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 March 31, 2023

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, 7th Floor 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 105,586,746 ordinary shares outstanding as of May 10, 2023.

Gamida Cell Ltd.
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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 and Omisirge are trademarks 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 MARCH 31, 2023

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)

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 46,763	$ 64,657
Prepaid expenses and other current assets	1,404	1,889
Total current assets	48,167	66,546
NON-CURRENT ASSETS:		
Restricted deposits	3,680	3,668
Property, plant and equipment, net	45,644	44,319
Operating lease right-of-use assets	4,726	7,024
Severance pay fund	1,649	1,703
Other long-term assets	1,266	1,513
Total non-current assets	56,965	58,227
Total assets	$ 105,132	$ 124,773

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)

	March 31, 2023 (unaudited)	December 31, 2022
LIABILITIES AND SHARHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Trade payables	$ 4,398	$ 6,384
Employees and payroll accruals	4,333	5,300
Operating lease liabilities	2,082	2,648
Accrued interest of convertible senior notes	986	1,652
Accrued expenses and other current liabilities	10,474	8,891
Total current liabilities	22,273	24,875
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	90,646	96,450
Accrued severance pay	1,862	1,914
Long-term operating lease liabilities	2,976	4,867
Other long-term liabilities	2,742	4,690
Total non-current liabilities	98,226	107,921
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' DEFICIT:		
Share capital -		
Ordinary shares of NIS 0.01 par value – Authorized: 150,000,000 shares at March 31, 2023 (unaudited) and December 31, 2022; Issued 82,157,317 and 74,703,030 at March 31, 2023 (unaudited) and December 31, 2022 respectively; Outstanding: 82,033,646 and 74,583,026 shares at March 31, 2023 (unaudited) and December 31, 2022, respectively	222	211
Treasury ordinary shares of NIS 0.01 par value – 123,671 and 120,004 shares at March 31, 2023 (unaudited) and December 31, 2022, respectively	*	*
Additional paid-in capital	422,203	408,598
Accumulated deficit	(437,792)	(416,832)
Total shareholders' deficit	(15,367)	(8,023)
Total liabilities and shareholders' deficit	$ 105,132	$ 124,773

* 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 March 31,	
	2023	**2022**
	(**unaudited**)	(**unaudited**)
Research and development expenses, net	$ 8,840	$ 11,305
Commercial expenses	5,576	3,879
General and administrative expenses	5,164	4,139
Total operating loss	19,580	19,323
Financial expenses, net	1,380	900
Comprehensive Loss	$ 20,960	$ 20,223
Net loss per share attributable to ordinary shareholders, basic and diluted	0.27	0.34
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	76,760,688	59,474,366

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

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)

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

	Three months ended March 31, 2022 (unaudited)					
	Ordinary shares		Additional paid-in capital	Treasury Shares	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	(75,117)	-	*	*	-	*
Exercise of options	47,426	*	76	-	-	76
Share-based compensation	-	-	1,194	-	-	1,194
Net Loss	-	-	-	-	(20,223)	(20,223)
Balance as of March 31, 2022	59,946,298	$ 169	$ 382,495	$*	$ (357,680)	$ 24,984

	Three months ended March 31, 2023 (unaudited)					
	Ordinary shares		Additional paid-in Capital	Treasury Shares	Accumulated deficit	Total" shareholders' equity
	Number	Amount				
Balance as of December 31, 2022	74,583,026	$ 211	$ 408,598	$*	$ (416,832)	$ (8,023)
Issuance of ordinary shares upon release of restricted share units	107,627	*	*	-	-	*
Treasury shares	(3,667)	*	*	*	-	*
Issuance of ordinary shares, for 2022 Note	3,774,545	1	6,899	-	-	6,900
Issuance of ordinary shares, net of issuance expenses**	3,572,115	10	5,207	-	-	5,217
Share-based compensation	-	-	1,499	-	-	1,499
Net Loss	-	-	-	-	(20,960)	(20,960)
Balance as of March 31, 2023	82,033,646	$ 222	$ 422,203	$*	$ (437,792)	$ (15,367)

* Represents an amount lower than $1.

** Issuance costs of approximately $161.

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)

	Three months ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Cash flows from operating activities:		
Net Loss	$ (20,960)	$ (20,223)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	106	112
Financing expense (income), net	(464)	(1,172)
Share-based compensation	1,499	1,194
Amortization of debt discount and issuance costs	196	191
Changes in operating assets and liabilities:		
Decrease in operating lease right-of-use assets	527	562
Decrease in operating lease liabilities	(686)	(613)
Increase in accrued severance pay, net	2	33
Decrease (increase) in prepaid expenses and other assets	607	(889)
Decrease in trade payables	(1,986)	(3,927)
Decrease in accrued expenses and current liabilities	(1,125)	(996)
Net cash used in operating activities	(22,284)	(25,728)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(827)	(723)
Purchase of marketable securities	-	(2,086)
Proceeds from maturity of marketable securities	-	14,126
Proceeds from restricted deposits	-	500
Net cash provided by (used in) investing activities	$ (827)	$ 11,817
Cash flows from financing activities:		
Proceeds from exercise of options	$ -	$ 76
Proceeds from share issuance , net	5,217	-
Net cash provided by financing activities	5,217	76
Decrease in cash and cash equivalents	(17,894)	(13,835)
Cash and cash equivalents at beginning of period	64,657	55,892
Cash and cash equivalents at end of period	$ 46,763	$ 42,057
Significant non-cash transactions:		
Purchase of property, plant and equipment on credit	$ -	$ 1,160
Conversion of 2022 Note	$ 6,900	$ -
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 2,203	$ 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 a cell therapy pioneer working to turn cells into powerful therapeutics. The Company applies a proprietary expansion platform leveraging the properties of nicotinamide, or NAM, to allogeneic cell sources including umbilical cord blood-derived cells and natural killer, or NK, cells to create cell therapy candidates, with the potential to redefine standards of care.

b. On April 17, 2023, the U.S. Food and Drug Administration approved the Company's allogenic cell therapy, Omisirge (omidubicel-onlv), for use in adult and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. In addition, the Company has applied its NAM cell expansion technology to NK cells, to develop its 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.

In March 2023, the Company announced a strategic reprioritization of its business activities to primarily focus on the commercial launch of Omisirge.

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, 2022 filed with the SEC on March 31, 2023. 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.

d. Prior to FDA approval of Omisirge in April 2023, the Company devoted substantially all of its efforts toward research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated deficit as of March 31, 2023 was $437,792 and negative cash flows from operating activities during the three-month period ended March 31, 2023 was $22,284. The Company's management plan is to seek additional financing as required to fund its operations until achieving positive cash flows or seek strategic partnership to support the commercialization of Omisirge. However, there is no assurance that capital financing and/or a strategic transaction 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. The subsidiary was created to assist with the commercialization of the Company's products in the United States.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

a. Use of estimates:

The preparation of the 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. Recently adopted accounting standards:

In June 2016, FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): measurement of Credit Losses on Financial Instruments. ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the more timely recognition of losses. Topic 326 is effective for the Company beginning on January 1, 2023. Effective January 1, 2023, the Company adopted the standard. Adoption of the standard did not have an impact on the financial statements.

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:

	Three months ended March 31,	
	2023	2022
	(unaudited)	
Operating lease costs	$ 663	$ 636
Short-term lease costs	82	24
Total lease costs	$ 745	$ 660

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

	Three months ended March 31, 2023 (unaudited)
Weighted average remaining lease term (in years)	3.24
Weighted average discount rate	3.41%

Maturities of lease liabilities were as follows:

	As of March 31, 2023
2023	$ 2,048
2024	1,231
2025	972
2026	704
Thereafter	541
Total undiscounted lease payments	5,496
Less: Imputed interest	(438)
Present value of lease liabilities	$ 5,058

NOTE 4:- CONVERTIBLE SENIOR NOTES, NET

a. On February 16, 2021, the Subsidiary issued convertible senior notes (the "2021 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 2021 Notes bear interest payable semiannually in arrears, at a rate of 5.875% per year. The 2021 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 2021 Notes have the right, prior to the close of business on the second scheduled trading day immediately preceding February 15, 2026, to convert any 2021 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 2021 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 2021 Notes may require the Company to repurchase for cash all or a portion of their 2021 Notes, in multiples of $1,000 principal amount, at a repurchase price equal to 100% of the principal amount of the 2021 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 2021 Notes may be increased.

Subject to the provisions of the Indenture, the Subsidiary may redeem for cash all or a portion of the 2021 Notes for cash, at its option, at a redemption price equal to 100% of the principal amount of the 2021 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 Company accounts for its 2021 Notes in accordance with ASC 470-20 “Debt with Conversion and Other Options”. The 2021 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 March 31, 2023	As of December 31, 2022
Liability component:		
Principal amount	$ 75,000	$ 75,000
Issuance costs	(4,223)	(4,223)
Net of issuance costs	70,777	70,777
Amortized issuance costs	1,628	1,423
Net carrying amount	$ 72,405	$ 72,200

The total issuance costs of the 2021 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 2021 Notes.

As of March 31, 2023, and December 31, 2022, the total estimated fair value of the 2021 Notes was $73,702 and $73,331, respectively. The fair value was determined using the Company’s effective rates for March 31, 2023 and December 31, 2022.

b. In December 2022, the Company, as guarantor, and the Subsidiary entered into a Loan and Security Agreement (the “Loan Agreement”) with certain funds managed by Highbridge Capital Management, LLC (collectively, “Highbridge”), as the lenders (together with the other lenders from time to time party thereto, the “Lenders”), and Wilmington Savings Fund Society, FSB, as collateral agent and administrative agent. Pursuant to the Loan Agreement, the Subsidiary issued $25 million aggregate principal amount of convertible senior notes (the “2022 Notes”). The 2022 Note bears interest of 7.5% which will be paid on a quarterly basis and monthly principal installment payments.

The 2022 Note is exchangeable, at the option of the Lenders, into ordinary shares at an exchange rate of 0.52356 ordinary shares per $1.00 principal amount, together with a make-whole premium equal to all accrued and unpaid and remaining coupons due through the maturity date. The exchange rate is subject to adjustment in the event of ordinary share dividends, reclassifications and certain other fundamental transactions affecting the ordinary shares. In addition, under certain circumstances, the Company can issue ordinary shares in exchange for the discharge of the monthly principal installment payments.

The Loan Agreement contains customary representations and warranties and covenants, including a $20.0 million minimum liquidity covenant and certain negative covenants restricting dispositions, changes in business and business locations, mergers and acquisitions, indebtedness, issuances of preferred stock, liens, collateral accounts, restricted payments, transactions with affiliates, compliance with laws, and issuances of capital stock. Most of these restrictions are subject to certain minimum thresholds and exceptions. Certain of the negative covenants will terminate when less than $5.0 million of principal amount is outstanding under the Loan Agreement. As of March 31, 2023, the Company is in compliance with such covenants.

The Company has elected the fair value option to measure the 2022 Note upon issuance, in accordance with ASC 825-10. Under the fair value option, the 2022 Note is measured at fair value each period with changes in fair value reported in the statements of operations. According to ASC 825-10, changes in fair value that are caused by changes in the instrument-specific credit risk will be presented in other comprehensive income (loss).

In January and March 2023, the Company issued 3,141,360 and 633,185 ordinary shares in exchange for the discharge of $6,000 of the aggregate outstanding balance and the discharge of a related $900 interest make-whole payment, respectively, in respect of the Lenders’ exchange option under the 2022 Note.

NOTE 5: FAIR VALUE MEASUREMENTS

The carrying amounts the Company's financial instruments, including cash and cash equivalents is stated at their carrying value, which approximates their fair value due to the short time to the expected receipt or payment.

The following table present information about our financial instruments that are measured at fair value as of March 31, 2023 and December 31, 2022:

	March 31, 2023			December 31, 2022		
	Level 1	Level 3	Total	Level 1	Level 3	Total
Financial assets:						
Money market funds included in cash and cash equivalents	$ 46,763	$ -	$ 46,763	$ 58,827	$ -	$ 58,827
Total Assets Measured at Fair Value	46,763	-	46,763	58,827		58,827
Financial Liabilities						
2022 Note	-	18,241	18,241	-	24,250	24,250
Total liabilities measured at fair value	$ -	$ 18,241	$ 18,241	$ -	$ 24,250	$ 24,250

The Company classifies the cash equivalents within Level 1, and the 2022 Note within Level 3, because the Company uses quoted market prices, alternative pricing sources and models utilizing market observable inputs or unobservable 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 March 31, 2023, the Company obtained bank guarantees in the amount of $2,929, primarily in connection with an Investment Center grant, of which $1,826 was received in 2022. The remaining $1,183 is expected to be received in 2023, 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 $38.0 million through March 31, 2023, of which $35.4 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 March 31, 2023, no royalties have been paid or accrued. The Company's contingent royalty liability to the IIA at March 31, 2023, including grants received by the Company and the associated LIBOR interest on all such grants totaled to $43.8 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.

On September 27, 2022, the Company entered into an underwriting agreement (the "Underwriting Agreement") with underwriters (the "Underwriters"), pursuant to which the Company issued and sold, in an underwritten public offering, an aggregate of 12,905,000 of its ordinary shares (the "Shares") at a public offering price of $1.55 per share

During the three months ended March 31, 2023, the Company raised $5.2 million through the sale and issuance of 3,572,115 shares via its ATM facility, at an average price per ordinary share of $1.46.

b. Warrants to investors:

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

c. Treasury Shares:

During the three months ended March 31, 2023, the Company cancelled 3,667 outstanding restricted shares.

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.

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 three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Dividend yield	0%	0%
Expected volatility of the share prices	69%	66%
Risk-free interest rate	3.6%	1.8%
Expected term (in years)	8	8

Based on the above inputs, the fair value of the options was determined to be $0.99 - $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 March 31, 2023 and related information:

	Number of options	Weighted average exercise price
Balance as of December 31, 2022	6,133,903	$ 4.62
Granted	1,951,534	1.53
Forfeited	(31,347)	3.94
Expired	(274,986)	6.00
Balance as of March 31, 2023 (unaudited)	7,779,104	
Exercisable as of March 31, 2023 (unaudited)	3,000,738	$ 5.62

As of March 31, 2023, there are $10,964 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 shares unit activity as of March 31, 2023 is as follows:

	Number of restricted shares and restricted share units	Weighted average grant date fair value
	(unaudited)	(unaudited)
Unvested as of December 31, 2022	1,126,743	$ 3.29
Granted	957,606	1.53
Vested	(190,093)	4.17
Forfeited	(18,305)	3.34
Unvested as of March 31, 2023	1,875,951	$ 2.30

d. The total share-based compensation expense related to all of the Company's equity-based awards, recognized for the three months ended March 31, 2023 and 2022 is comprised as follows:

	Three months ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Research and development expenses, net	$ 414	$ 465
Commercial expenses	334	290
General and administrative expenses	751	439
Total share-based compensation	$ 1,499	$ 1,194

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”.

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

	Three months ended March 31,			
	2023		2022	
	(unaudited)		(unaudited)	
	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	76,760,688	20,960	59,474,366	$ 20,223

All outstanding convertible senior note options, warrants, outstanding share options, and restricted shares for the three months ended March 31, 2023 and 2022 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 March 31,	
	2023	2022
	(unaudited)	(unaudited)
Convertible senior notes	17,428,634	6,334,455
Warrants	-	1,010,466
Outstanding share options	6,906,325	4,858,314
Restricted shares	1,644,992	1,100,059
Total	25,979,951	13,303,294

NOTE 10: SUBSEQUENT EVENTS

a. On April 17, 2023, the FDA approved the Company’s allogeneic cell therapy, Omisirge (omidubicel-onlv), for use in adult and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

b. From April 1, 2023 through May 12, 2023, we made a monthly installment payment of $1.0 million and discharged $0.5 million in related and deferred interest in exchange for the issuance of 1,804,623 ordinary shares, and we received voluntary exchange notices from the lender with respect to the discharge of an additional $5.5 million of aggregate principal amount, for which an aggregate of 2,905,758 ordinary shares were issued or issuable. We paid the $0.7 million of make whole interest associated with these voluntary exchanges in cash. The outstanding principal amount of the 2022 Note is $12.5 million.

c. On April 19, 2023, the Company issued and sold 17,500,000 of its ordinary shares and accompanying warrants to purchase 17,500,000 ordinary shares at a public offering price of $1.30 per ordinary share and accompanying warrant, for gross proceeds of approximately $22.8 million, before deducting underwriting discounts and commissions and estimated offering expenses, of $2.4 million. In addition, pursuant to the underwriting agreement for the transaction, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,625,000 of the Company’s ordinary shares and/or warrants to purchase up to 2,625,000 ordinary shares at the public offering price, less underwriting discounts and commissions.

d. During April 2023, the Company raised an additional $3.6 million through the sale and issuance of 3,757,091 ordinary shares via its ATM facility, at an average price per ordinary share of $1.00.

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, 2022 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, 2022, or Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on March 31, 2023. 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 a cell therapy pioneer working to turn cells into powerful therapeutics. We apply a proprietary expansion platform leveraging the properties of nicotinamide, or NAM, to allogeneic cell sources including umbilical cord blood-derived cells and natural killer, or NK, cells to create cell therapy candidates, with the potential to redefine standards of care. On April 17, 2023, the U.S. Food and Drug Administration (FDA) approved our allogenic cell therapy, Omisirge (omidubicel-onlv), for use in adult and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

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

There are multiple sources of donor cells. The best source for donor cells is often viewed as a sibling who is a matched related donor, or MRD, but the chances of having a sibling match in the United States are only 25% to 30%. The majority of patients rely on alternate sources of donor cells, including matched unrelated donor, or MUD, haploidentical, or "half-matched" donors, and mismatched unrelated donor, or MMUD, as well as umbilical cord blood. However, due to the need for genetic matching between the patient and the donor, and the potential for disease progression and other complications during the time needed to find a suitable donor, many patients cannot find an appropriate donor.

According to the CIBMTR, in the United States, there are approximately 8,000 patients above the age of 12 with hematologic malignancies who undergo an allogeneic stem cell transplant each year, and we believe that number of patients may grow over time. We estimate that there are approximately 1,200 patients each year, who are above the age of 12 and are deemed eligible for an allogeneic stem cell transplant but cannot find an appropriate donor.

We believe the commercial potential for Omisirge consists of two key opportunities: potentially improving outcomes for patients, and potentially increasing access for patients who are currently eligible for transplant and cannot find an appropriate donor. We estimate that in 2027 approximately 11,000 patients who are ages 12 and above with hematologic malignancies will be eligible for transplant and that Omisirge could be the treatment of choice for between 20% and 25% of this population.

In addition, we have applied our NAM cell expansion technology to 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 showed that therapy using GDA-201 with the monoclonal antibody rituximab 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 of 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, and on April 21, 2022, we received correspondence from the FDA indicating that the FDA had removed the clinical hold and cleared our IND for GDA-201. In August 2022, we treated the first patient with GDA-201 in this study. The study is currently enrolling patients in the dose escalation portion of the trial.

Beginning in March 2023, we initiated a strategic reprioritization of our business activities to primarily focus on the commercial launch of Omisirge. This launch will involve a more limited financial investment than we had previously planned in order to manage our financial resources, resulting in a slower ramp of sales. To support a more fulsome commercial launch of Omisirge, we are exploring potential commercial or strategic options, including a sale of our assets or merger of our company, securing additional financing, and commercial or strategic partnerships that would enable further commercialization and development of our programs. We have engaged Moelis & Company LLC to assist in the exploration of partnerships or broader strategic alternatives that would provide additional resources to support the launch of Omisirge and associated commercial activities in the United States and the rest of the world, and the duration of this process is uncertain. There can be no assurance that this strategic review process will result in our pursuing any transaction. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased shareholder value.

In connection with the strategic reprioritization of our business activities:

- We have allocated the vast majority of our resources to support the commercial launch of Omisirge, including manufacturing at our dedicated and certified Kiryat Gat facility. To manage our cash runway, we will hire employees at a reduced pace and reduce planned commercial and medical operating expenses, which we anticipate will result in lower sales than we had previously planned.

- Solely for financial reasons, we have reduced planned investment in the development of our clinical stage NK cell therapy candidate, GDA-201. While we will continue enrollment into the Phase 1/2 clinical trial of GDA-201 for the treatment of follicular and diffuse large B-cell lymphomas, we will pause any previously planned Phase 2 start-up activities. We intend to complete the treatment of patients in the Phase 1 portion of the Phase 1/2 study; however, following our assessment of the results from the Phase 1 portion of the study, we may decide not to proceed with the enrollment of patients in the Phase 2 portion of the study and we may wind down the Phase 1/2 study of GDA-201.

- Solely for financial reasons, we have discontinued development of our engineered NK cell therapy pipeline, including GDA-301, GDA-501, and GDA-601, but will retain the intellectual property rights to develop, sell or license these assets in the future.

- In March 2023, we implemented a reduction in force to rationalize the employee base to support the new business strategy, which includes closing our Jerusalem research and development facility and terminating the lease or securing a sub-tenant for the space. We expect that we will incur charges of approximately $1.0 million for severance and other employee termination-related costs primarily in the second quarter of 2023.

Although we have completed multiple debt and equity financings in the last two years, we will need to secure a strategic transaction or substantial additional funding to support our operating activities as we proceed to commercialize Omisirge. 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 or secure a partnership on terms acceptable to us, or at all, and any failure to raise capital or secure a partnership as and when needed could compromise our ability to execute on our business plan. As of March 31, 2023, we had total cash and cash equivalents of $46.8 million, and as of May 10, 2023, we had raised additional funds of approximately $24.4 million in net proceeds from our April underwritten public offering of securities and sales through our ATM facility. Although it is difficult to predict future liquidity requirements, we expect our current cash and cash equivalents to support our ongoing operating activities into 2024. This guidance is based on our current operational plans and excludes commercialization activities beyond the initial launch of Omisirge and any additional financing activities that may be undertaken. Our ability to successfully transition to profitability will be dependent upon achieving a level of revenue adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

We have incurred significant net losses since our formation in 1998. Our net losses were $21.0 million and $20.2 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, our accumulated deficit was $437.8 million. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. Our expectation that we will generate operating losses and negative operating cash flows in the future and the need for a strategic transaction or additional funding to support our planned operations raise substantial doubt regarding our 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 we are unable to secure additional financing or a commercial or strategic partnership for Omisirge, our board of directors may decide to pursue a dissolution and liquidation. In the event of such liquidation or other wind-down event, holders of our securities may suffer a total loss of their investment.

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 currently have one product, Omisirge, which was approved by the FDA in April 2023, 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 research and development. Our research and development expenses, net of IIA grants, consisted 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 March 31, 2023, we have received an aggregate of approximately $38.0 million in grants from the Israeli Innovation Authority, or the IIA, including from the Bereshit Consortium sponsored by the IIA, of which $35.4 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.

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.

With regard to clinical development activities, we are currently focused on advancing the Phase 1/2 clinical trial of GDA-201 for the treatment of follicular and diffuse large B-cell lymphomas, and our future research and development expenses will depend on the clinical success of GDA-201. If we proceed with the enrollment of patients in the Phase 2 portion of our Phase 1/2 clinical trial of GDA-201, development expenses may continue to be significant and may increase over at least the next several years as we continue to develop GDA-201. 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 our product candidates, other than Omisirge. On March 27, 2023, with the objective of extending our financial resources, we announced a workforce reduction plan, pursuant to which we plan to downsize our current workforce by approximately 17% by the end of the second quarter of 2023. We have initiated hiring and other expenditures in preparation for the commercialization of Omisirge.

Commercial expenses

Commercial expenses consist primarily of personnel costs, including share-based compensation, related to executive and commercial functions, preparation for the commercialization of Omisirge, 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 $274.9 million (including capital losses of $0.5 million) as of December 31, 2022. In addition, the Subsidiary has net operating losses carryforward of $37.5 million for federal tax purposes as of December 31, 2023. 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 March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating Expenses				
Research and development expenses, net[(1)]	$ 8,840	$ 11,305	$ (2,465)	(21.8)%
Commercial expenses[(1)]	5,576	3,879	1,697	43.7%
General and administrative expenses[(1)]	5,164	4,139	1,025	24.8%
Total operating loss	$ 19,580	$ 19,323	$ 257	1.3%
Financial expenses, net	1,380	900	480	53.3%
Loss	$ 20,960	$ 20,223	$ 737	3.6%

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

	Three months ended March 31,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Research and development expenses, net	$ 414	$ 465	$ (51)	(11.0)%
Commercial expenses	334	290	44	15.2%
General and administrative expenses	751	439	312	71.1%
Total share-based compensation	$ 1,499	$ 1,194	$ 305	25.5%

Research and development expenses, net

Research and development expenses, net, decreased by approximately $2.5 million to $8.8 million in the three months ended March 31, 2023 from $11.3 million in the three months ended March 31, 2022. The decrease was attributable mainly to a $2.4 million decrease in payments to Lonza for manufacturing services, a $1.3 million decrease in clinical activities relating to the conclusion of our Phase 3 clinical trial, offset by an increase of $1.2 million in GDA 201 clinical program. We anticipate our research and development expenses to decrease due to the discontinuation of development of our engineered NK cell therapy pipeline.

Commercial expenses

Our commercial expenses increased by approximately $1.7 million to $5.6 million in the three months ended March 31, 2023, from $3.9 million in the three months ended March 31, 2022. The increase was attributable mainly to an increase in launch readiness activities. Given the recent approval of Omisirge, we anticipate our commercial expenses to increase.

General and administrative expenses

General and administrative expenses increased by approximately $1.0 million to $5.1 million in the three months ended March 31, 2023, up from $4.1 million in the three months ended March 31, 2022. The increase was attributable to the increase in professional services expenses.

Given the recent approval of Omisirge, we anticipate that our general and administrative expenses will increase and that our payroll and expenses as a result of commercial operations, particularly as it relates to the sales and marketing of Omisirge, will increase.

Financial expenses, net

Financial expenses, net, were $1.4 million in the three months ended March 31, 2023, and $0.9 million in the three months ended March 31, 2022. The increase was attributable to interest due on the 2022 Note, offset by interest income from cash management.

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 March 31, 2023 was $437.8 million and negative cash flows from operating activities during the three months ended March 31, 2023 was $22.3 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 March 31, 2023, we had total cash and cash equivalents of $46.8 million, and as of May 10, 2023, we had raised additional funds of approximately $24.4 million in net proceeds from our April underwritten public offering of securities and sales through our ATM facility. As of May 10, 2023, the date of issuance of our condensed consolidated financial statements, we expect our current cash and cash equivalents to support our ongoing operating activities into 2024. This guidance is based on our current operational plans and excludes commercialization activities beyond the initial launch of Omisirge and any additional financing activities that may be undertaken. Although there is substantial doubt regarding our 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, 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, as well as in our consolidated financial statements appearing in our Annual Report, 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 notes

On February 15, 2021, we entered into a Note Purchase Agreement, pursuant to which Gamida Cell Ltd.'s wholly owned U.S. subsidiary, Gamida Cell Inc., issued convertible senior notes, or the 2021 Notes, with an aggregate original principal amount of $75.0 million in a private placement. The 2021 Notes are guaranteed by Gamida Cell Ltd. pursuant to an Indenture, dated February 16, 2021, between Gamida Cell Inc., Gamida Cell Ltd., and Wilmington Savings Fund Society, FSB.

The 2021 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. The 2021 Notes accrue interest payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2021, at a rate of 5.875% per year. The net proceeds from the private placement were approximately $70.8 million after deducting placement agent fees, escrowed amounts and other expenses, and the transaction closed on February 16, 2021.

On December 12, 2022, we entered into a Loan and Security Agreement, pursuant to which Gamida Cell Inc. issued $25.0 million in aggregate principal amount in a convertible senior note, or the 2022 Note, with a maturity date of December 12, 2024. The 2022 Note was issued with an original issue discount of 3.00% and bears interest of 7.5%, which is due on a quarterly basis beginning in April 2023. Also beginning in April 2023, monthly principal and interest installment payments are due under the 2022 Note. For April and May 2023, the principal amortization payments are $0.95 million per month, decreasing to $0.84 million thereafter. Under certain circumstances, we may issue our ordinary shares in exchange for the discharge of principal and interest due under the 2022 Note, at an exchange rate that is based on a volume weighted exercise price calculated as set forth in the 2022 Note. Further, the 2022 Note is exchangeable, at the option of the lenders, into ordinary shares at an exchange rate of 0.52356 ordinary shares per $1.00 principal amount, together with a make-whole premium equal to all accrued and unpaid remaining coupons due through the maturity date. The exchange rate is subject to adjustment in the event of ordinary share dividends, reclassifications and certain other fundamental transactions affecting the ordinary shares.

As of March 31, 2023, the lenders had elected to exchange $6.0 million of outstanding principal amount of the 2022 Note in exchange for 3,141,360 ordinary shares, and we had elected to discharge $0.9 million of related make-whole interest in exchange for the issuance of 633,185 ordinary shares.

From April 1, 2023 through May 12, 2023, we made a monthly installment payment of $1.0 million and discharged $0.5 million in related and deferred interest in exchange for the issuance of 1,804,623 ordinary shares, and we received voluntary exchange notices from the lender with respect to the discharge of an additional $5.5 million of aggregate principal amount, for which an aggregate of 2,905,758 ordinary shares were issued or issuable. We paid the $0.7 million of make whole interest associated with these voluntary exchanges in cash. The outstanding principal amount of the 2022 Note is $12.5 million. The net proceeds from issuance of the 2022 Note were approximately $22.8 million after deducting issuance expenses, and the transaction closed on December 12, 2022.

We account for the 2021 Notes in accordance with ASC 470-20 “Debt with Conversion and Other Options.” The 2021 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.

We have elected the fair value option to measure the 2022 Note upon issuance, in accordance with ASC 825-10. Under the fair value option, the 2022 Note is measured at fair value each period with changes in fair value reported in the statements of operations. According to ASC 825-10, changes in fair value that are caused by changes in the instrument-specific credit risk will be presented separately in other comprehensive income (loss).

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.

Known Trends, Events and Uncertainties

We are subject to risks and uncertainties as a result of adverse geopolitical and macroeconomic events, such as the ongoing conflict between Ukraine and Russia and related sanctions, and uncertain market conditions, including higher inflation and supply chain disruptions, which could have a material impact on our business and financial results.

Additionally, the recent trends towards rising inflation may also materially adversely affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates and overhead costs may adversely affect our operating results. Rising interest rates also present a recent challenge impacting the U.S. and Israeli economies and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets or banking sector in the near term, and could negatively affect our operations. Furthermore, such economic conditions have produced downward pressure on share prices. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19 and the ongoing conflict between Russia and Ukraine, and employee availability and wage increases, which may result in additional stress on our working capital resources.

Recent Accounting Pronouncements

See note 2 of the accompanying unaudited consolidated financial statements for the three months ended March 31, 2023 for a discussion of recent accounting pronouncements.

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 three months ended March 31, 2023, and March 31, 2022, we incurred a net loss of $21.0 million and $20.2 million, respectively, and net cash of $22.3 million and $25.7 million, respectively, was used in our operating activities. As of March 31, 2023, and December 31, 2022 we had working capital of $25.9 million and $41.7 million, respectively, and an accumulated deficit of $437.8 million and $416.8 million, respectively. Our principal sources of liquidity as of March 31, 2023, and December 31, 2022, consisted of cash and cash equivalents of $46.8 million and $64.7 million, respectively. In addition, on April 19, 2023, we entered into an underwritten public offering of 17,500,000 ordinary shares and 17,500,000 accompanying warrants at a public offering price of $1.30 per ordinary share and accompanying warrant with Piper Sandler & Co., for gross proceeds of $22.8 million, before deducting underwriting discounts and commissions and estimated offering expenses.

Capital Resources

Overview

Through March 31, 2023, we have financed our operations primarily through private placements and public offerings of equity securities, the 2021 Notes, the 2022 Note 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 $50.0 million from time to time under an “at the market offering” through Jefferies LLC, or our ATM facility. During the year ended December 31, 2022, we sold 1,540,165 ordinary shares for gross proceeds of $4.4 million, resulting in net proceeds of $4.2 million after deducting sales commissions and offering expenses of $0.2 million under our ATM facility. During the three months ended March 31, 2023, we sold 3,572,115 ordinary shares for net proceeds of $5.2 million, after deducting commissions under our ATM facility.

Cash flows

The following table summarizes our statement of cash flows for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Net cash provided by (used in)				
Operating activities	$ (22,284)	$ (25,728)	$ 3,444	13.4%
Investing activities	(827)	11,817	12,644	(107.0)
Financing activities	5,217	76	5,141	6,760.5

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 $22.3 million during the three months ended March 31, 2023, compared to $25.7 million used in operating activities during the three months ended March 31, 2022. The $3.4 million decrease in cash used is primarily related to the timing of cash payments in connection with Omisirge launch readiness activities.

Net cash provided by (used in) investing activities

Net cash used in investing activities was $0.8 million during the three months ended March 31, 2023, compared to $11.8 million provided by investing activities during the three months ended March 31, 2022. The $12.6 million decrease is a decrease of proceeds from maturity and purchase of marketable securities and changes in restricted deposits.

Net cash provided by financing activities

Net cash provided by financing activities was $5.2 million during the three months ended March 31, 2023, compared to $0.1 million during the three months ended March 31, 2023. The $5.1 million increase is primarily related to net proceeds of $5.2 million received from our ATM facility.

Funding Requirements

As of March 31, 2023, we had total cash and cash equivalents of $46.8 million, and as of May 10, 2023, we had raised additional funds of approximately $24.4 million in net proceeds from our April underwritten public offering of securities and sales through our ATM facility. Although it is difficult to predict future liquidity requirements, we expect our current cash and cash equivalents to support our ongoing operating activities into 2024. This guidance is based on our current operational plans and excludes commercialization activities beyond the initial launch of Omisirge and any additional financing activities that may be undertaken. We cannot provide any assurance that a strategic transaction or new financing will be available to us 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.

As a result of FDA approval of Omisirge, we plan to market Omisirge ourselves in the United States, which will require substantial additional funding. In addition, we are continuing to assess partnerships or broader strategic alternatives that would provide additional resources to support the launch of Omisirge and associated commercial activities in the United States and the rest of the world. Our present and future funding requirements will depend on many additional factors, including, among other things:

- selling, marketing and distribution activities undertaken in connection with the commercialization of Omisirge, including establishing internal infrastructure;
- the outcome of our strategic review process;
- the costs related to obtaining regulatory approval for GDA-201, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to any this product candidate; and

- 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.

We have annual operating lease obligations related to our Boston and Kiryat Gat facilities in aggregate of $0.9 million, which is included in general and administrative expense. Beginning in April 2023, monthly principal and interest installment payments are due under the 2022 Note. For April and May 2023, the principal amortization payments are $0.95 million per month, decreasing to $0.84 million per month thereafter. Under certain circumstances, we may issue our ordinary shares in discharge of the principal and interest due under the 2022 Note, at an exchange rate that is based on a volume weighted exercise price calculated as set forth in the 2022 Note.

Until such time, if ever, as we can generate substantial product revenue, we will need to secure a strategic transaction or obtain substantial additional funding in connection with our continuing operations. 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 collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product revenue streams, or product candidate or grant licenses on terms that may not be favorable to us.

A strategic transaction or 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 secure additional financing or a commercial or strategic partnership for Omisirge, our board of directors may decide to pursue a dissolution and liquidation. In the event of such liquidation or other wind-down event, holders of our securities may suffer a total loss of their investment. 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 March 31, 2023 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 March 31, 2023. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2023 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 March 31, 2023 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 March 31, 2023.

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 our 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 March 31, 2023 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 a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully below and include, but are not limited to, risks related to, the following:

- We are heavily dependent on the success of Omisirge, including obtaining regulatory approvals in geographies outside of the United States, and if Omisirge is not successfully commercialized, our business will be adversely affected.
- We do not have experience producing Omisirge at commercial levels or operating a cGMP compliant manufacturing facility.
- We currently have a limited marketing and sales organization. If we are unable to establish adequate sales and marketing capabilities to support the commercial launch of Omisirge or enter into agreements with third parties to market and sell Omisirge, we may be unable to generate any product revenue.
- Sales of Omisirge will be limited unless it achieves broad market acceptance by physicians, patients, third-party payers, hospital pharmacists and others in the medical community.
- It may be difficult for us to profitably sell Omisirge if coverage and reimbursement for Omisirge is limited by government authorities and/or third-party payer policies.
- Although we are exploring a range of strategic alternatives, there is no certainty that we will be able to execute on any transaction or that such a transaction will enhance shareholder value, and any such transaction, if available and achieved, may be highly dilutive to our stockholders.
- The costs associated with a potential strategic transaction may be significant.
- 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.
- 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 or complete a strategic transaction in the near-term 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 2021 Notes, and our first lien secured note that matures in December 2024, or the 2022 Note.

- The Indenture governing the 2021 Notes and the Loan Agreement governing the 2022 Note each contains restrictive and financial covenants and other provisions that adversely affect our liquidity and may make it more difficult to execute our strategy or to effectively compete.
- We have never generated any revenue from product sales and may never be profitable.
- We may be unable to obtain regulatory approval for GDA-201 or any future 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 GDA-201 is based on novel technologies, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of GDA-201 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.
- Omisirge, GDA-201, or any future 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, 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 GDA-201 or any of our future 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 Omisirge and GDA-201 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 may rely on third parties to conduct certain elements of our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- We rely on a single facility located in Kiryat Gat, Israel to manufacture Omisirge. 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.

- 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 Omisirge.

- If we are unable to obtain, maintain or protect intellectual property rights related to Omisirge, GDA-201 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.

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

- The exchange of some or all of the 2021 Notes or 2022 Note into our ordinary shares could result in significant dilution to existing shareholders, adversely affect the market price of our ordinary shares and impair our ability to raise capital through the sale of additional equity securities.

- 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.

Risks Related to Commercialization of Omisirge

We are heavily dependent on the success of Omisirge, including obtaining regulatory approvals in geographies outside of the United States, and if Omisirge is not successfully commercialized, our business will be adversely affected.

To date, we have deployed all our efforts and financial resources to: (i) research and develop our NAM cell expansion platform, our product, Omisirge, and our NK cell portfolio, including conducting preclinical and clinical studies and providing general and administrative support for these operations; (ii) develop and secure our intellectual property portfolio for our product candidates; and (iii) expand our manufacturing facility at Kiryat Gat to produce Omisirge for our clinical trials and commercial use.

Omisirge may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from Omisirge will depend on a number of factors, including:

- our success in educating medical professionals and patients about the benefits, administration and use of Omisirge;

- timing of market introduction of Omisirge as well as competitive medicines;

- our ability to successfully demonstrate the safety and efficacy of Omisirge;

- continued projected growth of the markets in which Omisirge competes;

- 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 physicians perform HSCT;

- prevalence and severity of any side effects;

- if and when we are able to obtain regulatory approvals for additional indications for Omisirge;

- availability of, and ability to maintain, coverage and adequate reimbursement and pricing from government and other third-party payers for procedures utilizing Omisirge;
- potential or perceived advantages or disadvantages of Omisirge over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support, including from any potential strategic partner;
- the price of Omisirge, both in absolute terms and relative to alternative treatments;
- impact of past and limitation of future medicine price increases;
- our ability to maintain a commercially viable manufacturing process that is compliant with cGMP and produces Omisirge at Kiryat Gat or through third party manufacturers;
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to Omisirge;
- the performance of third-party distribution partners, over which we have limited control; and
- medicine labeling or medicine insert requirements of the FDA or other regulatory authorities.

Many of these commercial risks are beyond our control. Accordingly, we cannot assure you that we will be able to commercialize Omisirge for its target indication. If we fail to achieve these objectives or overcome the challenges presented above, we could experience significant delays or an inability to successfully commercialize Omisirge. Accordingly, we may not be able to generate sufficient revenue through the sale of Omisirge to enable us to continue our business.

We do not have experience producing Omisirge at commercial levels or operating a cGMP manufacturing facility.

The Israeli Ministry of Health issued a certification of GMP compliance for our manufacturing facility at Kiryat Gat, Israel in July 2021 and we have established cGMP compliance under the FDA's regulations. The FDA has completed its pre-licensing inspection of the Kiryat Gat, Israel facility, and there are no 483 observations.

We do not have an extensive number of employees with the experience or ability to manufacture Omisirge at commercial levels. Although the FDA has determined that our manufacturing facility at Kiryat Gat is cGMP compliant, the FDA and equivalent foreign regulatory authority may still in the future find violations of cGMP at our facility. We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. We also 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 Omisirge.

We currently have a limited marketing and sales organization. If we are unable to establish adequate sales and marketing capabilities to support the commercial launch of Omisirge or enter into agreements with third parties to market and sell Omisirge, we may be unable to generate any product revenue.

Although we have a chief executive officer with commercial experience to lead our efforts to commercialize Omisirge, we currently have a limited sales and marketing organization, and we have limited experience selling and marketing Omisirge. To successfully commercialize Omisirge, we will need to develop these capabilities, either on our own or with others. We may establish a larger sales and marketing organization independently or by utilizing experienced third parties with technical expertise and supporting distribution capabilities to commercialize Omisirge 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 Omisirge.

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 Omisirge. As such, we may be required to hire sales representatives and third-party partners to adequately support the commercialization of Omisirge, 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 commercialize Omisirge. If our future collaborators do not commit sufficient resources to commercialize Omisirge, 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 Omisirge may require significant resources and may never be successful. If Omisirge fails to achieve market acceptance among physicians, patients or third-party payers, we will not be able to generate significant revenue from Omisirge, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Sales of Omisirge will be limited unless it achieves broad market acceptance by physicians, patients, third-party payers, hospital pharmacists and others in the medical community.

The commercial success of Omisirge will depend upon the acceptance of Omisirge by the medical community, including physicians, patients, healthcare payers and hospital personnel, including transplant teams and pharmacists. The degree of market acceptance will depend on a number of factors, including:

- the demonstration of clinical safety and efficacy of Omisirge in clinical trials;
- the efficacy, potential and perceived advantages of Omisirge over alternative treatments;
- the prevalence and severity of any adverse side effects;
- product labeling or product insert requirements of the FDA or other equivalent foreign regulatory authorities, including any limitations or warnings contained in Omisirge's approved labeling;
- distribution and use restrictions imposed by the FDA or other equivalent foreign regulatory authorities 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 Omisirge;
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage;
- the demonstration of the effectiveness of Omisirge in reducing the cost of alternative treatments;
- 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 Omisirge or competing products and treatments.

There are a number of alternatives to Omisirge, including stem cell transplantation using cells from matched related donors, matched unrelated donors, haploidentical donors or unmodified umbilical cord blood. If Omisirge does 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 Omisirge, 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 Omisirge may require significant resources and may never be successful.

It may be difficult for us to profitably sell Omisirge if coverage and reimbursement for Omisirge is limited by government authorities and/or third-party payer policies.

Significant uncertainty exists as to the coverage and reimbursement status of Omisirge. In the United States and markets in other countries, sales of Omisirge will depend, in part, on the extent to which third-party payers provide coverage, and establish adequate reimbursement levels, for Omisirge. 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 Omisirge may be separate from the process for setting the price of Omisirge or for establishing the reimbursement rate that such a payer will pay for Omisirge. 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 Omisirge, in addition to the costs required to obtain the FDA approvals. Omisirge may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for Omisirge does not imply that an adequate reimbursement rate will be approved. Further, the determination of one payer to provide coverage for Omisirge does not assure that other payers will also provide such coverage for Omisirge. 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 European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced EU Member States), can further reduce prices.

The Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025.

The marketability of Omisirge 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 Omisirge, 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 Omisirge will depend on, in part, the extent to which the procedures utilizing Omisirge, 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 Omisirge as medically useful, cost effective and safe, there is uncertainty on how exactly Omisirge 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 Omisirge.

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 Omisirge, or, if coverage is available, the level of direct or indirect reimbursement.

We expect to experience pricing pressures in connection with the sale of Omisirge 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 Omisirge.

Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer’s determination that use of Omisirge 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 Omisirge.

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 have submitted an application for Omisirge to be eligible under the NTAP program, but may withdraw the application if we determine that participation in the NTAP program would not be consistent with our reimbursement strategy. 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 Omisirge 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 Omisirge or procedures utilizing Omisirge. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Omisirge. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize Omisirge or achieve profitably.

We are subject to the risk of various legal and regulatory proceedings, including litigation in the ordinary course of business. Our business further 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.

In the ordinary course of business, we may become subject to various legal and regulatory proceedings, which may include but are not limited to those involving antitrust, tax, environmental, intellectual property, data privacy and other matters, including general commercial litigation. Any claims raised in legal and regulatory proceedings, whether with or without merit, could be time consuming and expensive to defend and could divert management's attention and resources. Additionally, the outcome of legal and regulatory proceedings may differ from our expectations because the outcomes of these proceedings are often difficult to predict reliably. Various factors and developments can lead to changes in our estimates of liabilities and related insurance receivables, where applicable, or may require us to make additional estimates, including new or modified estimates that may be appropriate due to a judicial ruling or judgment, a settlement, regulatory developments or changes in applicable law. A future adverse ruling, settlement or unfavorable development could result in charges that could have a material adverse effect on our results of operations in any particular period. In accordance with customary practice, we maintain insurance against some, but not all, of these potential claims. In the future, we may not be able to maintain insurance at commercially acceptable premium levels.

Furthermore, 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 Our Strategic Review Process

Although we are exploring a range of strategic alternatives, there is no certainty that we will be able to execute on any transaction or that such a transaction will enhance shareholder value, and any such transaction, if available and achieved, may be highly dilutive to our stockholders.

On March 27, 2023, we announced the initiation of a process to reprioritize our business activities to primarily focus on the commercial launch of Omisirge, and that we are exploring potential commercial and strategic options to support a broader launch of Omisirge. Certain potential transactions, if available and achieved, could result in substantial dilution to existing shareholders and have a material adverse effect on the price of our ordinary shares.

As of March 31, 2023, we had cash and cash equivalents of $46.8 million. In light of our ongoing and projected operational expenses, there can be no assurance that any potential financing transaction or any alternative strategic transaction, if available, would be sufficient for our financing needs. In light of our current share price, raising additional funds through the issuance of additional debt or equity securities, including as part of a strategic alternative, could result in substantial dilution to our existing shareholders, and increased fixed payment obligations. Furthermore, any issued securities may have rights senior to those of our ordinary shares. Any of these events could significantly harm our business, financial condition, and prospects.

There can be no assurance that our pursuit of financing or our board of directors' evaluation process will result in a transaction, or if any such a transaction is consummated, that it will successfully address our current liquidity challenges or otherwise enhance stockholder value. If a strategic transaction is insufficient to address our long-term financing needs, we will need to significantly delay or further scale back operations or potentially cease operations, in part or in full. If we decided to cease operations and dissolve and liquidate our assets, it is unclear to what extent we would be able to pay our obligations. In such a circumstance and in light of our current liquidity position, it is unlikely that substantial resources would be available for distribution to our shareholders.

The costs associated with a potential strategic transaction may be significant.

We expect to incur significant third party costs associated with identifying, evaluating, and negotiating a definitive agreement for a suitable acquisition or other strategic transaction. We can give no assurance as to the level of such costs, given that there can be no guarantee that negotiations to acquire any given target business or be acquired by a target will be successful. The greater the number of potential transactions that we negotiate and which do not reach completion, the greater the likely impact of such costs on our financial condition.

Risks Related to Our Financial Position

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 commercial-stage biopharmaceutical company. We have incurred net losses each year since our inception in 1998, including net losses of $79.4 million and $89.8 million for the years ended December 31, 2022 and 2021, respectively. As of March 31, 2023, we had an accumulated deficit of $437.8 million.

We have devoted substantially all our financial resources to designing and developing Omisirge and 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. Although we have implemented significant cost reduction and other cash-focused measures to manage liquidity, we expect to continue to incur significant expenses and operating losses for the foreseeable future. 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 plan to conduct a commercial launch of Omisirge ourselves in the United States that will require a more limited investment resulting in a slower ramp of sales. In addition, we continue to explore partnerships or broader strategic alternatives that would provide additional resources to support the launch of Omisirge and associated commercial activities in the United States and the rest of the world. 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. Though we have obtained regulatory approval from the FDA to market Omisirge in the United States, even if we obtain regulatory approval to market GDA-201 or any future product candidates, our future revenue will depend upon the size of any markets in which such product and product candidates receive approval, and our ability to achieve sufficient market acceptance, pricing and reimbursement from third-party payers for such product and 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 or complete a strategic transaction in the near-term to continue to sufficiently fund our operations and pay our substantial debt, including the 2021 Notes and 2022 Note.

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 or a strategic transaction 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 a strategic transaction 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 audited consolidated financial statements as of and for the year ended December 31, 2022 accompanying our previously filed Annual 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 Omisirge ourselves beyond our focused commercial launch, we will need to raise capital or enter into a strategic transaction. We may seek these funds through a combination of private and public equity offerings, debt financings, government grants, strategic collaborations and licensing arrangements. For example, in April 2023, we completed an underwritten public offering of 17,500,000 ordinary shares and accompanying warrants to purchase 17,500,000 ordinary shares at a public offering price of $1.30 per ordinary share and accompanying warrant, for gross proceeds of approximately $22.8 million, before deducting underwriting discounts and commissions and estimated offering expenses.

Additional financing or a strategic transaction 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 or enter into a strategic transaction, we will need to curtail or cease operations and wind down our business, in which case, we may liquidate and distribute remaining cash to shareholders, after satisfaction of any obligations. We would incur third party costs associated with any distribution which would further limit funds to shareholders. There would be significant costs associated with winding down, such as separation of employees and termination of contracts, and we could owe certain taxes on any such transaction, all of which will further reduce the cash resources available for distribution to our shareholders.

In addition, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the 2021 Notes and 2022 Note, 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 both 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 2021 Notes, and the Loan and Security Agreement governing the 2022 Note, 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 will require significant additional financing or a commercial or strategic partnership to fund our operations. Our present and future funding requirements will depend on many factors, including, but not limited to:

- selling, marketing and distribution activities undertaken in connection with the commercialization of Omisirge, including establishing internal infrastructure;

- the outcome of our strategic review process;

- the costs related to obtaining regulatory approval for GDA-201, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to GDA-201; and

- 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.

Conducting 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 of GDA-201. In addition, Omisirge, and GDA-201, if approved, may not achieve commercial success. Our product revenue for the next several years, if any, will be derived from or based on sales of Omisirge. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives or pursue a strategic transaction. Any strategic transaction or additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to commercialize our product. We cannot guarantee that a strategic transaction or any future financing will be available on terms acceptable to us, if at all, and the terms of any strategic transaction or financing may adversely affect the interests or rights of our shareholders.

In light of our current liquidity challenges, in the first quarter of 2023 our management implemented cost reduction and other cash-focused measures, including discontinuation of our NK cell pre-clinical product development activities, closure of our Jerusalem facilities and a reduction in force affecting 17% of our workforce to better align our workforce with the current needs of our business and focus our capital resources on commercial launch of Omisirge. To conserve cash, we have also strategically evaluated our arrangements with suppliers and service providers and have, in several instances, either initiated an orderly wind-down of those arrangements, where feasible, or transitioned such relationships to lower cost alternative providers.

The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while certain positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition, and results of operations may be materially adversely affected. Moreover, negative publicity associated with our cost-reduction activities and our evaluation of alternative strategic transactions, and the negative consequences should we be unable to raise additional capital or be unsuccessful in consummating an alternative transaction, could adversely affect our relationships with our suppliers, service providers, employees, and other third parties, which in turn could further adversely affect our operations and financial condition.

In addition, our ability to raise additional capital or enter into a strategic transaction may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, the COVID-19 pandemic, the military conflict between Ukraine and Russia, current and potential future bank failures, and otherwise. The recent closures of Silicon Valley Bank and Signature Bank have resulted in broader financial institution liquidity risk and concerns, and future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or corporate development, or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents may be threatened and our ability to borrow or raise additional capital could be substantially impaired.

The Indenture governing the 2021 Notes and the Loan Agreement governing the 2022 Note each contains restrictive and financial covenants and other provisions that adversely affect our liquidity and may make it more difficult to execute our strategy or to effectively compete.

The Indenture governing the 2021 Notes and the Loan and Security Agreement governing the 2022 Note each contain restrictive and financial covenants and other provisions that adversely affect our liquidity and may make it more difficult to execute our strategy or to effectively compete.

Subject to certain exceptions and qualifications, the Indenture governing the 2021 Notes and the Loan and Security Agreement restrict 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. Each of the Indenture and the Loan and Security Agreement also require us to make an offer to repurchase the 2021 Notes or the 2022 Note, as applicable, upon the occurrence of certain asset sales or disposition of certain material assets. Further, the Loan and Security Agreement requires us to make monthly installment payments in an amount equal to (a) a ratable amount of the outstanding principal amount of the Loan and Security Agreement divided by the remaining months to the maturity date plus (b) accrued and unpaid interest on such amount. Such installment payments will also include a 5% prepayment premium on the principal being repaid. These restrictions may make it difficult to successfully execute our business strategy or effectively compete with companies that are not similarly restricted.

In addition, pursuant to the Indenture and the Loan and Security Agreement, we are required 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 2021 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 2021 Notes may declare all the 2021 Notes to be due and payable immediately.

Both the Indenture and the Loan and Security Agreement provide that a number of events will constitute an event of default, including, among other things, payment defaults, material inaccuracy of representations and warranties, covenant defaults, bankruptcy and insolvency proceedings, cross-defaults to certain other agreements, judgments against us, and in the case of the Loan and Security Agreement, the occurrence of a change of control or material adverse change, the termination of any guaranty, the occurrence of certain events relating to governmental approvals and certain events relating to the collateral and lien priority. In the case of an event of default arising from certain events of bankruptcy or insolvency with respect to us, all obligations under the Indenture and the Loan and Security Agreement shall be immediately due and payable without action by the lenders. 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 2021 Notes, in the case of the Indenture, or the administrative agent, at the direction of certain of the lenders, may, without notice or demand, deliver a notice of an event of default and by notice to us declare all obligations under the 2021 Notes or the 2022 Note immediately due and payable. Such acceleration of our debt under the Indenture or the Loan and Security Agreement could have a material adverse effect on our liquidity if we are unable to negotiate mutually acceptable terms with the holders of the 2022 Note or the lenders of the Loan and Security Agreement or if alternate funding is not available to us. Furthermore, if we are unable to repay the 2022 Note or the loan under the Loan and Security Agreement upon an acceleration or otherwise, we would be forced into bankruptcy or liquidation.

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

We have never generated any revenue from product sales and our ability to generate future revenue from the commercialization of Omisirge is uncertain. Since we plan to conduct the initial commercial launch of Omisirge ourselves, we have had to undertake sufficient costs to build out a sales and distribution team. If in the future we enter into one or more partnerships for the commercialization of Omisirge, we will surrender a portion of our revenue to our partner or partners, and if we securitize royalty streams related to Omisirge, 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:

- commercialize Omisirge with collaborators or strategic partners;
- obtain regulatory approvals and marketing authorizations for Omisirge in jurisdictions outside of the United States;
- price Omisirge in a manner designed to encourage market acceptance from the medical community and third-party payers;
- expose, educate and train physicians and other medical professionals to use Omisirge;
- maintain regulatory approval for a sustainable and scalable in-house and/or third-party manufacturing process for Omisirge 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 the market demand for Omisirge;
- ensure procedures utilizing Omisirge 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 Omisirge or its prospective usage by medical professionals;
- 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; and
- avoid and defend against third-party interference, infringement or other intellectual property related claims; attract, hire and retain qualified personnel.

Though we have obtained regulatory approval to market Omisirge in the United States, our revenue will be dependent in part upon the size of the markets in the territories for which we gain regulatory approval for Omisirge, the accepted price for Omisirge, our ability to obtain reimbursement for Omisirge at any price, whether we own the commercial rights for that territory in which Omisirge has been approved and the expenses associated with manufacturing and marketing Omisirge for such markets. Therefore, we may not generate significant revenue from the sale of Omisirge. Further, if we are not able to generate significant revenue from the sale of Omisirge, we may be forced to curtail or cease our operations. Due to the numerous risks and uncertainties involved in product development and commercialization, it is difficult to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

Risks Related to the Clinical Development of GDA-201 and any Future Product Candidates

We may be unable to obtain regulatory approval for GDA-201 or any future 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 EU and 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. The FDA, European Commission or other regulatory agencies can delay, limit or deny approval of our product candidates for many reasons, including:

- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- our inability to demonstrate that the product candidates are safe and effective for the target indication to the satisfaction of the FDA, EMA or other regulatory agencies;
- regulatory requests to provide additional data regarding 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;
- 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, European Commission, 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, European Commission, 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 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.

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 European Commission 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 our product candidates, 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, European Commission, or other regulatory authorities may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and these regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. To the extent we seek regulatory approval in jurisdictions outside of the United States and European Union, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

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, IRBs or Ethics Committees 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 or Ethics Committees of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, by the FDA, national competent authorities of the EU Member States 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, national competent authorities of the EU Member States 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 public health crises (such as 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.

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 clinical trial of GDA-201, 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.

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 Omisirge and any 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 Omisirge obviate the need for patients to undergo HSCT procedures, our business prospects will be significantly harmed.

Because GDA-201 is based on novel technologies, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of GDA-201 and obtain the necessary regulatory approvals for commercialization.

Our product candidate, GDA-201, is 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. Cell therapies represent a relatively new therapeutic area, and the FDA and equivalent foreign regulatory authorities have cautioned consumers about potential safety risks associated with these therapies. To date, there are relatively few approved cell therapy 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 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 Omisirge, 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 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, 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.

Omisirge, GDA-201, or any future 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, and result in costly and damaging product liability claims against us.

Undesirable side effects, including toxicity caused by Omisirge, GDA-201, or any future product candidates, or the drugs encapsulated thereby, 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, European Commission, 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, European Commission or other regulatory agencies could order us to cease further development of or deny or withdraw approval of Omisirge, GDA-201, or any of our future 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 company 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. Omisirge may be associated with infusion reactions, graft versus host disease, engraftment syndrome, and graft failure, Infusion reactions occurred following Omisirge infusion, including hypertension, mucosal inflammation, dysphagia, dyspnea, vomiting and gastrointestinal toxicity were reported in 47% (55/117) patients transplanted with Omisirge. Grade 3-4 infusion reactions were reported in 15% (18/117) of patients transplanted with Omisirge. Primary graft failure, defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplantation, occurred in 3% (4/117) of patients in Omisirge clinical trials. Acute and chronic GvHD, including life-threatening and fatal cases, occurred in patients transplanted with Omisirge. Grade II-IV acute GvHD was reported in 58% (68/117) of patients transplanted with Omisirge. Grade III- IV acute GvHD was reported in 17% (20/117) of patients transplanted with Omisirge. Chronic GvHD occurred in 35% (41/117) of patients transplanted with Omisirge. Two patients treated with Omisirge developed post-transplant lymphoproliferative disorder (PTLD) in the second-year post-transplant. In our first Phase 1/2 clinical trial of GDA-201, adverse events included one patient who died of E. coli sepsis. 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 Omisirge 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 Omisirge, 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 we or others later identify undesirable side effects caused by Omisirge, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may suspend or withdraw approvals of Omisirge;
- regulatory authorities may require additional warnings on the label in addition to Omisirge's "black box" warning, such as a contraindication;
- additional restrictions may be imposed on the marketing of Omisirge or the manufacturing processes for Omisirge 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 Omisirge, change the way Omisirge is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- Omisirge may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Omisirge, 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 GDA-201 or any of our future 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.

Omisirge and any other approved products will remain subject to regulatory scrutiny.

An approved product 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, national competent authorities of the EU Member States 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 equivalent foreign 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 obtained Breakthrough Therapy Designation for Omisirge 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 a product candidate 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 obtained orphan drug designation for Omisirge from the FDA and the European Commission 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, potentially, ten years of market exclusivity following the granting of marketing authorization. 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 obtained orphan drug designation for Omisirge from the FDA for the treatment of hematologic malignancies and from the European Commission for allogeneic ex-vivo-expanded umbilical cord blood-derived haematopoietic CD34+ progenitor cells and allogeneic non-expanded umbilical cord blood-derived haematopoietic mature myeloid and lymphoid cells (also known as NiCord), orphan drug exclusivity may not effectively protect Omisirge 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 European Commission can subsequently approve the same drug with the same active moiety for the same condition if the FDA or European Commission 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 Omisirge and GDA-201 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, the Tax Cuts and Jobs Act of 2017, or 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. Further, there have been a number of health reform measures by the Biden administration that have impacted the PPACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and by creating a new manufacturer discount program. 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 will impact the PPACA and our business.

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 until 2032, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies are subject to changes in healthcare legislation and regulatory initiatives. For example, CMS has developed value-based payment models for a variety of care settings, including the inpatient prospective payment system used for reimbursing inpatient hospital services. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. 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. For example, 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, the Department of Health and Human Services, or 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. In addition, the IRA, among other things, (i) directs the Secretary of HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare Part B and Medicare Part D, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures 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 Omisirge, GDA-201, or our future 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. 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 Omisirge 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 ExCellThera and Garuda Therapeutics, 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 Omisirge 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 product;

- 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 though Omisirge is approved by the FDA for marketing in the United States, we may never obtain approval of Omisirge 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. Sales of Omisirge 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.

Even if a product candidate is approved in another country, 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 Omisirge 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.

In the United States, we obtained marketing approval for Omisirge for use in adult and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. We will train our Omisirge marketing and sales personnel or the marketing and sales personnel of any strategic partner to not promote Omisirge 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 Omisirge 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 Omisirge for these uses for which they are not approved. Furthermore, the use Omisirge 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, the national competent authorities of the EU Member States 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.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data.

Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for the processing of personal data of individuals located, respectively, within the EEA and the UK.

The EU and UK GDPR impose requirements relating to (a) having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area and/or the UK 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 EU and UK GDPR impose additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the EU 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 EU 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 EU GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to our Reliance on Third Parties

We may 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 may again rely upon, third-party vendors, including CROs, to monitor and manage data for our preclinical studies and clinical trials. We may 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 were to 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. We may also be subject to higher CRO 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 expect to 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 any future 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 equivalent foreign regulatory authorities. The FDA or other equivalent foreign 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 equivalent foreign 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 equivalent foreign 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 equivalent foreign 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 Omisirge 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 Omisirge. 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.

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 clinical and commercial supply of Omisirge. We have completed construction on the facility in Kiryat Gat. The FDA completed its pre-licensing inspections and approved our facility in Kiryat Gat to manufacture commercial supplies of Omisirge. Such inspection resulted in no 483 observations. In addition, the Israeli Ministry of Health has also completed physical inspections of the facility in Kiryat Gat, Israel. 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 Omisirge 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 Omisirge, we cannot guarantee that we will be able to establish an alternative source, supplier or partner for the manufacturing of Omisirge 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 Omisirge, 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 Omisirge.

CBUs are one of the raw materials for the manufacture of Omisirge. The CBUs currently used in the manufacture of Omisirge 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 Omisirge 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, 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 Omisirge. 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 Omisirge 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 Omisirge. 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 Omisirge 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 Omisirge. Any inability to procure adequate supplies of CBUs will adversely impact our ability to develop and commercialize Omisirge.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain or protect intellectual property rights related to Omisirge, GDA-201 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 2021 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 agreements governing the 2021 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 attract, retain and motivate qualified personnel.

We are highly dependent on our employees, consultants and advisors. The loss of their services without a proper replacement may adversely impact the achievement of our objectives. Our employees, consultants and advisors may leave our employment at any time. 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 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.

Our workforce reduction announced on March 27, 2023, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On March 27, 2023, we announced as part of the strategic reprioritization of our business activities that we had authorized a headcount reduction of 17%, with the majority of impacted employees tied to the discontinuation of the pre-clinical NK cell therapy candidates. We expect to substantially complete the terminations during the second quarter of 2023 and estimate that we will reduce our operating expenses going forward. However, these estimates are subject to several assumptions, and actual results may differ. We may not realize, in full or in part, the anticipated benefits and savings from this plan due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected cost savings from the announced plan, our operating results and financial condition could be adversely affected. The workforce reduction may be disruptive to our operations and could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and/or manufacturing personnel. Any failure to attract or retain qualified personnel could prevent us from successfully developing Omisirge or potential product candidates.

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 or product candidates to support and pursue 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. Our decision to terminate our NK-cell research and development program may also prove not to be optimal and could cause us to miss valuable opportunities. Furthermore, we made the decision to prioritize the development of Omisirge for the treatment of hematologic malignancies over sickle cell disease because our hematologic malignancy program was at a more advanced stage of development, and our sickle cell program remains exploratory. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, in particular for Omisirge, 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, public health crises, 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.

The war in Ukraine continues to cause geopolitical and macroeconomic uncertainty, and an escalation of the conflict could disrupt our supply chain, adversely affect our ability to conduct ongoing and future clinical trials of our product candidates or commercialize our products. Furthermore, both the ongoing COVID-19 pandemic and the war in Ukraine have resulted in significant disruptions to global financial markets and contributed to a general global economic slowdown. The resulting high inflation rates may materially affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates and overhead costs may adversely affect our operating results. Rising interest rates also present a recent challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. Furthermore, such economic conditions have produced downward pressure on share prices.

In addition, the war in Ukraine has had significant ramifications on global financial markets and contributed to a slowdown in the global economy, and which may adversely impact our ability to raise capital on favorable terms or at all.

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, malicious internet-based activity, online and offline fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, and other similar threats. 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, loss of sensitive data and income, reputational harm, and diversion of funds. 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. 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. 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.

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, 2027.

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 and other equivalent foreign regulations, provide accurate information to the FDA or equivalent foreign regulatory authorities, 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.

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 March 31, 2023 hold shares that represent approximately 3.4% 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:

- success of the initial commercial launch of Omisirge;
- investor reaction to the news of the strategic reprioritization of our business activities;
- 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, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures 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.

The exchange of some or all of the 2021 Notes or 2022 Note into our ordinary shares could result in significant dilution to existing shareholders, adversely affect the market price of our ordinary shares and impair our ability to raise capital through the sale of additional equity securities.

Our 2021 Notes may be exchanged, at the election of the holder, for our ordinary shares at an initial share price of $17.76. As of March 31, 2023, the 2021 Notes had an aggregate outstanding balance of approximately $72.4 million.

Our 2022 Note is exchangeable at the option of Highbridge into our ordinary shares at an exchange rate of 0.52356 ordinary shares per $1.00 principal amount, together with a make-whole premium equal to all accrued and unpaid remaining coupons due through December 12, 2024. In addition, under certain circumstances, we can issue ordinary shares in exchange for the discharge of the monthly principal installment payments and related interest. As of March 31, 2023, the 2022 Note had an aggregate outstanding balance of $19.0 million. In the first quarter of 2023, Highbridge elected to exchange $6.0 million of outstanding principal amount of the 2022 Note and we issued 3,774,545 ordinary shares on exchange of this principal amount and in payment of accrued and make-whole interest thereon. The exchange of some or all of the 2021 Notes or 2022 Note could result in significant dilution to existing shareholders, adversely affect the market price of our ordinary shares and impair our ability to raise capital through the sale of additional equity securities.

An increase in our authorized share capital will be required for future financings or other strategic transactions.

To fund our operations, we need to seek additional capital through public or private equity offerings, debt financings, partnerships or broader strategic alternatives. We have limited ordinary shares currently available and authorized for issuance under our amended and restated articles of association. Investors in prior transactions have purchased our ordinary shares as well as our convertible securities and exchangeable debt, such as our warrants, the 2021 Notes and the 2022 Note, for which we must reserve authorized and unissued ordinary shares. We therefore need to increase the number of authorized ordinary shares under our amended and restated articles of association, which requires shareholder approval, in order to issue ordinary shares or convertible securities to investors and potential strategic partners in capital raising transactions. If we are unable to increase our authorized shares, we will be limited in our efforts to raise additional capital and we will be required to make future principal and interest payments on our 2021 Note with cash. If we are unable to secure additional financing or a commercial or strategic partnership for Omisirge, our board of directors may decide to pursue a dissolution and liquidation. In the event of such liquidation or other wind-down event, holders of our securities may suffer a total loss of their investment.

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

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets (generally determined based on a weighted quarterly average) is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from commodities and securities transactions, certain gains from the disposition of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, having interest charges apply to distributions by us and gains from the sales of our shares, and additional tax reporting requirements.

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 may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ordinary shares, 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 upon the value of our assets, including any goodwill, and the nature and composition of our income and assets, we do not believe that we were classified as a PFIC for the taxable year ended December 31, 2022. 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 considered a PFIC in any taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ended December 31, 2022, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

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

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

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

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

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. For instance, the recently enacted Inflation Reduction Act of 2022 imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. 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.

For U.S. tax purposes, our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, U.S. federal net operating losses, or NOLs, generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOLs may be limited. In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its stock ownership over a three-year period) is subject to limitations on its ability to utilize its pre-change U.S. federal NOLs to offset future taxable income. If we have undergone an ownership change in the past, or if future changes in our stock ownership, some of which are outside of our control, results in an ownership change, our ability to utilize our U.S. federal NOLs may be limited by Section 382 of the Code. As a result, even if we earn net taxable income, our ability to use our NOLs to offset such income may be limited, which could increase our tax liability and decrease our cash flow. It is uncertain if and to what extent states will conform to U.S. federal income tax law with respect to the treatment of NOLs.

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 2022 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:

- 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 $1.24 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. We have elected to take advantage of this extended transition period. When we are no longer deemed to be an emerging growth company, which we expect to occur beginning on January 1, 2024, 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.

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 at Kiryat Gat, that may be influenced by regional instability, political 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.

The Israeli government is currently pursuing extensive changes to Israel's judicial system. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed changes may negatively impact the business environment in Israel including due to reluctance of foreign investors to invest or transact business in Israel as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in security markets, and other changes in macroeconomic conditions. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

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 2021 or 2022. 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 meeting of the shareholders. 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.

Our amended and restated articles of association also include, among others things, the following restrictions may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets:

- An amendment to our amended and restated articles of association generally require a vote of the holders of a majority of our outstanding ordinary shares entitled to vote present and voting on the matter at a general meeting of shareholders (referred to as simple majority), and the amendment of a number of provisions, such as the provision dividing our directors into three classes, requires a vote of the holders of at least 60% of our voting power. The affirmative vote of a majority of the directors in addition to the approval of our shareholders, is also required in order to amend our amended and restated articles of association.

- A director may not be removed except by a vote of the holders of at least 60% of our voting power, unless otherwise the director is prohibited from serving as a director under applicable law or upon a determination by the board that their physical or mental state prevents them from serving; and director vacancies may be filled by our board of directors.

- Subject to certain exceptions, we are restricted from engaging in certain business combination transactions, with any shareholder who holds 20% or more of our voting power. The transactions subject to such restrictions include mergers, consolidations and dispositions of our assets with a market value of 10% or more of our assets or outstanding shares. Subject to certain exceptions, such restrictions will apply for a period of three years following each time a shareholder became the holder of 20% or more of our voting power.

- Subject to certain exceptions, there is a restriction on certain transactions which may have a significant effect on the Company's structure, assets or business, including significant mergers and acquisitions, a disposition of all or substantially all of the assets of the Company, a voluntary dissolution and material changes to the principal business of the Company.

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 of 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 the Companies Law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S. corporations. In particular, pursuant to the Companies Law each shareholder of an Israeli company has to act in good faith in exercising his or her rights and fulfilling his or her obligations toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at the general meeting of shareholders and class meetings, on amendments to a company's articles of association, increases in a company's authorized share capital, mergers, and transactions requiring shareholders' approval under the Companies Law. In addition, a controlling shareholder of an Israeli company or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or who has the power to appoint or prevent the appointment of a director or officer in the company, or has other powers toward the company, has a duty of fairness toward the company. However, Israeli law does not define the substance of this duty of fairness.

Because Israeli corporate law has undergone extensive revision in recent years, there is little case law available to assist in understanding the implications of these provisions that govern shareholder behavior.

Our amended and restated articles of association provide that unless we consent to an alternate forum, the federal district courts of the United States shall be the exclusive forum of resolution of any claims arising under the Securities Act which may impose additional litigation costs on our shareholders.

Our amended and restated articles of association provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both U.S. state and federal courts have jurisdiction to entertain such claims. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may increase the costs associated with such lawsuits, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated articles of association inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in our share capital shall be deemed to have notice of and to have consented to the choice of forum provisions of our amended and restated articles of association described above. This provision would not apply to shall not apply to causes of action arising under the Exchange Act.

Our amended and restated articles of association provide that unless the Company consents otherwise, the competent courts of Tel Aviv, Israel shall be the sole and exclusive forum for substantially all disputes between the Company and its shareholders under the Companies Law and the Israeli Securities Law, which could limit its shareholders ability to brings claims and proceedings against, as well as obtain favorable judicial forum for disputes with the Company, its directors, officers and other employees.

The competent courts of Tel Aviv, Israel shall be the exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's shareholders, or (iii) any action asserting a claim arising pursuant to any provision of the Companies Law or the Israeli Securities Law. This exclusive forum provisions is intended to apply to claims arising under Israeli Law and would not apply to claims brought pursuant to the Securities Act or the Exchange Act or any other claim for which federal courts would have exclusive jurisdiction. Such exclusive forum provision in our amended and restated articles of association will not relieve the Company of its duties to comply with federal securities laws and the rules and regulations thereunder, and shareholders of the Company will not be deemed to have waived the Company's compliance with these laws, rules and regulations. This exclusive forum provision may limit a shareholders ability to bring a claim in a judicial forum of its choosing for disputes with the Company or its directors or other employees which may discourage lawsuits against the Company, its directors, officers and employees.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Amended and Restated Articles of Association of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-K (File No. 001-38716), filed with the SEC on March 31, 2023.
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).
4.2	Form of Ordinary Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K (File No. 001-38716), filed with the SEC on April 21, 2023.
10.1	Underwriting Agreement, dated as of April 19, 2023, by and between Gamida Cell Ltd. and Piper Sandler & Co., as representative of the several underwriters named therein (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K (File No. 001-38716), filed with the SEC on April 21, 2023.
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 and 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 Exhibit 32.1 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.

May 15, 2023

By: /s/ Abigail Jenkins

Abigail Jenkins
President, Chief Executive Officer and
Director (Principal Executive Officer)

May 15, 2023

By: /s/ Shai Lankry

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

Exhibit 31.1

CERTIFICATIONS

I, Abigail L. Jenkins, 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 assurance regarding the reliability of financial reporting and 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; and

   (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 fiscal 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: May 15, 2023

/s/ Abigail L. Jenkins
President and Chief Executive Officer
(*Principal Executive Officer)*

Exhibit 31.2

CERTIFICATIONS

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 assurance regarding the reliability of financial reporting and 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; and

   (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 fiscal 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: May 15, 2023

/s/ Shai Lankry
Chief Financial Officer
(*Principal Financial Officer)*

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Abigail L. Jenkins, President and Chief Executive Officer of Gamida Cell Ltd. (the "Company"), and Shai Lankry, Chief Financial Officer of the Company, each hereby certify that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: May 15, 2023

In Witness Whereof, the undersigned have set their hands hereto as of the 15th day of May, 2023.

/s/Abigail L. Jenkins	/s/ Shai Lankry
Abigail L. Jenkins	Shai Lankry
Principal Executive Officer	Principal Financial Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Gamida Cell Ltd. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."