or other entity with whom the transferor shares in common an investment manager or advisor, in each case who has investment discretionary authority with respect to the transferor's and such other entity's investments pursuant to an investment management, investment advisory or similar agreement; provided, however, that (a) in the case of clause (i), (ii), (iii), (iv), (vi) or (xi) above, it shall be a condition to the transfer or disposition that the donee, trustee, heir, distributee or other transferee, as the case may be, agrees to be bound in writing to the restrictions set forth herein during the Lock-Up Period, (b) any transfer or disposition pursuant to clause (i), (ii), (iii), (iv), (vi) or (xi) above shall not involve a disposition for value and (c) in the case of any transfer or distribution pursuant to clause (i), (ii), (iii), (iv), (v), (vii) or (xi) above, no filing by the undersigned or any other party under the Exchange Act or other public announcement shall be required or made voluntarily during the Lock-Up Period in connection with such transfer or distribution (other than (x) a filing on a Form 5 made after the expiration of the Lock-Up Period, and (y) a required filing on Schedule 13D, Schedule 13G or Form 13F under the Exchange Act if the undersigned is not an officer or director of the Company, so long as such required filing includes a reasonably detailed explanation of such transfer or distribution); and (d) in the case of clause (x) above, such trading plan does not provide for any sales or other dispositions of Restricted Securities during the Lock-Up Period and no public announcement or filing under the Exchange Act or otherwise is made by or on behalf of the undersigned or the Company regarding the establishment of, or sales under, such plan during the Lock-Up Period (other than a required filing on Schedule 13D, Schedule 13G or Form 13F under the Exchange Act, if the undersigned is not an officer or director of the Company, so long as such required filing includes a statement to the effect that no transfers will be made during the Lock-Up Period). For the purposes of this Lock-Up Agreement, "immediate family" shall mean any relationship by blood, marriage, domestic partnership or adoption, not more remote than first cousin.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of any Ordinary Shares owned either of record or beneficially by the undersigned, including rights to receive notice of the Offering.

This Lock-Up Agreement shall automatically terminate and become null and void (i) at such time as the Representatives, on the one hand, or the Company, on the other hand, advises the other in writing, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Offering, (ii) upon the termination of the Underwriting Agreement before the closing of the Offering, or (iii) on September 1, 2019, if the Offering shall not have closed by such date.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned. The undersigned understands that the Underwriters are entering into the Underwriting Agreement and proceeding with the Offering in reliance upon this Lock-Up Agreement.

[Remainder of page intentionally left blank]

This Lock-Up Agreement and any claim, controversy or dispute arising under or related to this Lock-Up Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be performed entirely within such state.		
	Very truly yours,	
	Name of Officer or Director	
	(Print exact name)	
	By:	
	Signature	



16 Abba Hillel Silver Rd., Ramat Gan, 5250608, Israel Telephone. + 972 3 6103100 Fax. + 972 3 6103111 Web Site. www.meitar.com

June 24, 2019

Gamida Cell Ltd. 5 Nahum Heftsadie Street, Givaat Shaul Jerusalem 91340 Israel

Re: Gamida Cell Ltd.

#### Ladies and Gentlemen:

We have acted as Israeli counsel for Gamida Cell Ltd., an Israeli company (the "Company"), in connection with the underwritten public offering by the Company, contemplating (i) the issuance and sale by the Company of an aggregate of 4,040,000 ordinary shares, par value NIS 0.01 per share ("Ordinary Shares") of the Company (the "Offering Shares") and (ii) the potential issuance and sale by the Company of up to an additional 606,000 Ordinary Shares (the "Additional Shares" and, collectively with the Offering Shares, the "Shares"), that are subject to an option to purchase additional shares proposed to be granted by the Company to the underwriters of the offering (the "Offering"). This opinion letter is rendered pursuant to Item 8(a) of Form F-1 promulgated by the United States Securities and Exchange Commission (the "SEC") and Items 601(b)(5) and (b)(23) of the SEC's Regulation S-K promulgated under the United States Securities Act of 1933, as amended (the "Securities Act").

In connection herewith, we have examined the originals, or photocopies or copies, certified or otherwise identified to our satisfaction, of: (i) the form of the registration statement on Form F-1, filed by the Company with the SEC under the Securities Act (as amended through the date hereof, the "**Registration Statement**") and to which this opinion is attached as an exhibit; (ii) a copy of the articles of association of the Company, as currently in effect; (iii) resolutions of the board of directors (the "**Board**") of the Company which have heretofore been approved and relate to the Registration Statement and other actions to be taken in connection with the Offering; and (iv) such other corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials and of officers of the Company as we have deemed relevant and necessary as a basis for the opinions hereafter set forth. We have also made inquiries of such officers as we have deemed relevant and necessary as a basis for the opinions hereafter set forth.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, confirmed as photostatic copies and the authenticity of the originals of such latter documents. As to all questions of fact material to these opinions that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

Based upon and subject to the foregoing, we are of the opinion that upon payment to the Company of the consideration per Share in such amount and form as shall be determined by the Board or an authorized committee thereof, the Shares, when issued and sold in the Offering as described in the Registration Statement, will be duly authorized, validly issued, fully paid and non-assessable.



Members of our firm are admitted to the Bar in the State of Israel, and we do not express any opinion as to the laws of any other jurisdiction. This opinion is limited to the matters stated herein and no opinion is implied or may be inferred beyond the matters expressly stated.

We consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to our firm appearing under the caption "Legal Matters" and "Enforceability of Civil Liabilities" in the prospectus forming part of the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act, the rules and regulations of the SEC promulgated thereunder or Item 509 of the SEC's Regulation S-K promulgated under the Securities Act.

This opinion letter is rendered as of the date hereof and we disclaim any obligation to advise you of facts, circumstances, events or developments that may be brought to our attention after the date of the Prospectus that may alter, affect or modify the opinions expressed herein.

Very truly yours,

/s/ Meitar Liquornik Geva Leshem Tal

Meitar Liquornik Geva Leshem Tal

# GAMIDA CELL LTD. 2017 SHARE INCENTIVE PLAN

*Unless otherwise defined, terms used herein shall have the meaning ascribed to them in Section 2 hereof.* 

#### 1. <u>PURPOSE; TYPES OF AWARDS; CONSTRUCTION</u>.

- 1.1. <u>Purpose</u>. The purpose of this 2017 Share Incentive Plan (as amended, this "<u>Plan</u>") is to afford an incentive to Service Providers of Gamida Cell Ltd., an Israeli company (together with any successor corporation thereto, the "<u>Company</u>"), or any Affiliate of the Company, which now exists or hereafter is organized or acquired by the Company or its Affiliates, to continue as Service Providers, to increase their efforts on behalf of the Company or its Affiliates and to promote the success of the Company's business, by providing such Service Providers with opportunities to acquire a proprietary interest in the Company by the issuance of Shares or restricted Shares ("<u>Restricted Shares</u>") of the Company, and by the grant of options to purchase Shares ("<u>Options</u>"), Restricted Share Units ("<u>RSUs</u>") and other Share-based Awards pursuant to Sections 11 through 13 of this Plan.
- 1.2. <u>Types of Awards</u>. This Plan is intended to enable the Company to issue Awards under various tax regimes, including:
- (i) pursuant and subject to the provisions of Section 102 of the Ordinance (or the corresponding provision of any subsequently enacted statute, as amended from time to time), and all regulations and interpretations adopted by any competent authority, including the Israeli Income Tax Authority (the "<u>ITA</u>"), including the Income Tax Rules (Tax Benefits in Stock Issuance to Employees) 5763-2003 or such other rules so adopted from time to time (the "<u>Rules</u>") (such Awards that are intended to be (as set forth in the Award Agreement) and which qualify as such under Section 102 of the Ordinance and the Rules, "<u>102 Awards</u>");
- (ii) pursuant to Section 3(9) of the Ordinance or the corresponding provision of any subsequently enacted statute, as amended from time to time (such Awards, "3(9) Awards");
- (iii) Incentive Stock Options within the meaning of Section 422 of the Code, or the corresponding provision of any subsequently enacted United States federal tax statute, as amended from time to time, to be granted to Employees who are deemed to be residents of the United States, for purposes of taxation, or are otherwise subject to U.S. Federal income tax (such Awards that are intended to be (as set forth in the Award Agreement) and which qualify as an incentive stock option within the meaning of Section 422(b) of the Code, "Incentive Stock Options"); and
- (iv) Awards not intended to be (as set forth in the Award Agreement) or which do not qualify as an Incentive Stock Option to be granted to Service Providers who are deemed to be residents of the United States for purposes of taxation, or are otherwise subject to U.S. Federal income tax ("Nonqualified Stock Options").

In addition to the issuance of Awards under the relevant tax regimes in the United States of America and the State of Israel, and without derogating from the generality of Section 25, this Plan contemplates issuances to Grantees in other jurisdictions or under other tax regimes with respect to which the Committee is empowered, but is not required, to make the requisite adjustments in this Plan and set forth the relevant conditions in an appendix to this Plan or in the Company's agreement with the Grantee in order to comply with the requirements of such other tax regimes.

- 1.3. <u>Company Status</u>. This Plan contemplates the issuance of Awards by the Company, both as a private and public company.
- 1.4. <u>Construction</u>. To the extent any provision herein conflicts with the conditions of any relevant tax law, rule or regulation which are relied upon for tax relief in respect of a particular Award to a Grantee, the Committee is empowered, but is not required, hereunder to determine that the provisions of such law, rule or regulation shall prevail over those of this Plan and to interpretand enforce such prevailing provisions.

#### DEFINITIONS.

- 2.1. Terms Generally. Except when otherwise indicated by the context, (i) the singular shall include the plural and the plural shall include the singular; (ii) any pronoun shall include the corresponding masculine, feminine and neuter forms; (iii) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, restated, supplemented or otherwise modified (subject to any restrictions on such amendments, restatements, supplements or modifications set forth therein or herein), (iv) references to any law, constitution, statute, treaty, regulation, rule or ordinance, including any section or other part thereof shall refer to it as amended from time to time and shall include any successor thereof, (v) reference to a "company" or "entity" shall include a, partnership, corporation, limited liability company, association, trust, unincorporated organization, or a government or agency or political subdivision thereof, and reference to a "person" shall mean any of the foregoing or an individual, (vi) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Plan in its entirety, and not to any particular provision hereof, (vii) all references herein to Sections shall be construed to refer to Sections to this Plan; (viii) the words "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; and (ix) use of the term "or" is not intended to be exclusive.
  - 2.2. Defined Terms. The following terms shall have the meanings ascribed to them in this Section 2:
- 2.3. "<u>Affiliate</u>" shall mean, (i) with respect to any person, any other person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such person (with the term "control" or "controlled by" within the meaning of Rule 405 of Regulation C under the Securities Act), including, without limitation, any Parent or Subsidiary, or (ii) for the purpose of 102 Awards, "<u>Affiliate</u>" shall only mean an "employing company" within the meaning and subject to the conditions of Section 102(a) of the Ordinance.
- 2.4. "<u>Applicable Law</u>" shall mean any applicable law, rule, regulation, statute, pronouncement, policy, interpretation, judgment, order or decree of any federal, provincial, state or local governmental, regulatory or adjudicative authority or agency, of any jurisdiction, and the rules and regulations of any stock exchange, over-the-counter market or trading system on which the Company's shares are then traded or listed.
  - 2.5. "Award" shall mean any Option, Restricted Share, RSUs or any other Share-based award granted under this Plan.
  - 2.6. "Board" shall mean the Board of Directors of the Company.
  - 2.7. Reserved.
- 2.8. "Code" shall mean the United States Internal Revenue Code of 1986, and any applicable regulations promulgated thereunder, all as amended.
- 2.9. "Committee" shall mean a committee established or appointed by the Board to administer this Plan, subject to Section 3.1.

- 2.10. "Companies Law" shall mean the Israel Companies Law, 5759-1999, and the regulations promulgated thereunder, all as amended from time to time.
  - 2.11. "Controlling Shareholder" shall have the meaning set forth in Section 32(9) of the Ordinance.
- 2.12. "<u>Disability</u>" shall mean (i) the inability of a Grantee to engage in any substantial gainful activity or to perform the major duties of the Grantee's position with the Company or its Affiliates by reason of any medically determinable physical or mental impairment which has lasted or can be expected to last for a continuous period of not less than 12 months (or such other period as determined by the Committee), as determined by a qualified doctor acceptable to the Company, (ii) if applicable, a "permanent and total disability" as defined in Section 22(e)(3) of the Code or Section 409A(a)(2)(c)(i) of the Code, as amended from time to time, or (iii) as defined in a policy of the Company that the Committee deems applicable to this Plan, or that makes reference to this Plan, for purposes of this definition.
- 2.13. "<u>Employee</u>" shall mean any person treated as an employee (including an officer or a director who is also treated as an employee) in the records of the Company or any of its Affiliates (and in the case of 102 Awards, subject to Section 9.3 or in the case of Incentive Stock Options, who is an employee for purposes of Section 422 of the Code); <u>provided, however</u>, that neither service as a director nor payment of a director's fee shall be sufficient to constitute employment for purposes of this Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of a person's rights, if any, under this Plan as of the time of the Company's determination, all such determinations by the Company shall be final, binding and conclusive, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination.
- 2.14. "employment", "employed" and words of similar import shall be deemed to refer to the employment of Employees or to the services of any other Service Provider, as the case may be.
- 2.15. "exercise" "exercised" and words of similar import, when referring to an Award that does not require exercise or that is settled upon vesting (such as may be the case with RSUs or Restricted Shares, if so determined in their terms), shall be deemed to refer to the vesting of such an Award (regardless of whether or not the wording included reference to vesting of such an Awards explicitly).
- 2.16. "<u>Exercise Period</u>" shall mean the period, commencing on the date of grant of an Award, during which an Award shall be exercisable, subject to any vesting provisions thereof (including any acceleration thereof, if any) and subject to the termination provisions hereof.
- 2.17. "Exercise Price" shall mean the exercise price for each Share covered by an Option or the purchase price for each Share covered by any other Award.
- 2.18. "Fair Market Value" shall mean, as of any date, the value of a Share or other property as determined by the Board, in its discretion, subject to the following: (i) if, on such date, the Shares are listed on any securities exchange, the average closing sales price per Share on which the Shares are principally traded over the thirty (30) day calendar period preceding the subject date (utilizing all trading days during such 30 calendar day period), as reported in The Wall Street Journal or such other source as the Company deems reliable; (ii) if, on such date, the Shares are then quoted in an over-the-counter market, the average of the closing bid and asked prices for the Shares in that market during the thirty (30) day calendar period preceding the subject date (utilizing all trading days during such 30 calendar day period), as reported in The Wall Street Journal or such other source as the Company deems reliable; and (iii) if, on such date, the Shares are not then listed on a securities exchange or quoted in an over-the-counter market, or in case of any other property, such value as the Committee, in its sole discretion, shall determine, with full authority to determine the method for making such determination and which determination shall be conclusive and binding on all parties, and shall be made after such consultations with outside legal, accounting and other experts as the Committee may deem advisable; provided, however, that, if applicable, the Fair Market Value of the Shares shall be determined in a manner that satisfies the applicable requirements of and subject to Section 409A of the Code, and with respect to Incentive Stock Options, in a manner that satisfies the applicable requirements of and subject to Section 422 of the Code, subject to Section 422(c)(7) of the Code. The Committee shall maintain a written record of its method of determining such value. If the Shares are listed or quoted on more than one established stock exchange or over-the-counter market, the Committee shall determine the principal such exchange or market and utilize the price of the Shares on that exchange or market (determined as per the method described in clauses (i) or (ii) above, as applicable) for the purpose of determining Fair Market Value.

- 2.19. "Grantee" shall mean a person who has been granted an Award(s) under this Plan.
- 2.20. "Ordinance" shall mean the Israeli Income Tax Ordinance (New Version) 5271-1961, and the regulations and rules (including the Rules) promulgated thereunder, all as amended from time to time.
- 2.21. "Parent" shall mean any company (other than the Company), which now exists or is hereafter organized, (i) in an unbroken chain of companies ending with the Company if, at the time of granting an Award, each of the companies (other than the Company) owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, that is a "parent corporation" of the Company, as defined in Section 424(e) of the Code.
- 2.22. "Retirement" shall mean a Grantee's retirement pursuant to Applicable Law or in accordance with the terms of any tax-qualified retirement plan maintained by the Company or any of its Affiliates in which the Grantee participates or is subject to.
- 2.23. "Securities Act" shall mean the U.S. Securities Act of 1933, and the rules and regulations promulgated thereunder, all as amended from time to time.
- 2.24. "Service Provider" shall mean an Employee, director, officer, consultant, advisor and any other person or entity who provides services to the Company or any Parent, Subsidiary or Affiliate thereof. Service Providers shall include prospective Service Providers to whom Awards are granted in connection with written offers of an employment or other service relationship with the Company or any Parent, Subsidiary or any Affiliates thereof, provided however that such employment or service shall have actually commenced.
- 2.25. "Shares" shall mean Ordinary Shares, nominal value NIS 0.01 each, of the Company (as adjusted for stock split, reverse stock split, bonus shares, combination or other recapitalization events), or shares of such other class of shares of the Company as shall be designated by the Board in respect of the relevant Award(s). "Shares" include any securities or property issued or distributed with respect thereto.
- 2.26. "<u>Subsidiary</u>" shall mean any company (other than the Company), which now exists or is hereafter organized or acquired by the Company, (i) in an unbroken chain of companies beginning with the Company if, at the time of granting an Award, each of the companies other than the last company in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, that is a "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.
- 2.27. "<u>Ten Percent Shareholder</u>" shall mean a Grantee who, at the time an Award is granted to the Grantee, owns shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Company or any Parent or Subsidiary, within the meaning of Section 422(b)(6) of the Code.

- 2.28. "<u>Trustee</u>" shall mean the trustee appointed by the Committee to hold the Awards (and, in relation with 102 Awards, approved by the ITA), if so appointed.
- 2.29. <u>Other Defined Terms</u>. The following terms shall have the meanings ascribed to them in the Sections set forth below:

<u>Term</u>	Section
102 Awards	1.2(i)
102 Capital Gains Track Awards	9.1
102 Non-Trustee Awards	9.2
102 Ordinary Income Track Awards	9.1
102 Trustee Awards	9.1
3(9) Awards	1.2(ii)
Award Agreement	6
Cause	6.6.4.4
Company	1.1
Effective Date	24.1
Election	9.2
Eligible 102 Grantees	9.3.1
Incentive Stock Options	1.2(iii)
ITA	1.1(i)
Market Stand-Off	17.1
Market Stand-Off Period	17.1
Merger/Sale	14.2
Nonqualified Stock Options	1.2(iv)
Plan	1.1
Recapitalization	14.1
Required Holding Period	9.5
Restricted Period	11.2
Restricted Share Agreement	11
Restricted Share Unit Agreement	12
Restricted Shares	1.1
RSUs	1.1
Rules	1.1(i)
Securities	17.1
Successor Corporation	14.2.1
Withholding Obligations	18.5
_	

#### 3. ADMINISTRATION.

- 3.1. To the extent permitted under Applicable Law, the Articles of Association and any other governing document of the Company, this Plan shall be administered by the Committee. In the event that the Board does not appoint or establish a committee to administer this Plan, this Plan shall be administered by the Board and all references herein to the Committee shall be deemed as references to the Board. In the event that an action necessary for the administration of this Plan is required under Applicable Law to be taken by the Board without the right of delegation, or if such action or power was explicitly reserved by the Board in appointing, establishing and empowering the Committee, then such action shall be so taken by the Board. In any such event, all references herein to the Committee shall be construed as references to the Board. Even if such a Committee was appointed or established, the Board may take any actions that are stated to be vested in the Committee, and shall not be restricted or limited from exercising all rights, powers and authorities under this Plan or Applicable Law.
- 3.2. The Board shall appoint the members of the Committee, may from time to time remove members from, or add members to, the Committee, and shall fill vacancies in the Committee, however caused, provided that the composition of the Committee shall at all times be in compliance with any mandatory requirements of Applicable Law, the Articles of Association and any other governing document of the Company. The Committee may select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. The Committee may appoint a Secretary, who shall keep records of its meetings, and shall make such rules and regulations for the conduct of its business as it shall deem advisable and subject to mandatory requirements of Applicable Law.
- 3.3. Subject to the terms and conditions of this Plan, any mandatory provisions of Applicable Law and any provisions of any Company policy required under mandatory provisions of Applicable Law, and in addition to the Committee's powers contained elsewhere in this Plan, the Committee shall have full authority, in its discretion, from time to time and at any time, to determine any of the following, or to recommend to the Board any of the following if it is not authorized to take such action according to Applicable Law:
  - (i) eligible Grantees,
- (ii) grants of Awards and setting the terms and provisions of Award Agreements (which need not be identical) and any other agreements or instruments under which Awards are made, including, but not limited to, the number of Shares underlying each Award and the class of Shares underlying each Award (if more than one class was designated by the Board),
  - (iii) the time or times at which Awards shall be granted,
- (iv) the terms, conditions and restrictions applicable to each Award (which need not be identical) and any Shares acquired upon the exercise or (if applicable) vesting thereof, including, without limitation, (1) designating Awards under Section 1.2; (2) the vesting schedule, the acceleration thereof and terms and conditions upon which Awards may be exercised or become vested, (3) the Exercise Price, (4) the method of payment for Shares purchased upon the exercise or (if applicable) vesting of the Awards, (5) the method for satisfaction of any tax withholding obligation arising in connection with the Awards or such Shares, including by the withholding or delivery of Shares, (6) the time of the expiration of the Awards, (7) the effect of the Grantee's termination of employment with the Company or any of its Affiliates, and (8) all other terms, conditions and restrictions applicable to the Award or the Shares not inconsistent with the terms of this Plan,
- (v) to accelerate, continue, extend or defer the exercisability of any Award or the vesting thereof, including with respect to the period following a Grantee's termination of employment or other service,

- (vi) the interpretation of this Plan and any Award Agreement and the meaning, interpretation and applicability of terms referred to in Applicable Laws,
- (vii) policies, guidelines, rules and regulations relating to and for carrying out this Plan, and any amendment, supplement or rescission thereof, as it may deem appropriate,
- (viii) to adopt supplements to, or alternative versions of, this Plan, including, without limitation, as it deems necessary or desirable to comply with the laws of, or to accommodate the tax regime or custom of, foreign jurisdictions whose citizens or residents may be granted Awards,
  - (ix) the Fair Market Value of the Shares or other property,
- (x) the tax track (capital gains, ordinary income track or any other track available under the Section 102 of the Ordinance) for the purpose of 102 Awards,
- (xi) the authorization and approval of conversion, substitution, cancellation or suspension under and in accordance with this Plan of any or all Awards or Shares,
- (xii) the amendment, modification, waiver or supplement of the terms of each outstanding Award (with the consent of the applicable Grantee, if such amendments refers to the increase of the Exercise Price of Awards or reduction of the number of Shared underlying an Award (but, in each case, other than as a result of an adjustment or exercise of rights in accordance with Section 14)) unless otherwise provided under the terms of this Plan,
- (xiii) without limiting the generality of the foregoing, and subject to the provisions of Applicable Law, to grant to a Grantee, who is the holder of an outstanding Award, in exchange for the cancellation of such Award, a new Award having an Exercise Price lower than that provided in the Award so canceled and containing such other terms and conditions as the Committee may prescribe in accordance with the provisions of this Plan or to set a new Exercise Price for the same Award lower than that previously provided in the Award,
- (xiv) to correct any defect, supply any omission or reconcile any inconsistency in this Plan or any Award Agreement and all other determinations and take such other actions with respect to this Plan or any Award as it may deem advisable to the extent not inconsistent with the provisions of this Plan or Applicable Law, and
- (xv) any other matter which is necessary or desirable for, or incidental to, the administration of this Plan and any Award thereunder.
- 3.4. The authority granted hereunder includes the authority to modify Awards to eligible individuals who are foreign nationals or are individuals who are employed outside Israel to recognize differences in local law, tax policy or custom, in order to effectuate the purposes of this Plan but without amending this Plan.
- 3.5. The Board and the Committee shall be free at all times to make such determinations and take such actions as they deem fit. The Board and the Committee need not take the same action or determination with respect to all Awards, with respect to certain types of Awards, with respect to all Service Providers or any certain type of Service Providers and actions and determinations may differ as among the Grantees, and as between the Grantees and any other holders of securities of the Company.
- 3.6. All decisions, determinations, and interpretations of the Committee, the Board and the Company under this Plan shall be final and binding on all Grantees (whether before or after the issuance of Shares pursuant to Awards), unless otherwise determined by the Committee, the Board or the Company, respectively. The Committee shall have the authority (but not the obligation) to determine the interpretation and applicability of Applicable Laws to any Grantee or any Awards. No member of the Committee or the Board shall be liable to any Grantee for any action taken or determination made in good faith with respect to this Plan or any Award granted hereunder.

3.7. Any officer or authorized signatory of the Company shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election which is the responsibility of or which is allocated to the Company herein, provided such person has apparent authority with respect to such matter, right, obligation, determination or election. Such person or authorized signatory shall not be liable to any Grantee for any action taken or determination made in good faith with respect to this Plan or any Award granted hereunder.

#### 4. <u>ELIGIBILITY</u>.

Awards may be granted to Service Providers of the Company or any Affiliate thereof, taking into account, at the Committee's discretion and without an obligation to do so, the qualification under each tax regime pursuant to which such Awards are granted, subject to the limitation on the granting of Incentive Stock Options set forth in Section 8.1. A person who has been granted an Award hereunder may be granted additional Awards, if the Committee shall so determine, subject to the limitations herein. However, eligibility in accordance with this Section 4 shall not entitle any person to be granted an Award, or, having been granted an Award, to be granted an additional Award.

Awards may differ in number of Shares covered thereby, the terms and conditions applying to them or on the Grantees or in any other respect (including, that there should not be any expectation (and it is hereby disclaimed) that a certain treatment, interpretation or position granted to one shall be applied to the other, regardless of whether or not the facts or circumstances are the same or similar).

#### 5. <u>SHARES</u>.

- 5.1. The maximum aggregate number of Shares that may be issued pursuant to Awards under this Plan (the "Pool") shall be the sum of (a) 2,809,338 Shares plus (and without the need to further amend the Plan) (b) on January 1st, 2019 and on January 1st of each calendar year thereafter during the term of the Plan, a number of Shares equal to the lesser of: (i) three and a half percent (3.5%) of the total number of Shares outstanding as of the end of the last day of the immediately preceding calendar year, and (ii) an amount determined by the Board, if so determined prior to the January 1st of the calendar year in which the increase will occur (in each case, without the need to amend the Plan in case of such determination); in all events subject to adjustment as provided in Section 14.1. The total number of Shares that may be issued pursuant to Incentive Stock Options granted under this Plan shall be the number of Shares determined in accordance with this Section 5.2, as adjusted in accordance with Section 5.2 and pursuant to Section 14.1. The Board may, at its discretion, reduce the number of Shares that may be issued pursuant to Awards under this Plan, at any time (provided that such reduction does not derogate from any issuance of Shares in respect Awards then outstanding).
- 5.2. Any Shares (a) underlying an Award granted hereunder that has expired, or was cancelled, terminated, forfeited or, repurchased or settled in cash in lieu of issuance of Shares, for any reason, without having been exercised; (b) if permitted by the Company, tendered to pay the Exercise Price of an Award, or withholding tax obligations with respect to an Award; or (c) if permitted by the Company, subject to an Award that are not delivered to a Grantee because such Shares are withheld to pay the Exercise Price of such Award, or withholding tax obligations with respect to such Award; shall automatically, and without any further action on the part of the Company or any Grantee, again be available for grant of Awards and Shares issued upon exercise of (if applicable) vesting thereof for the purposes of this Plan (unless this Plan shall have been terminated) or unless the Board determines otherwise. Such Shares may, in whole or in part, be authorized but unissued Shares, treasury shares (dormant shares) or Shares otherwise that shall have been or may be repurchased by the Company (to the extent permitted pursuant to the Companies Law).

- 5.3. Any Shares under the Pool that are not subject to outstanding or exercised Awards at the termination of this Plan shall cease to be reserved for the purpose of this Plan.
- 5.4. From and after the Effective Date, no further grants or awards shall be made under any prior equity incentive plans of the Company; however, Awards made under any prior equity incentive plan of the Company before the Effective Date shall continue in effect in accordance with their terms.

# 6. TERMS AND CONDITIONS OF AWARDS.

Each Award granted pursuant to this Plan shall be evidenced by a written or electronic agreement between the Company and the Grantee or a written or electronic notice delivered by the Company (the "Award Agreement"), in substantially such form or forms and containing such terms and conditions, as the Committee shall from time to time approve. The Award Agreement shall comply with and be subject to the following general terms and conditions and the provisions of this Plan (except for any provisions applying to Awards under different tax regimes), unless otherwise specifically provided in such Award Agreement, or the terms referred to in other Sections of this Plan applying to Awards under such applicable tax regimes, or terms prescribed by Applicable Law. Award Agreements need not be in the same form and may differ in the terms and conditions included therein.

- 6.1. <u>Number of Shares</u>. Each Award Agreement shall state the number of Shares covered by the Award.
- 6.2. <u>Type of Award</u>. Each Award Agreement may state the type of Award granted thereunder, provided that the tax treatment of any Award, whether or not stated in the Award Agreement, shall be as determined in accordance with Applicable Laws.
- 6.3. <u>Exercise Price</u>. Each Award Agreement shall state the Exercise Price, if applicable. Unless otherwise set forth in this Plan, an Exercise Price of an Award of less than the nominal value of the Shares (if shares bear a nominal value) shall comply with Section 304 of the Companies Law. Subject to Sections 3, 7.2 and 8.2 and to the foregoing, the Committee may reduce the Exercise Price of any outstanding Award, on terms and subject to such conditions as it deems advisable. The Exercise Price shall also be subject to adjustment as provided in Section 14 hereof.
- Manner of Exercise. An Award may be exercised, as to any or all Shares as to which the Award has become 6.4. exercisable, by written notice delivered in person or by mail (or such other methods of delivery prescribed by the Company) to the Chief Financial Officer of the Company or, if no such officer is then incumbent, to the Chief Executive Officer of the Company or to such other person as determined by the Committee, or in any other manner as the Committee shall prescribe from time to time, specifying the number of Shares with respect to which the Award is being exercised (which may be equal to or lower than the aggregate number of Shares that have become exercisable at such time, subject to the last sentence of this Section), accompanied by payment of the aggregate Exercise Price for such Shares in the manner specified in the following sentence. The Exercise Price shall be paid in full with respect to each Share, at the time of exercise, either in (i) cash, (ii) if the Company's shares are listed for trading on any securities exchange or over-the-counter market, and if the Committee so determines, all or part of the Exercise Price and any withholding taxes may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to a securities broker approved by the Company to sell Shares and to deliver all or part of the sales proceeds to the Company or the Trustee, (iii) if the Company's shares are listed for trading on any securities exchange or over-the-counter market, and if the Committee so determines, all or part of the Exercise Price and any withholding taxes may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to pledge Shares to a securities broker or lender approved by the Company. as security for a loan, and to deliver all or part of the loan proceeds to the Company or the Trustee, or (iv) in such other manner as the Committee shall determine, which may include procedures for cashless exercise. For as long as the Company's shares are not listed for trading on any securities exchange or over-the-counter market and unless the Committee determines otherwise, a Grantee may not exercise Awards unless the aggregate Exercise Price thereof is equal to or in excess of the lower of: (a) the aggregate Exercise Price for all Shares as to which the Award has become exercisable at such time; or (b) US\$2,000.

# 6.5. <u>Term and Vesting of Awards</u>.

- 6.5.1. Each Award Agreement shall provide the vesting schedule for the Award as determined by the Committee. The Committee shall have the authority to determine the vesting schedule and accelerate the vesting of any outstanding Award at such time and under such circumstances as it, in its sole discretion, deems appropriate. Unless otherwise resolved by the Committee and stated in the Award Agreement, and subject to Sections 6.6 and 6.7 hereof, Awards shall vest and become exercisable under the following schedule: twenty-five percent (25%) of the Shares covered by the Award, on the first anniversary of the vesting commencement date determined by the Committee (and in the absence of such determination, of date on which such Award was granted), and six and one-quarter percent (6.25%) of the Shares covered by the Award at the end of each subsequent three-month period thereafter over the course of the following three (3) years; provided that the Grantee remains continuously as a Service Provider of the Company or its Affiliates throughout such vesting dates.
- 6.5.2. The Award Agreement may contain performance goals and measurements (which, in case of 102 Awards, shall, if then required, be subject to obtaining a specific tax ruling or determination from the ITA), and the provisions with respect to any Award need not be the same as the provisions with respect to any other Award. Such performance goals may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee. The Committee may adjust performance goals pursuant to Awards previously granted to take into account changes in law and accounting and tax rules and to make such adjustments as the Committee deems necessary or appropriate to reflect the inclusion or the exclusion of the impact of extraordinary or unusual items, events or circumstances.
- 6.5.3. The Exercise Period of an Award will be 10 years from the date of grant of the Award, unless otherwise determined by the Committee and stated in the Award Agreement, but subject to the vesting provisions described above and the early termination provisions set forth in Sections 6.6 and 6.7 hereof. At the expiration of the Exercise Period, any Award, or any part thereof, that has not been exercised within the term of the Award and the Shares covered thereby not paid for in accordance with this Plan and the Award Agreement shall terminate and become null and void, and all interests and rights of the Grantee in and to the same shall expire.

#### 6.6. Termination.

- 6.6.1. Unless otherwise determined by the Committee, and subject to Section 6.7 hereof, an Award may not be exercised unless the Grantee is then a Service Provider of the Company or an Affiliate thereof or, in the case of an Incentive Stock Option, a company or a parent or subsidiary company of such company issuing or assuming the Option in a transaction to which Section 424(a) of the Code applies, and unless the Grantee has remained continuously so employed since the date of grant of the Award and throughout the vesting dates.
- In the event that the employment or service of a Grantee shall terminate (other than by reason of death, Disability or Retirement), all Awards of such Grantee that are unvested at the time of such termination shall terminate on the date of such termination, and all Awards of such Grantee that are vested and exercisable at the time of such termination may be exercised within up to three (3) months after the date of such termination (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan; provided, however, that if the Company (or the Subsidiary or Affiliate, when applicable) shall terminate the Grantee's employment or service for Cause (as defined below) or if at any time during the Exercise Period or thereafter (whether prior to or after termination of employment or service, and whether or not the Grantee's employment or service is terminated by either party as a result thereof), facts or circumstances arise or are discovered with respect to the Grantee that would have constituted Cause, all Awards theretofore granted to such Grantee (whether vested or not) shall, to the extent not theretofore exercised, terminate on the date of such termination (or on such subsequent date on which such facts or circumstances arise or are discovered, as the case may be) unless otherwise determined by the Committee; and any Shares issued upon exercise or (if applicable) vesting of Awards (including other Shares or securities issued or distributed with respect thereto), whether held by the Grantee or by the Trustee for the Grantee's benefit, shall be deemed to be irrevocably offered for sale to the Company, any of its Affiliates or any person designated by the Company to purchase, at the Company's election and subject to Applicable Law, either for no consideration, for the nominal value of such Shares (if such Shares bear a nominal value) or against payment of the Exercise Price previously received by the Company for such Shares upon their issuance, as the Committee deems fit, upon written notice to the Grantee at any time after the Grantee's termination of employment or service. Such Shares or other securities shall be sold and transferred within 30 days from the date of the Company's notice of its election to exercise its right. If the Grantee fails to transfer such Shares or other securities to the Company, the Company, at the decision of the Committee, shall be entitled to forfeit or repurchase such Shares and to authorize any person to execute on behalf of the Grantee any document necessary to effect such transfer, whether or not the share certificates are surrendered. The Company shall have the right and authority to affect the above either by: (i) repurchasing all of such Shares or other securities held by the Grantee or by the Trustee for the benefit of the Grantee, or designate any other person who shall have the right and authority to purchase all of such Shares or other securities, for the Exercise Price paid for such Shares, the nominal value of such Shares (if such Shares bear a nominal value) or for no payment or consideration whatsoever, as the Committee deems fit; (ii) forfeiting all such Shares or other securities; (iii) redeeming all such Shares or other securities, for the Exercise Price paid for such Shares, the nominal value of such Shares (if such Shares bear a nominal value) or for no payment or consideration whatsoever, as the Committee deems fit; (iv) taking action in order to have such Shares or other securities converted into deferred shares entitling their holder only to their nominal value (if such Shares bear a nominal value) upon liquidation of the Company; or (v) taking any other action which may be required in order to achieve similar results; all as shall be determined by the Committee, at its sole and absolute discretion, and the Grantee is deemed to irrevocably empower the

Company or any person which may be designated by it to take any action by, in the name of or on behalf of the Grantee to comply with and give effect to such actions (including, voting such shares, filling in, signing and delivering share transfer deeds, etc.).

6.6.3. Notwithstanding anything to the contrary, the Committee, in its absolute discretion, may, on such terms and conditions as it may determine appropriate, extend the periods for which Awards held by any Grantee may continue to vest and be exercisable; it being clarified that such Awards may lose their entitlement to certain tax benefits under Applicable Law as a result of the modification of such Awards and/or in the event that the Award is exercised beyond the later of: (i) three (3) months after the date of termination of the employment or service relationship; or (ii) the applicable period under Section 6.7 below with respect to a termination of the employment or service relationship because of the death, Disability or Retirement of Grantee.

#### 6.6.4. For purposes of this Plan:

- 6.6.4.1. a termination of employment or service of a Grantee shall not be deemed to occur (except to the extent required by the Code with respect to the Incentive Stock Option status of an Option) in case of (i) a transition or transfer of a Grantee among the Company and its Affiliates, (ii) a change in the capacity in which the Grantee is employed or renders service to the Company or any of its Affiliates or a change in the identity of the employing or engagement entity among the Company and its Affiliates, provided, in case of (i) and (ii) above, that the Grantee has remained continuously employed by and/or in the service of the Company and its Affiliates since the date of grant of the Award and throughout the vesting period; or (iii) if the Grantee takes any unpaid leave as set forth in Section 6.8(i) below.
- 6.6.4.2. An entity or an Affiliate thereof assuming an Award or issuing in substitution thereof in a transaction to which Section 424(a) of the Code applies or in a Merger/Sale in accordance with Section 14 shall be deemed as an Affiliate of the Company for purposes of this Section 6.6, unless the Committee determines otherwise.
- 6.6.4.3. In the case of a Grantee whose principal employer or service recipient is a Subsidiary or Affiliate, the Grantee's employment shall also be deemed terminated for purposes of this Section 6.6 as of the date on which such principal employer or service recipient ceases to be a Subsidiary or Affiliate.
- The term "Cause" shall mean (irrespective of, and in addition to, any definition included in 6.6.4.4. any other agreement or instrument applicable to the Grantee, and unless otherwise determined by the Committee) any of the following: (i) any theft, fraud, embezzlement, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, falsification of any documents or records of the Company or any of its Affiliates, felony or similar act by the Grantee (whether or not related to the Grantee's relationship with the Company); (ii) an act of moral turpitude by the Grantee, or any act that causes significant injury to, or is otherwise adversely affecting, the reputation, business, assets, operations or business relationship of the Company (or a Subsidiary or Affiliate, when applicable); (iii) any breach by the Grantee of any material agreement with or of any material duty of the Grantee to the Company or any Subsidiary or Affiliate thereof (including breach of confidentiality, nondisclosure, non-use non-competition or non-solicitation covenants towards the Company or any of its Affiliates) or failure to abide by code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct); (iv) any act which constitutes a breach of a Grantee's fiduciary duty towards the Company or an Affiliate or Subsidiary, including disclosure of confidential or proprietary information thereof or acceptance or solicitation to receive unauthorized or undisclosed benefits, irrespective of their nature, or funds, or promises to receive either, from individuals, consultants or corporate entities that the Company or a Subsidiary does business with; (v) the Grantee's unauthorized use, misappropriation, destruction, or diversion of any tangible or intangible asset or corporate opportunity of the Company or any of its Affiliates (including, without limitation, the improper use or disclosure of confidential or proprietary information); or (vi) any circumstances that constitute grounds for termination for cause under the Grantee's employment or service agreement with the Company or Affiliate, to the extent applicable. For the avoidance of doubt, the determination as to whether a termination is for Cause for purposes of this Plan, shall be made in good faith by the Committee and shall be final and binding on the Grantee.

#### 6.7. <u>Death, Disability or Retirement of Grantee</u>.

- 6.7.1. If a Grantee shall die while employed by, or performing service for, the Company or its Affiliates, or within the three (3) month period (or such longer period of time as determined by the Board, in its discretion) after the date of termination of such Grantee's employment or service (or within such different period as the Committee may have provided pursuant to Section 6.6 hereof), or if the Grantee's employment or service shall terminate by reason of Disability, all Awards theretofore granted to such Grantee may (to the extent otherwise vested and exercisable and unless earlier terminated in accordance with their terms) be exercised by the Grantee or by the Grantee's estate or by a person who acquired the legal right to exercise such Awards by bequest or inheritance, or by a person who acquired the legal right to exercise such Awards in accordance with applicable law in the case of Disability of the Grantee, as the case may be, at any time within one (1) year (or such longer period of time as determined by the Committee, in its discretion) after the death or Disability of the Grantee (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan. In the event that an Award granted hereunder shall be exercised as set forth above by any person other than the Grantee, written notice of such exercise shall be accompanied by a certified copy of letters testamentary or proof satisfactory to the Committee of the right of such person to exercise such Award.
- 6.7.2. In the event that the employment or service of a Grantee shall terminate on account of such Grantee's Retirement, all Awards of such Grantee that are exercisable at the time of such Retirement may, unless earlier terminated in accordance with their terms, be exercised at any time within the three (3) month period after the date of such Retirement (or such different period as the Committee shall prescribe).
- 6.8. <u>Suspension of Vesting</u>. Unless the Committee provides otherwise, vesting of Awards granted hereunder shall be suspended during any unpaid leave of absence, other than in the case of any (i) leave of absence which was pre-approved by the Company explicitly for purposes of continuing the vesting of Awards, or (ii) transfers between locations of the Company or any of its Affiliates, or between the Company and any of its Affiliates, or any respective successor thereof. For clarity, for purposes of this Plan, military leave, statutory maternity or paternity leave or sick leave are not deemed unpaid leave of absence.
- 6.9. Securities Law Restrictions. Except as otherwise provided in the applicable Award Agreement or other agreement between the Service Provider and the Company, if the exercise of an Award following the termination of the Service Provider's employment or service (other than for Cause) would be prohibited at any time solely because the issuance of Shares would violate the registration requirements under the Securities Act or equivalent requirements under equivalent laws of other applicable jurisdictions, then the Award shall remain exercisable and terminate on the earlier of (i) the expiration of a period of three (3) months (or such longer period of time as determined by the Board, in its discretion) after the termination of the Service Provider's employment or service during which the exercise of the Award would not be in such violation, or (ii) the expiration of the term of the Award as set forth in the Award Agreement or pursuant to this Plan. In addition, unless otherwise provided in a Grantee's Award Agreement, if the sale of any Shares received upon exercise or (if applicable) vesting of an Award following the termination of the Grantee's employment or service (other than for Cause) would violate the Company's insider trading policy, then the Award shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Grantee's employment or service during which the exercise of the Award would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Award as set forth in the applicable Award Agreement or pursuant to this Plan.
- 6.10. <u>Voting Proxy</u>. Until immediately after the listing for trading on a stock exchange or market or trading system of the Company's (or the Successor Corporation's) shares, the Shares subject to an Award or to be issued pursuant to an Award or any other Securities, shall, unless otherwise determined by the Committee, be subject to an irrevocable proxy and power of attorney by the Grantee or the Trustee (if so requested from the Trustee), as the case may be, to the Company, which shall designate such person or persons (with a right of substitution) from time to time as determined by the Committee (and in the absence of such determination, the Chief Executive Officer of the Company or the Chairman of the Board, ex officio (or, in no Chairman is in office, any other member designated by the Board)). The Trustee is deemed to be instructed by the Grantee to sign such proxy, as requested by the Company. The proxy shall entitle the holder thereof to receive notices, vote and take such other actions in respect of the Shares or other Securities. Any person holding or exercising such voting proxies shall do so solely in his capacity as the proxy holder and not individually. All Awards granted hereunder shall be conditioned upon the execution of such irrevocable proxy in substantially the form prescribed by the Committee from time to time. So long as any such Shares are subject to such irrevocable proxy and power of attorney or held by a Trustee (and unless a proxy was given by the Trustee as aforesaid), (i) in any shareholders meeting or written consent in lieu thereof, such Shares shall be voted by the proxy holder (or the Trustee, as applicable), unless directed otherwise by the Board, in the same proportion as the result of the vote at the shareholders' meeting (or written consent in lieu thereof) in respect of which the Shares are being voted (whether an extraordinary or annual meeting, and whether of the share capital as one class or of any class thereof), and (ii) or in any act or consent of shareholders under the Company's Articles of Association or otherwise, such Shares shall be cast by the proxy holder (or the Trustee, as applicable), unless directed otherwise by the Board, in the same proportion as the result of the shareholders' act or consent. The provisions of this Section shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.
- 6.11. Other Provisions. The Award Agreement evidencing Awards under this Plan shall contain such other terms and conditions not inconsistent with this Plan as the Committee may determine, at or after the date of grant, including provisions in connection with the restrictions on transferring the Awards or Shares covered by such Awards, which shall be binding upon the Grantees and any purchaser, assignee or transferee of any Awards, and other terms and conditions as the Committee shall deem appropriate.

#### 7. NONQUALIFIED STOCK OPTIONS.

Awards granted pursuant to this Section 7 are intended to constitute Nonqualified Stock Options and shall be subject to the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 7 and the other terms of this Plan, this Section 7 shall prevail.

- 7.1. <u>Certain Limitations on Eligibility for Nonqualified Stock Options</u>. Nonqualified Stock Options may not be granted to a Service Provider who is deemed to be a resident of the United States for purposes of taxation or who is otherwise subject to United States federal income tax unless the Shares underlying such Options constitute "service recipient stock" under Section 409A of the Code or unless such Options comply with the payment requirements of Section 409A of the Code.
- 7.2. <u>Exercise Price</u>. The Exercise Price of a Nonqualified Stock Option shall not be less than 100% of the Fair Market Value of a Share on the date of grant of such Option unless the Committee specifically indicates that the Awards will have a lower Exercise Price and the Award complies with Section 409A of the Code. Notwithstanding the foregoing, a Nonqualified Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of that complies with Section 424(a) of the Code1.409A-1(b)(5)(v)(D) of the U.S. Treasury Regulations or any successor guidance.

#### 8. INCENTIVE STOCK OPTIONS.

Awards granted pursuant to this Section 8 are intended to constitute Incentive Stock Options and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 8 and the other terms of this Plan, this Section 8 shall prevail.

- 8.1. <u>Eligibility for Incentive Stock Options</u>. Incentive Stock Options may be granted only to Employees of the Company, or to Employees of a Parent or Subsidiary, determined as of the date of grant of such Options. An Incentive Stock Option granted to a prospective Employee upon the condition that such person become an Employee shall be deemed granted effective on the date such person commences employment, with an exercise price determined as of such date in accordance with Section 8.2.
- 8.2. <u>Exercise Price</u>. The Exercise Price of an Incentive Stock Option shall not be less than one hundred percent (100%) of the Fair Market Value of the Shares covered by the Awards on the date of grant of such Option or such other price as may be determined pursuant to the Code. Notwithstanding the foregoing, an Incentive Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code.
- 8.3. <u>Date of Grant</u>. Notwithstanding any other provision of this Plan to the contrary, no Incentive Stock Option may be granted under this Plan after 10 years from the date this Plan is adopted, or the date this Plan is approved by the shareholders, whichever is earlier.
- 8.4. <u>Exercise Period</u>. No Incentive Stock Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Award, subject to Section 8.6. No Incentive Stock Option granted to a prospective Employee may become exercisable prior to the date on which such person commences employment.

- 8.5. \$100,000 Per Year Limitation. The aggregate Fair Market Value (determined as of the date the Incentive Stock Option is granted) of the Shares with respect to which all Incentive Stock Options granted under this Plan and all other "incentive stock option" plans of the Company, or of any Parent or Subsidiary or Affiliate, become exercisable for the first time by each Grantee during any calendar year shall not exceed one hundred thousand United States dollars (\$100,000) with respect to such Grantee. To the extent that the aggregate Fair Market Value of Shares with respect to which such Incentive Stock Options and any other such incentive stock options are exercisable for the first time by any Grantee during any calendar year exceeds one hundred thousand United States dollars (\$100,000), such options shall be treated as Nonqualified Stock Options. The foregoing shall be applied by taking options into account in the order in which they were granted. If the Code is amended to provide for a different limitation from that set forth in this Section 8.5, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Awards as required or permitted by such amendment to the Code. If an Option is treated as an Incentive Stock Option in part and as a Nonqualifed Stock Option in part by reason of the limitation set forth in this Section 8.5, the Grantee may designate which portion of such Option the Grantee is exercising. In the absence of such designation, the Grantee shall be deemed to have exercised the Incentive Stock Option portion of the Option first. Separate certificates representing each such portion may be issued upon the exercise of the Option.
- 8.6. <u>Ten Percent Shareholder</u>. In the case of an Incentive Stock Option granted to a Ten Percent Shareholder, (i) the Exercise Price shall not be less than one hundred and ten percent (110%) of the Fair Market Value of a Share on the date of grant of such Incentive Stock Option, and (ii) the Exercise Period shall not exceed five (5) years from the effective date of grant of such Incentive Stock Option.
- 8.7. <u>Payment of Exercise Price</u>. Each Award Agreement evidencing an Incentive Stock Option shall state each alternative method by which the Exercise Price thereof may be paid.
- 8.8. <u>Leave of Absence</u>. Notwithstanding Section 6.8, a Grantee's employment shall not be deemed to have terminated if the Grantee takes any leave as set forth in Section 6.8(i); <u>provided</u>, <u>however</u>, that if any such leave exceeds three (3) months, on the day that is six (6) months following the commencement of such leave any Incentive Stock Option held by the Grantee shall cease to be treated as an Incentive Stock Option and instead shall be treated thereafter as a Nonqualified Stock Option, unless the Grantee's right to return to employment is guaranteed by statute or contract.
- 8.9. Exercise Following Termination for Disability. Notwithstanding anything else in this Plan to the contrary, Incentive Stock Options that are not exercised within three (3) months following termination of the Grantee's employment with the Company or its Parent or Subsidiary or a corporation or a Parent or Subsidiary of such corporation issuing or assuming an Option in a transaction to which Section 424(a) of the Code applies, or within one year in case of termination of the Grantee's employment with the Company or its Parent or Subsidiary due to a Disability (within the meaning of Section 22(e)(3) of the Code), shall be deemed to be Nonqualified Stock Options.
- 8.10. <u>Adjustments to Incentive Stock Options</u>. Any Awards Agreement providing for the grant of Incentive Stock Options shall indicate that adjustments made pursuant to this Plan with respect to Incentive Stock Options could constitute a "modification" of such Incentive Stock Options (as that term is defined in Section 424(h) of the Code) or could cause adverse tax consequences for the holder of such Incentive Stock Options and that the holder should consult with his or her tax advisor regarding the consequences of such "modification" on his or her income tax treatment with respect to the Incentive Stock Option.
- 8.11. <u>Notice to Company of Disqualifying Disposition</u>. Each Grantee who receives an Incentive Stock Option must agree to notify the Company in writing immediately after the Grantee makes a Disqualifying Disposition of any Shares received pursuant to the exercise of Incentive Stock Options. A "Disqualifying Disposition" is any disposition (including any sale) of such Shares before the later of (i) two years after the date the Grantee was granted the Incentive Stock Option, or (ii) one year after the date the Grantee acquired Shares by exercising the Incentive Stock Option. If the Grantee dies before such Shares are sold, these holding period requirements do not apply and no disposition of the Shares will be deemed a Disqualifying Disposition.

# 9. <u>102 AWARDS</u>.

Awards granted pursuant to this Section 9 are intended to constitute 102 Awards and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 9 and the other terms of this Plan, this Section 9 shall prevail.

- 9.1. <u>Tracks</u>. Awards granted pursuant to this Section ⊠9 are intended to be granted pursuant to Section 102 of the Ordinance pursuant to either (i) Section 102(b)(2) thereof, under the capital gain track ("<u>102 Capital Gain Track Awards</u>"), or (ii) Section 102(b)(1) thereof under the ordinary income track ("<u>102 Ordinary Income Track Awards</u>", and together with 102 Capital Gain Track Awards, "<u>102 Trustee Awards</u>"). 102 Trustee Awards shall be granted subject to the special terms and conditions contained in this Section 9, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Options under different tax laws or regulations.
- 9.2. <u>Election of Track</u>. Subject to Applicable Law, the Company may grant only one type of 102 Trustee Awards at any given time to all Grantees who are to be granted 102 Trustee Awards pursuant to this Plan, and shall file an election with the ITA regarding the type of 102 Trustee Awards it elects to grant before the date of grant of any 102 Trustee Awards (the "<u>Election</u>"). Such Election shall also apply to any other securities, including bonus shares, received by any Grantee as a result of holding the 102 Trustee Awards. The Company may change the type of 102 Trustee Awards that it elects to grant only after the expiration of at least 12 months from the end of the year in which the first grant was made in accordance with the previous Election, or as otherwise provided by Applicable Law. Any Election shall not prevent the Company from granting Awards, pursuant to Section 102(c) of the Ordinance without a Trustee ("102 Non-Trustee Awards").

# 9.3. Eligibility for Awards.

9.3.1. Subject to Applicable Law, 102 Awards may only be granted to an "employee" within the meaning of Section 102(a) of the Ordinance (which as of the date of the adoption of this Plan means (i) individuals employed by an Israeli company being the Company or any of its Affiliates, and (ii) individuals who are serving and are engaged personally (and not through an entity) as "office holders" by such an Israeli company), but may not be granted to a Controlling Shareholder ("<u>Eligible 102 Grantees</u>"). Eligible 102 Grantees may receive only 102 Awards, which may either be granted to a Trustee or granted under Section 102 of the Ordinance without a Trustee.

#### 9.4. 102 Award Grant Date.

- 9.4.1. Each 102 Award will be deemed granted on the date determined by the Committee, subject to Section 9.4.2, provided that (i) the Grantee has signed all documents required by the Company or pursuant to Applicable Law, and (ii) with respect to 102 Trustee Award, the Company has provided all applicable documents to the Trustee in accordance with the guidelines published by the ITA, and if an agreement is not signed and delivered by the Grantee within 90 days from the date determined by the Committee (subject to Section 9.4.2), then such 102 Trustee Award shall be deemed granted on such later date as such agreement is signed and delivered and on which the Company has provided all applicable documents to the Trustee in accordance with the guidelines published by the ITA. In the case of any contradiction, this provision and the date of grant determined pursuant hereto shall supersede and be deemed to amend any date of grant indicated in any corporate resolution or Award Agreement.
- 9.4.2. Unless otherwise permitted by the Ordinance, any grants of 102 Trustee Awards that are made on or after the date of the adoption of this Plan or an amendment to this Plan, as the case may be, that may become effective only at the expiration of thirty (30) days after the filing of this Plan or any amendment thereof (as the case may be) with the ITA in accordance with the Ordinance shall be conditional upon the expiration of such 30-day period, such condition shall be read and is incorporated by reference into any corporate resolutions approving such grants and into any Award Agreement evidencing such grants (whether or not explicitly referring to such condition), and the date of grant shall be at the expiration of such 30-day period, whether or not the date of grant indicated therein corresponds with this Section. In the case of any contradiction, this provision and the date of grant determined pursuant hereto shall supersede and be deemed to amend any date of grant indicated in any corporate resolution or Award Agreement.

# 9.5. <u>102 Trustee Awards</u>.

- 9.5.1. Each 102 Trustee Award, each Share issued pursuant to the exercise of any 102 Trustee Award, and any rights granted thereunder, including bonus shares, shall be issued to and registered in the name of the Trustee and shall be held in trust for the benefit of the Grantee for the requisite period prescribed by the Ordinance or such longer period as set by the Committee (the "Required Holding Period"). In the event that the requirements under Section 102 of the Ordinance to qualify an Award as a 102 Trustee Award are not met, then the Award may be treated as a 102 Non-Trustee Award or 3(9) Award, all in accordance with the provisions of the Ordinance. After expiration of the Required Holding Period, the Trustee may release such 102 Trustee Awards and any such Shares, provided that (i) the Trustee has received an acknowledgment from the ITA that the Grantee has paid any applicable taxes due pursuant to the Ordinance, or (ii) the Trustee and/or the Company and/or its Affiliate withholds all applicable taxes and compulsory payments due pursuant to the Ordinance arising from the 102 Trustee Awards and/or any Shares issued upon exercise or (if applicable) vesting of such 102 Trustee Awards. The Trustee shall not release any 102 Trustee Awards or Shares issued upon exercise or (if applicable) vesting thereof prior to the payment in full of the Grantee's tax and compulsory payments arising from such 102 Trustee Awards and/or Shares or the withholding referred to in (ii) above.
- 9.5.2. Each 102 Trustee Award shall be subject to the relevant terms of the Ordinance, the Rules and any determinations, rulings or approvals issued by the ITA, which shall be deemed an integral part of the 102 Trustee Awards and shall prevail over any term contained in this Plan or Award Agreement that is not consistent therewith. Any provision of the Ordinance, the Rules and any determinations, rulings or approvals by the ITA not expressly specified in this Plan or Award Agreement that are necessary to receive or maintain any tax benefit pursuant to Section 102 of the Ordinance shall be binding on the Grantee. The Grantee granted a 102 Trustee Awards shall comply with the Ordinance and the terms and conditions of the trust agreement entered into between the Company and the Trustee. The Grantee shall execute any and all documents that the Company and/or its Affiliates and/or the Trustee determine from time to time to be necessary in order to comply with the Ordinance and the Rules.
- 9.5.3. During the Required Holding Period, the Grantee shall not release from trust or sell, assign, transfer or give as collateral, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Trustee Awards and/or any securities issued or distributed with respect thereto, until the expiration of the Required Holding Period. Notwithstanding the above, if any such sale, release or other action occurs during the Required Holding Period it may result in adverse tax consequences to the Grantee under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Grantee. Subject to the foregoing, the Trustee may, pursuant to a written request from the Grantee, but subject to the terms of this Plan, release and transfer such Shares to a designated third party, provided that both of the following conditions have been fulfilled prior to such release or transfer: (i) payment has been made to the ITA of all taxes and compulsory payments required to be paid upon the release and transfer of the Shares, and confirmation of such payment has been received by the Trustee and the Company, and (ii) the Trustee has received written confirmation from the Company that all requirements for such release and transfer have been fulfilled according to the terms of the Company's corporate documents, any agreement governing the Shares, this Plan, the Award Agreement and any Applicable Law.
- 9.5.4. If a 102 Trustee Award is exercised or (if applicable) vested, the Shares issued upon such exercise or (if applicable) vesting shall be issued in the name of the Trustee for the benefit of the Grantee.
- 9.5.5. Upon or after receipt of a 102 Trustee Award, if required, the Grantee may be required to sign an undertaking to release the Trustee from any liability with respect to any action or decision duly taken and executed in good faith by the Trustee in relation to this Plan, or any 102 Trustee Awards or Share granted to such Grantee thereunder.
- 9.6. <u>102 Non-Trustee Awards</u>. The foregoing provisions of this Section 9 relating to 102 Trustee Awards shall not apply with respect to 102 Non-Trustee Awards, which shall, however, be subject to the relevant provisions of Section 102 of the Ordinance and the applicable Rules. The Committee may determine that 102 Non-Trustee Awards, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Non-Trustee Awards and/or any securities issued or distributed with respect thereto, shall be allocated or issued to the Trustee, who shall hold such 102 Non-Trustee Awards and all accrued rights thereon (if any), in trust for the benefit of the Grantee and/or the Company, as the case may be, until the full payment of tax arising from the 102 Non-Trustee Awards, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Non-Trustee Awards and/or any securities issued or distributed with respect thereto. The Company may choose, alternatively, to force the Grantee to provide it with a guarantee or other security, to the satisfaction of each of the Trustee and the Company, until the full payment of the applicable taxes.

- 9.7. <u>Israeli Index Base for 102 Awards</u>. Each 102 Award will be subject to the Israeli index base of the Value of Benefit, as defined in Section 102(a) of the Ordinance, as determined by the Committee in its discretion, pursuant to the Rules, from time to time. The Committee may amend (which may have a retroactive effect) the Israeli index base, pursuant to the Ordinance, without the Grantee's consent.
- 9.8. Written Grantee Undertaking. To the extent and with respect to any 102 Trustee Award, and as required by Section 102 of the Ordinance and the Rules, by virtue of the receipt of such Award, the Grantee is deemed to have undertaken and confirm in writing the following (and such undertaking is deemed incorporated into any documents signed by the Grantee in connection with the employment or service of the Grantee and/or the grant of such Award). The following written undertaking shall be deemed to apply and relate to all 102 Trustee Awards granted to the Grantee, whether under this Plan or other plans maintained by the Company, and whether prior to or after the date hereof.
- 9.8.1. The Grantee shall comply with all terms and conditions set forth in Section 102 of the Ordinance with regard to the "Capital Gain Track" or the "Ordinary Income Track", as applicable, and the applicable rules and regulations promulgated thereunder, as amended from time to time;
- 9.8.2. The Grantee is familiar with, and understands the provisions of, Section 102 of the Ordinance in general, and the tax arrangement under the "Capital Gain Track" or the "Ordinary Income Track" in particular, and its tax consequences; the Grantee agrees that the 102 Trustee Awards and Shares that may be issued upon exercise or (if applicable) vesting of the 102 Trustee Awards (or otherwise in relation to the 102 Trustee Awards), will be held by a trustee appointed pursuant to Section 102 of the Ordinance for at least the duration of the "Holding Period" (as such term is defined in Section 102) under the "Capital Gain Track" or the "Ordinary Income Track", as applicable. The Grantee understands that any release of such 102 Trustee Awards or Shares from trust, or any sale of the Share prior to the termination of the Holding Period, as defined above, will result in taxation at marginal tax rate, in addition to deductions of appropriate social security, health tax contributions or other compulsory payments; and
- 9.8.3. The Grantee agrees to the trust deed signed between the Company, his employing company and the trustee appointed pursuant to Section 102 of the Ordinance.

#### 10. <u>3(9) AWARDS</u>.

Awards granted pursuant to this Section 10 are intended to constitute 3(9) Awards and shall be granted subject to the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 10 and the other terms of this Plan, this Section 10 shall prevail.

- 10.1. To the extent required by the Ordinance or the ITA or otherwise deemed by the Committee to be advisable, the 3(9) Awards and/or any shares or other securities issued or distributed with respect thereto granted pursuant to this Plan shall be issued to a Trustee nominated by the Committee in accordance with the provisions of the Ordinance. In such event, the Trustee shall hold such Awards and/or any shares or other securities issued or distributed with respect thereto in trust, until exercised or (if applicable) vested by the Grantee and the full payment of tax arising therefrom, pursuant to the Company's instructions from time to time as set forth in a trust agreement, which will have been entered into between the Company and the Trustee. If determined by the Board or the Committee, and subject to such trust agreement, the Trustee shall be responsible for withholding any taxes to which a Grantee may become liable upon issuance of Shares, whether due to the exercise or (if applicable) vesting of Awards.
- 10.2. Shares pursuant to a 3(9) Award shall not be issued, unless the Grantee delivers to the Company payment in cash or by bank check or such other form acceptable to the Committee of all withholding taxes due, if any, on account of the Grantee acquired Shares under the Award or gives other assurance satisfactory to the Committee of the payment of those withholding taxes.

## 11. RESTRICTED SHARES

The Committee may award Restricted Shares to any eligible Grantee, including under Section 102 of the Ordinance. Each Award of Restricted Shares under this Plan shall be evidenced by a written agreement between the Company and the Grantee (the "Restricted Share Agreement"), in such form as the Committee shall from time to time approve. The Restricted Shares shall be subject to all applicable terms of this Plan, which in the case of Restricted Shares granted under Section 102 of the Ordinance shall include Section 9 hereof, and may be subject to any other terms that are not inconsistent with this Plan. The provisions of the various Restricted Shares Agreements entered into under this Plan need not be identical. The Restricted Share Agreement shall comply with and be subject to Section 9 and the following terms and conditions, unless otherwise specifically provided in such Agreement and not inconsistent with this Plan, or Applicable Law:

- 11.1. <u>Purchase Price</u>. Section 6.4 shall not apply. Each Restricted Share Agreement shall state an amount of Exercise Price to be paid by the Grantee, if any, in consideration for the issuance of the Restricted Shares and the terms of payment thereof, which may include, payment in cash or, subject to the Committee's approval, by issuance of promissory notes or other evidence of indebtedness on such terms and conditions as determined by the Committee.
- Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged, hypothecated or otherwise disposed 11.2. of, except by will or the laws of descent and distribution (in which case they shall be transferred subject to all restrictions then or thereafter applicable thereto), until such Restricted Shares shall have vested (the period from the date on which the Award is granted until the date of vesting of the Restricted Share thereunder being referred to herein as the "Restricted Period"). The Committee may also impose such additional or alternative restrictions and conditions on the Restricted Shares, as it deems appropriate, including the satisfaction of performance criteria. Such performance criteria may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee or pursuant to the provisions of any Company policy required under mandatory provisions of Applicable Law. Certificates for shares issued pursuant to Restricted Share Awards, if issued, shall bear an appropriate legend referring to such restrictions, and any attempt to dispose of any such shares in contravention of such restrictions shall be null and void and without effect. Such certificates may, if so determined by the Committee, be held in escrow by an escrow agent appointed by the Committee, or, if a Restricted Share Award is made pursuant to Section 102 of the Ordinance, by the Trustee. In determining the Restricted Period of an Award the Committee may provide that the foregoing restrictions shall lapse with respect to specified percentages of the awarded Restricted Shares on successive anniversaries of the date of such Award. To the extent required by the Ordinance or the ITA, the Restricted Shares issued pursuant to Section 102 of the Ordinance shall be issued to the Trustee in accordance with the provisions of the Ordinance and the Restricted Shares shall be held for the benefit of the Grantee for at least the Required Holding Period.
- 11.3. <u>Forfeiture; Repurchase</u>. Subject to such exceptions as may be determined by the Committee, if the Grantee's continuous employment with or service to the Company or any Affiliate thereof shall terminate for any reason prior to the expiration of the Restricted Period of an Award or prior to the timely payment in full of the Exercise Price of any Restricted Shares, any Shares remaining subject to vesting or with respect to which the purchase price has not been paid in full, shall thereupon be forfeited, transferred to, and redeemed, repurchased or cancelled by, as the case may be, in any manner as set forth in Section 6.6.2(i) through (v), subject to Applicable Laws and the Grantee shall have no further rights with respect to such Restricted Shares.
- 11.4. Ownership. During the Restricted Period the Grantee shall possess all incidents of ownership of such Restricted Shares, subject to Section 6.10 and Section 11.2, including the right to vote and receive dividends with respect to such Shares. All securities, if any, received by a Grantee with respect to Restricted Shares as a result of any stock split, stock dividend, combination of shares, or other similar transaction shall be subject to the restrictions applicable to the original Award.

## 12. <u>RESTRICTED SHARE UNITS</u>.

An RSU is an Award covering a number of Shares that is settled, if vested and (if applicable) exercised, by issuance of those Shares. An RSU may be awarded to any eligible Grantee, including under Section 102 of the Ordinance, provided that, to the extent required by Applicable Laws, a specific ruling is obtained from the ITA to grant RSUs as 102 Trustee Awards. The Award Agreement relating to the grant of RSUs under this Plan (the "Restricted Share Unit Agreement"), shall be in such form as the Committee shall from time to time approve. The RSUs shall be subject to all applicable terms of this Plan, which in the case of RSUs granted under Section 102 of the Ordinance shall include Section 9 hereof, and may be subject to any other terms that are not inconsistent with this Plan. The provisions of the various Restricted Share Unit Agreements entered into under this Plan need not be identical. RSUs may be granted in consideration of a reduction in the recipient's other compensation.

- 12.1. <u>Exercise Price</u>. No payment of Exercise Price shall be required as consideration for RSUs, unless included in the Award Agreement or as required by Applicable Law (including, Section 304 of the Companies Law), and Section 6.4 shall apply, if applicable.
- 12.2. <u>Shareholders' Rights</u>. The Grantee shall not possess or own any ownership rights in the Shares underlying the RSUs and no rights as a shareholder shall exist prior to the actual issuance of Shares in the name of the Grantee.
- 12.3. <u>Settlements of Awards</u>. Settlement of vested RSUs shall be made in the form of Shares. Distribution to a Grantee of an amount (or amounts) from settlement of vested RSUs can be deferred to a date after settlement as determined by the Committee. The amount of a deferred distribution may be increased by an interest factor or by dividend equivalents. Until an RSUs is settled, the number of Shares underlying such RSUs shall be subject to adjustment pursuant hereto.
- 12.4. <u>Section 409A Restrictions</u>. Notwithstanding anything to the contrary set forth herein, any RSUs granted under this Plan that are not exempt from the requirements of Section 409A of the Code shall contain such restrictions or other provisions so that such RSUs will comply with the requirements of Section 409A of the Code, if applicable to the Company. Such restrictions, if any, shall be determined by the Committee and contained in the Restricted Share Unit Agreement evidencing such RSU. For example, such restrictions may include a requirement that any Shares that are to be issued in a year following the year in which the RSU vests must be issued in accordance with a fixed, pre-determined schedule.

## 13. OTHER SHARE OR SHARE-BASED AWARDS.

- 13.1. The Committee may grant other Awards under this Plan pursuant to which Shares (which may, but need not, be Restricted Shares pursuant to Section 11 hereof), cash (in settlement of Share-based Awards) or a combination thereof, are or may in the future be acquired or received, or Awards denominated in stock units, including units valued on the basis of measures other than market value.
- 13.2. The Committee may also grant stock appreciation rights without the grant of an accompanying option, which rights shall permit the Grantees to receive, at the time of any exercise of such rights, cash equal to the amount by which the Fair Market Value of the Shares in respect to which the right was granted is so exercised exceed the exercise price thereof. The exercise price of any such stock appreciation right granted to a Grantee who is subject to U.S. federal income tax shall be determined in compliance with Section 7.2.
- 13.3. Such other Share-based Awards as set forth above may be granted alone, in addition to, or in tandem with any Award of any type granted under this Plan.

#### 14. EFFECT OF CERTAIN CHANGES.

- General. In the event of a division or subdivision of the outstanding share capital of the Company, any distribution 14.1. of bonus shares (stock split), consolidation or combination of share capital of the Company (reverse stock split), reclassification with respect to the Shares or any similar recapitalization events (each, a "Recapitalization"), a merger (including, a reverse merger and a reverse triangular merger), consolidation, amalgamation or like transaction of the Company with or into another corporation, a reorganization (which may include a combination or exchange of shares, spin-off or other corporate divestiture or division, or other similar occurrences, the Committee shall have the authority to make, without the need for a consent of any holder of an Award, such adjustments as determined by the Committee to be appropriate, in its discretion, in order to adjust (i) the number and class of shares reserved and available for grants of Awards, (ii) the number and class of shares covered by outstanding Awards, (iii) the Exercise Price per share covered by any Award, (iv) the terms and conditions concerning vesting and exercisability and the term and duration of the outstanding Awards, and (v) any other terms of the Award that in the opinion of the Committee should be adjusted. Any fractional shares resulting from such adjustment shall be treated as determined by the Committee, and in the absence of such determination shall be rounded to the nearest whole share, and the Company shall have no obligation to make any cash or other payment with respect to such fractional shares. No adjustment shall be made by reason of the distribution of subscription rights or rights offering to outstanding shares or other issuance of shares by the Company, unless the Committee determines otherwise. The adjustments determined pursuant to this Section 14.1 (including a determination that no adjustment is to be made) shall be final, binding and conclusive.
- 14.2. Merger/Sale of Company. In the event of (i) a sale of all or substantially all of the assets of the Company, or a sale (including an exchange) of all or substantially all of the shares of the Company, to any person, or a purchase by a shareholder of the Company or by an Affiliate of such shareholder, of all the shares of the Company held by all or substantially all other shareholders or by other shareholders who are not Affiliated with such acquiring party; (ii) a merger (including, a reverse merger and a reverse triangular merger), consolidation, amalgamation or like transaction of the Company with or into another corporation; (iii) a scheme of arrangement for the purpose of effecting such sale, merger, consolidation, amalgamation or other transaction; (iv) approval by the shareholders of the Company of a complete liquidation or dissolution of the Company, or (v) such other transaction or set of circumstances that is determined by the Board, in its discretion, to be a transaction subject to the provisions of this Section 14.2 excluding any of the above transactions in clauses (i) through (v) if the Board determines that such transaction should be excluded from the definition hereof and the applicability of this Section 14.2 (such transaction, a "Merger/Sale"), then, without derogating from the general authority and power of the Board or the Committee under this Plan, without the Grantee's consent and action and without any prior notice requirement:
- 14.2.1. Unless otherwise determined by the Committee in its sole and absolute discretion, any Award then outstanding shall be assumed or be substituted by the Company, or by the successor corporation in such Merger/Sale or by any parent or Affiliate thereof, as determined by the Committee in its discretion (the "Successor Corporation"), under terms as determined by the Committee or the terms of this Plan applied by the Successor Corporation to such assumed or substituted Awards.

For the purposes of this Section 14.2.1, the Award shall be considered assumed or substituted if, following a Merger/Sale, the Award confers on the holder thereof the right to purchase or receive, for each Share underlying an Award immediately prior to the Merger/Sale, either (i) the consideration (whether stock, cash, or other securities or property, or any combination thereof) distributed to or received by holders of Shares in the Merger/Sale for each Share held on the effective date of the Merger/Sale (and if holders were offered a choice or several types of consideration, the type of consideration as determined by the Committee), or (ii) regardless of the consideration received by the holders of Shares in the Merger/Sale, solely shares or any type of Awards (or their equivalent) of the Successor Corporation at a value to be determined by the Committee in its discretion, or a certain type of consideration (whether stock, cash, or other securities or property, or any combination thereof) as determined by the Committee. Any of the above consideration referred to in clauses (i) and (ii) shall be subject to the same vesting and expiration terms of the Awards applying immediately prior to the Merger/Sale, unless determined by the Committee in its discretion that the consideration shall be subject to different vesting and expiration terms, or other terms, and the Committee may determine that it be subject to other or additional terms. The foregoing shall not limit the Committee's authority to determine, in its sole discretion, that in lieu of such assumption or substitution of Awards for Awards of the Successor Corporation, such Award will be substituted for any other type of asset or property, including as set forth in Section 14.2.2 hereunder.

- 14.2.2. Regardless of whether or not Awards are assumed or substituted, the Committee may (but shall not be obligated to), in its sole discretion:
- 14.2.2.1. provide for the Grantee to have the right to exercise the Award in respect of Shares covered by the Award which would otherwise be exercisable or vested, under such terms and conditions as the Committee shall determine, and the cancellation of all unexercised Awards (whether vested or unvested) upon or immediately prior to the closing of the Merger/Sale, unless the Committee provides for the Grantee to have the right to exercise the Award, or otherwise for the acceleration of vesting of such Award, as to all or part of the Shares covered by the Award which would not otherwise be exercisable or vested, under such terms and conditions as the Committee shall determine; and/or

- 14.2.2.2. provide for the cancellation of each outstanding Award at or immediately prior to the closing of such Merger/Sale, and if and to the extent payment shall be made to the Grantee of an amount in cash, shares of the Company, the acquiror or of a corporation or other business entity which is a party to the Merger/Sale or other property, as determined by the Committee to be fair in the circumstances, and subject to such terms and conditions as determined by the Committee. The Committee shall have full authority to select the method for determining the payment (being the Black-Scholes model or any other method). *Inter alia*, and without limitation of the following determination being made in other circumstances, the Committee's determination may provide that payment shall be set to zero if the value of the Shares is determined to be less than the Exercise Price, or in respect of Shares covered by the Award which would not otherwise be exercisable or vested, or that payment may be made only in excess of the Exercise Price.
- 14.2.3. The Committee may, in its sole discretion, determine that any payments made in respect of Awards shall be made or delayed to the same extent that payment of consideration to the holders of the Shares in connection with the Merger/Sale is made or delayed as a result of escrows, indemnification, earn outs, holdbacks or any other contingencies or conditions; and the terms and conditions applying to the payment made to the Grantees, including participation in escrow, indemnification, releases, earn-outs, holdbacks or any other contingencies.
- 14.2.4. The Committee may, in its sole discretion, determine to suspend the Grantee's rights to exercise any vested portion of an Award for a period of time prior to the completion of a Merger/Sale transaction.
- 14.2.5. Notwithstanding anything to the contrary, in the event of a Merger/Sale, the Committee may determine, in its sole discretion, that upon completion of such Merger/Sale the terms of any Award shall be otherwise amended, modified or terminated, as the Committee shall deem in good faith to be appropriate and without any liability to the Company or its Affiliates and to their respective officers, directors, employees and representatives and the respective successors and assigns of any of the foregoing in connection with the method of treatment or chosen course of action permitted hereunder.
- 14.2.6. Neither the authorities and powers of the Committee under this Section 14.2, nor the exercise or implementation thereof, shall (i) be restricted or limited in any way by any adverse consequences (tax or otherwise) that may result to any holder of an Award, and (ii) as, *inter alia*, being a feature of the Award upon its grant, be deemed to constitute a change or an amendment of the rights of such holder under this Plan, nor shall any such adverse consequences (as well as any adverse tax consequences that may result from any tax ruling or other approval or determination of any relevant tax authority) be deemed to constitute a change or an amendment of the rights of such holder under this Plan, and may be effected without consent of any Grantee and without any liability to the Company or its Affiliates and to their respective its officers, directors, employees and representatives and the respective successors and assigns of any of the foregoing. The Committee need not take the same action with respect to all Awards or with respect to all Service Providers. The Committee may take different actions with respect to the vested and unvested portions of an Award. The Committee may determine an amount or type of consideration to be received or distributed in a Merger/Sale which may differ as among the Grantees, and as between the Grantees and any other holders of shares of the Company.
- 14.2.7. The Committee's determinations pursuant to this Section 14 shall be conclusive and binding on all Grantees.
- 14.2.8. If determined by the Committee, the Grantees shall be subject to the definitive agreement(s) in connection with the Merger/Sale as applying to holders of Shares including, such terms, conditions, representations, undertakings, liabilities, limitations, releases, indemnities, participating in transaction expenses, shareholders/sellers representative expense fund and escrow arrangement, in each case as determined by the Committee. Each Grantee shall execute such separate agreement(s) or instruments as may be requested by the Company, the Successor Corporation or the acquiror in connection with such in such Merger/Sale and in the form required by them. The execution of such separate agreement(s) may be a condition to the receipt of assumed or substituted Awards, payment in lieu of the Award or the exercise of any Award.

14.3. Reservation of Rights. Except as expressly provided in this Section 14 (if any), the Grantee of an Award hereunder shall have no rights by reason of any Recapitalization of shares of any class, any increase or decrease in the number of shares of any class, or any dissolution, liquidation, reorganization (which may include a combination or exchange of shares, spin-off or other corporate divestiture or division, or other similar occurrences), Merger/Sale. Any issue by the Company of shares of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number, type or price of shares subject to an Award. The grant of an Award pursuant to this Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes of its capital or business structures or to merge or to consolidate or to dissolve, liquidate or sell, or transfer all or part of its business or assets or engage in any similar transactions.

## 15. NON-TRANSFERABILITY OF AWARDS; SURVIVING BENEFICIARY.

- All Awards granted under this Plan by their terms shall not be transferable other than by will or by the laws of descent and distribution, unless otherwise determined by the Committee or under this Plan, provided that with respect to Shares issued upon exercise or (if applicable) the vesting of Awards the restrictions on transfer shall be the restrictions referred to in Section 16 (Conditions upon Issuance of Shares) hereof. Subject to the above provisions, the terms of such Award, this Plan and any applicable Award Agreement shall be binding upon the beneficiaries, executors, administrators, heirs and successors of such Grantee. Awards may be exercised or otherwise realized, during the lifetime of the Grantee, only by the Grantee or by his guardian or legal representative, to the extent provided for herein. Any transfer of an Award not permitted hereunder (including transfers pursuant to any decree of divorce, dissolution or separate maintenance, any property settlement, any separation agreement or any other agreement with a spouse) and any grant of any interest in any Award to, or creation in any way of any direct or indirect interest in any Award by, any party other than the Grantee shall be null and void and shall not confer upon any party or person, other than the Grantee, any rights. A Grantee may file with the Committee a written designation of a beneficiary, who shall be permitted to exercise such Grantee's Award or to whom any benefit under this Plan is to be paid, in each case, in the event of the Grantee's death before he or she fully exercises his or her Award or receives any or all of such benefit, on such form as may be prescribed by the Committee and may, from time to time, amend or revoke such designation. If no designated beneficiary survives the Grantee, the executor or administrator of the Grantee's estate shall be deemed to be the Grantee's beneficiary. Notwithstanding the foregoing, upon the request of the Grantee and subject to Applicable Law the Committee, at its sole discretion, may permit the Grantee to transfer the Award to a trust whose beneficiaries are the Grantee and/or the Grantee's immediate family members (all or several of them).
- 15.2. Notwithstanding any other provisions of the Plan to the contrary, no Incentive Stock Option may be sold, transferred, pledged, assigned or otherwise alienated or hypothecated, other than by will or by the laws of descent and distribution or in accordance with a beneficiary designation pursuant to Section 15.1. Further, all Incentive Stock Options granted to a Grantee shall be exercisable during his or her lifetime only by such Grantee.
- 15.3. As long as the Shares are held by the Trustee in favor of the Grantee, all rights possessed by the Grantee over the Shares are personal, and may not be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution.
- 15.4. If and to the extent a Grantee is entitled to transfer an Award and/or Shares underlying an Award in accordance with the terms of the Plan and any other applicable agreements, such transfer shall be subject (in addition, to any other conditions or terms applying thereto) to receipt by the Company from such proposed transferee of a written instrument, on a form reasonably acceptable to the Company, pursuant to which such proposed transferee agrees to be bound by all provisions of the Plan and any other applicable agreements, including without limitation, any restrictions on transfer of the Award and/or Shares set forth herein (however, failure to so deliver such instrument to the Company as set forth above shall not derogate from all such provisions applying on any transferee).
- 15.5. The provisions of this Section  $\boxtimes$ 15 shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.

- <u>Legal Compliance</u>. The grant of Awards and the issuance of Shares upon exercise or settlement of Awards shall be subject to compliance with all Applicable Laws as determined by the Company, including, applicable requirements of federal, state and foreign law with respect to such securities. The Company shall have no obligations to issue Shares pursuant to the exercise or settlement of an Award and Awards may not be exercised or settled, if the issuance of Shares upon exercise or settlement would constitute a violation of any Applicable Laws as determined by the Company, including, applicable federal, state or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Shares may then be listed. In addition, no Award may be exercised unless (i) a registration statement under the Securities Act shall at the time of exercise or settlement of the Award be in effect with respect to the shares issuable upon exercise of the Award, or (ii) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain authority from any regulatory body having jurisdiction, if any, deemed by the Company to be necessary to the lawful issuance and sale of any Shares hereunder, and the inability to issue Shares hereunder due to non-compliance with any Company policies with respect to the sale of Shares, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority or compliance shall not have been obtained or achieved. As a condition to the exercise of an Award, the Company may require the person exercising such Award to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any Applicable Law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company, including to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares, all in form and content specified by the Company.
- Provisions Governing Shares. Shares issued pursuant to an Award shall be subject to the Articles of Association of 16.2. the Company, any limitation, restriction or obligation included in any shareholders agreement applicable to all or substantially all of the holders of shares (regardless of whether or not the Grantee is a formal party to such shareholders agreement), any other governing documents of the Company, all policies, manuals and internal regulations adopted by the Company from time to time, in each case, as may be amended from time to time, including any provisions included therein concerning restrictions or limitations on disposition of Shares (such as, but not limited to, right of first refusal and lock up/market stand-off) or grant of any rights with respect thereto, forced sale and bring along provisions, any provisions concerning restrictions on the use of inside information and other provisions deemed by the Company to be appropriate in order to ensure compliance with Applicable Laws. Each Grantee shall execute such separate agreement(s) as may be requested by the Company relating to matters set forth in this Section 16.2. The execution of such separate agreement(s) may be a condition by the Company to the exercise of any Award.
- 16.3. Forced Sale. In the event the that Board approves a Merger/Sale effected by way of a forced or compulsory sale (whether pursuant to the Company's Articles of Association or pursuant to Section 341 of the Companies Law), then, without derogating from such provisions and in addition thereto, the Grantee shall be obligated, and shall be deemed to have agreed to the offer to effect the Merger/Sale on the terms approved by the Board (and the Shares held by or for the benefit of the Grantee shall be included in the shares of the Company approving the terms of such Merger/Sale for the purpose of satisfying the required majority), and shall sell all of the Shares held by or for the benefit of the Grantee on the terms and conditions applying to the holders of Shares, in accordance with the instructions then issued by the Board, whose determination shall be final. No Grantee shall contest, bring any claims or demands, or exercise any appraisal rights related to any of the foregoing. The proxy pursuant to Section 6.10 includes an authorization of the holder of such proxy to sign, by and on behalf of any Grantee, such documents and agreements as are required to affect the sale of Shares in connection with such Merger/Sale.

#### 17. **MARKET STAND-OFF**

In connection with any underwritten public offering of equity securities of the Company pursuant to an effective registration statement filed under the Securities Act or equivalent law in another jurisdiction, the Grantee shall not directly or indirectly, without the prior written consent of the Company or its underwriters, (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares or other Awards, any securities of the Company (whether or not such Shares were acquired under this Plan), or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Shares or securities of the Company and any other shares or securities issued or distributed in respect thereto or in substitution thereof (collectively, "Securities"), or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Securities, whether any such transaction described in clauses (i) or (ii) is to be settled by delivery of Securities, in cash or otherwise. The foregoing provisions of this Section 17.1 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement. Such restrictions (the "Market Stand-Off") shall be in effect for such period of time (the "Market Stand-Off Period"): (A) following the first public filing of the registration statement relating to the underwritten public offering until the extirpation of 180 days following the effective date of such registration statement relating to the Company's initial public offering or 90 days following the effective date of such registration statement relating to any other public offering, in each case, provided, however, that if (1) during the last 17 days of the initial Market Stand-Off Period, the Company releases earnings results or announces material news or a material event or (2) prior to the expiration of the initial Market Stand-Off Period, the Company announces that it will release earnings results during the 15-day period following the last day of the initial Market Stand-Off Period, then in each case the Market Stand-Off Period will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event; or (B) such other period as shall be requested by the Company or the underwriters. Notwithstanding anything herein to the contrary, if the underwriter(s) and the Company agree on a termination date of the Market Stand-Off Period in the event of failure

- 17.2. In the event of a subdivision of the outstanding share capital of the Company, the distribution of any securities (whether or not of the Company), whether as bonus shares or otherwise, and whether as dividend or otherwise, a recapitalization, a reorganization (which may include a combination or exchange of shares or a similar transaction affecting the Company's outstanding securities without receipt of consideration), a consolidation, a spin-off or other corporate divestiture or division, a reclassification or other similar occurrence, any new, substituted or additional securities which are by reason of such transaction distributed with respect to any Shares subject to the Market Stand-Off, or into which such Shares thereby become convertible, shall immediately be subject to the Market Stand-Off.
- 17.3. In order to enforce the Market Stand-Off, the Company may impose stop-transfer instructions with respect to the Shares acquired under this-Plan until the end of the applicable Market Stand-Off period.
- 17.4. The underwriters in connection with a registration statement so filed are intended third party beneficiaries of this Section 17 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Grantee shall execute such separate agreement(s) as may be requested by the Company or the underwriters in connection with such registration statement and in the form required by them, relating to Market Stand-Off (which need not be identical to the provisions of this Section 17, and may include such additional provisions and restrictions as the underwriters deem advisable) or that are necessary to give further effect thereto. The execution of such separate agreement(s) may be a condition by the Company to the exercise of any Award.
- 17.5. Without derogating from the above provisions of this Section 17 or elsewhere in this Plan, the provisions of this Section 17 shall apply to the Grantee and the Grantee's heirs, legal representatives, successors, assigns, and to any purchaser, assignee or transferee of any Awards or Shares.

## 18. AGREEMENT REGARDING TAXES; DISCLAIMER.

- 18.1. If the Committee shall so require, as a condition of exercise of an Award, the release of Shares by the Trustee or the expiration of the Restricted Period, a Grantee shall agree that, no later than the date of such occurrence, the Grantee will pay to the Company (or the Trustee, as applicable) or make arrangements satisfactory to the Committee and the Trustee (if applicable) regarding payment of any applicable taxes and compulsory payments of any kind required by Applicable Law to be withheld or paid.
- 18.2. TAX LIABILITY. ALL TAX CONSEQUENCES UNDER ANY APPLICABLE LAW WHICH MAY ARISE FROM THE GRANT OF ANY AWARDS OR THE EXERCISE THEREOF, THE SALE OR DISPOSITION OF ANY SHARES GRANTED HEREUNDER OR ISSUED UPON EXERCISE OR (IF APPLICABLE) THE VESTING OF ANY AWARD, THE ASSUMPTION, SUBSTITUTION, CANCELLATION OR PAYMENT IN LIEU OF AWARDS OR FROM ANY OTHER ACTION IN CONNECTION WITH THE FOREGOING (INCLUDING WITHOUT LIMITATION ANY TAXES AND COMPULSORY PAYMENTS, SUCH AS SOCIAL SECURITY OR HEALTH TAX PAYABLE BY THE GRANTEE OR THE COMPANY IN CONNECTION THEREWITH) SHALL BE BORNE AND PAID SOLELY BY THE GRANTEE, AND THE GRANTEE SHALL INDEMNIFY THE COMPANY, ITS SUBSIDIARIES AND AFFILIATES AND THE TRUSTEE, AND SHALL HOLD THEM HARMLESS AGAINST AND FROM ANY LIABILITY FOR ANY SUCH TAX OR PAYMENT OR ANY PENALTY, INTEREST OR INDEXATION THEREON. EACH GRANTEE AGREES TO, AND UNDERTAKES TO COMPLY WITH, ANY RULING, SETTLEMENT, CLOSING AGREEMENT OR OTHER SIMILAR AGREEMENT OR ARRANGEMENT WITH ANY TAX AUTHORITY IN CONNECTION WITH THE FOREGOING WHICH IS APPROVED BY THE COMPANY.
- 18.3. <u>NO TAX ADVICE</u>. THE GRANTEE IS ADVISED TO CONSULT WITH A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING, EXERCISING OR DISPOSING OF AWARDS HEREUNDER. THE COMPANY DOES NOT ASSUME ANY RESPONSIBILITY TO ADVISE THE GRANTEE ON SUCH MATTERS, WHICH SHALL REMAIN SOLELY THE RESPONSIBILITY OF THE GRANTEE.

- TAX TREATMENT. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY OR 18.4. RESPONSIBILITY TO THE EFFECT THAT ANY AWARD SHALL QUALIFY WITH ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT, OR BENEFIT FROM ANY PARTICULAR TAX TREATMENT OR TAX ADVANTAGE OF ANY TYPE AND THE COMPANY SHALL BEAR NO LIABILITY IN CONNECTION WITH THE MANNER IN WHICH ANY AWARD IS EVENTUALLY TREATED FOR TAX PURPOSES. REGARDLESS OF WHETHER THE AWARD WAS GRANTED OR WAS INTENDED TO QUALIFY UNDER ANY PARTICULAR TAX REGIME OR TREATMENT. THIS PROVISION SHALL SUPERSEDE ANY TYPE OF AWARDS OR TAX QUALIFICATION INDICATED IN ANY CORPORATE RESOLUTION OR AWARD AGREEMENT, WHICH SHALL AT ALL TIMES BE SUBJECT TO THE REQUIREMENTS OF APPLICABLE LAW. THE COMPANY DOES NOT UNDERTAKE AND SHALL NOT BE REQUIRED TO TAKE ANY ACTION IN ORDER TO QUALIFY THE AWARD WITH THE REQUIREMENT OF ANY PARTICULAR TAX TREATMENT AND NO INDICATION IN ANY DOCUMENT TO THE EFFECT THAT ANY AWARD IS INTENDED TO OUALIFY FOR ANY TAX TREATMENT SHALL IMPLY SUCH AN UNDERTAKING. NO ASSURANCE IS MADE BY THE COMPANY OR ANY OF ITS AFFILIATES THAT ANY PARTICULAR TAX TREATMENT ON THE DATE OF GRANT WILL CONTINUE TO EXIST OR THAT THE AWARD WOULD OUALIFY AT THE TIME OF EXERCISE OR DISPOSITION THEREOF WITH ANY PARTICULAR TAX TREATMENT. THE COMPANY AND ITS AFFILIATES SHALL NOT HAVE ANY LIABILITY OR OBLIGATION OF ANY NATURE IN THE EVENT THAT AN AWARD DOES NOT QUALIFY FOR ANY PARTICULAR TAX TREATMENT, REGARDLESS WHETHER THE COMPANY COULD HAVE OR SHOULD HAVE TAKEN ANY ACTION TO CAUSE SUCH QUALIFICATION TO BE MET AND SUCH QUALIFICATION REMAINS AT ALL TIMES AND UNDER ALL CIRCUMSTANCES AT THE RISK OF THE GRANTEE. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY TO CONTEST A DETERMINATION OR INTERPRETATION (WHETHER WRITTEN OR UNWRITTEN) OF ANY TAX AUTHORITIES, INCLUDING IN RESPECT OF THE QUALIFICATION UNDER ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT. IF THE AWARDS DO NOT QUALIFY UNDER ANY PARTICULAR TAX TREATMENT IT COULD RESULT IN ADVERSE TAX CONSEQUENCES TO THE GRANTEE.
- 18.5. The Company or any Subsidiary or Affiliate may take such action as it may deem necessary or appropriate, in its discretion, for the purpose of or in connection with withholding of any taxes and compulsory payments which the Trustee, the Company or any Subsidiary or Affiliate is required by any Applicable Law to withhold in connection with any Awards (collectively, "Withholding Obligations"). Such actions may include (i) requiring a Grantees to remit to the Company in cash an amount sufficient to satisfy such Withholding Obligations and any other taxes and compulsory payments, payable by the Company in connection with the Award or the exercise or (if applicable) the vesting thereof; (ii) subject to Applicable Law, allowing the Grantees to provide Shares to the Company, in an amount that at such time, reflects a value that the Committee determines to be sufficient to satisfy such Withholding Obligations; (iii) withholding Shares otherwise issuable upon the exercise of an Award at a value which is determined by the Committee to be sufficient to satisfy such Withholding Obligations; or (iv) any combination of the foregoing. The Company shall not be obligated to allow the exercise of any Award by or on behalf of a Grantee until all tax consequences arising from the exercise of such Award are resolved in a manner acceptable to the Company.
- 18.6. Each Grantee shall notify the Company in writing promptly and in any event within ten (10) days after the date on which such Grantee first obtains knowledge of any tax bureau inquiry, audit, assertion, determination, investigation, or question relating in any manner to the Awards granted or received hereunder or Shares issued thereunder and shall continuously inform the Company of any developments, proceedings, discussions and negotiations relating to such matter, and shall allow the Company and its representatives to participate in any proceedings and discussions concerning such matters. Upon request, a Grantee shall provide to the Company any information or document relating to any matter described in the preceding sentence, which the Company, in its discretion, requires.
- 18.7. With respect to 102 Non-Trustee Options, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate with whom the Grantee is employed a security or guarantee for the payment of taxes due at the time of sale of Shares, all in accordance with the provisions of Section 102 of the Ordinance and the Rules.
- 18.8. For the purpose hereof "tax(es)" means (a) all federal, state, local or foreign taxes, charges, fees, imposts, levies or other assessments, including all income, capital gains, transfer, withholding, payroll, employment, social security, national security, health tax, wealth surtax, stamp, registration and estimated taxes, customs duties, fees, assessments and charges of any similar kind whatsoever (including under Section 280G of the Code), (b) all interest, indexation differentials, penalties, fines, additions to tax or additional amounts imposed by any taxing authority in connection with any item described in clause (a), (c) any transferee or successor liability in respect of any items described in clauses (a) or (b) payable by reason of contract, assumption, transferee liability, successor liability, operation of Applicable Law, or as a result of any express or implied obligation to assume Taxes or to indemnify any other person, and (d) any liability for the payment of any amounts of the type described in clause (a) or (b) payable as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group for any taxable period, including under U.S. Treasury Regulations Section 1.1502-6(a) (or any predecessor or successor thereof of any analogous or similar provision under Law) or otherwise.
- 18.9. If a Grantee makes an election under Section 83(b) of the Code to be taxed with respect to an Award as of the date of transfer of Shares rather than as of the date or dates upon which the Grantee would otherwise be taxable under Section 83(a) of the Code, such Grantee shall deliver a copy of such election to the Company upon or prior to the filing such election with the U.S. Internal Revenue Service. Neither the Company nor any Affiliate shall have any liability or responsibility relating to or arising out of the filing or not filing of any such election or any defects in its construction.

## 19. RIGHTS AS A SHAREHOLDER; VOTING AND DIVIDENDS.

- 19.1. Subject to Section 11.4, a Grantee shall have no rights as a shareholder of the Company with respect to any Shares covered by an Award until the Grantee shall have exercised the Award, paid the Exercise Price therefor and becomes the record holder of the subject Shares. In the case of 102 Awards or 3(9) Awards (if such Awards are being held by a Trustee), the Trustee shall have no rights as a shareholder of the Company with respect to the Shares covered by such Award until the Trustee becomes the record holder for such Shares for the Grantee's benefit, and the Grantee shall not be deemed to be a shareholder and shall have no rights as a shareholder of the Company with respect to the Shares covered by the Award until the date of the release of such Shares from the Trustee to the Grantee and the transfer of record ownership of such Shares to the Grantee (provided however that the Grantee shall be entitled to receive from the Trustee any cash dividend or distribution made on account of the Shares held by the Trustee for such Grantee's benefit, subject to any tax withholding and compulsory payment). No adjustment shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distribution of other rights for which the record date is prior to the date on which the Grantee or Trustee (as applicable) becomes the record holder of the Shares covered by an Award, except as provided in Section 14 hereof.
- 19.2. With respect to all Awards issued in the form of Shares hereunder or upon the exercise or (if applicable) the vesting of Awards hereunder, any and all voting rights attached to such Shares shall be subject to Section 6.9, and the Grantee shall be entitled to receive dividends distributed with respect to such Shares, subject to the provisions of the Company's Articles of Association, as amended from time to time, and subject to any Applicable Law.
- 19.3. The Company may, but shall not be obligated to, register or qualify the sale of Shares under any applicable securities law or any other Applicable Law.

## 20. NO REPRESENTATION BY COMPANY.

By granting the Awards, the Company is not, and shall not be deemed as, making any representation or warranties to the Grantee regarding the Company, its business affairs, its prospects or the future value of its Shares. The Company shall not be required to provide to any Grantee any information, documents or material in connection with the Grantee's considering an exercise of an Award. To the extent that any information, documents or materials are provided, the Company shall have no liability with respect thereto. Any decision by a Grantee to exercise an Award shall solely be at the risk of the Grantee.

## 21. NO RETENTION RIGHTS.

Nothing in this Plan, any Award Agreement or in any Award granted or agreement entered into pursuant hereto shall confer upon any Grantee the right to continue in the employ of, or be in the service of the Company or any Subsidiary or Affiliate thereof as a Service Provider or to be entitled to any remuneration or benefits not set forth in this Plan or such agreement, or to interfere with or limit in any way the right of the Company or any such Subsidiary or Affiliate to terminate such Grantee's employment or service (including, any right of the Company or any of its Affiliates to immediately cease the Grantee's employment or service or to shorten all or part of the notice period, regardless of whether notice of termination was given by the Company or its Affiliates or by the Grantee). Awards granted under this Plan shall not be affected by any change in duties or position of a Grantee, subject to Sections 6.6 through 6.8. No Grantee shall be entitled to claim and the Grantee hereby waives any claim against the Company or any Subsidiary or Affiliate that he or she was prevented from continuing to vest Awards as of the date of termination of his or her employment with, or services to, the Company or any Subsidiary or Affiliate. No Grantee shall be entitled to any compensation in respect of the Awards which would have vested had such Grantee's employment or engagement with the Company (or any Subsidiary or Affiliate) not been terminated.

#### 22. PERIOD DURING WHICH AWARDS MAY BE GRANTED.

Awards may be granted pursuant to this Plan from time to time within a period of ten (10) years from the Effective Date, which period may be extended from time to time by the Board. From and after such date (as extended) no grants of Awards may be made and this Plan shall continue to be in full force and effect with respect to Awards or Shares issued thereunder that remain outstanding.

#### 23. AMENDMENT OF THIS PLAN AND AWARDS.

- 23.1. The Board at any time and from time to time may suspend, terminate, modify or amend this Plan, whether retroactively or prospectively. Any amendment effected in accordance with this Section shall be binding upon all Grantees and all Awards, whether granted prior to or after the date of such amendment, and without the need to obtain the consent of any Grantee. No termination or amendment of this Plan shall affect any then outstanding Award unless expressly provided by the Board.
- 23.2. Subject to changes in Applicable Law that would permit otherwise, without the approval of the Company's shareholders, there shall be (i) no increase in the maximum aggregate number of Shares that may be issued under this Plan as Incentive Stock Options (except by operation of the provisions of Section 14.1), (ii) no change in the class of persons eligible to receive Incentive Stock Options, and (iii) no other amendment of this Plan that would require approval of the Company's shareholders under any Applicable Law. Unless not permitted by Applicable Law, if the grant of an Award is subject to approval by shareholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval. Failure to obtain approval by the shareholders shall not in any way derogate from the valid and binding effect of any grant of an Award, which is not an Incentive Stock Option. Upon approval of an amendment to this Plan by the shareholders of the Company as set forth above, all Incentive Stock Options granted under this Plan on or after such amendment shall be fully effective as if the shareholders of the Company had approved the amendment on the same date.
- 23.3. The Board or the Committee at any time and from time to time may modify or amend any Award theretofore granted, including any Award Agreement, whether retroactively or prospectively.

## 24. APPROVAL.

- 24.1. This Plan shall take effect upon its adoption by the Board (the "Effective Date").
- 24.2. Solely with respect to grants of Incentive Stock Options, this Plan shall also be subject to shareholders' approval, within one year of the Effective Date, by a majority of the votes cast on the proposal at a meeting or a written consent of shareholders (however, if the grant of an Award is subject to approval by shareholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval). Failure to obtain such approval by the shareholders within such period shall not in any way derogate from the valid and binding effect of any grant of an Award, except that any Options previously granted under this Plan may not qualify as Incentive Stock Options but, rather, shall constitute Nonqualified Stock Options. Upon approval of this Plan by the shareholders of the Company as set forth above, all Incentive Stock Options granted under this Plan on or after the Effective Date shall be fully effective as if the shareholders of the Company had approved this Plan on the Effective Date.
- 24.3. 102 Awards are conditional upon the filing with or approval by the ITA, if required, as set forth in Section 9.4. Failure to so file or obtain such approval shall not in any way derogate from the valid and binding effect of any grant of an Award, which is not an 102 Award.

## 25. RULES PARTICULAR TO SPECIFIC COUNTRIES; SECTION 409A.

- 25.1. Notwithstanding anything herein to the contrary, the terms and conditions of this Plan may be supplemented or amended with respect to a particular country or tax regime by means of an appendix to this Plan, and to the extent that the terms and conditions set forth in any appendix conflict with any provisions of this Plan, the provisions of such appendix shall govern. Terms and conditions set forth in such appendix shall apply only to Awards granted to Grantees under the jurisdiction of the specific country or such other tax regime that is the subject of such appendix and shall not apply to Awards issued to a Grantee not under the jurisdiction of such country or such other tax regime. The adoption of any such appendix shall be subject to the approval of the Board or the Committee, and if determined by the Committee to be required in connection with the application of certain tax treatment, pursuant to applicable stock exchange rules or regulations or otherwise, then also the approval of the shareholders of the Company at the required majority.
- 25.2. This Section 25.2 shall only apply to Awards granted to Grantees who are subject to United States Federal income tax.
- 25.2.1. It is the intention of the Company that no Award shall be deferred compensation subject to Code Section 409A unless and to the extent that the Committee specifically determines otherwise as provided in Section 25.2.2, and the Plan and the terms and conditions of all Awards shall be interpreted and administered accordingly.

- 25.2.2. The terms and conditions governing any Awards that the Committee determines will be subject to Section 409A of the Code, including any rules for payment or elective or mandatory deferral of the payment or delivery of Shares or cash pursuant thereto, and any rules regarding treatment of such Awards in the event of a Change in Control, shall be set forth in the applicable Award Agreement and shall be intended to comply in all respects with Section 409A of the Code, and the Plan and the terms and conditions of such Awards shall be interpreted and administered accordingly.
- 25.2.3. The Company shall have complete discretion to interpret and construe the Plan and any Award Agreement in any manner that establishes an exemption from (or compliance with) the requirements of Code Section 409A. If for any reason, such as imprecision in drafting, any provision of the Plan and/or any Award Agreement does not accurately reflect its intended establishment of an exemption from (or compliance with) Code Section 409A, as demonstrated by consistent interpretations or other evidence of intent, such provision shall be considered ambiguous as to its exemption from (or compliance with) Code Section 409A and shall be interpreted by the Company in a manner consistent with such intent, as determined in the discretion of the Company. If, notwithstanding the foregoing provisions of this Section 25.2.3, any provision of the Plan or any such agreement would cause a Grantee to incur any additional tax or interest under Code Section 409A, the Company shall reform such provision in a manner intended to avoid the incurrence by such Grantee of any such additional tax or interest; provided that the Company shall maintain, to the extent reasonably practicable, the original intent and economic benefit to the Grantee of the applicable provision without violating the provisions of Code Section 409A.
- 25.2.4. Notwithstanding any other provision in the Plan, any Award Agreement, or any other written document establishing the terms and conditions of an Award, if any Grantee is a "specified employee," within the meaning of Section 409A of the Code, as of the date of his or her "separation from service" (as defined under Section 409A of the Code), then, to the extent required by Treasury Regulation Section 1.409A-3(i)(2) (or any successor provision), any payment made to such Grantee on account of his or her separation from service shall not be made before a date that is six months after the date of his or her separation from service. The Committee may elect any of the methods of applying this rule that are permitted under Treasury Regulation Section 1.409A-3(i)(2)(ii) (or any successor provision).
- 25.2.5. Notwithstanding any other provision of this Section 25.2 to the contrary, although the Company intends to administer the Plan so that Awards will be exempt from, or will comply with, the requirements of Code Section 409A, the Company does not warrant that any Award under the Plan will qualify for favorable tax treatment under Code Section 409A or any other provision of federal, state, local, or non-United States law. The Company shall not be liable to any Grantee for any tax, interest, or penalties the Grantee might owe as a result of the grant, holding, vesting, exercise, or payment of any Award under the Plan.

## 26. GOVERNING LAW; JURISDICTION.

This Plan and all determinations made and actions taken pursuant hereto shall be governed by the laws of the State of Israel, except with respect to matters that are subject to tax laws, regulations and rules of any specific jurisdiction, which shall be governed by the respective laws, regulations and rules of such jurisdiction. Certain definitions, which refer to laws other than the laws of such jurisdiction, shall be construed in accordance with such other laws. The competent courts located in Tel-Aviv-Jaffa, Israel shall have exclusive jurisdiction over any dispute arising out of or in connection with this Plan and any Award granted hereunder. By signing any Award Agreement or any other agreement relating to an Award, each Grantee irrevocably submits to such exclusive jurisdiction.

## 27. NON-EXCLUSIVITY OF THIS PLAN.

The adoption of this Plan shall not be construed as creating any limitations on the power or authority of the Company to adopt such other or additional incentive or other compensation arrangements of whatever nature as the Company may deem necessary or desirable or preclude or limit the continuation of any other plan, practice or arrangement for the payment of compensation or fringe benefits to employees generally, or to any class or group of employees, which the Company or any Affiliate now has lawfully put into effect, including any retirement, pension, savings and stock purchase plan, insurance, death and disability benefits and executive short-term or long-term incentive plans.

#### 28. MISCELLANEOUS.

- 28.1. <u>Survival</u>. The Grantee shall be bound by and the Shares issued upon exercise or (if applicable) the vesting of any Awards granted hereunder shall remain subject to this Plan after the exercise or (if applicable) the vesting of Awards, in accordance with the terms of this Plan, whether or not the Grantee is then or at any time thereafter employed or engaged by the Company or any of its Affiliates.
- 28.2. <u>Additional Terms</u>. Each Award awarded under this Plan may contain such other terms and conditions not inconsistent with this Plan as may be determined by the Committee, in its sole discretion.
- 28.3. <u>Fractional Shares</u>. No fractional Share shall be issuable upon exercise or vesting of any Award and the number of Shares to be issued shall be rounded down to the nearest whole Share, with in any Share remaining at the last vesting date due to such rounding to be issued upon exercise at such last vesting date.
- 28.4. <u>Severability</u>. If any provision of this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction. In addition, if any particular provision contained in this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall for any reason be held to be excessively broad as to duration, geographic scope, activity or subject, it shall be construed by limiting and reducing such provision as to such characteristic so that the provision is enforceable to fullest extent compatible with Applicable Law as it shall then appear.
- 28.5. <u>Captions and Titles</u>. The use of captions and titles in this Plan or any Award Agreement or any other agreement entered into in connection with an Award is for the convenience of reference only and shall not affect the meaning or interpretation of any provision of this Plan or such agreement.

# COMPENSATION POLICY GAMIDA CELL LTD.

## **Compensation Policy for Executive Officers and Directors**

(As Adopted by the Shareholders on October 24, 2018, Effective as of October 26, 2018)

	<u>Page</u>
A. Overview and Objectives	1
B. Base Salary and Benefits	3
D. Dusc omary and Deficites	3
C. Cash Bonuses	5
D. Equity Based Compensation	7
E. Retirement and Termination of Service Arrangements	8
F. Exculpation, Indemnification and Insurance	9
G. Arrangements upon Change of Control	10
H. Board of Directors Compensation	11
I. Miscellaneous	11

## A. Overview and Objectives

#### 1. Introduction

This document sets forth the Compensation Policy for Executive Officers and Directors (this "Compensation Policy" or "Policy") of Gamida Cell Ltd. ("Gamida" or the "Company"), in accordance with the requirements of the Companies Law, 5759-1999 (the "Companies Law").

Compensation is a key component of Gamida's overall human capital strategy to attract, retain, reward, and motivate highly skilled individuals that will enhance Gamida's value and otherwise assist Gamida to reach its long-term goals. Accordingly, the structure of this Policy is established to tie the compensation of each officer to Gamida's goals and performance.

For purposes of this Policy, "Executive Officers" shall mean "Office Holders" as such term is defined in Section 1 of the Companies Law, excluding, unless otherwise expressly indicated herein, Gamida's directors.

This policy is subject to applicable law and is not intended, and should not be interpreted as limiting or derogating from, provisions of applicable law to the extent not permitted.

This Policy shall apply to compensation agreements and arrangements which will be approved after the date on which this Policy is approved by the shareholders of Gamida and shall serve as Gamida's Compensation Policy for the maximum period of time permitted by any applicable law, commencing as of the closing of the initial public offering of Gamida's shares.

The Compensation Committee and the Board of Directors of Gamida (the "Board") shall review and reassess the adequacy of this Policy from time to time, as required by the Companies Law.

## 2. **Objectives**

Gamida's objectives and goals in setting this Policy are to attract, motivate and retain highly experienced leaders who will contribute to Gamida's success and enhance shareholder value, while demonstrating professionalism in a highly achievement-oriented culture that is based on merit and rewards excellent performance in the long term, and embedding Gamida's core values as part of a motivated behavior. To that end, this Policy is designed, among others:

- 2.1. To closely align the interests of the Executive Officers with those of Gamida's shareholders in order to enhance shareholder value;
- 2.2. To align a significant portion of the Executive Officers' compensation with Gamida's short and long-term goals and performance;
- 2.3. To provide the Executive Officers with a structured compensation package, including competitive salaries, performance-motivating cash and equity incentive programs and benefits, and to be able to present to each Executive Officer an opportunity to advance in a growing organization;
- 2.4. To strengthen the retention and the motivation of Executive Officers in the long term;
- 2.5. To provide appropriate awards in order to incentivize superior individual excellency and corporate performance; and
- 2.6. To maintain consistency in the way Executive Officers are compensated.

This Compensation Policy was prepared taking into account the Company's nature, size and business and financial characteristics.

## 3. **Compensation Instruments**

Compensation instruments under this Policy may include the following:

- 3.1. Base salary;
- 3.2. Benefits;
- 3.3. Cash bonuses (short-to-medium term incentive);
- 3.4. Equity based compensation (medium-to-long term incentive); and
- 3.5. Retirement and termination terms.

#### 4. Overall Compensation - Ratio Between Fixed and Variable Compensation

- 4.1. This Policy aims to balance the mix of "**Fixed Compensation**" (comprised of base salary and benefits) and "**Variable Compensation**" (comprised of cash bonuses and equity based compensation, which are based on the fair value on the date of grant, calculated annually, on a linear basis, excluding adjustment period/retirement bonuses, granted in accordance with section 16 below) in order to, among others, appropriately incentivize Executive Officers to meet Gamida's short and long term goals while taking into consideration the Company's need to manage a variety of business risks.
- 4.2. The total Variable Compensation of each Executive Officer shall not exceed 90% of the total compensation package of such Executive Officer on an annual basis. The Board believes that such range expresses the appropriate compensation mix in the event that all performance objectives are achieved and assumes that all compensation elements are granted with respect to a given year.

4.3. It should be clarified, that the Fixed Compensation may constitute 100% of the total compensation package for an Executive Officer in any year (under circumstances in which a variable component will not be approved for that year and/or in the event of a failure to meet the set goals, if and when determined).

## 5. Inter-Company Compensation Ratio

- 5.1. In the process of drafting this Policy, Gamida's Board and Compensation Committee have examined the ratio between employer cost associated with the engagement of the Executive Officers ((the "Executive Officers Cost"), including directors, and the average and median employer cost associated with the engagement of Gamida's other employees, including contractor employees as defined in the Companies Law (the "Other Employees Cost" and the "Ratio", respectively).
- 5.2. The Board believes that the current Ratio does not adversely impact the work environment in Gamida. The possible ramifications of the Ratio on the daily working environment in Gamida were examined and will continue to be examined by Gamida from time to time in order to ensure that levels of executive compensation, as compared to the overall workforce will not have a negative impact on work relations in Gamida.

## B. Base Salary Benefits

## 6. Base Salary

- 6.1. A Base Salary provides stable compensation to Executive Officers and allows Gamida to attract and retain competent executive talent and maintain a stable management team. The base salary varies among Executive Officers, and is individually determined according to the educational background, prior vocational experience, qualifications, company's role, business responsibilities and the past performance of each Executive Officer.
- 6.2. Since a competitive base salary is essential to Gamida's ability to attract and retain highly skilled professionals, Gamida will seek to establish a base salary that is competitive with base salaries paid to Executive Officers in a peer group of companies relevant to Gamida's field of business, while considering, among others, Gamida's size and field of operation and the geographical location of the employed Executive Officer. To that end, Gamida shall utilize as a reference, comparative market data and practices, which may include among others a compensation survey that compares and analyses the level of the overall compensation package offered to an Executive Officer of the Company with compensation packages in similar positions to that of the relevant Executive Officer in other companies operating in business sectors that are similar in their characteristics to Gamida's, as much as possible, while considering, among others, such companies' size and characteristics including their revenues, profitability rate, number of employees and operating arena (in Israel or globally). Such compensation survey may be conducted internally or through an external consultant.
- 6.3. The Compensation Committee and the Board may periodically consider and approve base salary adjustments for Executive Officers. The main considerations for salary adjustment are similar to those used in initially determining the base salary, but may also include among others, educational background, prior vocational experience, expertise and qualifications, change of role, business authorities and responsibilities, past performance and previous compensation arrangements with such Executive Officer, recognition for professional achievements, regulatory or contractual requirements, budgetary constraints or market trends. The Compensation Committee and the Board will also consider the previous and existing compensation arrangements of the Executive Officer whose base salary is being considered for adjustment. When determining the Base Salary, the Company may also decide to consider, at the sole discretion of the Compensation Committee and the Board and as required, the prevailing pay levels in the relevant market, Base Salary and the total compensation package of comparable Executive Officers in the Company, the proportion between the Executive Officer's compensation package and the salaries of other employees in the Company and specifically the median and average salaries and the effect of such proportions on the work relations in the Company.

## 7. **Benefits**

- 7.1. In addition to the Base Salary, the following benefits may be granted to the Executive Officers (subject to any applicable approval procedures), in order, among other things, to comply with legal requirements. It shall be clarified, that the list below is an open list and Gamida (subject to the applicable required approvals) may grant to its Executive Officers other similar, comparable or customary benefits, subject to the applicable law.
  - 7.1.1. Vacation days in accordance with market practice and the applicable law up to a cap of 30 days per annum;
  - 7.1.2. Sick days in accordance with market practice and the applicable law; However, the Company may decide to cover sick days from the first day;
  - 7.1.3. Convalescence pay according to applicable law;
  - 7.1.4. Medical Insurance in accordance with market practice and the applicable law;
  - 7.1.5. With respect to Executive Officers employed in Israel, Monthly remuneration for a study fund, as allowed by applicable law and with reference to Gamida's practice and the common market practice;
  - 7.1.6. Gamida shall contribute on behalf of the Executive Officer to an managers' insurance policy or a pension fund, as allowed by applicable law and with reference to Gamida's policies and procedures and the common market practice; and
  - 7.1.7. Gamida shall contribute on behalf of the Executive Officer towards work disability insurance, as allowed by applicable law and with reference to Gamida's policies and procedures and to the common market practice.
- 7.2. Non-Israeli Executive Officers may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which they are employed. Such customary benefits shall be determined based on the methods described in Section 6.2 of this Policy (with the necessary changes).
- 7.3. In the event of relocation of an Executive Officer to another geography, such Executive Officer may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which he or she is employed. Such benefits shall include reimbursement for out of pocket one-time payments and other ongoing expenses, such as housing allowance, car allowance, and home leave visit, etc.
- 7.4. Gamida may offer additional benefits to its Executive Officers, which will be comparable to customary market practices, including but not limited to: cellular and land line phone benefits, company car and travel benefits, reimbursement of business travel including a daily stipend when traveling and other business related expenses, insurances, other benefits (such as newspaper subscriptions, academic and professional studies), etc., provided, however, that such additional benefits shall be determined in accordance with Gamida's policies and procedures.

- 7.5. Gamida may reimburse its Executive Officers for reasonable work-related expenses incurred as part of their activities, including without limitations, meeting participation expenses, reimbursement of business travel, including a daily stipend when traveling and accommodation expenses.
- 7.6. At the discretion of the Compensation Committee and the Board (and with respect to the CEO- also the Company's general meeting of shareholders), Gamida may grant a newly recruited Executive Officer a signing bonus. Such bonus may be granted in cash, equity or a combination of both. The signing bonus will not exceed: (1) 50% of such Executive Officer's annual Base Salary, if the signing bonus is granted in cash; (2) 100% of such Executive Officer's annual Base Salary, if the signing bonus is a combination of cash and equity, its limit shall be proportional to the cash and equity components, calculated in accordance with the ratios mentioned in sections (1) and (2) above.

#### C. <u>Cash Bonuses</u>

## 8. Annual Cash Bonuses – The Objective

- 8.1. The Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may grant cash bonuses to its Executive Officers on a quarterly or annually basis, or on a shorter or longer period basis, in accordance with the principles detailed below.
- 8.2. Compensation in the form of an annual cash bonus is an important element in aligning the Executive Officers' compensation with Gamida's objectives and business goals. Therefore, a pay-for-performance element, as payout eligibility and levels are determined based on actual financial and operational results, as well as individual performance.
- 8.3. An annual cash bonus may be awarded to Executive Officers upon the attainment of pre-set periodical objectives and individual targets determined by the Compensation Committee (and, if required by law, by the Board) at the beginning of each calendar year, or upon engagement, in case of newly hired Executive Officers, taking into account Gamida's short and long-term goals, as well as its compliance and risk management policies. The Compensation Committee and the Board may also determine any applicable minimum thresholds that must be met for entitlement to the annual cash bonus (all or any portion thereof) and the formula for calculating any annual cash bonus payout, with respect to each calendar year, for each Executive Officer. In special circumstances, as determined by the Compensation Committee and the Board (e.g., regulatory changes, significant changes in Gamida's business environment, a significant organizational change and a significant merger and acquisition events), the Compensation Committee and the Board may modify the objectives and/or their relative weights during the calendar year.
- 8.4. In the event the employment of an Executive Officer is terminated prior to the end of a fiscal year, the Company may pay such Executive Officer a full annual cash bonus or a prorated one. Such bonus will become due on the same scheduled date for annual cash bonus payments by the Company.

#### 9. Annual Cash Bonuses - The Formula

#### **Executive Officers other than the CEO**

- 9.1. The annual cash bonus of Gamida's Executive Officers, other than the chief executive officer (the "CEO"), will be based on performance objectives and a discretionary evaluation of the Executive Officer's overall performance by the CEO and subject to minimum thresholds. The performance objectives will be recommended by Gamida's CEO and approved by the Compensation Committee (and, if required by law, by Gamida's Board) at the commencement of each calendar year (or upon engagement, in case of newly hired Executive Officers or in special circumstances as indicated in Section 8.3 above) on the basis of, but not limited to, company and individual objectives. Notwithstanding the above, the Company may determine that, with respect to any Executive Officer subordinated to the CEO, which does not serve as a director, a portion or all of his or her annual cash bonus will be based on the evaluation of the CEO.
- 9.2. The target annual cash bonus that an Executive Officer, other than the CEO, will be entitled to receive for any given calendar year, will not exceed 50% of such Executive Officer's annual base salary.
- 9.3. The maximum annual cash bonus including for overachievement performance that an Executive Officer, other than the CEO, will be entitled to receive for any given calendar year, will not exceed 100% of such Executive Officer's annual base salary.

## **CEO**

- 9.4. The annual cash bonus of Gamida's CEO will be mainly based on performance measurable objectives and subject to minimum thresholds. Such performance measurable objectives will be determined annually by Gamida's Compensation Committee (and, if required by law, by Gamida's Board) at the commencement of each calendar year (or upon engagement, in case of newly hired CEO or in special circumstances as indicated in Section 8.3 above) on the basis of, but not limited to, company and personal objectives. These performance measurable objectives, which include the objectives and the weight to be assigned to each achievement in the overall evaluation, will be categorized as described below:
  - 9.4.1. Between 40%-60% will be based on overall company performance measurable objectives;
  - 9.4.2. Between 20%-50% will be based on goals set forth in the Company's annual operating plan and long-term plan;
  - 9.4.3. The less significant part of the annual cash bonus granted to Gamida's CEO, and in any event not more than 25% of the annual cash bonus, may be based on a discretionary evaluation of the CEO's overall performance by the Compensation Committee and the Board.
- 9.5. The target annual cash bonus that the CEO will be entitled to receive for any given calendar year, will not exceed 100% of his or her annual base salary.
- 9.6. The maximum annual cash bonus including for overachievement performance that the CEO will be entitled to receive for any given calendar year, will not exceed 150% of his or her annual base salary.

#### 10. Other Bonuses

- 10.1. <u>Special Bonus</u>. Gamida may grant its Executive Officers a special bonus as an award for special achievements (such as in connection with mergers and acquisitions, offerings, achieving target budget or business plan under exceptional circumstances or special recognition in case of retirement) at the CEO's discretion (and in the CEO's case, at the Board's discretion), subject to any additional approval as may be required by the Companies Law (the "**Special Bonus**"). The Special Bonus will not exceed 30% of the Executive Officer's total compensation package on an annual basis.
- 10.2. <u>Signing Bonus</u>. Gamida may grant a newly recruited Executive Officer a signing bonus at the CEO's discretion (and in the CEO's case, at the Board's discretion), subject to any additional approval as may be required by the Companies Law (the "**Signing Bonus**"). The Signing Bonus will not exceed three (3) monthly entry base salaries of the Executive Officer.
- 10.3. Relocation Bonus. Gamida may grant its Executive Officers a special bonus in the event of relocation of an Executive Officer to another geography (the "Relocation Bonus"). The Relocation bonus will include customary benefits associated with such relocation and its monetary value will not exceed 30% of the Executive Officer's annual base salary.

## 11. Compensation Recovery ("Clawback")

- 11.1. In the event of an accounting restatement, Gamida shall be entitled to recover from its Executive Officers the bonus compensation in the amount in which such bonus exceeded what would have been paid under the financial statements, as restated ("Compensation Recovery"(, provided that a claim is made by Gamida prior to the third anniversary of fiscal year end of the restated financial statements.
- 11.2. Notwithstanding the aforesaid, the compensation recovery will not be triggered in the following events:
  - 11.2.1. The financial restatement is required due to changes in the applicable financial reporting standards;
  - 11.2.2. The Compensation Committee has determined that Clawback proceedings in the specific case would be impossible, impractical or not commercially or legally efficient; or
  - 11.2.3. The amount to be paid under the clawback proceedings is less than 10% of the relevant bonus received by the Executive Officer.
- 11.3. Nothing in this Section 11 derogates from any other "Clawback" or similar provisions regarding disgorging of profits imposed on Executive Officers by virtue of applicable securities laws.

## D. <u>Equity Based Compensation</u>

## 12. The Objective

12.1. The equity-based compensation for Gamida's Executive Officers is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the Executive Officers' interests with the long term interests of Gamida and its shareholders, and to strengthen the retention and the motivation of Executive Officers in the long term. In addition, since equity-based awards are structured to vest over several years, their incentive value to recipients is aligned with longer-term strategic plans.

- 12.2. The equity-based compensation offered by Gamida is intended to be in a form of share options and/or other equity based awards, such as RSUs, in accordance with the Company's equity incentive plan in place as may be updated from time to time.
- 12.3. All equity-based incentives granted to Executive Officers, other than performance-based incentives, shall be subject to vesting periods in order to promote long-term retention of the awarded Executive Officers. Unless determined otherwise in a specific award agreement approved by the Compensation Committee and the Board, grants to Executive Officers, other than directors and performance-based incentives, shall vest gradually over a period of between three (3) to five (5) years. Performance based incentives shall vest upon the Executive Officer achieving of performance measurable objectives.
- 12.4. All other terms of the equity awards shall be in accordance with Gamida's incentive plans and other related practices and policies. Accordingly, the Board may, following approval by the Compensation Committee, extend the period of time for which an award is to remain exercisable and make provisions with respect to the acceleration of the vesting period of any Executive Officer's awards, including, without limitation, in connection with a corporate transaction involving a change of control, subject to any additional approval as may be required by the Companies Law.

## 13. General guidelines for the grant of awards

- 13.1. The equity-based compensation shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the Executive Officer.
- 13.2. The fair market value of the equity-based compensation for the Executive Officers will be determined according to acceptable valuation practices at the time of grant based on a straight line approach.

## E. Retirement and Termination of Service Arrangements

#### 14. Advanced Notice Period

- 14.1. Gamida may provide an Executive Officer, pursuant to an Executive Officer's employment agreement and according to the Company's decision per each case, a prior notice of termination of up to six (6) months, except for the CEO whose prior notice may be of up to twelve (12) months (the "Advance Notice Period"), during which the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her equity awards.
- 14.2. During the Advance Notice Period, an Executive Officer will be required to keep performing his/her duties pursuant to his/her agreement with the Company, unless the Company has waived the Executive Officer's services to the Company during the Advance Notice Period and pay the amount payable in lieu of notice, plus the value of benefits.

## 15. Adjustment Period

Gamida may provide an additional adjustment period to an Executive Officer, other than the CEO, according to his/her seniority in the Company, his/her contribution to the Company's goals and achievements and the circumstances of retirement and to the CEO, during which the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options (the "Additional Adjustment Period"). The maximum adjustment period/retirement bonus that may be paid to each Executive Officer shall be up to six (6) month Base Salaries and may only be granted to Executive Officers who have served in the Company for at least one year.

#### 16. Additional Retirement and Termination Benefits

Gamida may provide additional retirement and terminations benefits and payments as may be required by applicable law (e.g., mandatory severance pay under Israeli labor laws), or which will be comparable to customary market practices.

#### 17. Non-Compete Grant

Upon termination of employment and subject to applicable law, Gamida may grant to its Executive Officers a non-compete grant as an incentive to refrain from competing with Gamida for a defined period of time. The terms and conditions of the Non-Compete grant shall be decided by the Board and shall not exceed such Executive Officer's monthly base salary multiplied by twelve (12).

## 18. Cap for Retirement and Termination of Service Arrangements

The maximum non-statutory retirement and termination of service arrangements payment to be granted to an Executive Officer will not exceed 200% of his or her annual base salary.

#### F. Exculpation, Indemnification and Insurance

#### 19. Exculpation

Subject to the provisions of the Companies Law, the Company may releases, in advance, any director or Executive Officer from liability towards the Company for any damage that arises from the breach of the director or Executive Officer duty of care to the Company (within the meaning of such terms under Sections 252 and 253 of the Companies Law), other than breach of the duty of care towards the Company in a distribution (as such term is defined in the Companies Law).

#### 20. **Insurance and Indemnification**

- 20.1. Gamida may indemnify its directors and Executive Officers to the fullest extent permitted by applicable law, for any liability and expense that may be imposed on the director or the Executive Officer, as provided in the Indemnity Agreement between such individuals and Gamida, all subject to applicable law and the Company's articles of association.
- 20.2. Gamida will provide directors' and officers' liability insurance (the "Insurance Policy") for its directors and Executive Officers as follows:
  - 20.2.1. The annual premium to be paid by the Gamida shall not exceed \$500,000;
  - 20.2.2. The limit of liability of the insurer shall not exceed the greater of \$50 million or 25% of the Company's shareholders equity based on the most recent financial statements of the Company at the time of approval by the Compensation Committee; and
  - 20.2.3. The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Compensation Committee (and, if required by law, by the Board) which shall determine that the sums are reasonable considering Gamida's exposures, the scope of coverage and the market conditions and that the Insurance Policy reflects the current market conditions, and it shall not materially affect the Company's profitability, assets or liabilities.

- 20.3. Upon circumstances to be approved by the Compensation Committee (and, if required by law, by the Board), Gamida shall be entitled to enter into a "run off" Insurance Policy of up to seven (7) years, with the same insurer or any other insurance, as follows:
  - 20.3.1. The limit of liability of the insurer shall not exceed the greater of \$50 million or 25% of the Company's shareholders equity based on the most recent financial statements of the Company at the time of approval by the Compensation Committee;
  - 20.3.2. The annual premium shall not exceed 400% of the last paid annual premium; and
  - 20.3.3. The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Compensation Committee (and, if required by law, by the Board) which shall determine that the sums are reasonable considering the Company's exposures covered under such policy, the scope of cover and the market conditions, and that the Insurance Policy reflects the current market conditions and that it shall not materially affect the Company's profitability, assets or liabilities.
- 20.4. Gamida may extend the Insurance Policy in place to include cover for liability pursuant to a future public offering of securities as follows:
  - 20.4.1. The additional premium for such extension of liability coverage shall not exceed 50% of the last paid annual premium; and
  - 20.4.2. The Insurance Policy, as well as the additional premium shall be approved by the Compensation Committee (and if required by law, by the Board) which shall determine that the sums are reasonable considering the exposures pursuant to such public offering of securities, the scope of cover and the market conditions and that the Insurance Policy reflects the current market conditions, and it does not materially affect the Company's profitability, assets or liabilities.

## G. Arrangements upon Change of Control

- 21. The following benefits may be granted to the Executive Officers in addition to the benefits applicable in the case of any retirement or termination of service upon a "Change of Control", following of which the employment of the Executive Officer is terminated or adversely adjusted in a material way:
  - 21.1. Vesting acceleration of outstanding options;
  - 21.2. Extension of the exercising period of options, restricted shares, restricted share units (RSUs) and/or other equity based awards for Gamida's Executive Officer for a period of up to five (5) years, following the date of employment termination; and
  - 21.3. Up to an additional six (6) months to the additional adjustment period. For avoidance of doubt, such Additional Adjustment Period shall be in addition to the Advance Notice Period and Additional Adjustment Period pursuant to Sections 14 and 15 of this Policy.
  - 21.4. A cash bonus not to exceed 100% of the Executive Officer's annual base salary in case of an Executive Officer other than the CEO and 150% in case of the CEO.

## H. Board of Directors Compensation

- 22. All Gamida's Board members shall be entitled to an equal annual and per-meeting compensation. Alternatively, Gamida's Board members may receive only an annual payment with respect to their services on the Board and additional annual payments for serving on board committees and as chairperson of the Board or its committees, without regard to their participation in meetings of the Board or its committees.
- 23. The compensation of the Company's external directors, if elected, shall be in accordance with the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 5760-2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel), 5760-2000, as such regulations may be amended from time to time ("Compensation of Directors Regulations") and, in any event, the annual payment and the per-meeting payment shall not be greater than two (2) times the maximal annual payment and per-meeting payment, respectively, allowed under the Compensation of Directors Regulations, in the case of Gamida.
- 24. The director's cash fee per calendar year shall not exceed an annual cash fee in the amount of \$120,000 plus VAT.
- 25. Notwithstanding the provisions of Sections 23 and 24 above, in special circumstances, such as in the case of a professional director, an expert director or a director who makes a unique contribution to the Company, such director's compensation may be different than the compensation of all other directors and maybe greater than the maximal amount allowed above.
- Each member of Gamida's Board, other than the chairperson, may be granted an annual equity-based compensation of up to half-a-percent (0.5%) of the fully diluted share capital of the Company. The chairperson of the Board may be granted an annual equity-based compensation up to one percent (1%) of the fully diluted share capital of the Company.
- 27. In addition, members of Gamida's Board may be entitled to reimbursement of expenses when traveling abroad on behalf of Gamida.
- 28. It is hereby clarified that the compensation stated under Section H will not apply to directors who serve as Executive Officers.

## I. Miscellaneous

- 29. It is hereby clarified that nothing in this Policy shall be deemed to grant any of Gamida's Executive Officers or employees or any third party any right or privilege in connection with their employment by the Company. Such rights and privileges shall be governed by the respective personal employment agreements. The Board may determine that none or only part of the payments, benefits and perquisites detailed in this Policy shall be granted, and is authorized to cancel or suspend a compensation package or part of it.
- 30. This Policy is subject to applicable law and is not intended, and should not be interpreted as limiting or derogating from, provisions of applicable law to the extent not permitted, nor should it be interpreted as limiting or derogating from the Company's Articles of Association.
- 31. This Policy is not intended to affect current agreements nor affect obligating customs (if applicable) between the Company and its Executive Officers as such may exist prior to the approval of this Compensation Policy, subject to any applicable law.

- 32. An Immaterial Change in the Terms of Employment of an Executive Officer other than the CEO may be approved by the CEO, provided that the amended terms of employment are in accordance with this Compensation Policy. An "Immaterial Change in the Terms of Employment" means a change in the terms of employment of an Executive Officer with an annual total cost to the Company not exceeding an amount equal to three (3) monthly gross salaries of such employee.
- 33. In the event that new regulations or law amendment in connection with Executive Officers and directors compensation will be enacted following the approval of this Compensation Policy, Gamida may follow such new regulations or law amendments, even if such new regulations are in contradiction to the compensation terms set forth herein.
- 34. It should be clarified, that the compensation components detailed in this Policy do not relate to various components that the Company may provide to all or part of its employees and/or its Executive Officers, such as: parking spaces, entry permits for its assets, reimbursement for meals and accommodation expenses, vacations, company events, etc.

\*\*\*

This Policy is designed solely for the benefit of Gamida and none of the provisions thereof are intended to provide any rights or remedies to any person other than Gamida.

[\*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

## MANUFACTURING SERVICES AGREEMENT

This Manufacturing Services Agreement (the "**Agreement**") is made as of May 31, 2019, (the "**Effective Date**") between with an office at Lonza Netherlands B.V., at Oxfordlaan 70, 6229EV Maastricht, The Netherlands ("**LONZA**"), and Gamida Cell Ltd., an Israeli corporation having an office at 5 Nahum Hafzadi St., Jerusalem 95484, Israel ("**GAMIDA**") (each of LONZA and GAMIDA, a "**Party**" and, collectively, the "**Parties**").

## **RECITALS**

- A. LONZA operates a multi-client production facility located at Urmonderbaan 20-B, 6167 RD Geleen, The Netherlands (the "Facility").
- **B.** GAMIDA desires to have LONZA produce a product containing human cells and intended for therapeutic use in humans, and LONZA desires to produce such product.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants hereinafter set forth, LONZA and GAMIDA, intending to be legally binding, hereby agree as follows:

#### **AGREEMENT**

#### 1 DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout this Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

- **1.1** "Acceptance Period" shall have the meaning set forth in Section 3.2.1.
- **1.2** "Affiliate" means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means direct or indirect ownership of more than fifty percent (50%) of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.
- **1.3** "Applicable Law" means any statute, law, treaty, rule, code, ordinance, regulation, that applies, as the context requires to: (i) the Agreement; (ii) the performance of obligations or other activities related to the Agreement; and (iii) a party, a party's Affiliates (if any), a party's subcontractors (if any), or to any of their representatives.
- **1.4 "APS Run"** means aseptic process simulation which must mimic the regular aseptic manufacturing processes used for specific products as closely as possible with respect to operator behavior, equipment and materials used. [\*] instead of product.

- **1.5 "Background Intellectual Property"** means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from performance under this Agreement during the term of the Agreement.
- **1.6 "Batch"** means a specific quantity of Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- **1.7 "Business Operating Hours**" means the hours and days when LONZA is available for business. Business hours are from 9:00 AM to 5:00 PM, Monday to Friday except for local public holidays.
- **1.8 "CAPEX"** means the fit out of existing (brownfield) buildings with certain pieces of equipment used to produce the Product, including, without limitation, the related documentation regarding the design, planning, validation, operation, calibration and maintenance of such equipment and the corresponding infrastructure and utilities.
- 1.9 "CBU" means [\*].
- **1.10** "cGMP" or "GMP" means the applicable regulatory requirements, as amended from time to time, for current good manufacturing practices, including without limitation those promulgated by (i) the FDA under the United States Federal Food, Drug and Cosmetic Act, 21 C.F.R. § 210 et seq., or (ii) the European Medicines Agency or under the European Union guide to good manufacturing practice for medicinal products.
- **1.11** "cGMP Batch" means any Batch which is required under this Agreement to be manufactured in accordance with cGMP for transplantation in patients (whether clinical or commercial) or for non-transplant purposes (e.g. process validation).
- **1.12** "Commencement Date" means [\*] or any other date agreed mutually by the Parties.
- **1.13** "Confidential Information" has the meaning set forth in Section 8.1.
- **1.14 "Dedicated Facility"** means an existing cleanroom [\*] (Launch Suite) followed by up to [\*] additional Suites within already available shell space (brownfield) located at the Facility and required support areas and systems to function as commercial manufacturing units, 100% owned by LONZA with LONZA responsible for all upkeep and repairs, and located at LONZA.
- **1.15** "**Disapproval Notice**" shall have the meaning set forth in Section 3.2.
- **1.16** "Engineering Batch" means a Batch that is intended to demonstrate the transfer of the Process to the Facility.

- **1.17** "**FDA**" means the U.S. Food and Drug Administration, and any successor agency thereof.
- **1.18** "GAMIDA Inventions" means any know-how media, assays, methods or inventions, whether or not patentable, conceived, developed or reduced to practice by, or on behalf of, GAMIDA on or before the Effective Date.
- **1.19** "GAMIDA New IP" has the meaning set forth in Section 9.1.2.
- 1.20 "GAMIDA Personnel" shall mean GAMIDA's employees and agents...
- **1.21** "GAMIDA Production Materials" has the meaning set forth in Section 2.3.
- **1.22** "GAMIDA-specific Operating Documents" shall mean any LONZA Operating Documents that are solely and specifically related to the Product.
- **1.23 "Intellectual Property"** means all worldwide patents, copyrights, trade secrets, know-how and all other intellectual property rights, including all applications and registrations with respect thereto, but excluding all trademarks, trade names, service marks, logos and other corporate identifiers.
- **1.24** "LONZA Inventions" means any know-how, media, assays, methods or other inventions, whether or not patentable, conceived, developed or reduced to practice by LONZA: (a) on or before the Effective Date; or (b) in connection with the performance of the Agreement but only to the extent such invention would not be GAMIDA New IP. For clarity, LONZA Inventions do not include GAMIDA New IP.
- **1.25** "LONZA New IP" has the meaning set forth in Section 9.1.3.
- **1.26 "LONZA Operating Documents"** means the standard operating procedures, standard manufacturing procedures, raw material specifications, protocols, validation documentation, and supporting documentation used by LONZA, such as environmental monitoring, for operation and maintenance of the Facility and the Dedicated Facility and LONZA equipment used in the process of producing the Product, excluding any of the foregoing that are unique to the manufacture of Product.
- **1.27** "**LONZA Parties**" has the meaning set forth in Section 13.2.
- **1.28** "Materials" means all raw materials and supplies to be used in the production of a Product.
- **1.29** "Master Batch Record" means the production record pertaining to a Batch.
- **1.30** "**Process**" means the manufacturing process for a Product.
- **1.31** "**Product(s)**" means the Products as set forth in Appendix 1
- **1.32** "**Product Warranties**" means those warranties as specifically stated in Section 3.1.
- **1.33 "Production Term"** shall have the meaning set forth in Section 2.5.

- **1.34 "Project Documentation"** means the compilation of documentation generated by LONZA and GAMIDA in preparation of and during the performance of the Agreement including, without limitation, executed batch records, component records, test records and test record forms, certificates of analysis, study protocols, study summary reports, deviation reports, laboratory investigations, environment excursions, formulation records, and other related documents
- **1.35** "Quality Agreement" means the Quality Agreement relating to a Product entered into by the Parties by signature of this Agreement or until August 31st, 2019 at the latest.
- **1.36** "Regulatory Approval" means the approval by the FDA or EMA to market and sell the Product in the respective markets.
- **1.37** "Services" means the activities to be performed by LONZA under the Agreement.
- **1.38** "Slot" means available manufacturing unit in order to produce the Product.
- **1.39** "SOP" means a standard operating procedure.
- **1.40** "Specifications" means the Product specifications set forth in the applicable SOPs and the certificate of analysis or as modified by the Parties, in writing, in connection with the production of a particular cGMP Batch of Product hereunder.
- **1.41** "Statement of Work" or "SOW" means the plan related to the commercial readiness activities. It is contemplated that each Statement of Work shall be incorporated and made a part of this Agreement.
- **1.42 "Suite"** means a clean room, which is a room, designed, maintained and controlled to prevent particle and microbiological contamination of the Product(s). Such a room is assigned and reproducibility meets an appropriate air cleanliness air classification, [\*].
- **1.43** "Third Party" means any party other than LONZA, GAMIDA or their respective Affiliates.
- **1.44** "Validation Batches" means commercial scale batches that are successfully manufactured consecutively in order to validate a process according to a validation protocol that was developed and authorized by both Parties ("Protocols").

#### 2 MANUFACTURE OF PRODUCT; ORDER PROCESS; DELIVERIES

2.1 Engineering Batches. If requested and agreed between the Parties LONZA shall manufacture Engineering Batches in accordance with the Agreement and Applicable Law. GAMIDA shall have the right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, such use is not for human use and does not violate any Applicable Law. [\*]. The expenses relating to any Engineering Batch manufactured in connection with the preparation of a new Suite will be covered by the payment due (if any) with respect to the activation of such new Suite and any Engineering Batch manufactured thereafter shall be covered as one of the Batches manufactured in the particular Suite. The Parties will discuss whether Engineering Batches will be required for any new Suites.

- **2.2 Validation Batches.** LONZA will, in accordance with the terms of this Agreement, Applicable Law and the Quality Agreement, manufacture at the Facility and release to GAMIDA, Validation Batches that comply with the Protocol, Process, cGMP and the Specifications, together with a certificate of analysis; provided, however, that cGMP manufacture shall not commence until at least one [\*] been manufactured in compliance with cGMP and Specifications, unless agreed between the Parties that [\*] is required with respect to certain Suite.
- **2.3 APS Runs.** LONZA shall perform in each Suite media fill / APS runs [\*]. The Parties will discuss in good faith the timing of such batches in order to avoid any interruption to the production.
- 2.4 GAMIDA Deliverables. GAMIDA will provide LONZA with the materials listed in Appendix 3 required for the production of the Product, and any handling instructions, protocols, SOPs and other documentation necessary to maintain the properties of such materials for the performance of the Agreement as set forth in Appendix 3 and to be amended from time to time (collectively, the "GAMIDA Production Materials"). In addition, GAMIDA shall be responsible for the procurement and shipment of the clinical starting material ('Cord Blood Unit CBU') from the Cord Blood Banks (CBBs) to LONZA following patient recruitment. The Parties will agree on the process of the confirmation of the applicable manufacturing Slot of each Suite and may use for this matter either a designated person to coordinate the Slots or use a designated software. GAMIDA shall provide CBU in such way that receipt at LONZA can be accommodated [\*] prior to a scheduled manufacturing run and LONZA undertakes to accept the CBU at LONZA at [\*]. For the avoidance of doubt, performance by LONZA on [\*]. LONZA will not use the GAMIDA Production Materials for any purpose other than the manufacture and supply of Product to GAMIDA under this Agreement and will treat GAMIDA Production Materials as GAMIDA Confidential Information.

**Operational Model.** LONZA's personnel will perform the work in a [\*] model per Suite as the CBUs are to be processed [\*] a week [\*]. Each Suite will have a maximum capacity of [\*] available Slots per year which can be used by GAMIDA for the production of Products either for commercialization, for clinical research or for any other purpose to be agreed by the Parties (such agreement of LONZA shall not be unreasonably withheld or delayed). For the avoidance of doubt the manufacturing will be done in accordance with an identical Process or any modified Process to be agreed by the Parties.

The initial launch is estimated for [\*] and will be performed in the existing Suite 007 in Module A ("Launch Suite"). The launch Suite has a maximum capacity of [\*] Slots per year.

The first built out Suite will be ready for commercial production (following successful manufacturing of Validation Batches) no later [\*]. LONZA will use commercially reasonable efforts to provide the first Suite earlier than [\*].

The dedicated Suites and allocated resources will be utilized to manufacture the Product. The number of headcounts and the throughput per Suite are based on current process assumptions and understandings, which may be adjusted, if required. LONZA will utilize a Suite-fee model assuming one (1) build out Suite as set forth in Appendix 4. Each Suite is approximately [\*] in size including [\*] workstations to support a maximum throughput of [\*] Slots per year (equals approximately [\*] Slots per month, equally distributed across the calendar year but taking into account the planned shutdown time; i.e. lost Slots cannot be recovered, based on a [\*] model). Each Suite is staffed with an estimated number of [\*] personnel including 20% overage to cover weekend work and overtime. Furthermore, each Suite undergoes a [\*] shut down for planned preventive maintenance and requalification which shall be coordinated with GAMIDA and in any event there will be no planned shut down while no other Suite is operational assuming GAMIDA commits to build out of the first Suite in [\*].

LONZA assumes that the Launch Suite has a maximum throughput of [\*] Slots per months, i.e. [\*] Slots per year, and is staffed with an estimated number of [\*].

LONZA will ramp up headcount in line with the updated forecast whereby it is estimated that hiring takes approximately [\*] and training takes approximately [\*], i.e. approximately [\*] in total, provided that any training of new personnel that intend to replace (for any reason) any existing personnel that was already trained shall be borne by LONZA, excluding any Materials that will be required with respect to any turnover of less than [\*] of the existing personnel (with respect to each calendar year) will be covered by GAMIDA. The training process shall include the following: [\*]. Without derogating from the foregoing, the complete training plans will be agreed by the Parties including any change to such plan. LONZA will use commercially reasonable efforts to use existing headcount for any *ad hoc* increases in forecast. LONZA and GAMIDA agree to work jointly on identifying efficiencies such as reduced headcount number, electronic batch records, and improvements of operations to reduce cost of manufacturing, as set forth in Appendix 5. LONZA will assess headcount requirements on a biannual basis and adjust as required while fees will be adjusted accordingly. For clarification, such adjustments will be governed by the Joint Steering Committee (JSC) as further defined below. It is agreed that in case that following the Commencement Date there is no manufacturing of Batches in the Suites, there will be at least [\*] manufacturing per [\*] in each Suite for maintenance purposes.

**2.5 Joint Steering Committee.** Promptly after execution of this Agreement, the Parties shall establish a steering committee to oversee, review and coordinate the activities of the Parties under this Agreement and facilitate communications between the Parties with respect to such activities (the "Joint Steering Committee" or "JSC" Each Party shall nominate representatives for the JSC.

The Joint Steering Committee shall meet at least [\*] per calendar year during the Term of the Agreement, or as otherwise mutually agreed by Parties. Decisions of the JSC shall be made by unanimity, with each Party having one vote. The decisions shall be reduced to writing and shall be shared with both parties.

- **2.6 Manufacturing by LONZA.** Upon the Commencement Date and for the Term of the Agreement (the "Production Term") the Product will be manufactured at the Facility. LONZA will use best efforts to manufacture package, ship, handle quality assurance and quality control for the Product and to deliver to GAMIDA the Product as requested, all in accordance with the terms set forth in this Agreement. LONZA will perform all activities under this Agreement in accordance with Applicable Law.
- 2.7 In the event of any suspension or delay caused or requested by GAMIDA which doesn't result from the fault or negligence of LONZA, GAMIDA will pay all sums owing to LONZA for work completed up to the effective termination date and reasonable costs incurred by LONZA in accordance with this Agreement during the term of the suspension or delay, including without limitation, LONZA's out-of-pocket expenses related to the purchase of unmarketable materials which have become unusable by reason of such suspension or delay, all uncancellable commitments which incur costs during the suspension or delay, labor charges, suite fees for suites and all professional services rendered through the term of suspension or delay. Within [\*] of the end of each calendar month during the term of the suspension or delay, LONZA shall submit an invoice for expenses and time expended during such month and any costs incurred by LONZA as a result of such suspension or delay.
- 2.8 In the event of any Manufacturing reduction (i.e. Manufacturing which does not comply with the binding Forecast) or suspension due to shortage of any of the LONZA Materials (excluding any shortage due to any LONZA's act or omission or failure to comply of its agreement with such supplier), then GAMIDA will pay: [\*]. For the avoidance of doubt in case LONZA will only manufacture [\*] Batches instead of a binding forecast of [\*] Batches per suite and per month with respect to the first [\*] the headcount fee and the suite fee per month shall be as follows: [\*]. It being agreed that both Parties will discuss and agree together by [\*] on a procurement plan with respect to all the Materials in order to avoid, as much as possible, any shortage of Materials.
- **2.9** Notwithstanding the foregoing, LONZA shall have the right to revise the production schedule provided that: (i) such schedule does not advance or delay the commencement date of any Batch by more than [\*]; and (ii) The original shipment day of the Product to the medical center is not changed.
- Agreement in effect at the time of performance by LONZA. LONZA will ship the Product in accordance with the date scheduled in advance provided that in the event GAMIDA requires to delay such date it will provide LONZA with not less than [\*] notice, provided that such notice is issued within Business Operating Hours and the shipping date is within Business Operating Hours. LONZA will ship the Product [\*] or as otherwise agreed upon in writing between the Parties. The shipping process of the Product will be agreed by the Parties before the Commencement Date. [\*]. Each shipment will be accompanied by the documentation agreed upon between the Parties. Risk and title in the Product will pass according to the Incoterms official guidelines (with respect to [\*]). The Parties will agree on performing the ordering, delivery and shipping using a designated system which will be qualified and in compliance with the regulatory requirement with respect to COC (chain of custody) and COI (chain of identity) and any other Applicable Laws. GAMIDA shall be required to take physical possession of a Batch of Product within [\*] after acceptance of such Batch in accordance with Section 3.2 (the "Delivery Period"), unless GAMIDA requests in writing, and LONZA consents in writing, to store the Batch on GAMIDA's behalf for a period of up to [\*] (free of charge).

- **2.11 Quality Agreement.** The Parties shall enter into a separate Quality Agreement no later than [\*] which will be based upon the quality agreement previously executed between the Parties, in a form to be agreed upon by the Parties. Such Quality Agreement when executed shall be appended separately to this Agreement and in case of a conflict between this Agreement and the Quality Agreement, the provisions under the Quality Agreement shall govern with respect to any quality matters.
- 2.12 Records. LONZA will maintain accurate records for the production of the Product, as required by Applicable Laws and the Quality Agreement. LONZA will retain possession of the Master Batch Records, all Project Documentation and LONZA Operating Documents. LONZA Operating Documents will remain LONZA Confidential Information and LONZA will provide electronic copies of the GAMIDA specific operating documents within [\*] following GAMIDA's request subject to the confidentiality obligations under this Agreement. LONZA Operating Documents which contain proprietary information of LONZA will not be shared electronically with GAMIDA but may be exceptionally and upon prior written LONZA internal approval by the Site Head of LONZA or any other designated person of the JSC be shared electronically. For the avoidance of doubt and except for the electronic copies of the GAMIDA-specific operating documents to be sent to GAMIDA, any LONZA operating Documents shall remain in the possession of LONZA. LONZA will provide GAMIDA and its representatives with copies of executed batch records for all product lots manufactured by LONZA. LONZA will provide GAMIDA and its representatives a Letter of Authorization to cross-reference to their Type V Facility Drug Manufacturing File ('DMF') for GAMIDA's IND amendment. LONZA will prepare section 32A1 facility and equipment and provide it to GAMIDA on time to include it in the BLA submission. LONZA will review relevant S and P BLA sections.

#### 2.13 GAMIDA Access

- 2.13.1 GAMIDA's employees may present in the production of the Product in case of repeated failures in Production only after they are "gowning qualified" by LONZA personnel.
- 2.13.2 GAMIDA will pay for the actual cost of repairing or replacing to its previous status (to the extent that LONZA determines, in its reasonable judgment, that repairs cannot be adequately effected) any property of LONZA damaged or destroyed by GAMIDA Personnel (as shall be reasonably proven by LONZA), provided GAMIDA shall not be liable for repair or replacement costs resulting from ordinary wear and tear.
- 2.13.3 GAMIDA Personnel visiting or having access to the Facility will abide by LONZA standard policies, operating procedures and the security procedures established by LONZA. GAMIDA will be liable for any breaches of security by GAMIDA Personnel. In addition, GAMIDA will reimburse LONZA for the cost of any lost security cards issued to GAMIDA Personnel, at the rate of [\*] per security card. All GAMIDA Personnel will agree to abide by LONZA policies and SOPs established by LONZA and conveyed in writing to GAMIDA, and will sign an appropriate confidentiality agreement.
- 2.13.4 GAMIDA will indemnify and hold harmless LONZA from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) arising out of any injuries suffered by GAMIDA Personnel while at the Facility or elsewhere, except to the extent caused by the gross negligence or willful misconduct on the part of any LONZA Party.
- **2.14 Disclaimers.** GAMIDA acknowledges and agrees that LONZA Parties will not engage in any Product refinement or development of the Product, other than as expressly set forth in this Agreement. GAMIDA acknowledges and agrees that LONZA Parties have not participated in the invention or testing of any Product, and have not evaluated its safety or suitability for use in humans or otherwise.

#### 3 PRODUCT WARRANTIES; ACCEPTANCE AND REJECTION OF PRODUCTS

**3.1 Product Warranties.** LONZA warrants that any Product manufactured by LONZA pursuant to this Agreement, at the time of delivery: (a) conforms to the Specifications, except with respect to Engineering Batches; (b) was manufactured in accordance with the Project Documentation; and (c) where applicable, was manufactured in accordance with cGMP and Applicable Law, except with respect to Engineering Batches.

#### 3.2 Approval of Product

3.2.1 When a cGMP Batch ordered by GAMIDA has been completed, LONZA will notify GAMIDA and supply GAMIDA with the required Project Documentation set forth in this Agreement. Within [\*] after GAMIDA's receipt of such documentation regarding such cGMP Batch (the "Acceptance Period"), GAMIDA shall determine by review of such documentation whether or not the given cGMP Batch conforms to the product warranties set forth in Section 3.1 above ("Product Warranties"). If GAMIDA asserts that the cGMP Batch does not comply with the Product Warranties set forth in Section 3.1 above, GAMIDA will deliver to LONZA, in accordance with the notice provisions set forth in Section 14.4 hereof, written notice of disapproval (the "Disapproval Notice") of such cGMP Batch, stating in reasonable detail the basis for such assertion of non-compliance with the Product Warranties. If a valid Disapproval Notice is received by LONZA during the Acceptance Period, then LONZA and GAMIDA will provide one another with all related paperwork and records (including, but not limited to, quality control tests) relating to both the production of the cGMP Batch and the Disapproval Notice. If a valid Disapproval Notice is not received during the Acceptance Period, the cGMP Batch will be deemed accepted and ready for shipment to GAMIDA, or storage for GAMIDA, as applicable. The above procedure shall not derogate from LONZA's liability for a period of time of 60 days after delivery of the Product for any failure to comply with the Product Warranties which could not reasonably have been determined by GAMIDA from the review of the Project Documentation.

- 3.2.2 If Product is to be shipped to GAMIDA, then upon acceptance, the Product shall be delivered to GAMIDA, and GAMIDA shall accept delivery thereof, in accordance with the shipping terms set forth in Section 2.8. If the Product is to be stored by LONZA for GAMIDA, LONZA shall do so in accordance with the terms as set forth in this Agreement and the Quality Agreement.
- 3.3 **Dispute Resolution.** LONZA and GAMIDA will attempt to resolve any dispute regarding the conformity of a cGMP Batch with the Product Warranties. If such dispute cannot be settled within [\*] of the submission by each Party of such related paperwork and records to the other Party, and if the cGMP Batch is alleged not to conform with the Product Warranties set forth in Section 3.1(a), then GAMIDA will submit a sample of the cGMP Batch of the disputed Product to an independent expert or independent testing laboratory of recognized repute either of which is selected by GAMIDA and approved by LONZA (such approval not to be unreasonably withheld) for analysis, under quality assurance approved procedures, of the conformity of such cGMP Batch with the Specifications. The costs associated with such analysis by such independent expert or independent testing laboratory will be paid by the Party whose assessment of the conformity of the cGMP Batch with the Specifications was mistaken. Without derogating from the foregoing, it is agreed that to the extent such independent testing laboratory is unable determine whether or not the Product conforms with the Product Warranties, then the dispute will be submitted to an arbitrator, with the requisite scientific background and training selected jointly by LONZA and GAMIDA. Such arbitrator will determine whether the Product shipped by LONZA conforms with the Product Warranties and either Party's responsibility to any nonconformity discovered (if any), and such arbitrator's findings will be final and binding. The arbitration shall take place in London (or other place to be agreed by the Parties) and shall be conducted in English. The costs and expenses of such arbitrator will be borne by the party that does not prevail in the arbitration proceeding.

#### 3.4 Remedies for Non-Conforming Product

3.4.1 In the event that the Parties agree, or an independent testing laboratory or arbitrator if applicable determines, pursuant to Section 3.3, that a cGMP Batch materially fails to conform to the Product Warranties (in a manner that the Product can't be used for the treatment), or Product and/or Materials are destroyed or damaged by LONZA Personnel, due to: (a) the failure of LONZA personnel properly to execute the Project Documentation; (b) the failure of LONZA personnel to comply with cGMP or (c) the negligence or willful misconduct of LONZA or LONZA personnel, then, at GAMIDA's request, LONZA will either (i) (at GAMIDA's discretion), as soon as it is commercially practicable to do so, produce [\*] for GAMIDA sufficient quantities of Product to replace the non-conforming, portion of such cGMP Batch (the "**Production Rerun**"), in accordance with the provisions of this Agreement and at no additional cost to GAMIDA, or (ii) refund the cost of the original Batch of Product, such refund shall include the cost of the applicable [\*], which shall be calculated as [\*], provided, however that in case Product and/or Materials are destroyed or damaged due to negligence of LONZA Personnel (excluding gross negligence or willful misconduct) the [\*] will be equally split between both Parties.

- 3.4.2 In the event that the Parties agree, or an independent testing laboratory determines, pursuant to Section 3.3, that a cGMP Batch materially fails to conform to the Product Warranties, or Product and/or Materials are destroyed or damaged by LONZA Personnel, for any reason other than as set forth in Section 3.4.1, then [\*] with respect to such cGMP Batch, Product or Material. Notwithstanding anything to the contrary set forth in Section 3.4, if during the manufacture of Product pursuant to this Agreement, Product or Materials are destroyed or damaged by LONZA Personnel while LONZA Personnel were acting at the written direction of GAMIDA Personnel, then [\*].
- 3.4.3 GAMIDA acknowledges and agrees that, other than as set forth in Section 13.1 and except for any failure under 3.4.1(a) (c), its sole remedy with respect to [\*], is as set forth in this Section 3.4, and in furtherance thereof, GAMIDA hereby waives all other remedies at law or in equity regarding the foregoing claims. Notwithstanding the foregoing and subject to Section 15.2 below, in the event of (a) [\*] failure rate (or more) of Products to conform to the Product Warranties (including due to Product and/or Materials destroyed or damaged by LONZA Personnel under Section 3.4.1 above) with respect to any calendar year following Commencement Date provided that such failures were caused due to LONZA's fault; or (b) [\*] failure rate (or more) of Products to conform to the Product Warranties with respect to any calendar year following Commencement Date (including due to Product and/or Materials destroyed or damaged by LONZA Personnel under Section 3.4.1 above), provided that (i) the termination right as set forth below will not apply with respect to [\*] if the failure rate at the end of [\*] following the applicable year is [\*], and (ii) the above failures were caused due to LONZA's fault; or (c) unplanned shutdown of any Suite due to LONZA's fault for a period of more than [\*], and such shutdown doesn't terminate within [\*], then GAMIDA may terminate this Agreement [\*]. With respect to each failure there will be a root cause study in order to decide what is the cause of the failure and whether the failure is due to LONZA's fault, if no conclusion can be made then the root cause shall be decided by the JSC and if the JSC fails to reach an agreement it will be escalated to the [\*]. In the case the Parties cannot come to an agreement in regards to the root cause, however, agree to a settlement resulting in a credit with regard to the failed Batch, this result will not be counted as a as a failure with respect to the failure rate of [\*] as set forth above.

#### 4 FORECASTS AND PRODUCTION SCHEDULE

- 4.1 No later than the [\*] of each calendar quarter starting with the Effective Date on May 31, 2019, GAMIDA shall supply LONZA with a written rolling non-binding forecast showing GAMIDA's good faith estimated annual requirements for Slots for the following [\*] (the "Forecast") as set forth in Appendix 2. No later than [\*] following LONZA's receipt of a Forecast, LONZA shall provide written notice to GAMIDA of whether it has (as of the date of receipt of the Forecast) capacity available to manufacture the number of Slots forecasted therein and shall provide GAMIDA with an estimated production schedule showing the estimated date for the commencement of the production of each Product and estimated delivery date of each Product. GAMIDA shall provide LONZA [\*] notice for shipment of CBUs for new manufacture.
- 4.2 The prerequisite is for LONZA to plan for additional Suite build-out (including facility validation, APS Runs and Process Validation) with a lead-time of [\*] with respect to the Suites subject to issuance of the respective Purchase Order within [\*] by GAMIDA and subsequent confirmation by LONZA (which shall not be unreasonably withheld or delayed); LONZA will use [\*] to reduce the time for build out. The forecast and notice of available capacity given in this Section 4.1 shall not be binding on GAMIDA or LONZA. The first [\*] of any Forecast shall be binding with respect to the Suites and [\*] with respect to the headcount ("Binding Forecast")
- **4.3** GAMIDA shall outsource to LONZA the greater of (i) LONZA proposed capacity as set forth in Appendix 2 as shall be amended in accordance with the ongoing Forecast, or (ii) at least [\*] of GAMIDA's commercial demand (collectively the "**Minimum Annual Binding Order**"). For the avoidance of doubt, if GAMIDA fails to outsource to LONZA at least the Minimum Annual Binding Order not due to any suspension of any Suite due to LONZA's fault or any other breach of the terms of this Agreement by LONZA, GAMIDA shall pay to LONZA the remaining Minimum Annual Binding Order within [\*] following the applicable calendar year end. GAMIDA will provide LONZA with annual reports sufficient for determining the applicable Minimum Annual Binding Order.

#### 5 CAPEX

**5.1** GAMIDA will fund [\*] of a conceptual engineering design study (which will be mutually agreed upon) to determine the Suite layout and cost for the build out of up to [\*]. The fee for such study is estimated to be [\*].

- 5.2 The Parties agree that for the Launch Suite no investment will be required. For the first Suite [\*] will cover the CAPEX for the build out of the Suite. Notwithstanding the foregoing, however, both Parties will [\*] the CAPEX to invest in the build out of Suites No. [\*]. LONZA will manage the construction of the Suite and accept for all overruns and contingency costs related to the agreed upon scope of the project as defined in the Conceptual Engineering Design. The CAPEX per Suite as determined by the engineering design study is estimated in the amount of [\*]. The actual CAPEX per Suite is to be determined after the completion of the engineering design study and subject to the actual market situation. All subsequent build outs of additional Suites will have to be costed subject to actual market conditions. LONZA shall provide GAMIDA immediately upon request and as needed with documentation supporting the cost of the CAPEX per each such Suite.
- 5.3 GAMIDA will fund all process equipment as detailed in Appendix 3. However, LONZA will be responsible for the procurement of all process equipment, including process-specific equipment provided that the purchases of such equipment will be approved and funded by GAMIDA. The installation and validation of the equipment will be performed by [\*]. During the Term of this Agreement LONZA will own all process equipment. All process equipment, funded by GAMIDA, will be returned to GAMIDA upon termination of this Agreement. GAMIDA will be responsible for all fees related to crating and shipping. GAMIDA will be responsible for all fees related to maintenance, repair, upgrade, replacement and requalification of process equipment except for repair or replacement costs related to any negligence act or omission of LONZA or LONZA Personnel. LONZA will manage all activities described above and related to process equipment.

#### 6 MATERIALS AND REGULATORY MATTERS

- 6.1 Pre-Production. LONZA will store Materials purchased on behalf of GAMIDA and shipped to LONZA for use in Production more than [\*] prior to the manufacturing of the Batch. These Materials include (but not limited to) disposables, media, supplements, and reagents which are required in the manufacture of the Product. No storage fees will be charged for any period [\*]. LONZA will maintain a minimum of [\*] worth of unexpired, usable Raw Materials at all times to prevent interruption in manufacturing. LONZA shall not be responsible or liable if any such Raw Materials become obsolete, expired, excess inventory or are otherwise no longer usable as long as the purchase thereof is made in accordance with the binding Forecast and with the FIFO principle, provided that a detailed report of the Production Materials (including the expiration date thereof) shall be produced and provided to GAMIDA on a monthly basis. The cost for LONZA's service with respect to the Materials purchased by both Parties is the amount of one Thousand US Dollars (US\$1,000) for each Batch manufactured by LONZA.
- **Post-Production**. LONZA will store at the Facility free of charge up to [\*] for GAMIDA in a validated, monitored, controlled Refrigerator, Freezer (<-20 °C), Ultra Low Freezer (<-70 °C) or LN2 freezer any in–process materials (other than Product manufactured hereunder and Production Materials which will be used for further Products' manufacturing) that remains at the Facility on the date of completion of the manufacturing of the applicable Product (collectively "**Remaining GAMIDA Property**"). LONZA will notify GAMIDA upon expiry of the [\*] storage for GAMIDA to advice on how to proceed within [\*].

- **6.3 Permits and Approvals.** During the term, LONZA will maintain any licenses, permits and approvals necessary for the manufacture of the Product in the Facility. LONZA will promptly notify GAMIDA if LONZA receives notice that any such license, permit, or approval is or may be revoked or suspended.
- **Inspections/Quality Audit by GAMIDA**. Except as otherwise set forth in the Quality Agreement, up to once per year and upon not less than [\*] prior written notice, LONZA will permit GAMIDA or its consultants or advisers [\*] and for [\*] maximum, or as otherwise agreed upon, at no charge, to inspect and audit the Dedicated Facility and any additional parts of the Facility which may be relevant to cGMP manufacturing of the Product in order to assess LONZA's compliance with cGMP and the Project Documentation, and to discuss any related issues with LONZA's management personnel. In addition to the foregoing, GAMIDA and/or its representatives shall have the right to perform "For Cause" audits at any time upon reasonable advance notice and during regular business hours. If a For Cause audit confirms that LONZA complied with its obligations under the Agreement and there was no basis for said audit, the audit shall be charged by LONZA at LONZA's standard hourly rates apply. Notwithstanding the foregoing, a For Cause audit shall also be at no cost for GAMIDA if it is GAMIDA's sole audit in such calendar year. For the avoidance of doubt, any and all costs related to modifications to the Dedicated Facility requested by GAMIDA (outside of those related to cGMP violations or other breach of the terms of this Agreement attributable to LONZA which costs shall be the sole responsibility of LONZA), will be subject to LONZA's approval (which will not be unreasonably withheld or delayed) and will be charged by LONZA in accordance with a fee agreed by the Parties in a separate Statement of Work.
- 6.5 Inspections by Regulatory Agencies. Except as otherwise set forth in the Quality Agreement, LONZA will allow representatives of any regulatory agency to inspect the relevant parts of the Facility where the manufacture of the Product is carried out and to inspect the Project Documentation and Batch Records to verify compliance with cGMP and other practices or regulations and will promptly notify GAMIDA of the scheduling of any such inspection relating to the manufacture of Product. Except as otherwise set forth in the Quality Agreement, LONZA will promptly send to GAMIDA a copy of any reports, citations, or warning letters received by LONZA in connection with an inspection of a regulatory agency to the extent such documents relate to or affect the manufacture of the Product. If a regulatory agency notifies LONZA and/or GAMIDA that certain actions are required by LONZA in order to comply with the regulations applicable to the manufacture of Product, then LONZA shall, at no additional charge to GAMIDA, perform such actions as soon as practicable. To the extent that such review, audit, or inspection relates solely to manufacture of Product and no other product manufactured by LONZA, GAMIDA shall be given the opportunity to be present at any such audit visit and to provide assistance to LONZA in responding to any such review, audit, or inspection. If GAMIDA elects to provide input to the response, such input will be provided by GAMIDA as promptly as practicable and within the time-frame specified at the time by LONZA.

**Cooperation.** LONZA will use commercially reasonable efforts to cooperate with GAMIDA with respect to any regulatory and manufacturing matters, including, but not limited to, by supplying, either directly to the respective regulatory agency when permitted or alternatively to GAMIDA under strict confidentiality to those employees or agents of GAMIDA who have a need to know for such purposes and under a separate confidentiality agreement specific to the request, all information, data, and GAMIDA-specific documents legally required by GAMIDA in connection with its regulatory submissions related to Product. For clarity, if GAMIDA-specific Operating Documents, and/or portions thereof are necessary for obtaining Regulatory Approvals of Product, then LONZA shall provide copies of the GAMIDA-specific Operating Documents, or the applicable portions of such GAMIDA-specific Operating Documents to the applicable regulatory agency, or GAMIDA if it is not possible for LONZA to provide directly to the applicable regulatory agency, whether by means of a drug master file in the U.S., or any foreign equivalent, or otherwise, and GAMIDA shall have the right to use, incorporate and/or reference such GAMIDA-specific Operating Documents, or applicable portions of such GAMIDA-specific Operating Documents, in connection with such Regulatory Approvals.

#### 7 FINANCIAL TERMS

- 7.1 Fees. For the manufacturing of the Product GAMIDA shall pay LONZA the fees as set forth in Appendix 4.
- 7.2 **Payments.** GAMIDA will make payments to LONZA in the amounts and on the dates set forth in the Agreement upon date of an invoice from LONZA. In the event that GAMIDA has not paid an invoice within [\*] of the applicable due date (as established by Section 7.3), GAMIDA's failure shall be considered a material breach under Section 12.2, subject to the cure provisions set forth therein. Further, in addition to all other remedies available to LONZA, in the event that GAMIDA has not paid an invoice within [\*] of the applicable due date (as established by Section 7.3), LONZA may elect to suspend the provision of all or a portion of the services under this Agreement. In the event that GAMIDA has a reasonable dispute with regard to any amounts invoice, GAMIDA shall provide written notice of such dispute, in reasonable detail, within [\*] of receipt of invoice. The Parties shall meet to discuss such dispute and shall use commercially reasonable efforts to resolve any such dispute within [\*] after the date of such written notice. Upon the determination that the amount is no longer in dispute and is and was properly payable, such amount shall be payable immediately.
- **7.3 Payment Terms**. All invoices shall be paid within [\*] from the end of the month during which the applicable invoice was received.
- **7.4 Invoices and Pricing.** LONZA will deliver invoices electronically by email, which shall be considered to be an original invoice. Invoices should be e-mailed to [\*], and/or to such other e-mail address(es) as GAMIDA may stipulate from time to time. LONZA will not deliver a paper invoice. Unless otherwise provided in the Agreement, all pricing excludes taxes and costs relating to shipping, validation and regulatory filings. The price shall be invoiced to GAMIDA in the local currency of the location of the Facility.

- **7.5 Taxes.** GAMIDA agrees that it is responsible for and will pay any sales, use or other taxes (the "**Taxes**") resulting from LONZA's production of Product under this Agreement (except for income or personal property taxes payable by LONZA). To the extent not paid by GAMIDA, GAMIDA will indemnify and hold harmless the LONZA Parties from and against any and all penalties, fees, expenses and costs whatsoever in connection with the failure by GAMIDA to pay the Taxes. LONZA will not collect any sales and use taxes from GAMIDA in connection with the production of any Product hereunder if GAMIDA provides to LONZA the appropriate valid exemption certificates.
  - If applicable laws require (Israel) withholding taxes, such taxes will be deducted from the sums in an amount and will be paid by GAMIDA to the proper taxing authority, and the proof of payment shall be sent to LONZA. The Parties agree to cooperate in all respects reasonably necessary to take advantage of such double taxation treaties as may be available.
- **7.6 Interest**. Any fee, charge or other payment due to LONZA by GAMIDA under this Agreement that is not paid within [\*] after it is due will accrue interest on a daily basis at a rate of [\*] (or the maximum legal interest rate allowed by applicable law, if less) from and after such date.
- **7.7 Method of Payment**. Except as otherwise set forth in Section 7.3, all payments to LONZA hereunder by GAMIDA will be in EURO and will be by check, wire transfer, money order, or other method of payment approved by LONZA. Bank information for wire transfers is as follows:

Mailing address for wire transfer payments:

[\*]

**7.8 Cost Adjustments.** As of [\*], LONZA may annually adjust the various costs and rates set forth in the Agreement attached hereto to reflect changes in labor rate paid by LONZA in connection with the production of Product under this Agreement; provided, however, that any increase in labor rates shall not exceed [\*] [\*]. LONZA shall provide GAMIDA with written notice and reasonable documentation of any such cost adjustment at least [\*] prior.

#### 8 CONFIDENTIAL INFORMATION

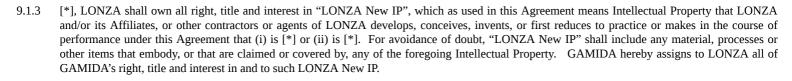
- **8.1 Definition**. "Confidential Information" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business, that has been disclosed by or on behalf of such Party or such Party's Affiliates to the other Party or the other Party's Affiliates either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement. Without limiting the foregoing, the terms of this Agreement will be deemed "Confidential Information" and will be subject to the terms and conditions set forth in this Article8. Notwithstanding anything to the contrary herein, "GAMIDA New IP" is the Confidential Information of GAMIDA regardless of the Party initially disclosing it.
- **8.2 Exclusions.** Notwithstanding the foregoing Section 8.1, any information disclosed by a Party to the other Party will not be deemed "Confidential Information" to the extent that such information:
  - **A.** at the time of disclosure is in the public domain;
  - B. becomes part of the public domain, by publication or otherwise, through no fault of the Party receiving such information;
  - **C.** at the time of disclosure is already in possession of the Party who received such information, as established by contemporaneous written records;
  - **D.** is lawfully provided to a Party, without restriction as to confidentiality or use, by a Third Party lawfully entitled to possession of such Confidential Information; or
  - **E.** is independently developed by a Party without use of or reference to the other Party's Confidential Information, as established by contemporaneous written records.
- **8.3 Disclosure and Use Restriction**. Except as expressly provided herein, the Parties agree that for the term of the Agreement and the [\*] period following any termination of the Agreement, each Party and its Affiliates will keep completely confidential and will not publish or otherwise disclose any Confidential Information of the other Party, its Affiliates or sub licensees, except in accordance with Section 8.4. Neither Party will use Confidential Information of the other Party except as necessary to perform its obligations or to exercise its rights under this Agreement.

- **Permitted Disclosures**. Each receiving Party agrees to (i) institute and maintain security procedures to identify and account for all copies of Confidential Information of the disclosing Party and (ii) limit disclosure of the disclosing Party's Confidential Information to its U.S. and European Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors having a need to know such Confidential Information for purposes of this Agreement; provided that such U.S. and European Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors are informed of the terms of this Agreement and are subject to obligations of confidentiality, non-disclosure and non-use similar to those set forth herein and further provided that each Party will remain liable for any breach of the confidentiality obligations under this Agreement by any of its or its Affiliates' officers, directors, employees, agents, consultants and independent contractors.
- **8.5 Government-Required Disclosure.** If a duly constituted government authority, court or regulatory agency orders that a Party hereto disclose information subject to an obligation of confidentiality under this Agreement, such Party shall comply with the order, but shall notify the other Party as soon as possible, so as to provide the said Party an opportunity to apply to a court of record for relief from the order.
- **8.6 Publicity.** Neither Party will refer to, display or use the other's name, trademarks or trade names confusingly similar thereto, alone or in conjunction with any other words or names, in any manner or connection whatsoever, including any publication, article, or any form of advertising or publicity, except with the prior written consent of the other Party or in connection with any correspondence or submissions to any regulatory authority.
- **8.7 Publications**. The Parties intend to agree on a mutual publication in a form to be agreed by the Parties.

#### 9 INTELLECTUAL PROPERTY

#### 9.1 Ownership

- 9.1.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party. Except as expressly otherwise provided herein, ownership of any Intellectual Property that is developed, conceived, invented, first reduced to practice or made in connection with the performance under this Agreement shall follow inventorship all as determined under U.S. Law.
- 9.1.2 [\*], GAMIDA shall own all right, title, and interest in and to any and all Intellectual Property that LONZA and/or its Affiliates develops, conceives, invents, first reduces to practice or makes, solely or jointly with GAMIDA or others, that is a [\*] and/or [\*] (collectively, "GAMIDA New IP"). LONZA hereby assigns to GAMIDA all of LONZA's right, title and interest in and to such GAMIDA New IP. LONZA shall promptly disclose to GAMIDA in writing all GAMIDA New IP. LONZA shall execute, and shall require its personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of this Agreement to execute, any documents reasonably required to confirm GAMIDA's ownership of GAMIDA New IP, and any documents required to apply for, maintain and enforce any patent or other right in the GAMIDA New IP.



#### 9.2 License Grants

- 9.2.1 During the term of this Agreement, GAMIDA hereby grants to LONZA a fully paid, non-exclusive license under any and all GAMIDA Intellectual Property that is necessary for LONZA to perform its obligations under this Agreement for the sole and limited purpose of LONZA's performance of its obligations under this Agreement, including, without limitation, the development of the Process and the manufacture of Product for GAMIDA.
- 9.2.2 Subject to the terms and conditions set forth herein (including the payment required under this Agreement), LONZA hereby grants to GAMIDA a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the LONZA New IP, [\*].
- 9.2.3 [\*].
- 9.2.4 [\*]
  - [\*].

**9.3 Further Assurances**. Each Party agrees to take all necessary and proper acts, and will cause its employees, Affiliates, contractors, and consultants to take such necessary and proper acts, to effectuate the ownership provisions set forth in this Article 9.

#### 9.4 Prosecution of Patents

- 9.4.1 LONZA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming LONZA Inventions and LONZA New IP at LONZA's expense. GAMIDA will cooperate with LONZA to file, prosecute and maintain patent applications and patents claiming LONZA Inventions, and will have the right to review and provide comments to LONZA relating to such patent applications and patents.
- 9.4.2 GAMIDA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming GAMIDA Inventions and GAMIDA New IP at GAMIDA's expense. LONZA will cooperate with GAMIDA to file, prosecute and maintain patent applications and patents claiming GAMIDA Inventions, and will have the right to review and provide comments to GAMIDA relating to such patent applications and patents.

#### 10 REPRESENTATIONS AND WARRANTIES

- **10.1 By GAMIDA.** GAMIDA hereby represents and warrants to LONZA that, to the best of its knowledge, (i) it has the requisite intellectual property and legal rights related to the GAMIDA Deliverables and the Product to authorize the performance of LONZA's obligations under this Agreement, and (ii) the performance of the Agreement and the production by LONZA of the Product as contemplated in this Agreement will not give rise to a potential cause of action by a Third Party against LONZA for infringement or another violation of intellectual property rights. Such representation and warranty will not apply to any production equipment supplied by LONZA.
- 10.2 By LONZA. LONZA hereby represents and warrants to GAMIDA that, to the best of its knowledge, (i) it or its Affiliates have the requisite intellectual property rights in its equipment and Facility to be able to perform its obligations under this Agreement, and (ii) [\*]. LONZA further represents and warrants to GAMIDA that: (a) it has the full corporate right, power, and authority to enter into this Agreement and perform its obligations hereunder; (b) it will not sub-contract any of its rights or obligations and/or the performance of the services to be rendered under this Agreement or any part thereof without prior written approval of GAMIDA and in any event it shall not nor shall it use any subcontractors for any performance of this Agreement that are on any excluded or denied party list of any agency of the United States Government, or if its export privileges are denied, suspended, or revoked by the United States Government; (c) it has not been: (A) debarred by the United States Food and Drug Administration under any provision of the Generic Drug Enforcement Act; or (B) excluded by the Office of the Inspector General of the United States Department of Health and Human Services, or by any other authority, from participating in any health care program (such as Medicare or Medicaid) funded by any Governmental Authority and further agrees that no person who has been debarred or excluded as described above will perform any of LONZA's obligations under the Agreement; (d) it and its subcontractors are not included on any list of restricted entities, persons, or organizations published by any member state of the European Union, the United States of America government, the United Nations, or other Governmental Authority, including the U.S. Treasury Department's List of Specially Designated Nationals and Blocked Persons, Sectoral Sanctions Identifications List, and Foreign Sanctions Evaders List, the U.S. Commerce Department's Entity List, Denied Persons List, and Unverified List, the U.S. State Department's nonproliferation lists, and the EU's Consolidated List of Designated Persons, (collectively, the "Sanctions Lists") or are owned or controlled by a person or entity which is included on such Sanctions Lists. LONZA will use commercially reasonable efforts to notify GAMIDA in writing within five (5) business days of any actions taken or pending that threaten or confirm a debarment or exclusion of any such person.

#### 11 DISCLAIMER; LIMITATION OF LIABILITY

- 11.1 DISCLAIMER. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, LONZA MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, WITH RESPECT TO THE PRODUCTS, MATERIALS, AND SERVICES PROVIDED UNDER THIS AGREEMENT, AND LONZA SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE WITH RESPECT TO SUCH PRODUCTS, MATERIALS, OR SERVICES.
- 11.2 Disclaimer of Consequential Damages. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
- 11.3 Limitation of Liability. BOTH PARTIES HEREBY AGREE THAT TO THE FULLEST EXTENT PERMITTED BY LAW, LONZA'S LIABILITY TO GAMIDA, FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT FROM ANY CAUSE OR CAUSES, INCLUDING, BUT NOT LIMITED TO, NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY ("TOTAL LIABILITY"), SHALL NOT EXCEED THE LESSER OF [\*] THE TOTAL CHARGES PAID BY GAMIDA TO LONZA UNDER THIS AGREEMENT DURING THE [\*] PRECEDING THE EVENT GIVING RISE TO LIABILITY OR [\*], PROVIDED THAT TO THE EXTENT THE EVENT GIVING RISE TO LIABILITY HAS OCCURRED BEFORE THE LAPSE OF THE [\*] FOLLOWING THE EFFECTIVE DATE, THEN THE TOTAL LIABILITY SHALL BE TWICE THE TOTAL EXPECTED FEES TO BE PAYABLE BY GAMIDA TO LONZA ACCORDING TO THE AGREEMENT AND ANY OUTSTANDING STATEMENTS OF WORK WITH RESPECT TO THE [\*] FOLLOWING THE EFFECTIVE DATE. TO THE EXTENT THAT THIS SECTION CONFLICTS WITH ANY OTHER SECTION, THIS SECTION SHALL TAKE PRECEDENCE OVER SUCH CONFLICTING SECTION. IF APPLICABLE LAW PREVENTS ENFORCEMENT OF THIS SECTION, THEN THIS SECTION SHALL BE DEEMED MODIFIED TO PROVIDE THE MAXIMUM PROTECTION FOR LONZA AS IS ALLOWABLE UNDER APPLICABLE LAW.

**11.4 Carve-Outs.** The limitations set forth in this Section 11 shall not apply to damages caused due to, or in connection with, either Party's (i) gross negligence or willful misconduct; (ii) breach of the confidentiality obligations as set forth in section 8; (iii) [\*] (iv) intentional misappropriation of other Party's Intellectual Property rights; and (v) [\*].

#### 12 TERM AND TERMINATION

- **12.1 Term**. The total term of this Agreement shall be, the shorter of seven (7) years from the signature of the Agreement or five (5) years after the first FDA approval ("Total Term"), unless terminated earlier as set forth below. [\*] prior to the expiration of the Total Term at the latest the Parties will discuss in good faith an extension of the Agreement by an additional term of two (2) years in writing.
- 12.2 Termination for Material Breach. Either Party may terminate this Agreement, by written notice to the other Party, for any material breach of this Agreement by the other Party, if such breach is not cured within forty five (45) days after the breaching Party receives written notice of such breach from the non-breaching Party; provided, however, that if such breach is not capable of being cured within such forty five-day period and the breaching Party has commenced and diligently continued actions to cure such breach within such [\*] period, except in the case of a payment default, the cure period shall be extended to [\*], so long as the breaching Party is making diligent and continuous efforts to do so. Such termination shall be effective upon expiration of such cure period. It is hereby agreed by the Parties that in the event that with respect to the Launch Suite GAMIDA is not ready for BLA submission (i.e. following successful manufacturing of Validation Batches summarized in a report signed by both Parties) due to LONZA's or its subcontractors fault by [\*] (as may be amended by the Parties), or if the Launch Suite is not ready for commercial production in accordance with this Agreement (including written approval of the FDA of successful Pre Approval Inspection) within [\*] from the Commencement Date, it shall be deemed as non-curable material breach of the Agreement and GAMIDA shall have the right to [\*] terminate the Agreement in accordance with this Section 12.2, and further provided that GAMIDA will pay [\*].

**Termination without Cause by GAMIDA**. Following the third (3rd) anniversary of the Effective Date (the "Initial term"), during which this Agreement shall be considered as non-cancellable without cause, GAMIDA shall have the right to terminate for convenience by providing LONZA with [\*] prior written notice (such notice period, "the GAMIDA Termination for Convenience Notice Period"). During the GAMIDA Termination for Convenience Notice Period, GAMIDA shall pay LONZA a termination for convenience payment equal to [\*] of Suite fees and [\*] of headcount fees as set forth in this Agreement. However, LONZA will use commercially reasonable efforts to reallocate headcount upon notice by GAMIDA and if such headcount can be reallocated, the associated headcount fees will be reduced to reflect such reallocation. GAMIDA must stop all manufacturing operations no later than [\*] prior to the final termination date to allow for organized wind down and retrofitting of Suites. LONZA will return all the process equipment purchased by or with the funding of GAMIDA. It is hereby clarified, that GAMIDA will pay the headcount fees following the termination notice if the headcount cannot fully be reallocated to another client.

**12.3 Termination without cause by LONZA**. Following the Initial term, LONZA shall have the right to terminate for convenience by providing GAMIDA with [\*] prior written notice (such notice period, "the LONZA Termination for Convenience Notice Period"). If requested, LONZA will provide up to [\*] people for [\*] to support any required tech transfer of the process to another manufacturing site. However and for the avoidance of doubt, any associated cost for LONZA shall not to exceed one (1) million € (including personnel and general costs) in expenses for support during the [\*].

For clarification, LONZA shall not have the right to terminate the Agreement within the first [\*] from the time of operational readiness of a Suite.

In the event that GAMIDA terminates the Agreement within the first [\*] from the time of operational readiness of a Suite, GAMIDA will be responsible for [\*] of applicable Suite fees and [\*] of headcount fees. LONZA will use commercially reasonable efforts to reallocate headcount upon notice by GAMIDA and associated headcount fees will be reduced.

**12.4 Termination for Regulatory Reasons.** In case GAMIDA does not receive market approval by [\*] or cease to pursue market approval GAMIDA has the right to terminate the Agreement upon [\*] written notice. Upon any such termination, GAMIDA shall pay LONZA a termination fee equal to the sum of: (i) [\*] of the Suite fee and (ii) [\*] of the then headcount fees as set forth in this Agreement.

It is hereby agreed by the Parties that in case the market approval may be delayed due to reasons outside LONZA's control the Parties will agree upon new terms and conditions of this Agreement and GAMIDA shall be responsible for all additional costs and expenses arising out of such delay, such as but not limited to Suite fees and Head Count Fees, provided that LONZA shall make its best efforts to minimize and mitigate such costs and expenses.

**12.5 Termination by Insolvency.** Either Party may terminate this Agreement upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [\*] of such appointment; (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within [\*] of filing.

#### 12.6 Effects of Termination

- 12.6.1 **Accrued Rights**. Termination of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to such termination. Such termination will not relieve a Party of obligations that are expressly indicated to survive the termination of this Agreement. Without limitation of the foregoing, in the event of termination hereunder (except for termination by GAMIDA under Section 12.2), LONZA shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; and (ii) all costs incurred or commitments through the date of termination, including costs and fees for Materials used or purchased for use in connection with the Services. In the case of termination by LONZA for GAMIDA's material breach, all scheduled Services and Batches shall be deemed cancelled by GAMIDA, and cancellation fees shall be calculated as of the date of written notice of termination.
- 12.6.2 **Disposition of Remaining GAMIDA Property and Confidential Information**. Upon termination or expiration of this Agreement, LONZA will store any Remaining GAMIDA Property as set forth in Section 6.2 and, at GAMIDA's option, return or destroy any GAMIDA Confidential Information in the possession or control of LONZA. Likewise, GAMIDA will, at LONZA's option, return or destroy any LONZA Confidential Information in the possession or control of GAMIDA. Notwithstanding the foregoing provisions: (i) LONZA may retain and preserve, at its sole cost and expense, samples and standards of each Product following termination or expiration of this Agreement solely for use in determining LONZA's rights and obligations hereunder; and (ii) each Party may retain a single copy of the other Party's Confidential Information for documentation purposes only and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.
- 12.6.3 **Survival**. Sections 1, 2.12, 3.1, 3.3, 3.4, 6.5, 6.6, 8, 9.1, 9.2.2, 9.2.3, 9.4, 11, 12.6, 13, 14 and 15 of this Agreement, together with any appendices referenced therein, will survive any expiration or termination of this Agreement.

#### 13 INDEMNIFICATION

- 13.1 Indemnification of GAMIDA. LONZA will indemnify GAMIDA, its Affiliates, and their respective directors, officers, employees and agents, and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all liability suits, investigations, claims or demands (collectively, "Losses") to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: (a) any material breach by LONZA of this Agreement, or (b) the gross negligence or willful misconduct on the part of one or more of the LONZA Parties in performing any activity contemplated by this Agreement, or (c) the use or practice by GAMIDA, its Affiliates of any LONZA Confidential Information, LONZA Background Intellectual Property, or LONZA New IP to the extent such use or practice is permitted under this Agreement, except for those Losses for which GAMIDA has an obligation to indemnify the LONZA Parties pursuant to Section 13.2, as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses.
- **13.2 Indemnification of LONZA**. GAMIDA will indemnify LONZA and its Affiliates, and their respective directors, officers, employees and agents (the "LONZA Parties"), and defend and hold each of them harmless, from and against any and all Losses to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: (a) any material breach by GAMIDA of this Agreement, (b) the use or sale of Products, except to the extent such Losses arise out of or result from a breach by LONZA of the Product Warranties, (c) the gross negligence or willful misconduct on the part of GAMIDA or its Affiliates in performing any activity contemplated by this Agreement, or (d) the use or practice by LONZA of any process, invention or other intellectual property supplied by GAMIDA to LONZA under this Agreement, except for those Losses for which LONZA has an obligation to indemnify GAMIDA pursuant to Section 13.1, as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses.

#### 13.3 Indemnification Procedure

- 13.3.1 An "**Indemnitor**" means the indemnifying Party. An "**Indemnitee**" means the indemnified Party, its Affiliates, and their respective directors, officers, employees and agents.
- 13.3.2 An Indemnitee which intends to claim indemnification under Section 13.1 or Section 13.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that in order for the Indemnitor to exercise such rights, such settlement shall not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

**13.4 Insurance**. GAMIDA will maintain, at all times during the term of this Agreement and for five years thereafter, a products liability insurance policy (the "**Insurance Policy**"), with a per occurrence limit of at least [\*] and an aggregate limit of at least [\*], and will provide a Certificate of Insurance to LONZA that the Insurance Policy has been endorsed to designate LONZA as an additional insured. GAMIDA will maintain the Insurance Policy with an insurance company having a minimum AM Best rating of A. GAMIDA will provide LONZA with at least [\*] written notice prior to termination of such Insurance Policy.

LONZA will maintain, at all times during the term of this Agreement and for five years thereafter, a products liability insurance policy or an equivalent mechanism (the "Insurance Policy"), with a per occurrence limit of at least [\*] and an aggregate limit of at least [\*], and will provide a Certificate of Insurance to GAMIDA that the Insurance Policy has been endorsed to designate GAMIDA as an additional insured. LONZA will maintain the Insurance Policy with an insurance company having a minimum AM Best rating of A. LONZA will provide GAMIDA with at least [\*] written notice prior to termination of such Insurance Policy. the evidence of an adequate cover either through an external insurance or through another vehicle. In addition, LONZA shall maintain, at all times during the term of this Agreement, (i) General liability policy with a per occurrence limit of at least [\*] and an aggregate limit of at least [\*]; and (ii) Employers liability insurance for at least [\*] limits.

#### 14 ADDITIONAL COVENANTS

**14.1 Non-Solicitation**. During the term of this Agreement and for [\*] thereafter, each of the Parties agrees not to seek to induce or solicit any employee of the other Party or its Affiliates to discontinue his or her employment with the other Party or its Affiliate in order to become an employee or an independent contractor of the soliciting Party or its Affiliate; provided, however, that neither Party shall be in violation of this Section 14.1 as a result of making a general solicitation for employees or independent contractors. For the avoidance of doubt, the publication of an advertisement shall not constitute solicitation or inducement.

#### 15 MISCELLANEOUS

- **15.1 Independent Contractors.** Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint ventures, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.
- Force Majeure. Neither Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of 15.2 any amounts due under this Agreement) occasioned by any reason beyond the control and without the fault or negligence of the Party affected thereby, including, without limitation, an act of God, fire, flood, act of government or state, war, civil commotion, insurrection, acts of terrorism, embargo, sabotage, prevention from or hindrance in obtaining energy or other utilities, labor disputes of whatever nature, or any other reason beyond the control and without the fault or negligence of the Party affected thereby (a "Force Majeure Event"). The Force Majeure Event shall also include a viral, bacterial or mycoplasma contamination which causes a shutdown of the Facility, but only to the extent it can be proved by LONZA that such event was not caused by LONZA or any part on its behalf. Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement as soon as it is commercially reasonable for the Party to do so. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable to fully perform its obligations under this Agreement. Each Party further agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as practicable (provided that in no event shall a Party be required to settle any labor dispute) and to give the other Party prompt written notice when it is again fully able to perform such obligations. It is hereby clarified that LONZA shall not be entitled to any payments or fees related to any services not completed and which cannot be completed appropriately after the correction the Force Majeure Event or if there is no more need for such services after the correction the Force Majeure Event and any such fees shall be calculated pro-rata on an annual basis.
- **15.3 Hardship**. Each Party may have the right to renegotiate the Agreement in case any event of legal, technical, political or financial nature may occur after the signature of the Agreement and which was unforeseeable at the time the Agreement has been agreed upon between the Parties, provided that such right will only be exercised following discussions between the CEOs of the Parties.
- **15.4 Condemnation**. LONZA shall use commercially reasonable efforts to oppose any Condemnation (as defined below) efforts, provided, however, that if the Facility is condemned or taken as a result of the exercise of the power of eminent domain or will be conveyed to a governmental agency having power of eminent domain under the threat of the exercise of such power (any of the foregoing, a "Condemnation"), then this Agreement will terminate as of the date on which title to the Facility vests in the authority so exercising or threatening to exercise such power and GAMIDA will not have any right to the Condemnation proceeds.

**Notices**. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with documented evidence of transmission), to the addresses or facsimile numbers of the other Party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to LONZA:

Group General Counsel LONZA Group Ltd. Münchensteinerstrasse 38 CH-4002 Basel

If to GAMIDA:

Gamida Cell Ltd., 5 Nahum Hafzadi St., Jerusalem, Israel

Fax: 972-2-6595616

Attn: Company Executive Officer

with a copy to:

Meitar Liquornik Geva Leshem Tal, Law Offices 16 Abba Hillel Silver Rd., Ramat Gan, Israel

Fax: 972-3-6103732 Attn: Boaz Mizrahi, Adv. e-mail: mizrahib@meitar.com

Either Party may change its address for notice by giving notice thereof in the manner set forth in this Section 15.5.

- **Entire Agreement; Amendments.** This Agreement, including the Appendices attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof and supersedes all prior agreements and understandings, oral and written, among the Parties with respect to the subject matter hereof. No terms, conditions, understandings or agreements purporting to amend, modify or vary the terms of this Agreement (including any Appendix hereto) shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.
- **15.7 Governing Law**. The construction, validity and performance of the Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to its conflicts of laws provisions.

- **15.8 Counterparts.** This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.
- **15.9 Severability**. If any part of this Agreement shall be found to be invalid or unenforceable under Applicable Law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.
- **15.10 Titles and Subtitles**. All headings, titles and subtitles used in this Agreement (including any Appendix hereto) are for convenience only and are not to be considered in construing or interpreting any term or provision of this Agreement (or any Appendix hereto).
- **15.11 Exhibits.** All "RECITALS", "DEFINITIONS", exhibits and appendices referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.
- **15.12 Pronouns**. Where the context requires, (i) all pronouns used herein will be deemed to refer to the masculine, feminine or neuter gender as the context requires, and (ii) the singular context will include the plural and vice versa.
- Assignment. This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld; provided, however, either Party shall be entitled without the prior written consent of the other Party to assign this Agreement to an Affiliate or to any company to which such Party may transfer all or substantially all of its assets or capital stock relating to the activities contemplated under this Agreement, whether through purchase, merger, consolidation or otherwise. Notwithstanding the forgoing, in the event LONZA assigns or transfers (whether through purchase, merger, consolidation or otherwise) its interest under this Agreement to a competitor, active in the same indication utilizing similar cell therapy technology of GAMIDA, GAMIDA shall have the right to terminate the Agreement upon [\*] prior written notice and LONZA will cooperate in a tech transfer process as shall be agreed by the Parties and in the event GAMIDA shall assigns or transfers (whether through purchase, merger, consolidation or otherwise) its interest under this Agreement to a competitor of LONZA of any kind LONZA shall have the right to terminate the Agreement up to [\*] prior written notice. Any permitted assignment of this Agreement by either Party will be conditioned upon that Party's permitted assignee agreeing in writing to comply with all the terms and conditions contained in this Agreement. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

- **15.14 Waiver**. The failure of any Party at any time or times to require performance of any provision of this Agreement (including any Appendix hereto) will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any term, provision or condition contained in this Agreement (including any Appendix hereto), whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement (including any Appendix hereto). For the avoidance of doubt, it is hereby clarified that unless specifically stated otherwise, the contents of any inspection report provided by GAMIDA in accordance with this Agreement and anything omitted from it, shall not constitute a waiver of any term, provision or condition of this Agreement or of any of GAMIDA's rights.
- **Dispute Resolution**. If the Parties are unable to resolve a dispute, despite its good faith efforts, either Party may refer the dispute to the President of each Party's respective business unit (or other designee). In the event that no agreement is reached by the Presidents (or other designees) with respect to such dispute within thirty (30) days after its referral to them, either Party may pursue any and all remedies available at law or in equity.
- **15.16 No Presumption Against Drafter.** For purposes of this Agreement, GAMIDA hereby waives any rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter.

#### [REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

**IN WITNESS WHEREOF**, the parties have executed this Agreement as of the date last signed by the parties hereto.

### GAMIDA CELL LTD.

June 10, 2019	By:	/s/ Julian Adams
Date		Name: Julian Adams
		Title: Chief Executive Officer
		/s/ Shai Lankry
		Name: Shai Lankry
		Title: Chief Financial Officer
	LONZA NETHERLANDS B.V.	
June 16, 2019	By:	/s/ Cordula Altekrüger
Date		Name: Cordula Altekrüger
		Title: Associate General Counsel
		/s/ Thomas Fellner
		Name: Thomas Fellner
		Title: Head of Business Development and Account Management, Cell and Gene Technologies

**Products** 

# List of equipment and material

Fees

## <u>Appendix 5</u>

## **Headcount Requirements**

## **GANTT** - milestones

Exhibit 23.1

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated February 25, 2019 in the Registration Statement on Form F-1 and related Prospectus of Gamida Cell Ltd. dated June 24, 2019.