Filed pursuant to Rule 424(b)(4)
Registration No. 333-232302

Prospectus

7,000,000 Ordinary Shares

Gamida Cell Ltd.

All of the 7,000,000 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 26, 2019, the last reported sale price of our ordinary shares on The Nasdaq Global Market was $5.10 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 10 to read about factors you should consider before buying our ordinary shares.

	Per Share	Total
Public offering price	$ 5.00	$ 35,000,000
Underwriting discount(1)	$ 0.30	$ 2,100,000
Proceeds to Gamida Cell Ltd., before expenses	$ 4.70	$ 32,900,000

(1) See “Underwriting” beginning on page 158 for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than 7,000,000 ordinary shares, the underwriters have the option to purchase up to an additional 1,050,000 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 $2,415,000, and the total proceeds to us, before expenses, will be $37,835,000.

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 July 1, 2019.

Joint Book-Running Managers

RBC Capital Markets **JMP Securities**

Co-Lead Managers

Oppenheimer & Co. **Needham & Company**

Prospectus dated June 26, 2019

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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

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

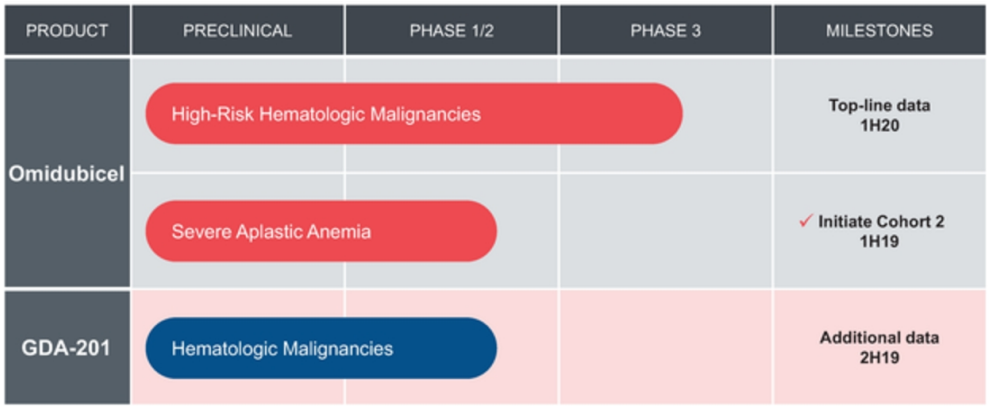
We are a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure cancer and rare, serious hematologic diseases. While cell therapies have the potential to address a variety of diseases, they are limited by availability of donor cells, matching 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:



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 0.5×10^9 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 20×10^9 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	7,000,000 ordinary shares
Ordinary shares to be outstanding immediately after this offering	32,140,048 ordinary shares (or 33,190,048 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 1,050,000 ordinary shares.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $32.2 million, or approximately $37.1 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. 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 1,050,000 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)	
	(in thousands, except share and per share amounts)				
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	689,898	689,898	25,038,261	689,898

	As of March 31, 2019	
	Actual	As Adjusted[1]
	(unaudited) (in thousands)	
Balance Sheet Data:		
Cash and cash equivalents, available-for-sale financial assets and short-term deposits	$ 50,406	$ 82,606
Working Capital[2]	43,124	75,324
Total Assets	61,047	93,247
Total Shareholders' Equity	13,145	45,345

(1) Data presented on an as adjusted basis to give effect to the sale of 7,000,000 ordinary shares in this offering at the public offering price of $5.00 per ordinary share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(2) 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 investigator-sponsored 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 re-examination, 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 7,000,000 ordinary shares in this offering (or 8,050,000 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 68.6% (or 66.5% 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 the public offering price of $5.00 per share, you will experience immediate dilution of $3.59 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 15.6% of the aggregate price paid by all purchasers of our shares but will own only approximately 21.8% 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 agreements.

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 $32.2 million, after deducting the estimated underwriting discount and estimated offering expenses payable by us, based on the public offering price of $5.00 per ordinary share. If the underwriters exercise their option to purchase up to an additional 1,050,000 ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately $37.1 million, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

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 $20.0 million to $25.0 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 7,000,000 ordinary shares in this offering at the public offering price of $5.00 per ordinary share, 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	$ 50,406	$ 82,606
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 outstanding, actual; 32,140,048 shares issued and outstanding, as adjusted	68	88
Share premium	197,967	230,147
Capital reserve due to actuarial gains	(160)	(160)
Available for sale reserve	(10)	(10)
Accumulated deficit	(184,720)	(184,720)
Total shareholders’ equity	13,145	45,345
Total capitalization	$ 13,145	$ 45,345

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 the public offering price of $5.00 per ordinary share, and after deducting the estimated underwriting discount and estimated offering expenses, our as adjusted net tangible book value at March 31, 2019 would have been $1.41 per share. This represents an immediate increase in as adjusted net tangible book value of $0.89 per share to existing shareholders and immediate dilution of $3.59 per ordinary share to new investors.

The following table illustrates this dilution per ordinary share:

Assumed public offering price per ordinary share		$ 5.00
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	$ 0.89	
As adjusted net tangible book value per ordinary share after this offering		$ 1.41
Dilution per ordinary share to new investors participating in this offering		$ 3.59

If the underwriters exercise in full their option to purchase 1,050,000 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 $3.49 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 31,	
	2018	2017	2016	2019	2018
				(unaudited)	
	(in thousands, except share and per share amounts)				
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	689,898	689,898	25,038,261	689,898

	As of December 31,			As of March 31,
	2018	2017	2016	2019
				(unaudited)
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents, available-for-sale financial assets and short-term deposits	$ 60,689	$ 41,083	$ 18,059	$ 50,406
Working capital[1]	55,486	39,046	16,538	43,124
Total assets	65,164	44,922	19,179	61,047
Total shareholders' equity	24,687	22,956	10,963	13,145

(1) 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 ended March 31,	
	2019	2018
	(unaudited, in thousands)	
Operating Expenses:		
Research and development expenses, net[(1)]	$ 7,283	$ 5,060
General and administrative expenses[(1)]	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

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

	Three months ended March 31,	
	2019	2018
	(unaudited, in thousands)	
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 thousands)	
Operating Expenses:		
Research and development expenses, net(1)	$ 22,045	$ 15,018
General and administrative expenses(1)	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:

	Year ended December 31,	
	2018	2017
	(in thousands)	
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 December 31,	
	2019	2018	2018	2017
	(unaudited, in thousands)		(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			
	Less Than 1 Year	2 to 5 Years	5 to 10 Years	Total
	(in thousands)			
Operating lease obligations[1]	$ 1,803	$ 2,522	$ 2,395	$ 6,720

(1) 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(1)

(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:

Valuation Date	Type of Shares	Fair Value per Share in 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(1)	$ 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.

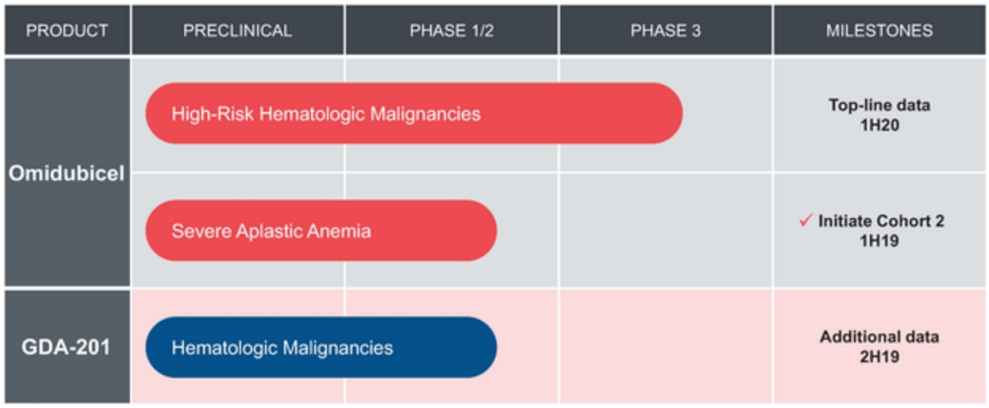
Omidubicel has the potential to be a universal stem cell graft in two broad patient groups: (i) patients with high-risk leukemias and lymphomas who require HSCTs but who lack access to genetically matched donors; and (ii) patients with severe hematologic disorders such as severe aplastic anemia. In the 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 0.5×10^9 per liter on three consecutive measurements on different days. Platelet engraftment is defined as achieving a platelet count of at least 20×10^9 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

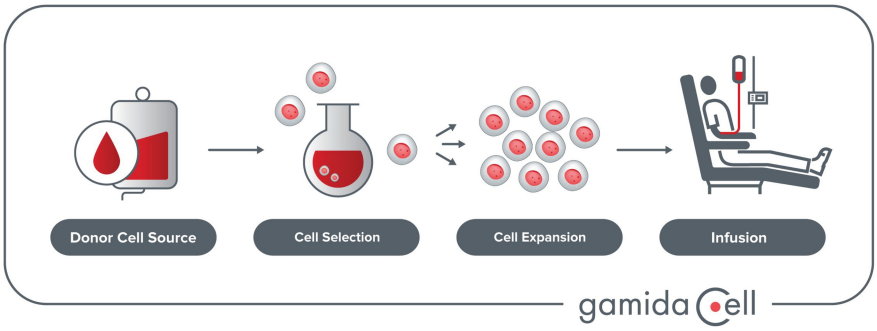
GDA-201 was highly active and generally well tolerated. Among the six NHL patients evaluable for activity, three patients achieved a complete response, one patient achieved a partial response, and two patients experienced progressive disease. Two of the patients who achieved a complete response subsequently 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

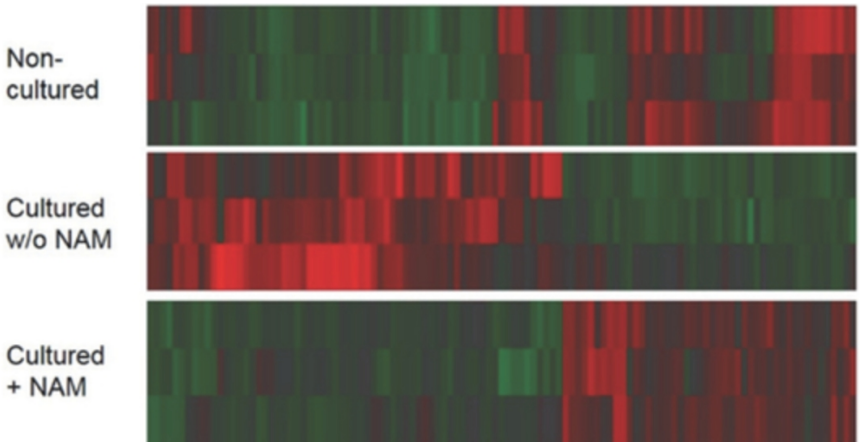
While cell-based therapies have the potential to address a variety of medical conditions, one of the key technical challenges for developing treatments with this approach is the expansion of therapeutically functional cells. In order for cell therapies to be clinically effective, there must be a sufficient 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.

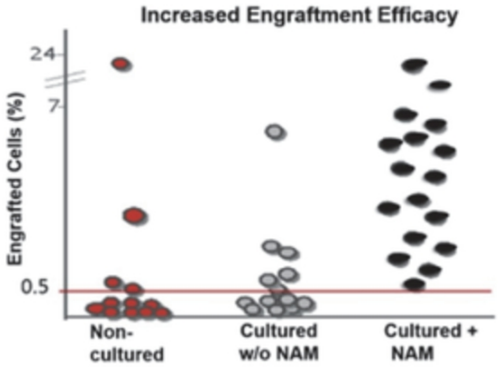
A key component of our cell expanded product candidates is NAM, which is a naturally occurring substance that regulates multiple processes including cellular stress, cellular energy, mitochondrial functions and gene expression. We have successfully demonstrated the effectiveness of NAM-based technology 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.

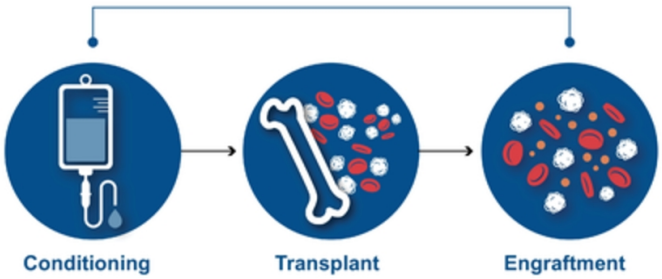
Based on the preclinical results, we advanced omidubicel into the clinic. We have also applied NAM-based technology for our second product candidate, GDA-201, and plan to explore this technology for other cells with therapeutic potential.

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:

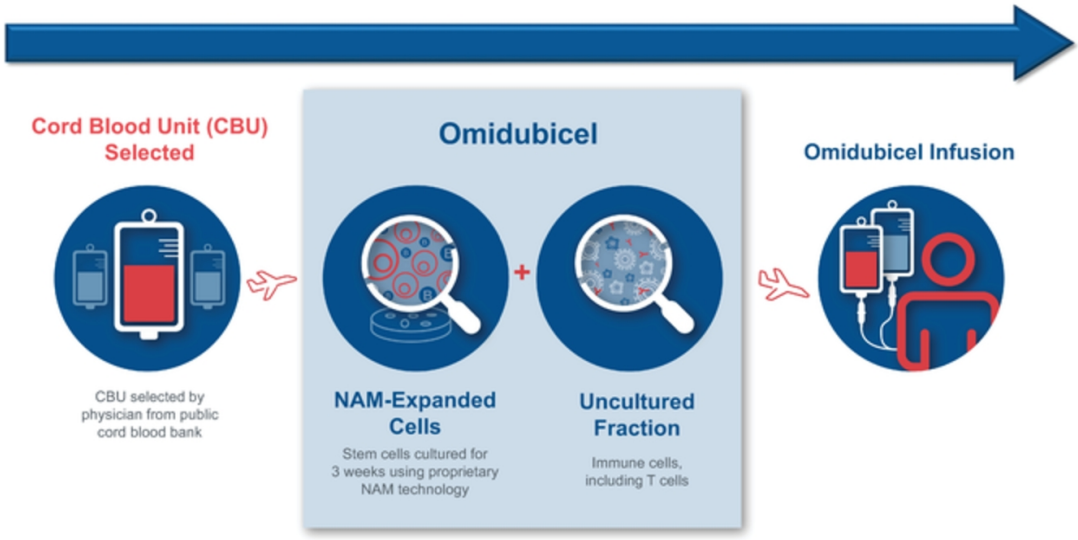
- delays in finding a suitable match, during which disease progression may make patients ineligible for a transplant;
- insufficient number or delayed engraftment of donor cells, leaving patients without a functioning immune system and leading to potentially life-threatening immune deficiency following 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 open-label 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.

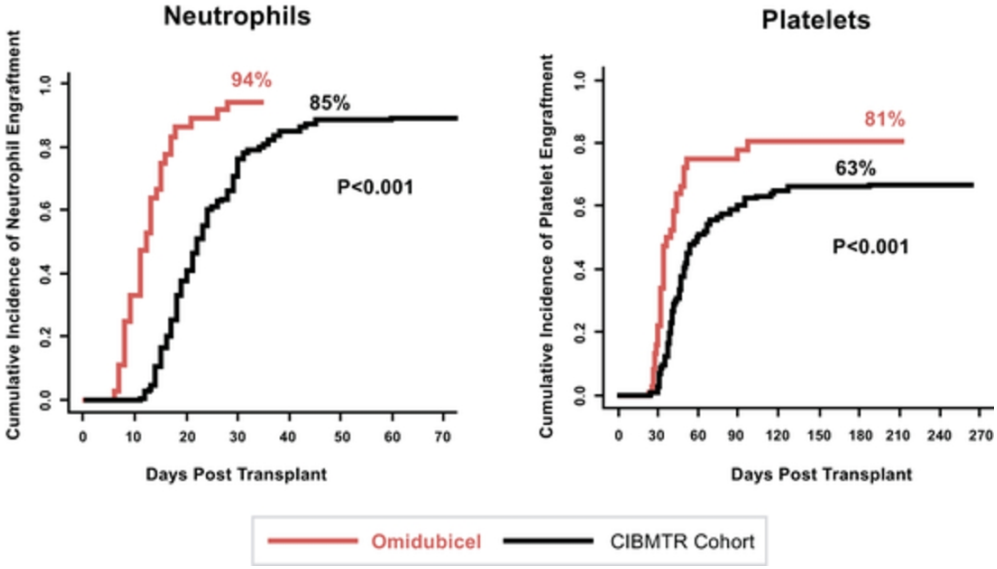
The main objective of the study was to evaluate the safety and efficacy of omidubicel treatment in patients with hematologic malignancies following myeloablative conditioning therapy. Myeloablative conditioning therapy is a combination of chemotherapy agents, and in some cases radiotherapy, that is expected 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 x 108 total nucleated cells, or TNC, while the non-cultured fraction contains at least 4.0×10^8 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.

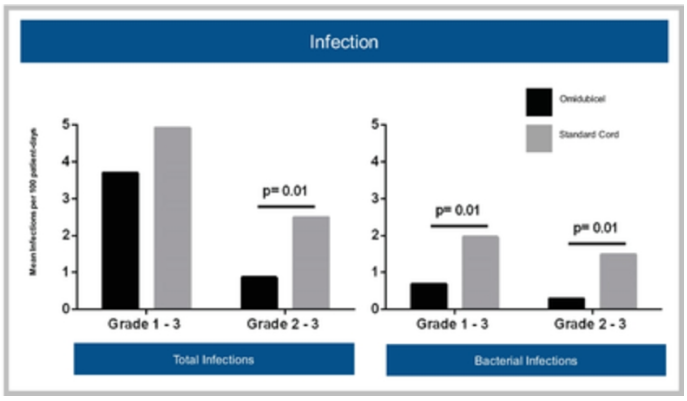
Neutrophils are infection-fighting white blood cells circulating in healthy individuals. A minimum neutrophil count, or ANC, of 0.5×10^9 cells per liter is necessary to prevent life-threatening infections. In all omidubicel clinical trials, neutrophil engraftment is defined as achieving an ANC $> 0.5 \times 10^9$ 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 20×10^9 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.



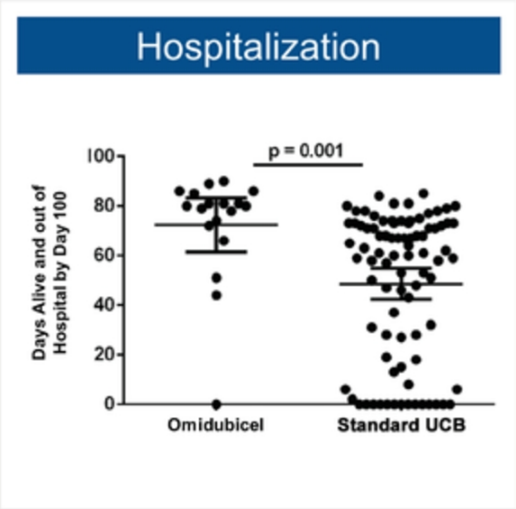
Additional endpoints included rates of acute GvHD, chronic GvHD, infections, hospitalization and overall survival. In the Phase 1/2 trial of omidubicel, rates of high grade acute GvHD were 11% in patients treated with omidubicel and 27% in the CIBMTR cohort (p=0.09 by Fine-Gray analysis). For chronic 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.

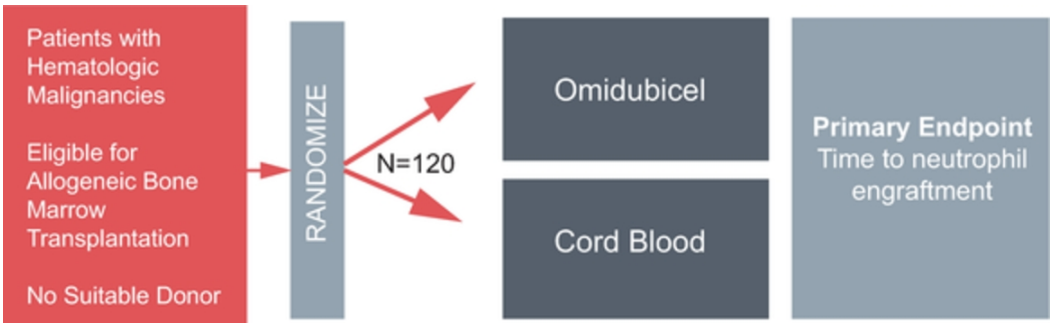
The speed and robustness of the immune system reconstitution also likely contributed to an observed reduction of 20 days in the number of days, post-transplant, that patients were hospitalized when compared to the length of hospital stays for similar patients treated with standard cord blood also at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

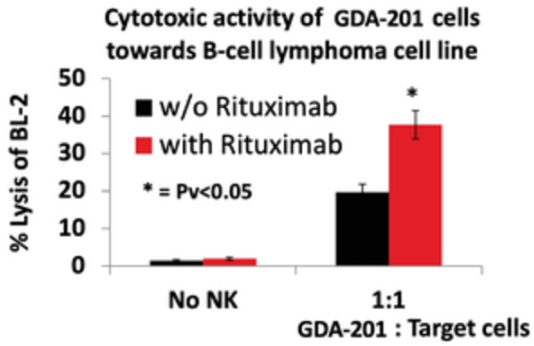
Extensive research efforts are ongoing to generate cellular products for the treatment of cancer patients. There is much interest in the field in the potential of NK cells because they have potent anti-tumor properties. In contrast to other immune cell therapies, NK cells can be used independently from 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

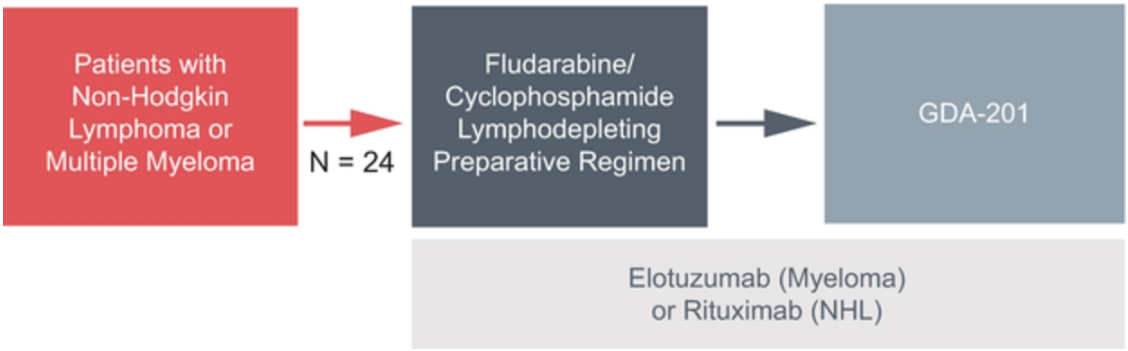
We have developed GDA-201, a cell therapy product candidate generated by expansion of NK cells using our NAM-based technology. We believe that GDA-201 has potential application in boosting the innate immune response to cancer. Functional studies have shown that our GDA-201 cells expanded in culture with our NAM technology and the cytokine IL-15 display increased tumor killing activity over NK cells expanded with IL-15 but without NAM. Our pre-clinical 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 x 10^8 TNC, while the non-cultured fraction contained at least 4.0 x 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
Hurler 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-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. 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®. 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®. 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:

(i) 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 for another director, may not be appointed 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 Nasdaq 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[1]	Salary[2]	Bonus	Share-based Compensation[3]	All other compensation[4]	Total
			In thousands USD $		
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	9	600

(1) All Covered Executives were employed on a full time (100%) basis during their term of employment in 2018.

(2) 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 non-employee 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[1]	Percentage Owned Before this Offering	Percentage Owned After this Offering
Holders of more than 5% of our voting securities:			
Access Industries[2]	6,792,489	26.4%	20.7%
Novartis Pharma AG[3]	5,194,054	19.6%	15.5%
Smartmix Limited[4]	2,857,331	10.7%	8.5%
Elbit Cord Blood Limited Partnership[5]	2,685,590	10.5%	8.2%
Shavit Capital Funds[6]	2,575,801	9.9%	7.8%
Israel HealthCare Ventures 2 LP Incorporated (IHCV II)[7]	1,915,508	7.4%	5.9%
Directors and executive officers who are not 5% holders:			
Dr. Julian Adams	*	*	*
Shai Lankry	*	*	*
Josh Hamermesh	*	*	*
Tzvi Palash	*	*	*
Tony Peled[8]	332,499	1.3%	1.0%
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)[9]	644,891	2.5%	2.0%

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

(1) The percentages shown are based on 25,606,423 ordinary shares issued and outstanding as of June 4, 2019.

(2) 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 AI Gamida Holdings LLC. Clal Industries Ltd. owns 47% of the outstanding shares of, and controls, CBI. Clal Industries Ltd. is wholly owned by Access AI Ltd., which is owned by AI Diversified Holdings S.à r.l., which is owned by AI Diversified Parent S.à r.l., which is owned by AI Diversified Holdings Limited, or AIDH Limited. AIDH Limited is controlled by AI SMS L.P., or AI SMS. Access Industries Holdings LLC, or AIH, owns a majority of the equity of AI 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.

(3) 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.

(4) 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 GP II Limited is VMS Investment Management Inc. The controlling shareholder of VMS Investment Management Inc. is VMS Financial Services Group Limited. The controlling shareholder of VMS Financial Services Group Limited is 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 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, and the chairman of the board of directors shall be entitled to receive an annual grant of options to purchase 15,000 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 compensation-related 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 and resulted in the acquirer becoming a holder of 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 year 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(1)	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	2,800,000
JMP Securities LLC	2,450,000
Oppenheimer & Co. Inc.	875,000
Needham & Company, LLC	875,000
Total	7,000,000

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 1,050,000 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 $0.18 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	$ 0.30	$ 0.30
Total	$ 2,100,000	$ 2,415,000

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 Nasdaq 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.

Israel

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 to be Paid
SEC registration fee	$ 4,878
FINRA filing fee	6,538
Printing and engraving expenses	50,000
Legal fees and expenses	300,000
Accounting fees and expenses	90,000
Miscellaneous expenses	248,584
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

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.

/s/ Kost Forer Gabbay & Kasierer
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

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
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
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
	6,705	4,576
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

The accompanying notes are an integral part of the consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands (except share and per share data)

	Year ended December 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

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Preferred shares						
	Number	Amount	Number	Amount	Share Premium	Available for sale reserve Amount	Capital reserve due 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 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 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	—	—	—	—	—	(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 an amount of $5,947	6,648,368	18	—	—	47,223	—	—	—	47,241
Exercise of warrants	293,489	1	—	—	3,850	—	—	—	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

The accompanying notes are an integral part of the consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Year ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (52,931)	$ (19,011)	$ (22,671)
Adjustments to reconcile net loss to net cash used in operating activities:			
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	17,600	(1,061)	(805)
Revaluation of liability to IIA	2,037	631	—
Other	—	—	37
	22,880	1,664	5,318
Changes in asset and liability items:			
Decrease (Increase) in other receivables, prepaid expenses and other current assets	942	(2,210)	13
(Decrease) Increase in trade payables	(405)	1,464	297
Decrease in related parties	—	—	148
Change in liability to IIA	—	—	4,030
Increase in accrued expenses and other payables and employees and payroll 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	(26,426)	(16,549)	(12,590)
Cash flows from investing activities:			
Purchase of property and equipment	(1,645)	(402)	(284)
Purchase of available-for-sale financial assets	(10,905)	(14,820)	—
Proceeds from (investment in) bank deposits	5,000	(5,000)	—
Investment in restricted bank deposits	(150)	—	—
Proceed from sale of available-for-sale financial assets	4,949	—	—
Proceeds from liquidation of joint venture and other assets	—	—	595
Net cash (used in) provided by investing activities	(2,751)	(20,222)	311

The accompanying notes are an integral part of the consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	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	—
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:			
IIA liability for grants to be received	$ —	$ 269	$ —
Exercise of warrants liabilities to equity	$ 3,851	$ —	$ —
Issuance expenses on credit	$ 238	$ —	$ —

The accompanying notes are an integral part of the consolidated financial statements.

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.

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

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:

	%
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.

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

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.

l. 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.

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:

1. 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.

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:

1. 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.

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.

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 non-lease 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:

	Machinery	Office furniture and equipment	Leasehold improvements	Project in process	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
Balance at December 31, 2018	1,753	345	847	—	2,945
Property and equipment, net at December 31, 2018	$ 1,401	$ 190	$ 252	$ 468	$ 2,311

2017:

	Machinery	Office furniture and equipment	Leasehold improvements	Project in process	Total
Cost:					
Balance at January 1, 2017	$ 1,902	$ 369	$ 943	$ —	$ 3,214
Additions	279	27	49	47	402
Balance at December 31, 2017	2,181	396	992	47	3,616
Accumulated depreciation:					
Balance at January 1, 2017	1,433	292	789	—	2,514
Depreciation	125	16	21	—	162
Balance at December 31, 2017	1,558	308	810	—	2,676
Property and equipment, net at December 31, 2017	$ 623	$ 88	$ 182	$ 47	$ 940

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:

	December 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	$ —	$ 24,049	$ 24,049

d. Description of significant unobservable inputs to valuation:

	December 31,	
	2018	2017
	Preferred F-2 shares	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,			
	2018		2017	
	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,			
	2018		2017	
	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	—	—	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:

	2018		2017	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
		USD		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.

2) 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 ended December 31,		
	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 ended December 31,		
	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 ended December 31,		
	2018	2017	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	$ 165	22	225
Total finance income	$ 1,042	$ 1,197	$ 1,193

NOTE 14:- RELATED PARTY TRANSACTIONS

Benefits to key executive personnel:

	December 31,		
	2018	2017	2016
Short-term benefits	$ 1,921	$ 1,578	$ 987
Other long-term benefits	63	569	61
Share-based payment	2,342	1,689	4,842
	$ 4,326	$ 3,836	$ 5,890

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. DOLLARS IN THOUSANDS

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
U.S. dollars in thousands

	March 31, 2019	March 31, 2018	December 31, 2018
	Unaudited		
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 43,749	$ 25,931	$ 40,272
Available-for-sale financial assets	6,507	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 shares at March 31, 2019 (unaudited) and December 31, 2018 respectively, and 689,898 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) and December 31, 2018 and 14,154,743 shares at March 31, 2018 (unaudited);	—	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		
Date of approval of the financial statements	Julian Adams Director and CEO	Shai Lankry Chief Financial Officer

The accompanying notes are an integral part of the interim consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
U.S. dollars in thousands (except share and per share data)

	March 31,		December 31,
	2019	2018	2018
	Unaudited		
Operating expenses:			
Research and development, net	$ 7,283	$ 5,060	$ 22,045
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 loss per share:			
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

The accompanying notes are an integral part of the interim consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)
U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Preferred shares						
	Number	Amount	Number	Amount	Share Premium	Available for sale reserve Amount	Capital reserve due to actuarial losses	Accumulated 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	—	—	—	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)	—	—	(49)
Total comprehensive loss	—	—	—	—	—	(49)	—	(7,391)	(7,440)
Share-based compensation	—	—	—	—	844	—	—	—	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 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 an amount of $5,947	6,648,368	18	—	—	47,223	—	—	—	47,241
Exercise of warrants	293,489	1	—	—	3,850	—	—	—	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

The accompanying notes are an integral part of the interim consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		
Cash flows from operating activities:			
Net loss	$ (15,507)	$ (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	542	49	269
Financial income, net	(191)	—	(858)
Cost of share-based compensation	1,091	844	3,575
Change in employee benefit liabilities, net	12	(16)	(15)
Interest received	—	(13)	—
Amortization of premium on available-for-sale financial assets	50	81	272
Revaluation of financial derivatives	3,906	400	17,600
Revaluation of liability to IIA	568	412	2,037
	5,978	1,757	22,880
Changes in asset and liability items:			
Increase in prepaid expenses and other current assets and other assets	409	100	942
Decrease in trade payables	(844)	(1,538)	(405)
Increase - in accrued expenses and other payables	21	260	2,296
	(414)	(1,178)	2,833
Cash received during the period for:			
Interest received	521	13	792
Interest paid	(28)	—	—
Net cash used in operating activities	(9,450)	(6,799)	(26,426)
Cash flows from investing activities:			
Purchase of property and equipment	(350)	(231)	(1,645)
Purchase of of available-for-sale financial assets	—	—	(10,905)
Proceed from sale of available-for-sale financial assets	13,893	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	13,543	9,753	(2,751)

The accompanying notes are an integral part of the interim consolidated financial statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		
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	$ —
Exercise of warrants liabilities to equity	$ 2,924	$ —	$ 3,851
Purchase of property, plant and equipment on credit	$ 199	$ —	$ —
Issuance expenses on credit	$ —	$ —	$ 238

The accompanying notes are an integral part of the interim consolidated financial statements.

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 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	Vehicles	Production Plant	Total	Lease liabilities
As of January 1, 2019	$ 2,104	$ 291	$ 4,711	$ 7,106	$ 7,032
Depreciation expenses	(292)	(32)	(140)	(464)	—
Interest expenses	—	—	—	—	237
Re-measurement	—	—	26	26	26
Payments	—	—	—	—	(468)
As of March 31, 2019	$ 1,812	$ 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
	Unaudited		
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,		December 31,
	2019	2018	2018
	Unaudited		Audited
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 months ended March 31,				Year ended December 31,	
	2019		2018		2018	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
		USD		USD		USD
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.

	Three months ended March 31,		December 31,
	2019	2018	2018
	Unaudited		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

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

7,000,000 Ordinary Shares

Gamida Cell Ltd.

PROSPECTUS

RBC Capital Markets

JMP Securities

Oppenheimer & Co.

Needham & Company

June 26, 2019