UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-38716

GAMIDA CELL LTD.

(Exact Name of Registrant as Specified in its Charter)

Israel	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
116 Huntington Avenue Boston, MA	**02116**
(Address of principal executive offices)	**(Zip Code)**

(617) 892-9080
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	GMDA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The registrant had 59,977,188 ordinary shares outstanding as of August 11, 2022.

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Trademarks and Trade Names

Unless the context requires otherwise, "Gamida," "Gamida Cell," "we," "us," "our" or the "Company" mean Gamida Cell Ltd. and its wholly-owned subsidiary, Gamida Cell Inc.

Gamida Cell is a trademark of ours that we use in this quarterly report on Form 10-Q, or Quarterly Report. This Quarterly Report 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 Quarterly Report 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 our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Part I—Financial Information

Item 1. Financial Statements.

GAMIDA CELL LTD. AND ITS SUBSIDIARY

INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AS OF JUNE 30, 2022

U.S. DOLLARS IN THOUSANDS

UNAUDITED

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CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 37,890	$ 55,892
Marketable securities	17,172	40,034
Prepaid expenses and other current assets	2,294	2,688
Total current assets	57,356	98,614
NON-CURRENT ASSETS:		
Restricted deposits	3,591	3,961
Property, plant and equipment, net	37,967	35,180
Operating lease right-of-use assets	6,107	7,236
Severance pay fund	1,579	2,148
Other long-term assets	1,421	1,647
Total non-current assets	50,665	50,172
Total assets	$ 108,021	$ 148,786

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

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	June 30, 2022	December 31, 2021
LIABILITIES AND SHARHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 2,738	$ 8,272
Employees and payroll accruals	4,978	4,957
Operating lease liabilities	2,517	2,699
Accrued interest of convertible senior notes	1,652	1,640
Accrued expenses and other current liabilities	10,412	7,865
Total current liabilities	22,297	25,433
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	71,801	71,417
Accrued severance pay	1,840	2,396
Long-term operating lease liabilities	4,233	5,603
Total non-current liabilities	77,874	79,416
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares of NIS 0.01 par value - Authorized: 150,000,000 shares at June 30, 2022 (unaudited) and December 31, 2021; Issued 60,059,873 and 59,970,389 at June 30, 2022 (unaudited) and December 31, 2021 respectively; Outstanding: 59,977,188 and 59,970,389 shares at June 30, 2022 (unaudited) and December 31, 2021, respectively	169	169
Treasury ordinary shares of NIS 0.01 par value - 82,685 and 0 shares at June 30, 2022 (unaudited) and December 31, 2021, respectively	*	-
Additional paid-in capital	383,915	381,225
Accumulated deficit	(376,234)	(337,457)
Total shareholders' equity	7,850	43,937
Total liabilities and shareholders' equity	$ 108,021	$ 148,786

* Represents an amount lower than $1.

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	Unaudited			
Research and development expenses, net	$ 10,563	$ 13,350	$ 21,868	$ 24,710
Commercial expenses	3,193	4,988	7,072	9,219
General and administrative expenses	4,290	3,874	8,429	7,387
Total operating loss	18,046	22,212	37,369	41,316
Financial expenses, net	508	1,345	1,408	1,427
Loss	$ 18,554	$ 23,557	$ 38,777	$ 42,743
Net loss per share attributable to ordinary shareholders, basic and diluted	0.31	0.40	0.65	0.72
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	59,546,273	59,253,315	59,510,918	59,188,504

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

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share and per share data)

	Three months ended June 30, 2022					
	Ordinary shares		Treasury shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount				
Balance as of March 31, 2022	59,946,298	$ 169	$ *	$ 382,495	$ (357,680)	$ 24,984
Treasury shares	(7,568)	-	*	*	-	*
Exercise of options	-	-	-	-	-	-
Issuance of ordinary shares, net of issuance expenses	38,458	-	-	84	-	84
Share-based compensation	-	-	-	1,336	-	1,336
Loss	-	-	-	-	(18,554)	(18,554)
Balance as of June 30, 2022	59,977,188	$ 169	$ *	$ 383,915	$ (376,234)	$ 7,850

	Six months ended June 30, 2022					
	Ordinary shares		Treasury shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount				
Balance as of December 31, 2021	59,970,389	$ 169	$ -	$ 381,225	$ (337,457)	$ 43,937
Grant of restricted shares	3,600	*	-	*	-	*
Treasury shares	(82,685)	-	*	*	-	*
Exercise of options	47,426	*	-	76	-	76
Issuance of ordinary shares, net of issuance expenses	38,458	-	-	84	-	84
Share-based compensation	-	-	-	2,530	-	2,530
Loss	-	-	-	-	(38,777)	(38,777)
Balance as of June 30, 2022	59,977,188	$ 169	$ *	$ 383,915	$ (376,234)	$ 7,850

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share and per share data)

	Three months ended June 30, 2021				
	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount			
Balance as of March 31, 2021	59,406,972	$ 167	$ 377,783	$ (266,850)	$ 111,100
Cancellation of restricted shares	(2,650)	-	-	-	-
Exercise of options	23,674	-	54	-	54
Share-based compensation	-	-	1,112	-	1,112
Loss	-	-	-	(23,557)	(23,557)
Balance as of June 30, 2021	59,427,996	$ 167	$ 378,949	$ (290,407)	$ 88,709

	Six months ended June 30, 2021				
	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount			
Balance as of December 31, 2020	59,000,153	$ 166	$ 376,369	$ (247,664)	$ 128,871
Grant of restricted shares	156,484	*	*	-	*
Exercise of options	271,359	1	555	-	556
Share-based compensation	-	-	2,025	-	2,025
Loss	-	-	-	(42,743)	(42,743)
Balance as of June 30, 2021	59,427,996	$ 167	$ 378,949	$ (290,407)	$ 88,709

*) Represents an amount lower than $1.

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands (except share and per share data)

	Six months ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Loss	$ (38,777)	$ (42,743)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	224	206
Financing expense (income), net	(273)	1,694
Share-based compensation	2,530	2,025
Amortization of issuance costs	385	269
Operating lease right-of-use assets	1,226	1,032
Operating lease liabilities	(1,649)	(1,187)
Accrued severance pay, net	14	-
Increase in prepaid expenses and other assets	(19)	(358)
Decrease in trade payables	(5,535)	(884)
Increase (decrease) in accrued expenses and current liabilities	2,285	(622)
Net cash used in operating activities	(39,589)	(40,568)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(1,540)	(6,118)
Purchase of marketable securities	(3,708)	(68,151)
Proceeds from maturity of marketable securities	26,175	17,824
Proceeds (investments) from restricted deposits	500	(1,000)
Net cash provided by (used in) investing activities	$ 21,427	$ (57,445)

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

CONDENSED CONSOLIDATED STATEEMENTS OF CASH FLOWS

U.S. dollars in thousands (except share and per share data)

	Six months ended June 30	
	2022	**2021**
Cash flows from financing activities:		
Proceeds from exercise of options	$ 76	$ 556
Proceeds from share issuance, net	84	-
Proceeds from issuance of convertible senior notes, net	-	70,777
Net cash provided by financing activities	160	71,333
Decrease in cash and cash equivalents	(18,002)	(26,680)
Cash and cash equivalents at beginning of period	55,892	127,170
Cash and cash equivalents at end of period	$ 37,890	$ 100,490
Significant non-cash transactions:		
Purchase of property, plant and equipment on credit	282	1,563
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ (2,203)	$ -

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

NOTE 1:- GENERAL

a. Gamida Cell Ltd. (the "Company"), founded in 1998, is an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases. The Company harnesses its cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need.

b. The Company has leveraged its NAM platform, or nicotinamide cell expansion technology platform, to develop a pipeline of product candidates designed to address the limitations of other cell therapies. The Company's proprietary technology allows for the proliferation and enhancement of donor cells, which allows for maintenance of the cells' functional therapeutic characteristics, providing a potential treatment alternative for patients.

The lead product candidate, omidubicel, is an advanced cell therapy in development as a potential life-saving treatment option for patients in need of a bone marrow transplant (BMT). In May 2020, the Company reported that omidubicel met its primary endpoint in an international, randomized, multi-center Phase 3 clinical study in 125 patients with high-risk hematologic malignancies undergoing bone marrow transplant and who had no available matched donor. The study evaluated the safety and efficacy of omidubicel compared to standard umbilical cord blood. BMT 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.

In October 2021, the complete results from the Company's pivotal Phase 3 clinical study of omidubicel in 125 patients with various hematologic malignancies were published in the peer-reviewed medical journal Blood. The trial achieved its primary endpoint of time to neutrophil engraftment as well as all three of the prespecified secondary endpoints. These secondary endpoints were the proportion of patients who achieved platelet engraftment by day 42, the proportion of patients with grade 2 or grade 3 bacterial or invasive fungal infections in the first 100 days following transplant, and the number of days alive and out of the hospital in the first 100 days following transplant. All three secondary endpoints demonstrated statistical significance in an intent-to-treat analysis.

Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and has received orphan drug designation in the U.S. and in Europe.

In June 2022, the Company announced completion of the rolling Biologics License Application (BLA) submission to the FDA for omidubicel for the treatment of patients with blood cancers in need of an allogenic hematopoietic stem cell transplant.

In August 2022, the Company announced the FDA had accepted for filing the Company's BLA for omidubicel for the treatment of patients with blood cancers in need of an allogenic hematopoietic stem cell transplant. The FDA granted Priority Review for the BLA and has set a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2023.

NOTE 1:- GENERAL (Cont.)

In addition to omidubicel, the Company is developing GDA-201, an investigational natural killer ("NK") cell-based cancer immunotherapy that is intended to be used in combination with standard-of-care therapeutic antibodies, as well as other product candidates in the Company's NK cell pipeline. 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 is currently in an investigator-sponsored Phase 1/2 study for the treatment of relapsed or refractory non-Hodgkin lymphoma (NHL). Data from the 35 patients in the Phase 1/2 study demonstrated that GDA-201 was clinically active and generally well tolerated. Among the 19 patients with NHL, 13 complete responses and one partial response were observed, with an overall response rate of 74% and a complete response rate of 68%.

At the December 2021 Annual Meeting of America Society of Hematology, the Company reported two-year follow-up data from this clinical trial on outcomes and cytokine biomarkers associated with survival. The data demonstrated a median duration of response of 16 months (range 5-36 months), an overall survival at two years of 78% (95% CI, 51%–91%) and a safety profile similar to that reported previously.

On April 26, 2022, the Company announced that the FDA cleared its investigational new drug (IND) application and removed the clinical hold for a cryopreserved formulation of GDA-201. In June the Company announced the activation of the initial clinical sites to screen and enroll patients in the company-sponsored Phase 1/2 study evaluating a cryopreserved formulation of GDA-201, a readily available cell therapy candidate for the treatment of follicular and diffuse large B cell lymphomas.

c. Basis of presentation of the financial statements:

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the U.S Securities and Exchange Commission (the "SEC"). Certain information or footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a complete presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K as of December 31, 2021 filed with the SEC on March 24, 2022. The interim period results do not necessarily indicate the results that may be expected for any other interim period or for the full fiscal year.

NOTE 1:- GENERAL (Cont.)

Prior to 2021, the Company prepared its financial statements in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB), as permitted in the United States based on the Company's qualification as a "foreign private issuer" under the rules and regulations of the SEC. In connection with the loss of the Company's status as a foreign private issuer effective on January 1, 2022, the Company, as a domestic filer, prepared its consolidated financial statements in accordance with U.S. GAAP.

d. The Company continues to devote 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 June 30, 2022 was $376,234 and negative cash flows from operating activities during the six-month period ended June 30, 2022 was $39,589. The Company is planning to finance its operations from its existing and future working capital resources and to continue to evaluate additional sources of capital and financing. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in amounts required.

e. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The unaudited condensed consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company were unable to continue as a going concern.

f. The Company has a wholly owned U.S. subsidiary, Gamida Cell Inc. (the "Subsidiary"), which was incorporated in 2000, under the laws of the State of Delaware. The Company has one operating segment and reporting unit.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. Use of estimates:

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements, and the reported amount of expenses during the reporting periods. Actual results could differ from those estimates.

b. Convertible senior notes:

The Company accounts for its convertible senior notes in accordance with ASC 470-20 "Debt with Conversion and Other Options". The Company early adopted ASU 2020-06 using the modified retrospective approach. The convertible senior notes are accounted for as a single liability measured at its amortized cost, as no other embedded features require bifurcation and recognition as derivatives according to ASC 815-40.

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

c. Basic and diluted net loss per share:

The Company computes net loss per share using the two-class method required for participating securities. The two-class method requires income available to ordinary shareholders for the period to be allocated between ordinary shares and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company considers its restricted shares to be participating securities as the holders of the restricted shares would be entitled to dividends that would be distributed to the holders of ordinary shares, on a pro-rata basis. These participating securities do not contractually require the holders of such shares to participate in the Company's losses. As such, net loss for the periods presented was not allocated to the Company's participating securities.

The Company's basic net loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted-average number of shares of ordinary shares outstanding for the period, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive ordinary shares are anti-dilutive.

NOTE 3:- LEASES

The Company entered into operating leases primarily for its production plant, and its laboratories and offices. The leases have remaining lease terms of up to six years, and the Company does not assume renewals in its determination of the lease term unless the renewals are considered as reasonably certain at lease commencement.

The components of operating lease costs were as follows:

	Six months ended June 30,	
	2022	**2021**
Operating lease costs	$ 1,417	$ 1,170
Short-term lease costs	84	74
Total lease costs	$ 1,501	$ 1,244

Supplemental balance sheet information related to operating leases is as follows:

	Six months ended June 30, 2022
Weighted average remaining lease term (in years)	3.93
Weighted average discount rate	2.58%

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 3:- LEASES (Cont.)

Maturities of lease liabilities were as follows:

	As of June 30, 2022
2022	$ 1,344
2023	1,602
2024	1,608
2025	1,206
2026	708
Thereafter	544
Total undiscounted lease payments	7,012
Less: Imputed interest	(262)
Present value of lease liabilities	$ 6,750

NOTE 4:- CONVERTIBLE SENIOR NOTES, NET

On February 16, 2021, the Subsidiary issued convertible senior notes (the "Convertible Notes") due in 2026, in the aggregate principal amount of $75 million, pursuant to an Indenture between the Company, the Subsidiary, and Wilmington Savings Fund Society, FSB, dated February 16, 2021 (the "Indenture"). The Convertible Notes bear interest payable semiannually in arrears, at a rate of 5.875% per year. The Convertible Notes will mature on February 15, 2026, unless earlier converted, redeemed or repurchased in accordance with their terms.

Subject to the provisions of the Indenture, the holders of the Convertible Notes have the right, prior to the close of business on the second scheduled trading day immediately preceding February 15, 2026, to convert any Convertible Notes or portion thereof that is $1,000 or an integral multiple thereof, into the Company's ordinary shares at an initial conversion rate of 56.3063 shares per $1,000 principal amount of Convertible Notes (equivalent to an exchange price of $17.76 per share). The conversion rate is subject to adjustment in specified events.

Upon the occurrence of a fundamental change (as defined in the Indenture), holders of the Convertible Notes may require the Company to repurchase for cash all or a portion of their Convertible Notes, in multiples of $1,000 principal amount, at a repurchase price equal to 100% of the principal amount of the Convertible Notes, plus any accrued and unpaid interest, if any, to, but excluding, interest accrued after the date of such repurchase notice. If certain fundamental changes referred to as make-whole fundamental changes occur, the conversion rate for the Convertible Notes may be increased.

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 4:- CONVERTIBLE SENIOR NOTES, NET (Cont.)

Subject to the provisions of the Indenture, the Subsidiary may redeem for cash all or a portion of the Convertible Notes for cash, at its option, at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest on the notes to be redeemed, if the last reported closing price of the Company's ordinary shares has been at least 130% of the exchange price then in effect for at least 20 trading days during any 30 consecutive trading day period, and in the event of certain tax law changes.

The Convertible Notes are accounted for as a single liability measured at its amortized cost, as no other embedded features require bifurcation and recognition as derivatives according to ASC 815-40.

	As of June 30, 2022
Liability component:	
Principal amount	$ 75,000
Issuance costs	(4,223)
Net of issuance costs	70,777
Amortized issuance costs	1,024
Net carrying amount	$ 71,801

The total issuance costs of the Convertible Notes amounted to $4,223 and are amortized to interest expenses at an annual effective interest rate of 7.37%, over the term of the Convertible Notes.

NOTE 5:- FAIR VALUE MEASUREMENTS

The following tables present the fair value of money market funds and marketable securities as of June 30, 2022 and December 31, 2021:

	June 30, 2022			December 31, 2021		
	Level 1	Level 2	Total	Level 1	Level 2	Total
Cash equivalents:						
Money market funds	$ 32,682	$ -	$ 32,682	$ 51,021	$ -	$ 51,021
Marketable securities:						
Corporate debentures	-	8,230	8,230	-	19,605	19,605
Government debentures	-	8,942	8,942	-	20,429	20,429
Total assets measured at fair value	$ 32,682	$ 17,172	$ 49,854	$ 51,021	$ 40,034	$ 91,055

We classify our cash equivalents and marketable securities within Level 1 or Level 2 because we use quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair value.

NOTE 6:- CONTINGENT LIABILITIES AND COMMITMENTS

a. Legal proceedings:

From time to time the Company or its subsidiary may be involved in legal proceedings and/or litigation arising in the ordinary course of business. While the outcome of these matters cannot be predicted with certainty, the Company does not believe it will have a material effect on its consolidated financial position, results of operations, or cash flows.

b. Bank guarantees:

As of June 30, 2022, the Company obtained bank guarantees in the amount of $2,964, primarily in connection with an Investment Center grant of up to $2,819 expected to be received in 2022 which requires a bank guarantee in order to ensure the fulfillment of the grant terms.

c. Governments grants:

The Company has received grants from the IIA to finance its research and development programs in Israel, through which the Company received IIA participation payments in the aggregate amount of $36.6 million through June 30, 2022, of which $34.0 million is royalty-bearing grants and $2.6 million is non-royalty-bearing grants. In return, the Company is committed to pay IIA royalties at a rate of 3-3.5% of future sales of the developed products, up to 100% of the amount of grants received plus interest at LIBOR rate. Through June 30, 2022, no royalties have been paid or accrued. The Company's contingent royalty liability to the IIA at June 30, 2022, including grants received by the Company and the associated LIBOR interest on all such grants totaled to $41.7 million.

NOTE 7:- SHAREHOLDERS' EQUITY

a. Ordinary shares:

Subject to the Company's amended and restated Articles of Association, the holders of the Company's ordinary shares have the right to receive notices to attend and vote in general meetings of the Company's shareholders, and the right to participated in dividends and other distributions upon liquidation.

b. Warrants to investors:

As part of its 2017 investment round, the Company granted certain investors 4,323,978 warrants that will expire in July 2022. As of June 30, 2022, 1,010,466 of such warrants have been exercised into the Company's ordinary shares. As of July 3, 2022 all 3,313,512 outstanding warrants expired.

NOTE 8:- SHARE-BASED COMPENSATION

a. Option plans:

On November 23, 2014, the Company's Board of Directors approved, subject to the approval of the shareholders, creation of the Company's ordinary C share class, with nominal value NIS 0.01 per share and classification of 1,500,000 ordinary shares for such class of shares, whereby 1,152,044 of such shares were allocated to the Company's employees under the amended 2014 Israel Share Option Plan (the "2014 Plan"). The exercise price of the options granted under the 2014 Plan may not be less than the nominal value of the shares into which the options are exercised. The options vest primarily over three years. There are no cash settlement alternatives. On December 29, 2014, the Company's shareholders ratified and approved the aforesaid actions.

On January 23, 2017, the Company's Board of Directors approved the Company's 2017 Share Incentive Plan (the "2017 Plan" and together with the 2014 Plan, the "Option Plans"), and the subsequent grant of options to the Company's employees, officers and directors. Pursuant to the 2017 Plan, the Company initially reserved for issuance 312,867 ordinary shares, nominal value NIS 0.01 each. On February 28, 2017, the Company's shareholders approved the 2017 Plan.

The 2017 Plan provides for the grant of awards, including options, restricted shares and restricted share units to the Company's directors, employees, officers, consultants and advisors.

On June 26, 2017 and on December 28, 2017, the Company's Board of Directors approved the reservation of 463,384 and 559,764 additional ordinary shares, respectively, for issuance under the 2017 Plan (totaling, including previous plans, an aggregate of 1,338,015 ordinary Shares).

On February 25, 2021 and November 17, 2021, the board of directors and shareholders, respectively, approved an amendment and restatement of the 2017 Plan. 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, 2022), the number of ordinary shares available under the 2017 Plan automatically increases by the lesser of the following: (i) 4% 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 of directors.

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.

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 8:- SHARE-BASED COMPENSATION (Cont.)

Expected volatility was calculated based upon the Company's historical share price and 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 option-pricing model used for the fair value measurement of equity-settled share options for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,	
	2022	2021
	(unaudited)	
Dividend yield	0%	0%
Expected volatility of the share prices	66%	66%
Risk-free interest rate	1.8% - 2.75%	1.5% - 1.6%
Expected term (in years)	8	8

Based on the above inputs, the fair value of the options was determined to be $1.29 - $1.85 per option at the grant date.

b. The following table summarizes the number of options granted to employees under the Option Plans as of June 30, 2022 and related information:

	Amount of options	Weighted average exercise price
	(unaudited)	(unaudited)
Balance as of December 31, 2021	4,411,424	$ 6.01
Granted	1,219,100	2.93
Exercised	(47,426)	1.60
Forfeited	(333,580)	6.67
Expired	(116,597)	5.20
Balance as of June 30, 2022	5,132,921	5.30
Exercisable as of June 30, 2022	2,517,106	$ 5.95

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 8:- SHARE-BASED COMPENSATION (Cont.)

As of June 30, 2022, there are $10,435 of total unrecognized costs related to share-based compensation that are expected to be recognized over a period of up to four years.

c. A summary of restricted shares and restricted share units activity as of June 30, 2022 is as follows:

	Amount of restricted shares and restricted share units	Weighted average grant date fair value
	(unaudited)	(unaudited)
Unvested as of December 31, 2021	531,477	$ 5.48
Granted	945,300	2.92
Vested	(61,810)	8.19
Forfeited	(92,185)	5.96
Unvested as of June 30, 2022	1,322,782	$ 3.49

d. The total share-based compensation expense related to all of the Company's equity-based awards, recognized for the three and six months ended June 30, 2022 and 2021 is comprised as follows:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(unaudited)			
Research and development expenses, net	$ 553	$ 372	$ 1,018	$ 683
Commercial expenses	358	229	648	400
General and administrative expenses	425	511	864	942
Total share-based compensation	$ 1,336	$ 1,112	$ 2,530	$ 2,025

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 9:- BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per ordinary share is computed by dividing net loss for each reporting period by the weighted-average number of ordinary shares outstanding during each year. Diluted net loss per ordinary share is computed by dividing net loss for each reporting period by the weighted average number of ordinary shares outstanding during the period, plus dilutive potential ordinary shares considered outstanding during the period, in accordance with ASC No. 260-10 "Earnings Per Share". The Company has a loss for the three and six months ended June 30, 2022 and 2021; hence all potentially dilutive ordinary shares were excluded due to their anti-dilutive effect.

Details of the number of shares and loss used in the computation of loss per share:

	Three months ended June 30,				Six months ended June 30,			
	2022		2021		2022		2021	
	Weighted number of shares	Net loss attributable to Ordinary shares of the Company	Weighted number of shares	Net loss attributable to Ordinary shares of the Company	Weighted number of shares	Net loss attributable to Ordinary shares of the Company	Weighted number of shares	Net loss attributable to Ordinary shares of the Company
For the computation of basic and diluted loss	59,546,273	18,554	59,253,315	23,557	59,510,918	38,777	59,188,504	42,743

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U.S. dollars in thousands (except share and per share data and unless otherwise indicated)

NOTE 9:- BASIC AND DILUTED NET LOSS PER SHARE (Cont.)

All outstanding convertible senior note options, warrants, outstanding share options, and restricted shares for the three and six months ended June 30, 2022 and 2021 have been excluded from the calculation of the diluted net loss per share, because all such securities are anti-dilutive for all periods presented. The total number of potential shares excluded from the calculation of diluted net loss per share are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(unaudited)			
Convertible senior notes	4,222,973	4,222,973	4,222,973	3,126,400
Warrants	3,313,512	3,313,512	3,313,512	3,313,512
Outstanding share options	5,132,921	4,272,846	4,946,420	4,003,264
Restricted shares	1,322,782	156,299	1,178,583	107,169
Total	13,992,188	11,965,630	13,661,488	10,550,345

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2021, or Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on March 24, 2022. The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These statements speak only as of their date. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Company Overview

We are an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. 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 NAM platform, or nicotinamide cell expansion technology platform to develop a pipeline of product candidates designed to address the limitations of other cell therapies. Our proprietary technology allows for the proliferation and enhancement of donor cells, which allows for maintaining the cells' functional therapeutic characteristics, providing a treatment alternative for patients.

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; (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; and (iv) older donor age may correspond to a negative impact on the patient's outcome. In addition, there is ethnic and racial disparity in access to HSCT: data from 2018 indicate that white patients of European descent are approximately four times more likely to receive a transplant than Black patients.

Umbilical cord blood is a readily available source of stem cells for patients who need HSCT and do not have a matched related donor. 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. 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 hematopoietic stem cell transplantation. Omidubicel consists of NAM-expanded and enhanced hematopoietic stem cells and differentiated immune cells, including T cells. The final cell therapy product is cryopreserved until the patient is ready to begin the transplant, when it is thawed and infused. Omidubicel has the potential to be a stem cell graft in two broad patient groups: (i) patients with high-risk leukemias and lymphomas who require HSCT but who lack access to an appropriate matched related donor; and (ii) patients with severe hematologic disorders such as severe aplastic anemia.

In October 2021, the complete results from our pivotal Phase 3 clinical study of omidubicel in 125 patients with various hematologic malignancies were published in the peer-reviewed medical journal *Blood*. The trial achieved its primary endpoint of time to neutrophil engraftment as well as all three of the prespecified secondary endpoints. These secondary endpoints were the proportion of patients who achieved platelet engraftment by day 42, the proportion of patients with grade 2 or grade 3 bacterial or invasive fungal infections in the first 100 days following transplant, and the number of days alive and out of the hospital in the first 100 days following transplant. All three secondary endpoints demonstrated statistical significance in an intent-to-treat analysis.

In December 2021, we also reported data from an analysis of a subset of 37 patients from the Phase 3 randomized trial of omidubicel at Annual Meeting of the American Society of Hematology, or ASH. The analysis was aimed at investigating the reduced infection rates observed in the study and showed that the omidubicel-treated patients had more rapid recovery of a wide variety of immune cells including CD4+ T cells, B cells, NK cells and dendritic cell subtypes. The robust recovery of the immune system provides rationale for fewer severe bacterial, fungal and viral infections in patients treated with omidubicel. Additional analyses are ongoing to further characterize the immune recovery following omidubicel transplantation. In June 2022, we completed the submission of our omidubicel BLA to the FDA, and in July 2022, it was accepted for priority review. The FDA set an action date of January 30, 2023 under the Prescription Drug User Fee Act, or PDUFA, and indicated that it was not planning to hold an advisory committee meeting as part of the BLA review.

In addition, we have applied our NAM cell expansion technology to natural killer, or NK, cells, to develop our initial NK product candidate, GDA-201, an investigational, NK cell-based immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. A fresh formulation of GDA-201 was evaluated in a Phase 1/2 investigator-sponsored trial for the treatment of relapsed or refractory non-Hodgkin lymphoma, or NHL, and multiple myeloma, or MM. Data from the trial demonstrate that GDA-201 was well-tolerated and no dose-limiting toxicities were observed in 19 patients with NHL and 16 patients with MM. The data show that therapy using GDA-201 with monoclonal antibodies demonstrated significant clinical activity in heavily pretreated patients with advanced NHL. Of the 19 patients with NHL, 13 complete responses and one partial response were observed, with an overall response rate of 74% and a complete response rate of 68%. At the December 2021 Annual Meeting of ASH, we reported two-year follow-up data from this clinical trial and reported on two-year outcomes and cytokine biomarkers associated with survival. The data demonstrated a median duration of response of 16 months (range 5-36 months), an overall survival at two years of 78% (95% CI, 51%–91%) and a safety profile similar to that reported previously.

In September 2021, we submitted an investigational new drug application, or IND, for a Phase 1/2 clinical trial of a cryopreserved formulation GDA-201 in patients with follicular and diffuse large B-cell lymphomas, which was subsequently placed on clinical hold prior to the initiation of patient dosing. On April 21, 2022, we received correspondence from the FDA indicating that we satisfactorily addressed all clinical hold issues identified by the FDA and that the FDA has removed the clinical hold and cleared our IND for GDA-201. In May 2022, we opened enrollment in our Phase 1/2 study of GDA-201 in patients with follicular and diffuse large B-cell lymphomas. In August 2022, we announced that the first patient was dosed with GDA-201 in this study.

We have incurred significant net losses since our formation in 1998. Our net losses were $38.8 million and $42.7 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, our accumulated deficit was $376.2 million. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We are currently assessing whether, if the FDA approves omidubicel for marketing in the United States, to market the product ourselves or to pursue strategic alternatives for the commercialization of omidubicel. If we decide to market omidubicel ourselves, we will require substantial additional funding.

We expect that our expenses will increase substantially in connection with our ongoing activities as we:

- seek regulatory approval for omidubicel and work with the FDA during the priority review period for our BLA for omidubicel;

- establish a sales, marketing and distribution infrastructure, if we do not pursue a strategic partnership for commercialization, and scale up manufacturing capabilities to commercialize omidubicel upon obtaining regulatory approval;
- progress our ongoing Phase 1/2 clinical trial of GDA-201 in patients with NHL;
- continue the preclinical development of our other product candidates;
- 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.

Although we completed two equity financing transactions in 2020 and a convertible debt financing in 2021, 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.

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 our current total existing funds will be sufficient to fund our operations into mid-2023, excluding the cost of commercializing omidubicel. Our ability to successfully transition to profitability or cash flow positivity 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.

Through June 30, 2022, the Company has funded its operations with the proceeds from the sale of equity and debt. The Company has incurred recurring losses since its inception, including net losses of $38.8 million and $42.7 million for the six months ended June 30, 2022 and 2021, respectively. In addition, the Company had an accumulated deficit of $376.2 million as of June 30, 2022. The Company expects to continue to generate operating losses for the foreseeable future. The Company's expectation that it will generate operating losses and negative operating cash flows in the future and the need for additional funding to support its planned operations raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date of the condensed consolidated financial statements included elsewhere in this Quarterly Report. If the Company is unable to obtain additional funding, the Company will be forced to delay, reduce or eliminate some or all of its clinical development programs, assess strategic alternatives for the commercialization of omidubicel or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments that might result from the outcome of the uncertainties described above.

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 IIA grants, 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, for the conduct of our 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 and development expenses (net of grants) are recognized in the consolidated statements of comprehensive loss when incurred.

Through June 30, 2022, we have received an aggregate of approximately $36.6 million in grants from the Israeli Innovation Authority, or the IIA, including from the Bereshit Consortium sponsored by the IIA, of which $34.0 million is royalty-bearing grants, and $2.6 million is non-royalty-bearing grants, and all of which was awarded for research and development funding. Pursuant to the terms of the royalty-bearing grants, we are obligated to pay the IIA royalties at the rate of between 3% to 3.5% 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 the 12-month LIBOR. We have not paid any royalties to the IIA to date. The Bereshit Consortium program does not require payments of royalties to the IIA, but all other restrictions under the Innovation Law, such as local manufacturing obligations and know-how transfer limitations, as further detailed hereunder, are applicable to the know how developed by us with the funding received in such consortium program.

On July 27, 2017, the United Kingdom's Financial Conduct Authority, or the FCA, which regulates LIBOR, announced that it intends to phase out LIBOR by the end of 2021. Following consultations in December 2020 and January 2021, the ICE Benchmark Administration Limited, or the IBA, announced that (i) it intended to cease publication of 1-week and 2-month U.S. dollar LIBOR at the end of 2021 and (ii) subject to compliance with applicable regulations, it intends to continue publication of the remaining U.S. dollar LIBOR tenors until June 30, 2023, effectively extending the LIBOR transition period to June 30, 2023. However, the FCA has indicated it will not compel panel banks to continue to contribute to LIBOR after the end of 2021 and the Federal Reserve Board, the Office of the Comptroller of the Currency, and the Federal Deposit Insurance Corporation have encouraged banks to cease entering into new contracts that use U.S. dollar LIBOR as a reference rate no later than December 31, 2021. There is currently no definitive information regarding the future utilization of LIBOR or of any particular replacement rate.

A committee established by the Federal Reserve, the Alternative Reference Rates Committee, announced the replacement of LIBOR with a new index, based on overnight repurchase agreements collateralized by U.S. Treasury securities, called the Secured Overnight Financing Rate, or the SOFR. The Federal Reserve Bank of New York began publishing SOFR in April 2018. Other jurisdictions have also proposed their own alternative to LIBOR, including the Sterling Overnight Index Average for Sterling markets, the Euro Short Term Rate for Euros and Tokyo Overnight Average Rate for Japanese Yen. Although SOFR appears to be the preferred replacement rate for U.S. dollar LIBOR, at this time, it is not possible to predict whether SOFR will attain market traction as a LIBOR replacement tool, and the future of LIBOR is still uncertain. The effect of any such changes, any establishment of alternative reference rates or any other reforms to LIBOR or other reference rates that may be enacted in the United Kingdom or elsewhere cannot be predicted at this time, and it is not possible to predict whether LIBOR will continue to be viewed as an acceptable market benchmark, what rate or rates may become accepted alternatives to LIBOR, or what the effect of any such changes in views or alternatives may have on the financial markets for financial instruments based on LIBOR.

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.

Pursuant to the IIA's licensing rules, or the Licensing Rules, a grant recipient may 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 grant 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.

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. Government grants received from the IIA are recognized as a reduction of the related research and development expenses.

We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of omidubicel or any of our other product candidates. However, with the objective of extending our cash runway into mid-2023, consistent with the anticipated timeline for potential U.S. approval of omidubicel, we have been reducing operating expenses primarily by implementing a workforce reduction of approximately 10% in January 2022 and delaying other hiring and planned spending this year. A majority of the anticipated savings is in research and development expenses.

Commercial expenses

Commercial expenses consist primarily of personnel costs, including share-based compensation, related to executive and commercial functions, and external consulting service fees.

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 incur expenses related to audit, legal, regulatory and tax-related services, director and officer insurance premiums, executive compensation, and other customary costs associated with being a public company subject to the US domestic issuer listing requirements of Nasdaq and the SEC.

Financial expenses, net

Financial expenses, net, is our financing expenses from convertible senior notes after deducting financing 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 $237.4 million (including capital losses of $0.5 million) as of December 31, 2021. In addition, the US subsidiary has net operating losses carryforward of $33.1 million for federal tax purposes as of December 31, 2021. 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. We provided a full valuation allowance, to reduce deferred tax assets to their estimated realizable value, since it is more likely than not that all of the deferred tax assets will not be realized.

Analysis of Results of Operations

Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)			
Operating Expenses				
Research and development expenses, net[(1)]	$ 10,563	$ 13,350	$ (2,787)	(20.9)%
Commercial expenses[(1)]	3,193	4,988	(1,795)	(36.0)
General and administrative expenses[(1)]	4,290	3,874	416	10.7
Operating loss	18,046	22,212	(4,166)	(18.8)
Financial expenses, net	508	1,345	(837)	(62.2)
Loss	$ 18,554	$ 23,557	$ (5,003)	(21.2)%

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

	Three Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)			
Research and development expenses, net	$ 553	$ 372	$ 181	48.7%
Commercial expenses	358	229	129	56.3
General and administrative expenses	425	511	(86)	(17.0)
Total share-based compensation	$ 1, 336	$ 1,112	$ 224	20.0%

Research and development expenses, net

Research and development expenses, net, decreased by approximately $2.8 million to $10.6 million in the three months ended June 30, 2022 from $13.4 million in the three months ended June 30, 2021. The decrease was attributable mainly to a $2.4 million decrease in clinical activities relating to the conclusion of our Phase 3 clinical trial and decrease of $0.4 million in GDA 201 clinical program.

Commercial expenses

Our commercial expenses decreased by approximately $1.8 million to $3.2 million in the three months ended June 30, 2022 from $5.0 million in the three months ended June 30, 2021. The decrease was attributable mainly to an approximate $2.1 million decrease in launch readiness activities, offset by an increase of $0.3 million in headcount related expenses.

General and administrative expenses

General and administrative expenses increased by approximately $0.4 million to $4.3 million in the three months ended June 30, 2022, up from $3.9 million in the three months ended June 30, 2021. The increase was attributable to a $0.9 million increase in professional services expenses and a new U.S. office lease agreement, offset by a decrease of $0.5 million in headcount related expenses.

Financial expenses, net

Financial expenses, net, decreased by approximately $0.8 million to $0.5 million in the three months ended June 30, 2022, compared to $1.3 million in the three months ended June 30, 2021. The decrease was primarily due to $0.6 million in non-cash expenses and an increase of $0.2 million in interest income from cash management.

Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)			
Operating Expenses				
Research and development expenses, net[(1)]	$ 21,868	$ 24,710	$ (2,842)	% (11.5)%
Commercial expenses[(1)]	7,072	9,219	(2,147)	(23.3)
General and administrative expenses[(1)]	8,429	7,387	1,042	14.1
Operating loss	37,369	41,316	(3,947)	(9.6)
Financial expenses, net	1,408	1,427	(19)	(1.3)
Loss	$ 38,777	$ 42,743	$ (3,966)	% (9.3)

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

	Six Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)			
Research and development expenses, net	$ 1,018	$ 683	$ 335	% 49%
Commercial expenses	648	400	248	62
General and administrative expenses	864	942	(78)	(8.4)
Total share-based compensation	$ 2,530	$ 2,025	$ 505	% 24.9

Research and development expenses, net

Research and development expenses, net, decreased by approximately $2.8 million to $21.9 million in the six months ended June 30, 2022 from $24.7 million in the six months ended June 30, 2021. The decrease was attributable mainly to a $4.3 million decrease in clinical activities relating to the conclusion of our Phase 3 clinical trial and decrease in GDA 201 clinical program offset by an increase of $1.2 million in salaries and benefits, consisting primarily of additional headcount focused on operational activities in connection with the omidubicel BLA submission and an increase of $0.3 million in IIA grants and other expenses.

Commercial expenses

Our commercial expenses decreased by approximately $2.1 million to $7.1 in the six months ended June 30, 2021 from $9.2 million in the six months ended June 30, 2021. The decrease was attributable mainly to a $3.9 million decrease in launch readiness activities, offset by an increase of $1.8 million in headcount related expenses, including restructuring.

General and administrative expenses

General and administrative expenses increased by approximately $1.0 million to $8.4 million in the six months ended June 30, 2022, up from $7.4 million in the six months ended June 30, 2021. The increase was attributable to a $0.8 million increase in professional services expenses and a $0.2 million increase in new U.S. office lease agreement.

Financial expenses, net

Financial expenses, net, decreased by approximately $0.02 million to $1.4 million in the six months ended June 30, 2022, compared to $1.4 million in the six months ended June 30, 2021. The decrease was primarily due to an increase of $0.2 million in other non cash income offset by an increase of $0.2 million in financing interest expenses from our convertible senior notes.

Critical Accounting Policies and Estimates

This discussion and analysis of our consolidated financial statements has been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as set forth in the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC.

Prior to 2021, we prepared our financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, as permitted in the United States, based on our status as a foreign private issuer. At the end of the 2021 fiscal year, we lost our status as a foreign private issuer, and became subject to the U.S. domestic filer requirements, one of which requires us to prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

We are devoting substantially all of our efforts toward research and development activities. In the course of such activities, we have sustained operating losses and we expect such losses to continue in the foreseeable future. Our accumulated deficit as of June 30, 2022 was $376.2 million and negative cash flows from operating activities during the six months ended June 30, 2022 was $39.6 million. We are planning to finance our operations from our existing and potential future working capital resources and we continue to evaluate additional sources of capital and financing. However, there is no assurance that additional capital and/or financing will be available to us, and even if available, whether it will be on acceptable terms or in the amounts required. As of August 15, 2022, the date of issuance of these condensed consolidated financial statements, the Company expects that its cash, cash equivalents and investments of $55.1 million as of June 30, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements into mid-2023, excluding the cost of commercializing omidubicel. The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments that might result from the outcome of the uncertainties described in Note 1(d) to the financial statements. While our significant accounting policies are more fully described in the notes to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, as well as in our consolidated financial statements appearing in our Annual Report on form 10-K for the year ended December 31, 2021, 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.

Convertible senior notes

On February 16, 2021 Gamida Cell Ltd.'s wholly owned U.S. subsidiary, Gamida Cell Inc., issued convertible senior notes, or the Notes, with an aggregate original principal amount of $75.0 million in a private placement. The Notes were issued on a senior unsecured basis, have a maturity date of February 15, 2026, bear 5.875% interest, and may be exchanged, at the election of the holder, for ordinary shares of Gamida Cell Ltd. at an initial per share price of $17.76, subject to adjustments. We account for the Notes in accordance with ASC 470-20 "Debt with Conversion and Other Options." We early adopted ASU 2020-06 using the modified retrospective approach. The convertible senior notes are accounted for as a single liability measured at its amortized cost, as no other embedded features require bifurcation and recognition as derivatives according to ASC 815-40.

The Notes are included in the calculation of diluted earnings per share, or EPS, if the assumed conversion into ordinary shares is dilutive, using the "if-converted" method. This involves adding back the periodic interest expense net of taxes associated with the Notes to the numerator and by adding the shares that would be issued in an assumed conversion (regardless of whether the conversion option is in or out of the money) to the denominator for the purposes of calculating diluted EPS. Since the effect of the Notes on the diluted EPS was antidilutive, we did not include them in our calculation of the diluted EPS.

Share-based compensation

We account for share-based compensation in accordance with ASC No. 718 "Compensation - Stock Compensation," or ASC No. 718, which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the award is recognized as an expense over the requisite service periods, which is the vesting period of the respective award, on a straight-line basis when the only condition to vesting is continued service. We selected the binominal option-pricing model as the most appropriate fair value method for our option awards. The fair value of restricted shares, is based on the closing market value of the underlying shares at the date of grant. 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. We recognize forfeitures of equity-based awards as they occur.

Significant Accounting Policies

See note 2 of the accompanying unaudited consolidated financial statements for the six months ended June 30, 2022 for a discussion of significant accounting policies.

Internal Control over Financial Reporting

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, completed 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. Based on this process, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Liquidity and Capital Resources.

Sources of Liquidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the six months ended June 30, 2022 and June 30, 2021, we incurred a net loss of $38.8 million and $42.7 million, respectively, and net cash of $39.6 million and $40.6 million, respectively, was used in our operating activities. As of June 30, 2022 and December 31, 2021 we had working capital of $35.1 million and $73.2 million, respectively, and an accumulated deficit of $376.2 million and $337.5 million, respectively. Our principal sources of liquidity as of June 30, 2022 and December 31, 2021, consisted of cash and cash equivalents and trading financial assets of $55.1 million and $95.9 million, respectively.

Capital Resources

Overview

Through June 30, 2022, we have financed our operations primarily through private placements and public offerings of equity securities and through the grants received from the IIA. We have also entered into an Open Market Sale Agreement under which we have the option to offer and sell our ordinary shares having an aggregate gross sales price of up to $50 million from time to time through Jefferies LLC. Pursuant to the Open Market Sales Agreement and upon delivery of notice by the Company, Jefferies may sell our ordinary shares under an "at the market offering." From inception through to December 31, 2021 we did not sell any shares under this facility. During the six months ended June 30, 2022, we sold 38,458 shares pursuant to the Sales Agreement for net proceeds of $0.1 million, after deducting commissions.

Cash flows

The following table summarizes our statement of cash flows for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)			
Net cash provided by (used in)				
Operating activities	$ (39,589)	$ (40,568)	$ 979	2.4%
Investing activities	21,427	(57,445)	78,872	137.3
Financing activities	160	71,333	(71,173)	(99.8)

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 share based compensation.

Net cash used in operating activities was $39.6 million during the six months ended June 30, 2022, compared to $40.6 million used in operating activities during the six months ended June 30, 2021. The $1.0 million decrease in cash used was attributable primarily due to cash payment relating to delays in launch readiness.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $21.4 million during the six months ended June 30, 2022, compared to $57.4 million used in investing activities during the six months ended June 30, 2021. The $78.9 million increase is primarily related to increase of $74.3 million of proceeds from maturity and purchase of marketable securities and changes in restricted deposits, and, by a decrease of $4.6 million from the Kiryat Gat equipment purchase.

Net cash provided by financing activities

Net cash provided by financing activities was $0.2 million during the six months ended June 30, 2022, compared to $71.3 million during the six months ended June 30, 2021. The $71.1 million decrease is primarily related to net proceeds of $70.8 million received from the 2021 issuance of our convertible senior notes.

Funding Requirements

We believe that our existing funds will enable us to fund our operating expenses and capital expenditure requirements into mid-2023, excluding the cost of commercializing omidubicel. We cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all. These conditions raise substantial doubt about our ability to continue as a going concern. 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.

We are currently assessing whether, if the FDA approves omidubicel for marketing in the United States, to market the product ourselves or to pursue strategic alternatives for the commercialization of omidubicel. If we decide to market omidubicel ourselves, we will require substantial additional funding. Our present and future funding requirements will depend on many additional factors, including, among other things:

- the progress of the FDA's priority review of our BLA filing for omidubicel;
- the progress of our ongoing Phase 1/2 clinical trial of GDA-201, and the progress, timing and completion of preclinical studies 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, if we determine to internally commercialize the product, if approved;
- 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 scaling up manufacturing capabilities to commercialize any products for which we obtain regulatory approval and determine to commercialize internally.

We have annual operating lease obligations related to our Haddasah production facility of approximately $1.0 million, which is included in research and development expense. We additionally have annual operating lease obligations related to our Boston and Kiryat Gat facilities in aggregate of $1.1 million, which is included in general and administrative expense.

Furthermore, we expect to continue to incur substantial costs associated with operating as a public company subject to US domestic filer regulations. 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.

Additional financing may not be available when we need it or may not be available on terms that are 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 "Item 1A. Risk Factors—Principal Risk Factors."

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2022 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Our management, with participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2022 to provide reasonable assurance that the information required to be disclosed by us in this Quarterly Report was (a) reported within the time periods specified by SEC rules and regulations and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive, financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2022 based on the framework in Internal Control—Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of June 30, 2022.

Attestation Report of the Registered Public Accounting Firm

This Quarterly Report does not include an attestation report of our registered public accounting firm due to the Company's emerging growth company status which provides an exemption.

Cybersecurity

We utilize information technology for internal and external communications with vendors, clinical sites, banks, investors and shareholders. Loss, disruption or compromise of these systems could significantly impact operations and results.

We are not aware of any material cybersecurity violation or occurrence. We believe our efforts toward prevention of such violation or occurrence, including system design and controls, processes and procedures, training and monitoring of system access, limit, but may not prevent unauthorized access to our systems.

Other than temporary disruption to operations that may be caused by a cybersecurity breach, we consider cash transactions to be the primary risk for potential loss. We and our financial institution take steps to minimize the risk by requiring multiple levels of authorization and other controls.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the fiscal quarter ended June 30, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

Part II—Other Information

Item 1. 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.

Item 1A. 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 Quarterly Report, including the consolidated financial statements and the related notes included elsewhere in this Quarterly Report, 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.

Summary of Selected Risk Factors

Our business is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in this "Risk Factors" section and include, among others:

- 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, which raises substantial doubt regarding our ability to continue as a going concern absent access to additional sources of liquidity.
- Operating our business and servicing our debt requires a significant amount of cash, and we will need to obtain additional funding in the future to continue to sufficiently fund our operations and pay our substantial debt, including our 5.875% convertible senior notes that mature in February 2026, or the Notes.
- We may not have the ability to raise the funds necessary to repurchase the Notes for cash upon a fundamental change.
- The Indenture governing the Notes contains restrictions and other provisions regarding events of default that may make it more difficult to execute our strategy or to effectively compete or that could adversely affect our liquidity.
- Raising additional capital may cause dilution to our shareholders and our share price to fall, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We have never generated any revenue from product sales and may never be profitable.
- Our business could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.
- 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.
- We may be unable to obtain regulatory approval for 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.

- Interim, "topline" 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.

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

- 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.

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

- 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.

- 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 narrower indication than we seek or be subject to other limitations or restrictions that limit its commercial profile.

- 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.

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

- 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.

- 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 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.

- 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.

- 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.

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

- We do not have experience producing our product candidates at commercial levels or operating 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 currently have limited marketing and sales organization. If we are unable to establish adequate sales and marketing capabilities to support the potential commercial launch of omidubicel or enter into agreements with third parties to market and sell omidubicel, if approved, we may be unable to generate any product revenue.

- 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 payers, hospital pharmacists and others in the medical community.

- The market price of our ordinary shares may fluctuate significantly, which could result in substantial losses by our investors.

- Significant parts of our operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military conditions in Israel.

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 $89.8 million and $61.6 million for the years ended December 31, 2021 and 2020, respectively. As of June 30, 2022, we had an accumulated deficit of $376.2 million.

We have devoted substantially all our financial resources to designing and developing our product candidates, including conducting preclinical studies and clinical trials, building a manufacturing facility at Kiryat Gat, Israel 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, and to obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products. 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.

We are currently assessing whether, if the FDA approves omidubicel for marketing in the United States, to market the product ourselves or to pursue strategic alternatives for the commercialization of omidubicel. If we decide to market omidubicel ourselves, we will require substantial additional funding. We anticipate that our expenses will increase substantially based on a number of additional factors, including to the extent that we:

- continue our clinical development of omidubicel, GDA-201 and other potential product candidates;

- 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 manufacturing facilities in accordance with current good manufacturing practices, or cGMP;

- 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, manufacturing 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 public offerings of equity securities, private placements of debt and 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, including from Bereshit Consortium, sponsored by the IIA. 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 omidubicel or any other 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 and reimbursement from third-party payers 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.

There is substantial doubt regarding our ability to continue as a going concern. Operating our business and servicing our debt requires a significant amount of cash, and we will need to obtain additional funding in the future to continue to sufficiently fund our operations and pay our substantial debt, including our convertible senior notes that mature in February 2026.

Our financial statements have been prepared on a going concern basis under which an entity is able to realize its assets and satisfy its liabilities in the ordinary course of business. Our future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that we will be successful in completing equity or debt financing or in achieving profitability. The financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern. Our unaudited condensed consolidated financial statements and of and for the three and six months ended June 30, 2022 accompanying this quarterly report 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, including commercializing omidubicel ourselves, 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. 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. In June 2022, we completed the submission of our omidubicel BLA to the FDA, and in July 2022, it was accepted for priority review. The FDA set an action date of January 30, 2023 under the Prescription Drug User Fee Act, or PDUFA, and indicated that it was not planning to hold an advisory committee meeting as part of the BLA review. We also plan to continue our Phase 1/2 investigator-sponsored clinical trial of omidubicel for the treatment of severe aplastic anemia, and we opened enrollment of our Phase 1/2 clinical trial of GDA-201 in patients with follicular and diffuse large B-cell lymphomas in May 2022.

In addition, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may never generate cash flow from operations sufficient to support our operations, service our debt and make necessary capital expenditures. As a result, we may be required to adopt one or more alternatives, subject to the restrictions contained in the Indenture between Gamida Cell Ltd., Gamida Cell Inc., and Wilmington Savings Fund Society, FSB, entered into on February 16, 2021, or the Indenture, governing the Notes, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous and which are likely to be highly dilutive. We currently believe that our existing capital resources will be sufficient to meet our projected operating requirements into mid-2023, excluding the cost of commercializing omidubicel. 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 cost, timing and outcomes of regulatory reviews of omidubicel, GDA-201 and our other potential product candidates;
- the progress, results and costs of our current and planned clinical trials of GDA-201 and our other product candidates;
- the costs of qualifying our planned commercial-scale cGMP manufacturing facility at 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.

We may not have the ability to raise the funds necessary to repurchase the Notes for cash upon a fundamental change.

Holders of the Notes have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. This use of cash may have a material adverse effect on our liquidity. Furthermore, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes. In addition, our ability to repurchase the Notes for cash may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase Notes for cash at a time when the repurchase is required by the Indenture pursuant to which the Notes were issued would constitute a default under the Indenture.

The Indenture governing the Notes contains restrictions and other provisions regarding events of default that may make it more difficult to execute our strategy or to effectively compete or that could adversely affect our liquidity.

Subject to certain exceptions and qualifications, the Indenture governing the Notes restricts our ability to, among other things, (i) pay dividends or make other payments or distributions on capital stock, or purchase, redeem, defease or otherwise acquire or retire for value any capital stock, (ii) incur indebtedness or issue preferred stock, other than certain forms of permitted debt, (iii) sell assets or dispose of certain material assets, (iv) enter into certain transactions with affiliates, (v) merge, consolidate or sell all or substantially all assets. The Indenture also requires us to make an offer to repurchase the Notes upon the occurrence of certain asset sales or disposition of certain material assets. These restrictions may make it difficult to successfully execute our business strategy or effectively compete with companies that are not similarly restricted. The Indenture governing the Notes also provides that a number of events will constitute an event of default, including, among other things, (i) a failure to pay interest or additional amounts for 30 days, (ii) failure to pay the principal of the notes when due at maturity, upon redemption, upon any required repurchase, upon declaration of acceleration or otherwise, (iii) failure to comply with our obligation to exchange the Notes in accordance with the Indenture upon a holder's exercise of its exchange right, (iv) not issuing certain notices required by the Indenture within a timely manner, (v) failure to comply with the other covenants or agreements in the Notes or the Indenture, (vi) a default or other failure by us to make required payments under our other indebtedness having an outstanding principal amount of $10.0 million or more, (vii) failure by us to pay final judgments aggregating in excess of $20.0 million, and (viii) certain events of bankruptcy or insolvency. In particular, pursuant to the Indenture, we have agreed to maintain a consolidated cash and cash equivalents balance of at least $20 million. Our failure to comply with this liquidity covenant would constitute a default under the Indenture, which would mature into an event of default if we continue to be out of compliance for more than 60 days after notice from the holders or the trustee. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to us, all outstanding Notes will become due and payable immediately without further action or notice. If any other event of default occurs and is continuing, the trustee or the holders of at least 25% in aggregate principal amount of the then outstanding Notes may declare all the Notes to be due and payable immediately. Such acceleration of our debt could have a material adverse effect on our liquidity if we are unable to negotiate mutually acceptable terms with the holders of the Notes or if alternate funding is not available to us. Furthermore, if we are unable to repay the Notes upon an acceleration or otherwise, we would be forced into bankruptcy or liquidation.

Raising additional capital may cause dilution to our shareholders and our share price to fall, 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, 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.

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.

We have also entered into an Open Market Sale Agreement, or the Sales Agreement under which we may offer and sell our ordinary shares having an aggregate gross sales price of up to $50 million from time to time through Jefferies LLC. Pursuant to the Sales Agreement and upon delivery of notice by the Company, Jefferies may sell our ordinary shares under an "at the market offering". The sale of a substantial amount of our ordinary shares in this manner may depress the market price for our ordinary shares.

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. Our ability to generate future revenue from the commercialization of omidubicel is uncertain. If we decide to commercialize omidubicel on our own, we will have to undertake sufficient costs to build out a sales and distribution team. If we enter into one or more partnerships for the commercialization of omidubicel, we will surrender a portion of our revenue to our partner or partners, and if we securitize royalty streams related to omidubicel, future revenues would be held in trust for beneficiaries of the financing in exchange for which we would receive certain payments based on an assessment of future sales. Furthermore, revenue from product sales will depend heavily on our ability to:

- obtain regulatory approvals and marketing authorizations for omidubicel and those of our other 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 for omidubicel that meets all applicable regulatory standards;
- 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;
- complete research and preclinical and clinical development of our product candidates in a timely and successful manner;
- 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;
- price omidubicel and our other product candidates, if and when approved, in a manner designed to encourage market acceptance from the medical community and third-party payers;
- 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 payers 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 knowhow;
- 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.

Our business could be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our operations, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Uncertainty caused by the ongoing COVID-19 pandemic and related government and private sector responsive actions have impacted and may continue to impact the global economy and financial markets. The COVID-19 pandemic has also disrupted the global supply chain. Despite the increased availability of COVID-19 vaccines, due to the continuing and evolving nature of the COVID-19 pandemic and the potential for periods of increases in case numbers and the emergence and spread of virus variants in communities in which we and our customers operate, it is impossible to predict all the effects and the ultimate impact of the COVID-19 pandemic, as the situation continues to evolve.

Our business could be adversely affected by the effects of the ongoing COVID-19 pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations as well as causing significant disruption in the operations and business of third-party manufacturers, CROs, and other services providers.

Some of our third-party manufacturers which we use for the supply of materials for product candidates or other materials necessary to manufacture product to conduct preclinical tests and clinical trials are located in countries that continue to be highly affected by COVID-19. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities, or the availability or cost of materials, which would disrupt our supply chain, and should they experience additional disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these tests and trials. Currently, we expect no material impact on the clinical supply of omidubicel or GDA-201.

Our clinical trials may also be affected by the COVID-19 pandemic. While clinical site initiation and patient enrollment in our Phase 1/2 clinical trial of GDA-201 are underway, we may experience delays due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our future clinical trial operations.

The uncertainty around the duration of business disruptions may materially and adversely impact the national and/or global economy. The full extent of the COVID-19 pandemic's impact on our operations and financial performance depends on future developments that are uncertain and unpredictable, including the timing, acceptance, and efficacy of vaccinations and possible achievement of herd immunity in various locations, the occurrence of virus mutations and variants, the pandemic's impact on capital and financial markets, and any new information that may emerge concerning the virus, vaccines, and containment, all of which may vary across regions. Any of these factors could have a material adverse impact on our business, financial condition, operating results, and ability to execute and capitalize on our strategies.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section and in the "Risk Factors" incorporated by reference herein.

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 our efforts and financial resources to: (i) research and develop our NAM, or nicotinamide, cell expansion platform, our lead product candidate, omidubicel, for the treatment of hematologic malignancies, and our second product candidate, GDA-201, for the treatment of NHL, and our other potential 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:

- our ability to develop, qualify and maintain a commercially viable manufacturing process that is compliant with cGMP and produces omidubicel that has the same treatment profile as the products used in our clinical trials, whether at our facility at Kiryat Gat or through third party manufacturers;

- successful progress on and completion of the Phase 1/2 clinical trial of GDA-201;

- 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;

- the acceptance by the FDA 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;

- 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 payers provide coverage and adequate reimbursement for procedures utilizing our products; and/or
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our product candidates and 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, including with respect to our and our third-party manufacturer's production of omidubicel in commercial processes that has the same treatment profile as the product used in our successful Phase 3 clinical trial;
- 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;

- regulatory requests to provide additional data regarding analytical and clinical comparability from our planned commercial manufacturing sites, or the failure of a regulatory agency to accept the manufacturing processes or facilities at our manufacturing site or those of third-party manufacturers with which we contract;

- 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, including the clinical hold the FDA placed on our GDA-201 IND prior to the initiation of patient dosing for our planned Phase 1/2 study in NHL, which was removed by the FDA on April 21, 2022;

- 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 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 are required to submit a BLA to obtain FDA approval before marketing omidubicel or 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. In November 2021, we completed a Type B Pre-Biologics License Application, or pre-BLA meeting, with the FDA for omidubicel during which the FDA requested that we provide revised analysis of the manufacturing data generated at our wholly-owned commercial manufacturing facility in Kiryat Gat, Israel to demonstrate the comparability to the omidubicel that was produced at the clinical manufacturing sites for the Phase 3 study. Although the FDA has agreed that we established analytical comparability between the omidubicel product that is manufactured at our commercial manufacturing facility and the omidubicel product that was manufactured for the Phase 3 trial, there is no guarantee that we will continue to meet the FDA's manufacturing requirements in the future.

As part of the review process for our omidubicel BLA, the FDA will likely conduct an inspection of our Kiryat Gat, Israel manufacturing facility to ensure that it can manufacture omidubicel and our other product candidates, if and when approved, in compliance with the applicable regulatory requirements. The FDA also inspected our clinical trial sites to ensure that our studies were properly conducted. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. Although the FDA has accepted our BLA for filing on a priority review basis, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will approve our application. If the FDA requires additional studies or data, or if our manufacturing facility fails to pass inspection, 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 nonclinical 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 receive approval of any regulatory filing for omidubicel, the FDA may grant any such 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 omidubicel or 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 noncompliance 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 product 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.

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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter difficulties or delays in initiating, screening, enrolling, conducting, or completing our ongoing and planned preclinical studies and clinical trials. Clinical site initiation and patient screening and enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be limited, which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. Specifically, the submission of our BLA for omidubicel was delayed, in part, as a result of the impact of the COVID-19 pandemic on our operations.

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, our first Phase 1/2 clinical trial, which was an investigator-initiated trial using the fresh formulation of GDA-201 demonstrated no dose-limiting toxicities and significant clinical activity in patients with non-Hodgkin lymphoma, with 13 complete responses and one partial response observed in 19 patients, for an overall response rate of 74%. However, further clinical trials may show that the response rate in a larger sample size is lower than 74%, or there may be new toxicities reported. A decrease in efficacy or a significantly different safety profile cause us to abandon further development of GDA-201 in this indication.

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 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.

Interim, "topline" 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 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 technology 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 expansion technology platform 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 technology platform would be adopted into the current standard of care for hematopoietic stem cell transplant, or 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 technology platform, and unexpected problems related to this new technology may arise that could 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.

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.

In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, the impact of public health epidemics, such as the ongoing COVID-19 pandemic, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical trials, miss follow-up visits, or otherwise fail to follow clinical trial protocols, whether as a result of the COVID-19 pandemic or actions taken to slow the spread of COVID-19 or otherwise, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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 obtain 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. Severe (grade 4) infusion reactions have also been reported in approximately 4% of patients treated with omidubicel. The most common adverse events related to omidubicel were graft versus host disease, or GvHD, (10%), pain (8%), transplant failure (4%), hypertension (4%), and dyspnea (2%). 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 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 first Phase 1/2 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 narrower 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. 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 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 to qualify for Breakthrough Therapy Designation.

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 PPACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payers. Among the provisions of the PPACA, 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 hospital personnel including transplant teams, including reporting "transfers of value" made or distributed to physicians, as defined by such law, 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.

There have been judicial and Congressional challenges to certain aspects of the PPACA. 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, included 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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 26, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration.

In addition, 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, 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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. Additionally, Congress is considering additional health reform measures. 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. Presidential executive orders, 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 payer programs, and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Additionally, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future.

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 payers 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. Any increase in European Union and national regulatory burdens on those wishing to develop and market products 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. It is also possible that additional government action is taken in response to the COVID-19 pandemic. 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 payers, 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 payers, 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, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, and civil monetary penalties laws which prohibit 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 and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information;

- 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), 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 payer, 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, individual 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 or mismatched unrelated donors, haploidentical donors or unmodified umbilical cord blood instead of using omidubicel or may choose other therapy options instead of 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 but not limited to Magenta Therapeutics, ExCellThera, Garuda Therapeutics and Bellicum Pharmaceuticals, and for NK cells, including, Takeda Pharmaceutical Company Limited, Fate Therapeutics, Artiva, Sanofi, MiNK Therapeutics, ONK Therapeutics, Shoreline, Cellularity, NKarta, Wugen, Century Therapeutics, Appia Bio and FujiFilm Cellular Dynamics. 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 of 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 or the marketing and sales personnel of any strategic partner to not promote our products, if approved, for any other uses outside of any FDA-cleared indications for use, known as "off-label use."

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.

Collection and use of data, including personal information, is governed by restrictive regulations that could lead to government enforcement actions, private litigation, adverse publicity, or other adverse actions that could negatively affect our operating results of business.

The collection and use of personal health data in the European Union are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or GDPR. This legislation imposes requirements relating to (a) 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, (b) providing details to those individuals regarding the processing of their personal information, (c) keeping personal information secure and confidential, (d) having data processing agreements with third parties who process personal information, (e) responding to individuals' requests to exercise their rights in respect of their personal information, (f) reporting security breaches involving personal data to the competent national data protection authority and, possibly, affected individuals, (g) appointing data protection officers, (h) conducting data protection impact assessments and (i) recordkeeping. 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. Further, the GDPR prohibits the transfer of personal data to countries outside the European Economic Area, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, they are subject to legal challenges and uncertainty regarding compliance with the European Union data protections laws. 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 (up to or the great of €20 million or 4% of annual global revenue), 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. Such civil claims, based on a private right of actions in the GDPR, allow data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

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 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 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 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 rely on a single facility located in Kiryat Gat, Israel to manufacture omidubicel. Severe natural or other disaster, power outages or disruption at this site could have a material adverse effect on our ability to manufacture sufficient commercial supply.

After the termination of the Services Agreement with Lonza and unless and until we establish an alternative supplier, we will be solely dependent on our facility in Kiryat Gat, Israel for the manufacture of the commercial supply of omidubicel, if omidubicel is approved. We have completed construction on the facility in Kiryat Gat and we are now working to qualify our manufacturing process and facility with the FDA's cGMP regulations. Severe natural or other disasters, power outages, ongoing or revived hostilities or other political or economic factors could severely disrupt our manufacturing operations at our Kiryat Gat facility. If any event occurred that prevented us from using all or a significant portion of this facility or otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue manufacturing omidubicel for a substantial period of time in sufficient quantities, or at all. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate to guarantee a sufficient continuation of supply in the event of a serious disaster or similar event. Although we intend to establish an alternative source supplier or manufacturer for the commercial supply of omidubicel, we cannot guarantee that we will be able to establish an alternative source, supplier or partner for the manufacturing of omidubicel at acceptable commercial terms, or at all.

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 have been 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;
- pregnancy and birth rates, which we expect to decline temporarily in response to the COVID-19 pandemic, and the willingness of mothers to consent to the donation of CBUs and the terms of such consent;
- 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, any or all of which may have been complicated by public health policies aimed at slowing the spread of the COVID-19 virus.

Additionally, we do not have control over the types of CBUs used 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 cord blood banks in testing CBUs before storage. This could result in CBUs that are found to be unsuitable for production after their arrival at the manufacturing site. In the United States, cord blood banks are required to file a BLA and meet certain continued regulatory requirements in order to bank and provide CBUs for transplantation. Despite these requirements, most of the cord blood banks in the United States are not licensed. While the FDA currently allows CBUs from unlicensed cord blood banks to be used for transplantation and we have used CBUs from such facilities in the manufacture of omidubicel for our clinical trials, the FDA may later prohibit the use of such 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, we anticipate we will not be able to use cord blood from non-U.S. cord blood banks for the manufacturing of omidubicel. 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 parts 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 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 knowhow, 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.

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. In addition, the Indenture governing our Notes contain restrictions that may limit our ability to enter into acquisition or in-licensing agreements.

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 are also subject to certain restrictions regarding obtaining licenses of third-party intellectual property pursuant to the terms of the indenture governing the Notes, and we 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 parties 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 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 or replace 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, including our chief executive officer, Julian Adams, and our chief financial officer, Shai Lankry. 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. We are actively conducting a process to identify a successor to Dr. Adams, our chief executive officer, in connection with his intended retirement and to support our potential evolution to a commercial-stage company, although we have not yet appointed any candidate to replace him and no definitive timeline has been set forth for the transition. Dr. Adams has committed to remain in his position until a qualified successor is installed, and thereafter he is expected to continue to serve our company as a director on our board and in an additional capacity to be determined. In addition, to support our potential evolution to a commercial-stage company, we are actively conducting a process to identify a successor to Mr. Lankry, our chief financial officer, although no candidate has yet been selected to replace him and no definitive timeline has been set forth for the transition. Mr. Lankry has also committed to remain in his position until a qualified successor is installed, and thereafter he is expected to continue to serve our company in a senior role within our Finance organization. Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, is 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 and where there is a "war for talent" among members of our industry. As a result, competition for skilled personnel is intense, and the turnover rate is high. We may not be able to attract and retain personnel, including a new chief executive officer or new chief financial officer, on acceptable terms or at all, given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical studies or a failure or delay in obtaining regulatory approval of our product candidates 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. Even if we are able to identify qualified personnel to replace senior management, including our chief executive officer and chief financial officer, the replacement of current members of our management team could be disruptive to our daily operations.

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 our hematologic malignancy program is at a more advanced stage of development, while our sickle cell program remains exploratory. In addition, we are evaluating alternatives for commercialization of omidubicel, if approved, which may include commercializing omidubicel ourselves or entering into potential strategic alliances or licensing arrangements with pharmaceutical companies and other partners. If we make the decision to commercialize omidubicel ourselves, we may have to significantly expand our commercial organization in time for omidubicel approval, which may jeopardize the success of a timely commercial launch and may reduce or delay our anticipated revenue from sales of omidubicel. Commercializing omidubicel ourselves will also require additional capital to fund an increase in workforce as well as operating expenses and capital expenses to expand our manufacturing facility in Kiryat Gat, Israel. If we decide to enter into licensing arrangements or other forms of collaboration, the potential for us to generate revenue from royalties on sales of such out-licensed products depends on the performance of our partners. If our partners do not perform in the manner we expect, fail to fulfill their responsibilities in a timely manner or at all, if the FDA, EMA or other similar regulatory authorities decline to grant a marketing authorization to them, or provide them with a restricted authorization, if our agreements with them terminate, they abandon the collaboration or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to our out-licensed product candidates could be delayed or terminated, and it could become necessary for us to assume the responsibility at our own expense, or seek new partners on reduced commercial terms, for the clinical development of such product candidates. 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.

Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses.

Our operations and those of our third-party suppliers and collaborators could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes, war or other business interruptions. Although we have limited business interruption insurance policies in place, any interruption could come with high costs for us, as salaries and loan payments would usually continue. Moreover, any interruption could seriously harm one or more of our research, development or manufacturing programs, the commercialization of any approved product or our clinical trial operations. For example, the current COVID-19 pandemic has, at points, caused an interruption in our ongoing and planned clinical trials activities. In addition, the submission of our BLA for omidubicel was delayed, in part, as a result of the impact of the COVID-19 pandemic on our operations. Moreover, at the end of 2021 and into 2022, tensions between the United States and Russia escalated when Russia amassed large numbers of military ground forces and support personnel on the Ukraine-Russia border and, in February 2022, Russia invaded Ukraine. In response, North Atlantic Treaty Organization, or NATO has deployed additional military forces to Eastern Europe, including to Lithuania, and the Biden administration implemented certain sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, adversely affect our ability to conduct ongoing and future clinical trials of our product candidates or commercialize our products. In addition, the conflict has had significant ramifications on global financial markets, which may adversely impact our ability to raise capital on favorable terms or at all.

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 and GDA-201, the success of our business also depends upon our ability to identify, discover or license additional product candidates, including within our NK-cell pipeline. 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 payers.

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 a variety of causes, including computer viruses, malware, intentional or accidental mistakes or errors by users with authorized access to our computer systems, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, or attachments to emails. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusions, 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 or compromise 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. Further, any breach, loss or compromise of clinical study participant personal data may also subject us to civil fines and penalties, including under GDPR and relevant member state law in the European Union, or, potentially, other relevant state and federal privacy laws in the United States.

In the current environment, there are numerous and evolving risks to cybersecurity and privacy, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error. We may be subject to elevated cybersecurity risk due to Russia's invasion of Ukraine. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. We can provide no assurance that our current IT systems, software, or third-party services, or any updates or upgrades thereto will be fully protected against third-party intrusions, viruses, hacker attacks, information or data theft or other similar threats.

Legislative or regulatory action in these areas is also evolving, and we may be unable to adapt our IT systems to accommodate these changes. We have experienced and expect to continue to experience sophisticated attempted cyber-attacks of our IT networks. Although none of these attempted cyber-attacks has had a material adverse impact on our operations or financial condition, we cannot guarantee that any such incidents will not have such an impact in the future.

We incur significant costs as a result of operating as a public company in the United States, and our management is required to devote substantial time to 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 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, which we expect to occur beginning on January 1, 2024, 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. Compliance with this additional requirement will entail additional costs and expenses.

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 substantial operations 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 payer reimbursement regimes, government payers, price 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 noncompetition 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.

We are vulnerable to interest rate risk with respect to the grants received from the Israel Innovation Authority

Since our incorporation, we have received grants from the IIA relating to various projects. We were members of Bereshit Consortium, sponsored by IIA in which certain of our technologies were developed, such program does not require payments of royalties to the IIA, but all other restrictions under the Innovation Law, such as local manufacturing obligations and know-how transfer limitations, as further detailed hereunder, are applicable to the know how developed by us with the funding received in such consortium program. No royalties have been paid to the IIA in respect of any grant. Our total outstanding obligation to the IIA, including the interest accrued through June 30, 2022, amounts to approximately $41.7 million.

The United Kingdom's Financial Conduct Authority, which regulates the London Interbank Offered Rate, or LIBOR, announced that it will no longer persuade or require banks to submit rates for LIBOR after January 1, 2022. The grants received from the IIA bear an annual interest rate based on the 12-month LIBOR. Accordingly, there is considerable uncertainty regarding the interest accrued to the IIA grants. While it is not currently possible to determine precisely whether, or to what extent, the withdrawal and replacement of LIBOR would affect us, the implementation of alternative benchmark rates to LIBOR may increase our financial liabilities to the IIA. Management continues to monitor the status and discussions regarding LIBOR. We are not yet able to reasonably estimate the expected impact. To date, the IIA has not issued any clarification regarding an alternative interest to be used instead of the LIBOR.

Risks Related to Commercialization of Our Product Candidates

We do not have experience producing our product candidates at commercial levels or operating 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.

The Israeli Ministry of Health issued a GMP certificate for our manufacturing facility at Kiryat Gat, Israel in July 2021 and we are working to establish cGMP compliance under the FDA's regulations. We do not have an extensive number of employees with 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. Although we completed the required studies and validation activities for the omidubicel BLA submission, FDA may request additional studies or validation activities. If we do not conduct all such necessary activities as requested by FDA, our commercialization efforts will be delayed.

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 and other market research, and may prove to be incorrect. Our target patient populations may be lower than expected, may not be otherwise amenable to treatment with our product candidates 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 limited marketing and sales organization. If we are unable to establish adequate sales and marketing capabilities to support the potential commercial launch of omidubicel or enter into agreements with third parties to market and sell omidubicel, if approved, we may be unable to generate any product revenue.

Although we have a chief commercial officer to lead our efforts to commercialize omidubicel should it receive regulatory approval and we decide to commercialize omidubicel ourselves, we currently have a limited sales and marketing organization, and we have limited 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 omidubicel or any other product candidate receives regulatory approval, we may 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 or identification of appropriate strategic partnering would adversely impact our ability to commercialize our product candidates.

Further, 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 partners 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 payers 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 payers, 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 are working to establish our own cGMP compliant manufacturing facility at Kiryat Gat, Israel. We have completed construction on the facility, and we are now working to qualify our manufacturing process and facility with the FDA's cGMP regulations. Before we can begin to commercially manufacture omidubicel or any product candidate in our facility, we must pass a pre-approval inspection of our manufacturing facility by the FDA before omidubicel or any product candidate can obtain marketing approval. A manufacturing authorization must also be obtained from the appropriate regulatory authorities in the European Union, Israel and worldwide. Such manufacturing authorizations must also be obtained for any third-party manufacturing facility and process. In order to obtain approval, we will need to ensure that all our processes, methods, relevant computer systems, 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. 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. While we continue to work to establish the cGMP compliance of our manufacturing facility at Kiryat Gat in Israel, we do not have another long-term partner for the manufacturing of omidubicel.

Qualifying our manufacturing facility is subject to other delays, including because of COVID-19 related shortages of labor and governmentally imposed shut-downs. Unexpected problems in the qualification 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.

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 payers, hospital pharmacists 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 payers and hospital personnel, including transplant teams and pharmacists. 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 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 payer coverage and adequate reimbursement for 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 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 payers and hospital personnel, including transplant teams and pharmacists, 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 payers 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 payer policies.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payers provide coverage, and establish adequate reimbursement levels, for such products. In the United States, third-party payers include federal and state healthcare programs, private managed care providers, health insurers and other organizations.

The process for determining whether a third-party payer will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication.

Third-party payers are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, the determination of one payer to provide coverage for a product does not assure that other payers will also provide such coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that in some countries subsidize a large part of the cost of those products for consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to then available therapies. Other EU member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any of our product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 payers, such as government health care programs, commercial insurance and managed care organizations. In the event health care providers and patients accept our product candidates as medically useful, cost effective and safe, there is uncertainty on how exactly our products will be reimbursed. Third-party payers 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. Coverage will be dependent on FDA-approval and other factors; reimbursement may vary across payers which is a risk for our product candidates. Establishment of reimbursement guidelines for products is difficult to predict at this time what third-party payers 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. Third-party payers decide which products and procedures they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers 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 payers limit coverage and reimbursement to the appropriate patient per a products label. 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 other treatments, has become increasingly intense. As a result, high barriers exist 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 payer may depend upon a number of factors including the third-party payer'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 & 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 payers 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 payers 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 New Technology Add-on Payment or NTAP program 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 are evaluating the potential application 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 payer 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 payer. 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 payers in the United States. Similarly, health care providers enter into participation agreements with third-party payers wherein reimbursement rates are negotiated. Therefore, coverage and reimbursement can differ significantly from payer to payer 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 Ownership of our Ordinary Shares

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

Certain of our executive officers, directors and holders of more than 5% of our voting securities beneficially owned as of June 30, 2022 shares that represent approximately 38.5% 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 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.

The market price of our ordinary shares may fluctuate significantly, which could result in substantial losses by our investors.

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 sell your ordinary shares at or above the initial 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 marketing of omidubicel or initiate further clinical trials of GDA-201;

- 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, and payer reimbursement requirements 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
- the other factors described in this “Risk Factors” section.

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.

Further, the stock market in general, the Nasdaq Global Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like ours, including due to coordinate buying and selling activities and market manipulation. Broad market and industry factors may negatively affect the market price of our ordinary shares regardless of our actual operating performance. In addition, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly. Price volatility of our ordinary shares might be worse if the trading volume of our ordinary shares is low. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful.

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. In addition, we have registered all ordinary shares that we may issue under our equity compensation plans, and, as such, these shares can be freely sold in the public market upon issuance.

Moreover, the liquidity of our ordinary shares may be limited, not only in terms of the number of ordinary shares that can be bought and sold at a given price, but by potential delays in the timing of executing transactions in our ordinary shares and a reduction in security analyst and media's coverage of our company, if any. These factors may result in lower prices for our ordinary shares than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our ordinary shares. In addition, without a large float, our ordinary shares will be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our ordinary shares may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our ordinary shares. Trading of a relatively small volume of our ordinary shares may have a greater impact on the trading price of our ordinary shares than would be the case if our public float were larger. We cannot predict the prices at which our ordinary shares will trade in the future.

If we are or become 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 (generally determined based on a weighted quarterly average) is attributable to assets that produce, or are held for the production of, passive income, we would be a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, certain gains from the sale of investment property, and rents and royalties (other than rents and royalties received from unrelated parties in connection with the active conduct of a trade or business), and passive assets generally include cash. Additionally, we generally are treated as holding and receiving directly our proportionate share of the assets and income, respectively, of any corporation in which we own, directly or indirectly, 25% of its stock by value. If we are a PFIC, our U.S. shareholders may suffer adverse tax consequences, including that gains realized on the sale of our ordinary shares will be treated as ordinary income, rather than capital gains, the preferential tax rate will not be applicable to dividends received on our ordinary shares by our individual U.S. shareholders, interest charges will apply to distributions by us and gains from the sale of our ordinary shares, and additional tax reporting requirements will apply, regardless of whether we continue to be a PFIC.

Our status as a PFIC generally will depend on the nature and composition of our income and the nature, composition, and value of our assets (which generally will 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 ordinary shares from time to time, which may be volatile). If our market capitalization declines while we hold a substantial amount of cash for any taxable year, we may be a PFIC for such taxable year. The manner and timeframe in which we spend the cash we raise in any offering, the transactions we enter into, and how our corporate structure may change in the future will affect the nature and composition of our income and assets. Until such time as we start generating revenue from operations, our PFIC status may depend, in part, on the treatment of payments we receive from other sources (including government grants), which is uncertain, and the magnitude of such payments compared to passive income from investments. Based on the value of our assets, including goodwill, and the nature and composition of our income and assets, we do not believe that we were not a PFIC for the taxable year ended December 31, 2021. 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 by applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation, there can be no assurance that we will not be a PFIC for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for any taxable year. Prospective investors should consult their tax advisors regarding the application of the PFIC rules to their investment in our ordinary shares in their particular circumstances.

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

If we are (or any of our non-U.S. subsidiaries is) a "controlled foreign corporation," certain of our U.S. shareholders may suffer adverse tax consequences as a result.

If a "United States person" for U.S. federal income tax purposes is treated as owning (directly, indirectly, or constructively) at least 10% of the total value or total combined voting power of our ordinary shares, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation," or CFC, in our group (if any). A non-U.S. corporation will be a CFC if United States shareholders own (directly, indirectly, or constructively) more than 50% of the total value or total combined voting power of the stock of the non-U.S. corporation. Because our group includes one or more U.S. corporate subsidiaries, certain of our current or future non-U.S. corporate subsidiaries could be treated as CFCs (regardless of whether we are treated as a CFC). A United States shareholder of a CFC may be required to report annually and include in its U.S. taxable income its pro rata share of the CFC's "Subpart F income," "global intangible low-taxed income," and investments of earnings in U.S. property (regardless of whether the CFC makes any distributions to its shareholders). Additionally, an individual United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a corporate United States shareholder. A failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties and prevent the statute of limitations from running with respect to the United States shareholder's U.S. federal income tax return for the taxable year in which reporting was due. There can be no assurance that we will assist our U.S. shareholders in determining whether we are (or any of our current or future non-U.S. subsidiaries is) treated as a CFC or whether such U.S. shareholders are treated as United States shareholders with respect to any such CFCs, or that we will furnish to any United States shareholders information that may be necessary to comply with CFC reporting and tax paying obligations. Prospective investors should consult their tax advisors regarding the application of the CFC rules to their investment in our ordinary shares in their particular circumstances.

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.

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. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful could increase our expected tax liability in one or more jurisdictions.

Future changes to tax laws could materially adversely affect our company and reduce net return to our shareholders

Tax laws are dynamic and subject to change as new laws are passed and interpretations of the law are issued or applied. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholder, and increase the complexity, burden and cost of tax compliance.

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 2021 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 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 do not publish or 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 ordinary shares, our share price and trading volume could be negatively impacted.

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.

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 until such time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earlier to occur of: (1) December 31, 2023; (2) 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 (4) 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

Significant parts of our operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military conditions in Israel.

We have substantial operations in Israel, including our research and development facilities and our manufacturing facilities, that may be influenced by regional instability and extreme military tension. Accordingly, political, economic and military conditions in Israel and the surrounding region could directly affect our business. Any armed conflicts, political instability, terrorism, cyberattacks or any other hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could affect adversely our operations.

Ongoing and revived hostilities or other Israeli political or economic factors, could prevent or delay shipments of our products, harm our operations and product development and cause any future sales to decrease. In the event that hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our operations may be materially adverse affected.

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 did not have a material adverse effect on our financial condition during 2020 or 2021. 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 affected 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 our directors are residents of the United States and most our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and enforcement of judgments obtained in the United States against us or our non-U.S. directors 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. 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. 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 Israeli Companies Law 5759-1999, or 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Articles of Association of the Registrant (incorporated by reference to Annex A to the Registrant's DEF 14A (File No. 001-38716), filed with the SEC on June 22, 2022, as amended on July 13, 2022).
3.2	Memorandum of Association of the Registrant (unofficial English translation from Hebrew original), as amended on September 14, 2006 (incorporated by reference to Exhibit 3.4 to the Registrant's Form F-1 (File No. 333-227601), filed with the SEC on September 28, 2018).
4.1	Description of Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Form 10-K (File No. 001-38716), filed with the SEC on March 24, 2022).
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-K (File No. 001-38716), filed with the SEC on March 24, 2022).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Gamida Cell Ltd.

August 15, 2022

By: /s/ Julian Adams

Julian Adams
Chief Executive Officer and Director
(Principal Executive Officer)

August 15, 2022

By: /s/ Shai Lankry

Shai Lankry
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Julian Adams, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gamida Cell Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurances regarding the reliability of financial reporting in the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

/s/ Julian Adams

By: **Julian Adams, Ph.D.**
Title: Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Shai Lankry, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gamida Cell Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurances regarding the reliability of financial reporting in the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

/s/ Shai Lankry

By: **Shai Lankry**
Title: Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Gamida Cell Ltd. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Julian Adams, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 15, 2022

/s/ Julian Adams

Julian Adams, Ph.D.
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Gamida Cell Ltd. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shai Lankry, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 15, 2022

/s/ Shai Lankry

Shai Lankry
Chief Financial Officer