UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 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 121,523,280 ordinary shares outstanding as of August 11, 2023.

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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 JUNE 30, 2023

U.S. DOLLARS IN THOUSANDS

UNAUDITED

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GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	June 30, 2023 (unaudited)	December 31, 2022
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		$ 54,075	$ 64,657
Restricted Cash		138	-
Inventory		2,390	-
Prepaid expenses and other current assets		2,262	1,889
Total current assets		58,865	66,546
NON-CURRENT ASSETS:			
Restricted deposits		3,150	3,668
Property, plant and equipment, net		43,639	44,319
Operating lease right-of-use assets	3	4,336	7,024
Severance pay fund		1,291	1,703
Other long-term assets		1,227	1,513
Total non-current assets		53,643	58,227
Total assets		$ 112,508	$ 124,773

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	June 30, 2023 (unaudited)	December 31, 2022
LIABILITIES AND SHARHOLDERS' DEFICIT			
CURRENT LIABILITIES:			
Trade payables		$ 2,440	$ 6,384
Employees and payroll accruals		5,545	5,300
Operating lease liabilities	3	2,176	2,648
Accrued interest of convertible senior notes		1,842	1,652
Accrued expenses and other current liabilities		8,735	8,891
Total current liabilities		20,738	24,875
NON-CURRENT LIABILITIES:			
Convertible senior notes, net	4, 5	86,117	96,450
Warrants liability	5	25,629	-
Accrued severance pay		1,403	1,914
Long-term operating lease liabilities	3	2,461	4,867
Other long-term liabilities		1,873	4,690
Total non-current liabilities		117,483	107,921
CONTINGENT LIABILITIES AND COMMITMENTS			
SHAREHOLDERS' DEFICIT:	7, 8		
Share capital -			
Ordinary shares of NIS 0.01 par value - Authorized: 225,000,000 and 150,000,000 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively; Issued: 112,425,611 and 74,703,030 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively; Outstanding: 112,274,165 and 74,583,026 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively		305	211
Treasury ordinary shares of NIS 0.01 par value - 151,446 and 120,004 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively		*	*
Additional paid-in capital		443,450	408,598
Accumulated deficit		(469,468)	(416,832)
Total shareholders' deficit		(25,713)	(8,023)
Total liabilities and shareholders' deficit		$ 112,508	$ 124,773

* Represents an amount lower than $1.

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
	Unaudited			
Research and development expenses, net	$ 8,687	$ 10,563	$ 17,527	$ 21,868
Commercial expenses	3,862	3,193	9,438	7,072
General and administrative expenses	6,253	4,290	11,417	8,429
Total operating loss	18,802	18,046	38,382	37,369
Financial expenses, net	12,874	508	14,254	1,408
Loss	$ 31,676	$ 18,554	$ 52,636	$ 38,777
Net loss per share attributable to ordinary shareholders, basic and diluted	0.31	0.31	0.59	0.65
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	102,921,207	59,546,273	89,913,214	59,510,918

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' DEFICIT

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

	Three months ended June 30, 2023					
	Ordinary shares		Treasury shares	Additional paid-in capital	Accumulated deficit	Total shareholders' deficit
	Number	Amount				
Balance as of March 31, 2023 (unaudited)	82,033,646	$ 222	$ *	$ 422,203	$ (437,792)	$ (15,367)
Issuance of ordinary shares upon release of restricted share units	4,742	*	-	*	-	*
Treasury shares	(27,775)	*	*	*	-	*
Exercise of options	246	*	-	*	-	*
Issuance of ordinary shares, net of issuance expenses**	24,210,755	67	-	10,315	-	10,382
Issuance of ordinary shares, for 2022 Note	6,019,281	16	-	9,465	-	9,481
Exercise of warrants liability	33,270	*	-	45	-	45
Share-based compensation	-	-	-	1,422	-	1,422
Loss	-	-	-	-	(31,676)	(31,676)
Balance as of June 30, 2023(unaudited)	112,274,165	$ 305	$ *	$ 443,450	$ (469,468)	$ (25,713)

	Six months ended June 30, 2023					
	Ordinary shares		Treasury shares	Additional paid-in capital	Accumulated deficit	Total shareholders' deficit
	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	112,369	*	-	*	-	*
Treasury shares	(31,442)	*	*	*	-	*
Exercise of options	246	*	-	*	-	*
Issuance of ordinary shares, net of issuance expenses***	27,782,870	77	-	15,522	-	15,599
Issuance of ordinary shares, for 2022 Note	9,793,826	17	-	16,364	-	16,381
Exercise of warrants liability	33,270	*	-	45	-	45
Share-based compensation	-	-	-	2,921	-	2,921
Loss	-	-	-	-	(52,636)	(52,636)
Balance as of June 30, 2023 (unaudited)	112,274,165	305	*	443,450	(469,468)	(25,713)

* Represents an amount lower than $1

** Issuance costs of approximately $2,163

*** Issuance costs of approximately $2,325

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

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

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

* Represents an amount lower than $1.

** Issuance costs of approximately $3.

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Six months ended June 30,	
	2023	**2022**
	(Unaudited)	
Cash flows from operating activities:		
Loss	$ (52,636)	$ (38,777)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	214	224
Financing expense (income), net	1,363	(273)
Share-based compensation	2,921	2,530
Change in Fair Value of Warrants liability	4,876	-
Change in Fair Value of convertible senior note	4,254	-
Warrants Issuance Costs	1,733	-
Amortization of loan issuance costs	455	385
Change in assets and liabilities:		
Inventory	(295)	-
Operating lease right-of-use assets	1,363	1,226
Operating lease liabilities	(1,553)	(1,649)
Accrued severance pay, net	(99)	14
Increase in prepaid expenses and other assets	(211)	(19)
Decrease in trade payables	(3,944)	(5,535)
Increase (decrease) in accrued expenses and other liabilities	(2,728)	2,285
Net cash used in operating activities	(44,287)	(39,589)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(821)	(1,540)
Purchase of marketable securities	-	(3,708)
Proceeds from maturity of marketable securities	-	26,175
Proceeds from restricted deposits	-	500
Net cash provided by (used in) investing activities	$ (821)	$ 21,427

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

GAMIDA CELL LTD. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Six months ended June 30	
	2023	**2022**
	(Unaudited)	
Cash flows from financing activities:		
Proceeds from exercise of options	$ -	$ 76
Proceeds from exercise of warrants liability	45	-
Proceeds from share issuance and warrants liability, net	34,785	84
Warrants issuance cost	(166)	-
Net cash provided by financing activities	34,664	160
Decrease in cash and cash equivalents and restricted cash	(10,444)	(18,002)
Cash and cash equivalents at beginning of period	64,657	55,892
Cash and cash equivalents and restricted cash at end of period	$ 54,213	$ 37,890
Significant non-cash transactions:		
Purchase of property, plant and equipment on credit	-	282
Exercise of 2022 Note principal	$ 15,000	$ -
Exercise of 2022 Note interest	$ 1,332	$ -
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ (3,228)	$ (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 ("FDA") 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. 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 June 30, 2023 was $469,468 and negative cash flows from operating activities during the six-month period ended June 30, 2023 were $44,287. The Company's management plan is to seek a strategic partnership to support the commercialization of Omisirge or seek additional financing as required to fund its operations until achieving positive cash flows. However, there is no assurance that a strategic transaction and/or capital financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in amounts required.

d. 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.

e. 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. 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 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.

b. Use of estimates:

The preparation of the unaudited 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.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

c. Inventories:

Inventories are stated at the lower of cost or net realizable value; cost is determined using the standard cost. The Company regularly evaluates its ability to realize the value of inventory. If the inventories are deemed damaged, if actual demand for the Company's therapies deteriorates, or if market conditions are less favorable than those projected, inventory write-offs may be required.

During the three and six months period ended June 30, 2023, no write-offs were recorded.

d. 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 was effective for the Company beginning on January 1, 2023, and 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 has entered into operating leases primarily for its production plant and its laboratories and offices. The leases have remaining lease terms of up to five 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 are as follows:

	Six months ended June 30,	
	2023	**2022**
Operating lease costs	$ 1,160	$ 1,417
Short-term lease costs	82	84
Total lease costs	$ 1,242	$ 1,501

	Three months ended June 30,	
	2023	**2022**
Operating lease costs	$ 497	$ 781
Short-term lease costs	-	60
Total lease costs	$ 497	$ 841

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

	Six months ended June 30, 2023
Weighted average remaining lease term (in years)	3.09
Weighted average discount rate	3.35%

NOTE 3:- LEASES (Cont.)

Maturities of lease liabilities were as follows:

	As of June 30, 2023
2023	1,347
2024	1,200
2025	1,062
2026	706
Thereafter	541
Total undiscounted lease payments	4,856
Less: Imputed interest	(219)
Present value of lease liabilities	$ 4,637

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 June 30, 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	1,836	1,423
Net carrying amount	$ 72,613	$ 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 June 30, 2023, and December 31, 2022, the total estimated fair value of the 2021 Notes was $74,883 and $73,331, respectively. The fair value was determined using the Company's effective rates for June 30, 2023 and December 31, 2022. The fair value of the 2021 Notes is classified as Level 3, see Note 5 below for further details.

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

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 Note"). 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 (equivalent to an exchange price of $1.91 per share), 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 June 30, 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 separately in other comprehensive income (loss).

As of June 30, 2023, the Company issued 8,737,870 and 1,055,956 ordinary shares in exchange for the discharge of $15,000 of the aggregate outstanding balance and the discharge of $1,331 interest make-whole payments, respectively, in respect of the 2022 Note.

NOTE 5: FAIR VALUE MEASUREMENTS

Cash and cash equivalents, restricted cash, restricted deposits, prepaid expenses and other assets, trade payables and accrued expenses and other liabilities, are stated at their carrying value which approximates their fair value due to the short time to the expected receipt or payment.

The following tables present information about the Company's financial assets and liabilities that are measured in fair value on a recurring basis as of June 30, 2023 and December 31, 2022:

	June 30, 2023			December 31, 2022		
	Level 1	Level 3	Total	Level 1	Level 3	Total
Financial assets:						
Money market funds included in cash and cash equivalent	$ 47,559		$ 47,559	$ 58,827	$ -	$ 58,827
Total Assets Measured at Fair Value	47,559		47,559	58,827	-	58,827
Financial Liabilities:						
2022 Note	-	13,504	13,504	-	24,250	24,250
Warrants liability	-	25,629	25,629	-	-	-
Total liabilities measured at fair value	$ -	$ 39,133	$ 39,133	$ -	$ 24,250	$ 24,250

NOTE 5: FAIR VALUE MEASUREMENTS (Cont.)

The Company classifies cash equivalents within Level 1, and the 2021 Notes, 2022 Note and warrants liability are classified within Level 3, because the Company uses quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair values.

The warrants liability was valued using a Black Scholes Option Pricing Model, which is considered to be a Level 3 fair value measurement. The Black Scholes model's primary unobservable input utilized in determining the fair value of the Private warrants is the expected volatility of the ordinary shares. The expected volatility was implied from a blend of the Company's own ordinary share and the average historical share volatilities of several unrelated public companies within the Company's industry that the Company considers to be comparable to its own business.

The following table summarizes the warrants liability activity as of June 30, 2023:

	Warrant liability
Initial Measurement (April 21, 2023)	$ 20,753
Change in fair value	4,876
Balance June 30, 2023	$ 25,629

The key inputs used in the valuation of the warrants liability as of June 30, 2023 and April 21, 2023, the initial measurement date, are included below:

Input	June 30, 2023	April, 21, 2023 Initial Measurement
Exercise Price	$ 1.35	$ 1.35
Share price on date	$ 1.93	$ 1.60
Risk-free rate	4.1%	3.7%
Expected Volatility	90%	91%
Time to liquidation (years)	4.7	5.0
Dividend Rate	0%	0%

The 2022 Note was valued using the Monte Carlo simulation analysis to generate expected future cash flows based on movement in the Company's stock price. These future cash flows were then discounted to present value. Cash flows associated with the future conversion of loan principal into shares were discounted at the risk-free rate commensurate with the remaining term of the loan. Future cash flows resulting from the contractual debt payments were discounted at a market yield. The significant inputs into the Monte Carlo simulation were the closing stock price as of June 30, 2023, volatility analysis of the stock, and the risk-free rate using U.S. Treasury Constant Maturity Rate for the remaining time between the valuation date and maturity date.

The fair value for the 2022 Note liability as of June 30, 2023 and December 31, 2022:

	2022 Notes
Balance December 31, 2022	$ 24,250
2023 Principal Reduction	(15,000)
Change in fair value	4,254
Balance June 30, 2023	$ 13,504

The key inputs used in the valuation of the 2022 Note liability as of June 30, 2023 and December 31, 2022 the initial measurement date:

Input	June 30, 2023	December 31, 2022
Voluntary Conversion Price	$ 1.91	$ 1.91
Share price on date	$ 1.93	$ 1.29
Risk-free rate	5.2%	4.4%
Expected Volatility	100%	75%
Implied Yield	31.0%	32.8%

NOTE 6: CONTINGENT LIABILITIES AND COMMITMENTS

a. Legal proceedings:

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

b. Bank guarantees:

As of June 30, 2023, the Company obtained bank guarantees in the amount of $2,773, primarily in connection with an Investment Center grant which requires a bank guarantee in order to ensure the fulfillment of the grant terms.

c. Government grants:

The Company has received grants from the Israeli Innovation Authority (the "IIA") to finance its research and development programs in Israel, through which the Company received IIA participation payments in the aggregate amount of $37,082 through June 30, 2023, of which $34,477 is royalty-bearing grants and $2,605 is non-royalty-bearing grants. In return, the Company is committed to pay IIA royalties at a rate of 3-5% of future sales of the developed products, up to 100% of the amount of grants received plus interest at LIBOR rate. Through June 30, 2023, no royalties have been paid or accrued. The Company's contingent royalty liability to the IIA at June 30, 2023, including grants received by the Company and the associated LIBOR interest on all such grants totaled to $43,187.

d. Lonza Settlement:

In December 2022, the Company signed an agreement with Lonza Netherlands B.V., or Lonza, to mutually terminate their Service Agreement, whereas the Company shall pay Lonza an aggregate amount of 8.0 million Euros. As of June 30, 2023, the Company paid the first payment of 1.5 million Euro, 2.5 million Euro will be paid in 2023 and the remaining 4 million Euro will be paid in 2024.

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 issued and sold, in an underwritten public offering, an aggregate of 12,905,000 of its ordinary shares at a public offering price of $1.55 per share for gross proceeds of approximately $20,000,000, before deducting underwriting discounts and commissions and estimated offering expenses.

On April 19, 2023, the Company issued and sold, in an underwritten public offering, 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 warrants, for gross proceeds of approximately $22.8 million, before deducting underwriting discounts and commissions, and estimated offering expenses of $1.9 million.

As of June 30, 2023, the Company raised $13,765 in net proceeds in 2023 by issuing 10,282,870 shares via an ATM facility, at an average public offering price of $1.38.

NOTE 7: SHAREHOLDERS' EQUITY (Cont.)

b. Warrants to investors:

As part of its April 2023 underwritten public offering of its securities, the Company granted certain investors 17,500,000 warrants to purchase the Company's ordinary shares that will expire on April 21, 2028. The warrants were classified as a liability on the balance sheet initially, and subsequently measured at fair value on the consolidated statement of operations, as the warrants are not considered indexed to the Company's own equity pursuant to ASC 815-40. The change in fair value of the warrants liability was recognized in financial expenses, net, in the consolidated statements of operation. As of June 30, 2023, 33,270 of such warrants have been exercised into the Company's ordinary shares.

c. Treasury Shares:

During the three months ended June 30, 2023, the Company cancelled 27,775 outstanding restricted shares.

NOTE 8: SHARE-BASED COMPENSATION

a. Option plans:

Under the Company's amended 2014 Israel Share Option Plan (the "2014 Plan"), 1,152,044 ordinary shares were allocated to the Company's employees. No equity grants under the 2014 Plan remain outstanding.

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.

NOTE 8: SHARE-BASED COMPENSATION (Cont.)

The following table lists the inputs to the binomial option-pricing model used for the fair value measurement of equity-settled share options for the six months ended June 30, 2023 and 2022:

	Six months ended June 30,	
	2023	2022
	(unaudited)	
Dividend yield	0%	0%
Expected volatility of the share prices	74%	66%
Risk-free interest rate	3.7%	2.8%
Expected term (in years)	8	8

Based on the above inputs, the fair value of the options was determined to be $1.06 - $1.85 per option at the grant date.

b. The following table summarizes the number of options granted to employees under the Option Plans as of June 30, 2023 and related information:

	Number of options	Weighted average exercise price
Balance as of December 31, 2022	6,133,903	$ 4.62
Granted	2,018,234	1.53
Exercised	(246)	0.25
Forfeited	(410,901)	3.01
Expired	(292,628)	6.00
Balance as of June 30, 2023 (unaudited)	7,448,362	3.86
Exercisable as of June 30, 2023 (unaudited)	3,343,425	5.36

As of June 30, 2023, there are $8,570 of total unrecognized costs related to share-based compensation that are expected to be recognized over a period of up to four years.

c. A summary of restricted shares and restricted share units activity as of June 30, 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	986,706	1.54
Vested	(212,843)	4.22
Forfeited	(222,191)	2.60
Unvested as of June 30, 2023 (unaudited)	1,678,415	2.23

NOTE 8: SHARE-BASED COMPENSATION (Cont.)

d. The total share-based compensation expense related to all of the Company's equity-based awards, recognized for the three and six months ended June 30, 2023 and 2022 is comprised as follows:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
	(unaudited)			
Research and development expenses, net	$ 382	$ 553	$ 796	$ 1,018
Commercial expenses	357	358	691	648
General and administrative expenses	683	425	1,434	864
Total share-based compensation	$ 1,422	$ 1,336	$ 2,921	$ 2,530

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 June 30,				Six months ended June 30,			
	2023		2022		2023		2022	
	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	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	102,921,207	31,676	59,546,273	18,554	89,913,214	52,636	59,510,918	38,788

All outstanding warrants, share options, and restricted shares, as well as any shares issuable upon exchange of the convertible senior notes, for the three and six months ended June 30, 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
	(unaudited)			
Convertible senior notes	11,832,124	4,222,973	11,832,124	4,222,973
Warrants	17,466,730	3,313,512	17,466,730	3,313,512
Share options	7,406,981	5,132,921	7,014,715	4,946,420
Restricted shares	1,696,224	1,322,782	1,503,128	1,178,583
Total	38,402,059	13,992,188	37,816,697	13,661,488

NOTE 10: SUBSEQUENT EVENTS

From July 1, 2023 through August 9, 2023, the Company raised an additional $14.0 million in net proceeds by issuing 9,249,115 ordinary shares via an ATM facility, at an average public offering price of $1.56.

From July 1, 2023 through August 9, 2023, we made a monthly installment payment of $0.6 million on the 2022 Note. As of August 9, 2023, the outstanding principal amount of the 2022 Note is $9.4 million.

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, or 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 Center for International Blood and Marrow Transplant Research, 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 1,700 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 2028 approximately 10,000 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 approximately 20% 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 malignancies 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. Results were recently published in the journal, Science Translational Medicine. 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%. The data demonstrated a median duration of response of 16 months (range 5-36 months), an overall survival at two years of 73% (CI = 43-89%) 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 and we have allocated the vast majority of our resources to support this launch. 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.

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 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 our business plan. As of June 30, 2023, we had total cash and cash equivalents of $54.1 million, and as of August 9, 2023, we had raised additional funds of approximately $14.0 million in net proceeds from 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 the second quarter of 2024 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 $52.6 million and $38.8 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, our accumulated deficit was $469.5 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 a strategic partnership to support the commercialization of Omisirge or additional financing, 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. In addition, if we fail to achieve clinical success or obtain regulatory approval of any of our other product candidates in a timely manner, our ability to generate future revenue may 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 June 30, 2023, we have received an aggregate of approximately $37.1 million in grants from the Israeli Innovation Authority, or the IIA, including from the Bereshit Consortium sponsored by the IIA, of which $34.5 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 5% on our gross 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, which was completed by the end of the second quarter of 2023. We incurred charges of approximately $0.8 million for severance and other employee termination related costs, primarily in the second quarter of 2023. We have initiated hiring and other expenditures for the commercialization of Omisirge.

Commercial expenses

Commercial expenses consist primarily of personnel costs, including share-based compensation, related to executive and commercial functions, 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, executives, 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, include our interest expenses associated with our convertible senior notes, the fair value impact on the 2022 Note, the fair value impact on our warrants liability and issuance costs from our April 2023 underwritten public offering, offset by interest income from deposits and marketable securities.

Income taxes

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately $274.9 million (including capital losses of $0.5 million) as of December 31, 2022. In addition, the Subsidiary has a net operating losses carryforward of $37.5 million for federal tax purposes as of December 31, 2022. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We provided a full valuation allowance, to reduce deferred tax assets to their estimated realizable value, since it is more likely than not that all of the deferred tax assets will not be realized.

Analysis of Results of Operations

Comparison of the three months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022:

	Three months ended June 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating Expenses				
Research and development expenses, net[(1)]	$ 8,687	$ 10,563	$ (1,876)	(17.8)%
Commercial expenses[(1)]	3,862	3,193	669	21.0%
General and administrative expenses[(1)]	6,253	4,290	1,963	45.8%
Total operating loss	$ 18,802	$ 18,046	$ 756	4.2%
Financial expenses, net	12,874	508	12,366	2,434.3%
Loss	$ 31,676	$ 18,554	$ 13,122	70.7%

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

	Three months ended June 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Research and development expenses, net	$ 382	$ 553	$ (171)	(30.9)%
Commercial expenses	357	358	(1)	(0.3)%
General and administrative expenses	683	425	258	60.7%
Total share-based compensation	$ 1,422	$ 1,336	$ 86	6.4%

Research and development expenses, net

Research and development expenses, net, decreased by approximately $1.9 million to $8.7 million in the three months ended June 30, 2023 from $10.6 million in the three months ended June 30, 2022. The decrease was attributable mainly to a $1.6 million decrease associated with the discontinuation of development of our engineered NK cell therapy pipeline and $0.7 million in decreased spending associated with the Phase 3 clinical trial of Omisirge, including a decrease in payments for manufacturing services, partially offset by a decrease of $0.4 in IIA income.

Commercial expenses

Our commercial expenses increased by approximately $0.7 million to $3.9 million in the three months ended June 30, 2023, from $3.2 million in the three months ended June 30, 2022. The increase was attributable mainly to an increase in Omisirge launch readiness activities. Given the recent approval of Omisirge, we anticipate our commercial expenses will continue to increase.

General and administrative expenses

General and administrative expenses increased by approximately $2.0 million to $6.3 million in the three months ended June 30, 2023, from $4.3 million in the three months ended June 30, 2022. The increase was attributable to higher professional services expenses, which were incurred in part in connection with our April public offering, and business development related costs.

Financial expenses, net

Financial expenses, net, increased by approximately $12.4 million to $12.9 million in the three months ended June 30, 2023, from $0.5 million in the three months ended June 30, 2022. The increase was mainly attributable to $4.9 million to account for the fair value of our warrants liability, $4.3 million to account for the fair value of the 2022 Note, $1.7 million of issuance costs from our April 2023 underwritten public offering, and an increase of $1.3 million in interest expenses from the 2022 Notes, partially offset by increased interest income.

Comparison of the six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating Expenses				
Research and development expenses, net[(1)]	$ 17,527	$ 21,868	$ (4,341)	(19.9)%
Commercial expenses[(1)]	9,438	7,072	2,366	33.5
General and administrative expenses[(1)]	11,417	8,429	2,988	35.4
Operating loss	38,382	37,369	1,013	2.7
Financial expenses, net	14,254	1,408	12,846	912.4
Loss	$ 52,636	$ 38,777	$ 13,859	35.7

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

	Six Months Ended June 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Research and development expenses, net	$ 796	$ 1,018	$ (222)	(21.8)%
Commercial expenses	691	648	43	6.6
General and administrative expenses	1,434	864	570	66.0
Total share-based compensation	$ 2,921	$ 2,530	$ 391	15.5

Research and development expenses, net

Research and development expenses, net, decreased by approximately $4.3 million to $17.5 million in the six months ended June 30, 2023 from $21.9 million in the six months ended June 30, 2022. The decrease was attributable mainly to a $3.7 million decrease in costs for the Phase 3 clinical trial of Omisirge, including lower payments for manufacturing services, and a decrease of $0.8 million in headcount related expenses associated with the discontinuation of development of our engineered NK cell therapy pipeline, partially offset by increase in GDA-201 clinical activity.

Commercial expenses

Our commercial expenses increased by approximately $2.3 million to $9.4 million in the six months ended June 30, 2023 from $7.1 million in the six months ended June 30, 2022. The increase was attributable mainly to Omisirge commercial launch activities.

General and administrative expenses

General and administrative expenses increased by approximately $3.0 million to $11.4 million in the six months ended June 30, 2023, from $8.4 million in the six months ended June 30, 2022. The increase was attributable to higher professional services expenses, which were incurred in part in connection with our April public offering, and salary-related costs.

Financial expenses, net

Financial expenses, net, increased by approximately $12.9 million to $14.3 million in the six months ended June 30, 2023, compared to $1.4 million in the six months ended June 30, 2022. The increase was mainly attributable to $4.9 million to account for the fair value of the warrants liability, $4.3 million to account for the fair value of the 2022 Note, an increase of $2.6 million in interest expenses from the 2022 Note, and $1.7 million due to issuance costs from our April 2023 underwritten public offering, partially offset by $1.0 million from increased interest income.

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 the commercialization of Omisirge and the clinical development of GDA-201. Historically, substantially all of our efforts were spent on research and clinical development. In the course of such activities, we have sustained operating losses and we expect such losses to continue in the foreseeable future. Our accumulated deficit as of June 30, 2023 was $469.5 million and negative cash flows from operating activities during the six months ended June 30, 2023 was $44.3 million. We are planning to finance our operations from our existing and potential future working capital resources and we continue to evaluate strategic transactions and 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 June 30, 2023, we had total cash and cash equivalents of $54.1 million, and as of August 9, 2023, we had raised additional funds of approximately $14.0 million in net proceeds from and the issuance of shares through our ATM facility. As of August 14, 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 the second quarter of 2024 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 unless such payment is waived by the lender. For April, the principal amortization payment was $0.95 million per month, decreasing to $0.59 million per month commencing July 15, 2023. 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 June 30, 2023, the lender had elected to exchange $14.1 million of outstanding principal amount of the 2022 Note in exchange for 7,356,018 ordinary shares, and we had elected to discharge $1.3 million of related make-whole interest in exchange for the issuance of 1,055,956 ordinary shares and the payment of $1.0 million in cash. Additionally, we made a monthly installment payment of $1.0 million and discharged $0.05 million in related and deferred interest in exchange for the issuance of 1,381,852 ordinary shares. The outstanding principal amount of the 2022 Note was $10.0 million as of June 30, 2023, and as of August 9, 2023, the outstanding principal amount of the 2022 Note is $9.4 million following a monthly installment payment of $0.6 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, production, commercialization 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 six months ended June 30, 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

Liquidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the six months ended June 30, 2023, and June 30, 2022, we incurred a net loss of $52.6 million and $38.8 million, respectively, and net cash of $44.3 million and $39.6, respectively, was used in our operating activities. As of June 30, 2023, and December 31, 2022 we had working capital of $38.1 million and $41.7 million, respectively, and an accumulated deficit of $469.5 million and $416.8 million, respectively. Our principal sources of liquidity as of June 30, 2023, and December 31, 2022, consisted of cash and cash equivalents of $54.1 million and $64.7 million, respectively.

Capital Resources

Overview

Through June 30, 2023, we have financed our operations primarily through private placements and public offerings of equity securities, the 2021 Note, the 2022 Note and through the grants received from the IIA. We have also entered into an Amended & Restated Open Market Sale Agreement[SM] with Jefferies LLC 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 six months ended June 30, 2023, we sold 10,282,870 ordinary shares for net proceeds of $13.8 million, after deducting commissions under our ATM facility. 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.

Cash flows

The following table summarizes our statement of cash flows for the six months ended June 30, 2023 and 2022:

	Six months ended June 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)			
Net cash provided by (used in)				
Operating activities	$ (44,287)	$ (39,589)	$ (4,698)	11.9%
Investing activities	(821)	21,427	(22,248)	(103.8)
Financing activities	34,664	160	34,504	22,565.0

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 consisted mainly of share based compensation, as well as the fair value impacts on our warrants liability and on the 2022 convertible note.

Net cash used in operating activities was $44.3 million during the six months ended June 30, 2023, compared to $39.6 million used in operating activities during the six months ended June 30, 2022. The $4.7 million increase in operating cash used was attributable primarily to higher net interest expense, lower trade payables and lower accrued liabilities.

Net cash used in investing activities was $0.8 million during the six months ended June 30, 2023, compared to $21.4 million provided by investing activities during the six months ended June 30, 2022. The $22.2 million decrease is primarily related to a decrease of $22.5 million of marketable securities used to fund ongoing operating activities.

Net cash provided by financing activities was $34.7 million during the six months ended June 30, 2023, compared to $0.2 million during the six months ended June 30, 2022. The $34.5 million increase is primarily related to net proceeds received from the issuance of ordinary shares and warrants in the April 2023 underwritten public offering and the issuance of shares through the ATM facility in 2023.

Funding Requirements

As of June 30, 2023, we had total cash and cash equivalents of $54.1 million. Although it is difficult to predict future liquidity requirements, we expect our current cash and cash equivalents, including additional net proceeds raised through our ATM facility through August 9, 2023, to support our ongoing operating activities into the second quarter of 2024, 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 are currently marketing Omisirge ourselves in the United States. 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, as well as considering additional financing transactions. 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 expenses. Beginning in April 2023, we began making monthly principal and interest installment payments under the 2022 Note. In April 2023, we made a principal amortization payment of $1.0 million, and such payments were waived in May and June 2023. Beginning July 15, 2023, the amount of the monthly payments decreased from $1.0 to $0.6 million. 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 a strategic partnership to support the commercialization of Omisirge or additional financing, 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 June 30, 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 June 30, 2023. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 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 June 30, 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 June 30, 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 June 30, 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 and we have limited experience 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 and Security 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 commercialize Omisirge and obtain marketing approval for and commercialize GDA-201 and may affect the prices we 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 disasters, power outages or disruptions 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 and we have limited experience 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 completed its pre-licensing inspection of the Kiryat Gat, Israel facility, and there were 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 stem cell transplant 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 the black box warning 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 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. 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.

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.

Omisirge was granted specific ICD-10-PCS codes which map to DRG-014. In addition, CMS did indicate that Omisirge would be reimbursed as a stem cell source for an alloHSCT, and, therefore would be considered an alloHSCT acquisition costs under 42 CFR 412.113(e)(2)(vii), and Medicare's share will be paid under reasonable cost as a donor source under the Section 108 legislation. As a result, we have withdrawn our NTAP application since the Omisirge reimbursement will be covered under Section 108. There is a risk that CMS may modify their coverage and/or reimbursement approach in the future for new therapies, including for Omisirge.

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 June 30, 2023, we had cash and cash equivalents of $54.1 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 transaction, 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 June 30, 2023, we had an accumulated deficit of $469.5 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 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. Additionally, during the three months ended June 30, 2023, the Company raised $8.6 million through the sale and issuance of 6,710,755 shares via its ATM facility, at an average price per ordinary share of $1.31.

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 a strategic partnership or additional financing 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, if approved, GDA-201, 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 certain 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 approximately 17% of our workforce, to better align our workforce with the needs of our business and focus our capital resources on commercial launch of Omisirge. To conserve cash, we also strategically evaluated our arrangements with suppliers and service providers and, 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 United States 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 bank closures 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 and Security 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. 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;
- 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 the Medicare drug price negotiation program is currently subject to legal challenges. 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 approximately 17%, with the majority of impacted employees tied to the discontinuation of the pre-clinical NK cell therapy candidates. We substantially completed 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 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, which may adversely affect our ability to raise capital or complete a strategic transaction. 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.

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 June 30, 2023 hold shares that represent approximately 21% 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 June 30, 2023, the 2021 Notes had an aggregate outstanding balance of approximately $75 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 June 30, 2023, the 2022 Note had an aggregate outstanding balance of $10.0 million. In the second quarter of 2023, Highbridge elected to exchange $8.1 million of outstanding principal amount of the 2022 Note and we issued 4,214,658 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.

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.

Since its inauguration in late 2022, the Israeli government has been pursuing extensive changes to Israel's judicial system. Recently, the Israeli Parliament has enacted an amendment to one of the Basic Laws, narrowing significantly the authority of Israeli courts to apply the "reasonableness" standard of review to acts and omissions of the government and its ministries. These developments have sparked an extensive on-going political debate. In response to the foregoing developments, many individuals, organizations and institutions, both within and outside of Israel, have been voicing concerns that such changes may negatively impact the business environment in Israel, reflected, among other things, in reluctance of foreign investors to invest or transact business in Israel and resulting, among other things, in currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. It is currently unknown to what extent the planned changes in the judicial system will be further promoted nor can it currently be predicted how the recent enactment will affect the Israeli economy and how investors will assess the impact of these changes on it. To the extent that any of the negative developments stated above occur or become more severe, 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. The salaries of our Israeli 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 which 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 asserting U.S. securities laws claims in Israel.

Service of process upon us and enforcement of judgments obtained in the United States against us 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 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.

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 8-K (File No. 001-38716), filed with the SEC on May 19, 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.
10.2*	Amended and Restated Consulting Agreement, entered into as of May 22, 2023, by and between Terry Coelho and Gamida Cell Ltd.
10.3*	Special Transaction Bonus Agreement, dated May 19. 2023, by and between Abbey Jenkins and Gamida Cell Ltd.
10.4*	Retention Bonus and Special Transaction Bonus Agreement, dated May 19. 2023, by and between Michelle Korfin and Gamida Cell Ltd.
10.5*	Retention Bonus and Special Transaction Bonus Agreement, dated May 19. 2023, by and between Josh Patterson and Gamida Cell Ltd.
10.6*	Retention Bonus and Special Transaction Bonus Agreement, dated May 19. 2023, by and between Ronit Simantov and Gamida Cell Ltd.
10.7*	Amended & Restated Open Market Sale Agreement℠, dated June 5, 2023, by and between Jefferies LLC and Gamida Cell Ltd.

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

* Filed herewith.

\# 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.

August 14, 2023

By: /s/ Abigail Jenkins

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

August 14, 2023

By: /s/ Terry Coelho

Terry Coelho
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 10.2

AMENDED & RESTATED CONSULTING AGREEMENT

THIS AMENDED & RESTATED CONSULTING AGREEMENT (the "***Agreement***") is entered into as of May 22, 2023 by and between **Gamida Cell Ltd.**, whose address is at 5 Nahum Heftsadie St., Jerusalem, Israel 9548401 (the "***Company***"), and **Terry Coelho**, an individual (the "***Consultant***").

WHEREAS, Company is in the business of research, development, and commercialization of advanced cell therapies and has a legitimate business need and interest to engage consultants for certain consulting services;

WHERES, the Company previously engaged Consultant to provide financial advisory and consulting services under the Original Agreement (defined below), and now wishes to engage Consultant to provide services in the capacity of Chief Financial Officer under this Agreement, including certain financial and accounting advisory services, and the Consultant has agreed to provide such services in accordance with the terms of this Agreement;

WHEREAS, the Company and Consultant previously entered into that certain Consulting Agreement dated April 14, 2023 (the "***Original Agreement***"), and now desire to amend and restate the Original Agreement effective as of the Effective Date; and

NOW THEREFORE, the parties hereto agree as follows:

1. The Services

1.1 The Company hereby engages the Consultant as an independent consultant and the Consultant hereby agrees to serve as a consultant to the Company and provide the consulting services specified in Schedule 1.1 attached hereto (the "***Services***"), as may be amended from time to time upon the mutual agreement of the parties. The engagement hereunder shall commence on May 22, 2023 (the "***Effective Date***").

1.2 In so far as permitted by Applicable Laws and professional rules and guidance, the Consultant shall cooperate with such employees, consultants and contractors of the Company as determined by the Company from time to time; the person within the Company who shall be in charge of the engagement of the Consultant shall be the Chief Executive Officer or such other person as determined by the Company from time to time. Where the nature of the Services so require, the Company may require from Consultant reports or other types of ongoing information concerning the Services as determined from time to time, whether or not set forth herein.

1.3 Consultant agrees that, during the term of this Agreement, Consultant shall provide Services based on her experience with the matters in relation to which the Services have been agreed between the Parties. Consultant agrees to devote her best efforts to performing the Services promptly and diligently in accordance with this Agreement, Schedule 1.1, and Applicable Laws.

1.4 The Consultant agrees to perform her duties described herein in a faithful, diligent and professional manner.

1.5 Where the nature of the Services so require, the Consultant shall be responsible for maintaining, at the Consultant's own expense, a place of work, any necessary equipment and supplies, and appropriate communications facilities.

1.6 Nothing in this Agreement shall be interpreted as preventing or restricting the Company in obtaining or seeking from any other person services of the same nature as the Services. Nothing in this Agreement shall be interpreted as preventing or restricting Consultant from supplying services to any third party, as long as such services to third parties (i) do not conflict with any obligation or undertaking of the Consultant hereunder, and (ii) do not interfere with the performance of or restrict the ability of the Consultant to perform the Services hereunder. However, Consultant has not and will not, during the term of this Agreement, enter into any agreement that would substantially affect Consultant's ability to provide the Services. Consultant represents that the performance of the Services will not breach any agreement or obligation with any third party, including any obligation to refrain from engaging in activities that may compete with such third party.

1.7 Consultant represents and warrants that Consultant is permitted to enter into this Agreement pursuant to the Applicable Laws and professional rules and guidelines and any policies concerning conflict of interest, competing activities, professional consulting and additional workload. Consultant agrees not to make any use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing the Services, nor take any other action that would result in a third party asserting ownership of, or other rights in, any Records or Inventions related to the Services.

2. Records; Company's Right to Audit.

2.1 Consultant will maintain complete and accurate records, accounts, reports and data pertaining to the Services in accordance with the Applicable Laws and professional rules and guidelines. During the term of this Agreement and for any longer period specified by the Applicable Laws, Consultant will maintain all materials, information, databases and records, accounts, reports, and data obtained or generated by Consultant in the course of providing the Services (collectively, the "***Records***"), including all computerized records and files, in a non-public and secure area, in accordance with Applicable Laws. Company may at any time have access to any and all records for the Services (and will be permitted to make copies thereof). At Company's request, Consultant will cooperate with any regulatory authorities and allow them access to applicable Records and data. Consultant will promptly inform Company of any request or effort by any regulatory authority to review Records and data, or to contact, visit, or inspect Consultant's Records and data, relating to the Services, and will notify Company immediately (and in no event later than within one calendar day) if any regulatory authority issues or gives to Consultant any notice of intent to inspect, notice of inspection, notice of inspectional observations, warning letter, or other written communication concerning the Services, and Consultant immediately (and in no event later than within one calendar day) will provide Company copies thereof. Where reasonable and practical, Company will have the opportunity to be present at such an inspection, at its own cost. Company will have the opportunity to review, revise, and/or approve of any response prior to submission of a response by Consultant to any regulatory authority submitted by Consultant during the course of the inspection. For the avoidance of doubt, Consultant shall not provide any regulatory authority with any documentation or provide regulatory authorities with any undertakings without the prior specific written approval of Company. Consultant shall immediately, and no later than 24 hours after the submission of such documents to the authority, provide Company with copies of all documents provided to any regulatory authority.

2.2 Consultant may not publish or refer to Records, in whole or in part, without the prior express written consent of Company.

3. Confidential Information

3.1 All information provided by Company or on Company's behalf, all data and information collected or generated by Consultant for or on behalf of Company in the performance of the Services and all Records and Inventions, are deemed to be the confidential information of Company ("***Confidential Information***") and will remain the sole and exclusive property of Company. Consultant will not disclose Confidential Information to any third party or use Confidential Information for any purpose other than for the performance of the Services, without the prior written consent of Company. Consultant will exercise due care, but no less than a reasonable degree of care, to prevent the unauthorized disclosure and use of Confidential Information. Confidential Information will not include information that (a) was known by Consultant before disclosure by Company in connection with the Services or this Agreement, with no restriction, (b) is independently discovered by Consultant, after the Effective Date, without use of or access to the Confidential Information, as evidenced by written records, (c) is in the public domain on the Effective Date or subsequently becomes publicly available through no fault or action of Consultant, or (d) is disclosed to Consultant by a third party not known by Consultant to be under any obligation prohibiting the disclosure of such information. If Consultant is required to disclose any Confidential Information or the substance of this Agreement in connection with a legal or administrative proceeding or otherwise to comply with a requirement imposed by the Applicable Laws and Regulations, Consultant will give Company, to the extent legally permissible, prompt notice (prior to disclosure, if possible) of such request so that Company may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If Company seeks a protective order or other remedy, Consultant will, at Company's expense, reasonably cooperate with and assist Company in such efforts. In any case, Consultant will only disclose that portion of Confidential Information that Consultant is advised by its counsel is required to be disclosed.

4. <u>Term and Termination</u>

4.1 This Agreement shall commence upon the Effective Date and shall continue in effect until December 31, 2023, at which time this Agreement will automatically expire.

4.2 This Agreement may be earlier terminated by either party (i) without cause at any time by giving the other Party 30 days' advance written notice, or (ii) for cause upon ten days' prior written notice to the other party specifying the reason for termination; *provided that* the breaching party will have the opportunity to cure the breach to the satisfaction of the non-breaching party during the ten-day notice period.

4.3 Nothing herein shall derogate from the Company's rights with respect to such termination for cause, including the right for set off damages from the Consultant's Consulting Fees (as defined in Section 5.1 below).

4.4 In the event of termination by the Company other than for cause, the Consultant shall be entitled to Consulting Fees only to the extent that she provides the Company with Services during the notice period.

5. Time Commitment; Consideration

5.1 Consultant will provide at least 40 hours of Services per week. In consideration for Consultant's performance of the Services under this Agreement, the Company shall pay the Consultant a consulting fee of (i) $500.00 per hour for the first 25 hours of Services performed by the Consultant in a given week, and (ii) $400.00 per hour for each hour in excess of 25 hours of Services performed by Consultant in a given week (such fees, collectively, the "***Consulting Fee***"). It is acknowledged and agreed that if Consultant and the Company mutually agree to substantially modify the scope of the Services set forth on Schedule 1.1, then the parties will negotiate in good faith and update the applicable consulting fee hourly rate to reflect such modified scope in Services. Consultant will invoice Company on a monthly basis for all Consulting Fees due for Consultant's performance of the Services performed in the prior calendar month. Consultant will include the Consulting Fees and a detailed description of the Services provided on each invoice and will send invoices to the following e-mail address: **ap@gamida-cell.com**. All undisputed payments will be made within 30 days from Company's receipt of Consultant's invoice. The Parties will work together in good faith to promptly resolve any disputes related to invoices. All payments will be made exclusively to the bank account of Consultant. No payment shall be made to a bank account of a third party. Consultant understands and agrees that, if all or part of the Services are not actually and effectively performed, Company has the right to withhold payment, in whole or in part, of the Consulting Fees related to the Services. Consultant shall comply with all Applicable Laws relating to anti-bribery and anti- corruption. It is expressly understood that nothing in this Agreement and no part of the Consulting Fees paid hereunder is intended (i) to be, nor should it be construed as, an obligation or inducement for Consultant, Consultant's employer or the any other person, either expressed or implied, to recommend, endorse, purchase, order, prescribe, promote, administer or otherwise support any particular medicinal or healthcare product or service, or (ii) to compromise Consultant's personal independent judgment or integrity.

5.2 The Consulting Fees are inclusive of any and all taxes, and the Consultant shall bear full responsibility for all tax obligations of any kind or nature relating, directly or indirectly, to the Consulting Fees and otherwise to the Services hereunder. To the extent that any such taxes may be imposed upon the Company, the Company may deduct such amounts from any payments due to the Consultant. The Company shall be entitled to withhold and deduct from payments hereunder any and all amounts as may be required from time to time under any applicable law. VAT shall be charged as required by law.

5.3 The Company shall reimburse the Consultant for any reasonable out of pocket business expenses actually incurred in connection with the Services rendered hereunder, *provided, however*, that the Company approves such expenses in advance. For the purpose of such reimbursement, the Consultant shall be required to maintain records of such expenses, including original invoices, and invoice the Company on a monthly basis.

5.4 In addition, in consideration for Consultant's performance of the Services pursuant to this Agreement, the Company shall recommend to the Board of Directors of the Company that the Consultant be granted options to purchase 10,000 ordinary shares of the Company (the "***Options***"), pursuant to the terms of the Company's Share Incentive Plan and applicable grant agreement, as approved and adopted by the Company Board (the applicable agreement and plan, collectively, the "***Plan***"), which Options shall vest upon the earlier to occur of (i) the date of the closing of a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended)), or (ii) the 12- month anniversary of the Effective Date, *so long as* (x) the Consultant has not provided the Company with notice of termination of this Agreement without cause, or (y) the Company has not provided notice of termination to Consultant for Consultant's breach (and Consultant has failed to cure such breach (if curable) in accordance with Section 4.2), in each case prior to either such applicable vesting date. All matters related to such Options, including but not limited to the exercise price and the required execution of any governing agreement and/or other documentation, shall be subject to the sole discretion of the Company Board. It is understood that nothing herein is intended to constitute a grant of, or right to, any share capital of the Company, and it is hereby confirmed that the Consultant shall be solely responsible for any tax liability incurred in connection with the Options, including but not limited to with respect to the grant, exercise, and/or sale of such Options.

If the Board of Directors of the Company approves a transaction bonus pool program to be used by the Chief Executive Officer (in her sole discretion) to reward certain employees and other personnel for their work related to the consummation of a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended), then the Company will consider, in the Chief Executive Officer's sole discretion, including Consultant as a recipient in such transaction bonus pool program.

5.5 Other than the consideration specified in this Section 5, which consideration constitutes full consideration for the Services rendered hereunder, the Consultant will not be entitled to any other consideration for rendering the Services hereunder.

6. Fees and related transparency obligations.

6.1 Consultant acknowledges and agrees that Company may disclose transfers of value made to Consultant pursuant to this Agreement, including, without limitation, fees and expenses paid by Company for the Services performed by Consultant in accordance with this Agreement, to the extent Company determines, in its sole discretion, that the disclosure thereof is required by the Applicable Laws or by Company's policy.

6.2 Consultant agrees that Company may post or report to any competent authorities all fees and other expenses paid to Consultant under this Agreement without prior notice. Consultant further agrees to provide, at Company's reasonable request, any and all information necessary for Company to make a required posting or reporting. Consultant agrees and covenants to notify Company immediately in the event that Consultant becomes aware that any such reporting by Company is incomplete or inaccurate.

6.3 Consultant agrees that whenever Consultant writes or speaks in public about a matter which relates to the Services, or serves on a committee or governing board that assists in or makes decisions concerning medicinal products, including decisions about reimbursement, or reimbursement levels, Consultant shall disclose the existence and nature of the Consultant's relationship with Company, and, as applicable, follow the procedures set forth by any such committees or governing body in response to such disclosure, which may include recusing the Consultant from discussions or decisions related to Company's products.

7. Confidentiality, Non-Solicitation and Invention Assignment Undertaking Simultaneously with the execution of this Agreement, and a condition hereto, the Consultant hereby signs the Undertaking attached hereto as Schedule 7.

8. Relationship of Parties

8.1 The Parties hereto hereby declare and approve, that the Consultant shall act as an independent contractor, and that nothing in this Agreement shall be interpreted or construed as creating or establishing any partnership, joint venture, employment relationship, franchise or agency or any other similar relationship between the Company or its Affiliates and Consultant or any of her agents and employees, and it is specifically clarified that with respect to the Services, no employer-employee relationship will be formed between the Company or its Affiliates and the Consultant or any of her agents and employees, that the Consultant is not entitled to any social or other benefits resulting from any employer-employee relationship and that the present Agreement shall not obligate the Company or any of its Affiliates by contract or otherwise without the Company's prior written authorization. Consultant shall not make any representations or warranties to anyone without the Company's prior written authorization.

8.2 The Consultant hereby acknowledges that the Company is relying upon the truthfulness and accuracy of the representations set forth in Section 8.1 in engaging the Consultant.

8.3 (a) The Consultant will defend, indemnify and hold the Company, or any third party on its behalf, harmless from and against all claims, damages, losses and expenses, including reasonable fees and expenses of attorneys and other professionals (i) relating to any obligation imposed upon the Company to pay any withholding taxes, social security, unemployment or disability insurance or similar terms in connection with compensation received by Consultant, or which are based upon a stipulation by a competent judicial authority that an employer - employee relationship was created between the Company or its Affiliates and Consultant and/or her agents and employees; and (ii) resulting from any act, omission or negligence on Consultant's or any of her employees' part in the performance or failure to perform the Services under this Agreement.

(b) The Company will indemnify the Consultant in accordance with the Company's standard form of indemnity agreement (the "***Indemnity Agreement***") to be signed contemporaneously herewith.

8.4 Intentionally omitted.

8.5 The Consultant shall be responsible to pay any and all payments, salary, taxes and all other benefits and any amounts due to any relevant social security or similar authority with respect to himself and/or the Services provided by her pursuant to this Agreement.

8.6 The Company will be entitled to deduct from and set off against amounts due to the Consultant pursuant to this Agreement and/or pursuant to any other agreement, law, or otherwise, any amounts, which the Company is required to pay the Consultant pursuant to this Agreement, any other agreement, any law, or otherwise.

9. Warranties

Consultant represents and warrants that:

9.1 The Consultant has not been excluded, suspended, or debarred, from participation in any U.S. federal health care program or human clinical research or any equivalent program or research in the United Kingdom, the EU or individual EU Member States or, to her knowledge, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in Consultant's debarment, suspension, or exclusion.

9.2 Consultant shall not use or exploit, during or in connection with the engagement hereunder any proprietary or confidential information, including any intellectual property, inventions, trade secrets or know how, of any other person or entity, including any previous employer, without due and timely written permission to do so.

10. Miscellaneous

10.1 In this Agreement the term "***Affiliate***" shall mean, any person or entity that directly or indirectly controls, is controlled by, or is under common control with, a party to this Agreement. For purposes hereof, the term "***control***" means the power to direct the management or affairs of a person or entity through the ownership of voting securities, by contract, or otherwise.

10.2 Consultant will perform the Services in a professional and workmanlike manner in compliance with this Agreement and all applicable international, EU, national, local, regional or provincial laws and regulations (collectively "***Applicable Laws***").

10.3 Neither this Agreement nor any interest herein may be assigned by the Consultant without the prior written consent of the Company. The Company may assign or transfer this Agreement or any of its rights and/or obligations under this Agreement without the Consultant's consent.

10.4 This Agreement (including the Indemnity Agreement) constitutes the entire agreement between the Consultant and the Company with respect to the subject matter hereof and supersedes any other arrangement, understanding or agreement, verbal or otherwise with respect to the subject matter hereof (including the Original Agreement). No amendment of or waiver of, or modification of any obligation under this Agreement will be enforceable unless set forth in a writing signed by the parties hereto. No delay or failure to require performance of any provision of this Agreement shall constitute a waiver of that provision as to that or any other instance.

10.5 Law; Jurisdiction. This Agreement shall be governed by the laws of the State of New York, USA (excluding its conflict of law principles) and the competent courts/tribunals of the State of New York, shall have exclusive jurisdiction over any disputes arising hereunder.

10.6 No failure or delay on the part of any party hereto in exercising any right, power or remedy thereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. Any waiver granted thereunder must be in writing and shall be valid only in the specific instance in which given.

10.7 If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the remainder of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

10.8 All notices hereunder will be in writing and shall be given by and be deemed received by the receiving party (i) if sent by a delivery service, on the date confirmed as the actual date of delivery by such service; (ii) if sent by registered air mail, return receipt requested, within seven days of mailing; (iii) if sent by facsimile with electronic confirmation of transmission, on the next business day after transmission, if not transmitted on a business day, or on the day of transmission, if transmitted on a business day; or (iv) if sent by e-mail with an automatic electronic written confirmation of delivery from the sender's server, on the next business day after transmission, if not transmitted on a business day, or on the day of transmission, if transmitted on a business day.

10.9 The provisions of Sections 2.1, 2.2, 3, 4, 6, 7, 8.3, 9 and 10 of this Agreement, including the provisions of Schedule 7, shall continue and remain in full force and effect following the termination or expiration of the relationship between the Company and the Consultant, for whatever reason.

Signature Page Follows

IN WITNESS WHERE OF, the parties have signed this Agreement as of the date hereof.

GAMIDA CELL LTD.

By: /s/ Abigail Jenkins
Abigail Jenkins, President & CEO

TERRY COELHO

By: /s/ Terry Coelho

SCHEDULE 1.1

SERVICES

The Consultant's Services shall consist of:

- Serving the Company in the capacity of (i) Chief Financial Officer and (ii) principle financial and accounting officer, with duties and responsibilities that include:
    - Oversight and management of the Company's financial and accounting function;
    - Participation in meetings of the Company's Audit Committee and Board;
    - Review, approval and certification of the Company's financial statements, quarterly reports on Form 10-Q and, if applicable, annual report on Form 10-K; and
    - All other responsibilities which typically fall within the purview of a public company CFO
- Planning for possibility of restructuring and preparing for BD/MA, including:
    - Creation of an independent cash flow analysis
    - Creation of an independent corporate model/business plan
    - Supporting work of Moelis corporate valuation as appropriate during process
    - Attending GMDA meetings, including EC and BoD meetings for topics relevant to BD/MA, finance, restructuring etc.
    - Support / review VDR and interface with Moelis and legal teams throughout the process
    - Support financing process
- Finance lead on the cross-functional BD team working with Moelis and main finance interface with legal BD and restructuring partners for those topics
- Reports to CEO

The Consultant shall also be reimbursed for reasonable, justified travel expenses for participating in in- person meetings at such rates as the parties shall mutually agree.

SCHEDULE 7

UNDERTAKING

THIS UNDERTAKING ("***Undertaking***") is entered into as of May 22, 2023 by **TERRY COELHO (**the **"*Consultant*").**

WHEREAS: Consultant wishes to be engaged by Gamida Cell Ltd. (the "***Company***"); and

WHEREAS: it is critical for the Company to preserve and protect its Confidential Information (as defined below), its rights in Inventions (as defined below) and in all related intellectual property rights, and Consultant is entering into this Undertaking as a condition to Consultant's engagement with the Company.

NOW, THEREFORE, Consultant undertakes and warrants towards the Company as follows:

References herein to the term "***Company***" shall include any of the Company's direct or indirect parent, subsidiary and affiliated companies, and their respective successors and assigns.

1. Confidentiality.

1.1 Consultant acknowledges that Consultant has had and is expected to have access to information that relates to the Company, its business, assets, financial condition, affairs, activities, plans and projections, customers, suppliers, partners, and other third parties with whom the Company agreed or agrees, from time to time, to hold information of such party in confidence (the "***Confidential Information***"). Confidential Information shall include, without limitation, information, whether or not marked or designated as confidential, concerning technology, products, research and development, patents, copyrights, inventions, trade secrets, test results, formulae, processes, data, know-how, marketing, promotion, business and financial plans, policies, practices, strategies, surveys, analyses and forecasts, financial information, customer lists, agreements, transactions, undertakings and data concerning employees, consultants, officers, directors, and shareholders. Confidential Information includes information in any form or media, whether documentary, written, oral, magnetic, electronically transmitted, through presentation or demonstration or computer generated. Confidential Information shall not include information that has become part of the public domain not as a result of a breach of any obligation owed by Consultant to the Company.

1.2 Consultant acknowledges and understands that the engagement by the Company and the access to Confidential Information creates a relationship of confidence and trust with respect to such Confidential Information.

1.3 During the term of Consultant's engagement and at any time after termination or expiration thereof, for any reason, Consultant shall keep in strict confidence and trust, shall safeguard, and shall not disclose to any person or entity, nor use for the benefit of any party other than the Company, any Confidential Information, other than with the prior express consent of the Company.

1.4 All right, title and interest in and to Confidential Information are and shall remain the sole and exclusive property of the Company or the third party providing such Confidential Information to the Company, as the case may be. Without limitation of the foregoing, Consultant agrees and acknowledges that all memoranda, books, notes, records, email transmissions, charts, formulae, specifications, lists and other documents (contained on any media whatsoever) made, reproduced, compiled, received, held or used by Consultant in connection with the engagement by the Company or that otherwise relates to any Confidential Information (the "***Confidential Materials***"), shall be the Company's sole and exclusive property and shall be deemed to be Confidential Information. All originals, copies, reproductions and summaries of the Confidential Materials shall be delivered by Consultant to the Company upon termination or expiration of Consultant's engagement for any reason, or at any earlier time at the request of the Company, without Consultant retaining any copies thereof.

1.5 During the term of Consultant's engagement with the Company, Consultant shall not remove from the Company's offices or premises any Confidential Materials unless and to the extent necessary in connection with the duties and responsibilities of Consultant and permitted pursuant to the then applicable policies and regulations of the Company. In the event that such Confidential Material is duly removed from the Company's offices or premises, Consultant shall take all actions necessary in order to secure the safekeeping and confidentiality of such Confidential Materials and return the Confidential Materials to their proper files or location as promptly as possible after such use.

1.6 During the term of Consultant's engagement with the Company, Consultant will not improperly use or disclose any proprietary or confidential information or trade secrets, and will not bring onto the premises of the Company any unpublished documents or any property, in each case belonging to any former employer or any other person to whom Consultant has an obligation of confidentiality and/or non-use (including, without limitation, any academic institution or any entity related thereto), unless generally available to the public or consented to in writing by that person.

2. Non- Solicitation.

2.1 Consultant undertakes that during the term of engagement with the Company and for a period of 12 months thereafter: (i) Consultant shall not, directly or indirectly, solicit, hire or retain as an employee, consultant or otherwise, any employee of the Company or induce or attempt to induce any such employee to terminate or reduce the scope of such employee's engagement with the Company; and (ii) Consultant shall not, directly or indirectly, solicit or induce, or attempt to solicit or induce, any consultant, service provider, agent, distributor, customer or supplier of the Company to terminate, reduce or modify the scope of such person's engagement with the Company.

2.2 Consultant acknowledges that in view of Consultant's exposure to, and involvement in, the Company's sensitive and valuable proprietary information, property (including, intellectual property) and technologies, as well as its goodwill and business plans (the "***Company's Major Assets***"), the provisions of this Section 2 above are reasonable and necessary to legitimately protect the Company's Major Assets, and are being undertaken by Consultant as a condition to the engagement of Consultant by the Company. Consultant confirms that Consultant has carefully reviewed the provisions of this Section 2, fully understands the consequences thereof, and has assessed the respective advantages and disadvantages to Consultant of entering into this Undertaking and, specifically, Section 2 hereof.

3. Ownership of Inventions.

3.1 Consultant will notify and disclose in writing to the Company, or any persons designated by the Company from time to time, all information, improvements, inventions, formulae, processes, techniques, know-how and data, whether or not patentable or registerable under copyright or any similar laws, made or conceived or reduced to practice or learned by Consultant, either alone or jointly with others, in the performance of Consultant's engagement with the Company (all such information, improvements, inventions, formulae, processes, techniques, know- how, and data are hereinafter referred to as the "***Invention(s)***") immediately upon discovery, receipt or invention as applicable.

3.2 Consultant agrees that all the Inventions are, upon creation, considered Inventions of the Company, shall be the sole property of the Company and its assignees, and the Company and its assignees shall be the sole owner of all patents, copyrights, trade secret and all other rights of any kind or nature, including moral rights, in connection with such Inventions. Consultant hereby irrevocably and unconditionally assigns to the Company all the following with respect to any and all Inventions: (i) patents, patent applications, and patent rights, including any and all continuations or extensions thereof; (ii) rights associated with works of authorship, including copyrights and copyright applications, Moral Rights (as defined below) and mask work rights; (iii) rights relating to the protection of trade secrets and confidential information; (iv) design rights and industrial property rights; (v) any other proprietary rights relating to intangible property including trademarks, service marks and applications therefor, trade names and packaging and all goodwill associated with the same; and (vi) all rights to sue for any infringement of any of the foregoing rights and the right to all income, royalties, damages and payments with respect to any of the foregoing rights. Consultant also hereby forever waives and agrees never to assert any and all Moral Rights Consultant may have in or with respect to any Inventions, even after termination of engagement on behalf of the Company. "***Moral Rights***" means any right to claim authorship of a work, any right to object to any distortion or other modification of a work, and any similar right, existing under the law of any country in the world, or under any treaty.

3.3 Consultant further agrees to perform, during and after engagement, all acts deemed reasonably necessary or desirable by the Company to permit and assist it, at the Company's expense, in obtaining, maintaining, defending and enforcing the Inventions in any and all countries. Such acts may include, but are not limited to, execution of documents and assistance or cooperation in legal proceedings. Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Consultant's agents and attorneys-in-fact to act for and on Consultant's behalf and instead of Consultant, to execute and file any documents and to do all other lawfully permitted acts to further the above purposes with the same legal force and effect as if executed by Consultant.

3.4 Consultant shall not be entitled, with respect to all of the above, to any monetary consideration or any other consideration except as explicitly set forth in the consulting agreement between Consultant and the Company. Without limitation of the foregoing, Consultant irrevocably confirms that the consideration explicitly set forth in this agreement is in lieu of any rights for compensation that may arise in connection with the Inventions under applicable law and waives any right to claim royalties or other consideration with respect to any Invention, including under Section 134 of the Israeli Patent Law - 1967. With respect to all of the above, any oral understanding, communication or agreement not memorialized in writing and duly signed by the Company shall be void.

4. <u>General</u>.

4.1 Consultant represents that the performance of all the terms of this Undertaking and Consultant's duties as a consultant of the Company does not and will not breach any invention assignment, proprietary information, non-compete, confidentiality or similar agreements with, or rules, regulations or policies of, any former employer or other party (including, without limitation, any academic institution or any entity related thereto). Consultant acknowledges that the Company is relying upon the truthfulness and accuracy of such representations in engaging Consultant.

4.2 Consultant acknowledges that the provisions of this Undertaking serve as an integral part of the terms of Consultant's engagement and reflect the reasonable requirements of the Company in order to protect its legitimate interests with respect to the subject matter hereof.

4.3 Consultant recognizes and acknowledges that in the event of a breach or threatened breach of this Undertaking by Consultant, the Company may suffer irreparable harm or damage and will, therefore, be entitled to injunctive relief to enforce this Undertaking (without limitation to any other remedy at law or in equity).

4.4 This Undertaking is governed by the laws of State of New York, USA (excluding its conflict of law principles), and the competent courts/tribunals of the State of New York shall have exclusive jurisdiction over any disputes arising hereunder

4.5 If any provision of this Undertaking is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Undertaking and the remainder of this Undertaking shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Undertaking shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction. In addition, if any particular provision contained in this Undertaking shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing the scope of such provision so that the provision is enforceable to the fullest extent compatible with applicable law.

4.6 The provisions of this Undertaking shall continue and remain in full force and effect following the termination or expiration of the relationship between the Company and Consultant, for whatever reason. This Undertaking shall not serve in any manner so as to derogate from any of Consultant's obligations and liabilities under any applicable law.

4.7 This Undertaking constitutes the entire agreement between Consultant and the Company with respect to the subject matter hereof. No amendment of or waiver of, or modification of any obligation under this Undertaking will be enforceable unless set forth in a writing signed by the Company. No delay or failure to require performance of any provision of this Undertaking shall constitute a waiver of that provision as to that or any other instance. No waiver granted under this Undertaking as to any one provision herein shall constitute a subsequent waiver of such provision or of any other provision herein, nor shall it constitute the waiver of any performance other than the actual performance specifically waived.

4.8 This Undertaking, the rights of the Company hereunder, and the obligations of Consultant hereunder, will be binding upon and inure to the benefit of their respective successors, assigns, heirs, executors, administrators and legal representatives. The Company may assign any of its rights under this Undertaking. Consultant may not assign, whether voluntarily or by operation of law, any of her obligations under this Undertaking, except with the prior written consent of the Company.

IN WITNESS WHEREOF, the undersigned, has executed this Undertaking as of the date first mentioned above.

CONSULTANT

Printed Name: **TERRY COELHO** Signature: /s/ Terry coelho

Exhibit 10.3

May 19, 2023

Abigail Jenkins
President & Chief Executive Officer
116 Huntington Avenue, 7th Floor
Boston, MA 02116

Re: Special Transaction Bonus

Dear Abbey:

In recognition of the critical role you have played with Gamida Cell Inc. (the "Company") and will continue to play in the Company's (or its affiliate, Gamida Cell Ltd.'s) efforts to consummate either (x) an exclusive license agreement with a third party to commercialize Omisirge® (omidubicel-onlv), or (y) a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended)) (each of (x) and (y), a "***Corporate Transaction***"), we are pleased to offer you the opportunity to earn a special transaction bonus of Two Hundred Eighty-Seven Thousand Five Hundred Dollars ($287,500.00), less applicable withholdings (the "***Special Transaction Bonus***").

Therefore, if you are employed by the Company in good standing on the date the Company or its affiliate, Gamida Cell Ltd., closes a Corporate Transaction (the "Closing Date"), then within 60 days after the Closing Date, the Company or the Acquirer (if applicable) will pay you the Special Transaction Bonus. For the avoidance of doubt, if you resign from the Company or are terminated by the Company for Cause, in each case prior to the Closing Date, then you will not be eligible to receive, and will not be paid, any portion of the Special Transaction Bonus.

For purposes of this letter, "***Cause***" for termination will mean: (a) your commission of any felony or crime involving dishonesty; (b) your participation in any fraud against the Company or an Acquirer; (c) material breach of your duties to the Company or an Acquirer; (d) your persistent unsatisfactory performance of job duties after written notice from the your supervisor or manager and a reasonable opportunity to cure (if deemed curable); (e) your intentional damage to any property of the Company or an Acquirer; (f) your misconduct, or other violation of Company or Acquirer policy that causes harm; (g) your breach of any written agreement with the Company or an Acquirer; or (h) conduct by you which in the good faith and reasonable determination of the Company or an Acquirer demonstrates gross unfitness to serve.

For purposes of this letter, an "***Acquirer***" shall mean the acquiring company in any Merger/Sale, as such term is defined under the Company's 2017 Share Incentive Plan (as amended).

Please note that this letter relates only to the terms and conditions under which the Special Transaction Bonus may become earned and payable to you and does not constitute a guarantee of employment for any specified period of time or modify any other aspects of your employment terms and conditions, including your at-will employment. This Special Transaction Bonus shall not affect any other bonuses for which you are eligible.

Thank you again for your hard work and for continuing to make Gamida Cell a successful company.

Sincerely,

Gamida Cell Inc.

By: /s/ Shawn Tomasello
Shawn Tomasello
Chairwoman of the Board

By my signature below, I accept all the terms of the Special Transaction Bonus offer set forth herein.

/s/ Abigail Jenkins
Abigail Jenkins

5/19/2023
Date

Exhibit 10.4

May 19, 2023

Michele Korfin
Chief Operating and Chief Commercial Officer
116 Huntington Avenue, 7th Floor
Boston, MA 02116

Re: Retention Bonus and Special Transaction Bonus

Dear Michele:

Retention Bonus

In recognition of the critical role you have played with Gamida Cell Inc. (the "***Company***") and will continue to play, we are pleased to offer you a special retention bonus of One Hundred Ninety-Two Thousand Two Hundred Eighty Dollars ($192,280.00), less applicable withholdings (the "***Retention Bonus***"). The Company agrees to advance you the Retention Bonus, prior to it being earned, within the next regularly scheduled payroll cycle after May 31, 2023.

To earn the Retention Bonus, you must remain continuously employed by the Company or an Acquirer (as defined herein) in good standing through the earlier of (a) the date the Company or an Acquirer terminates your employment without Cause (as defined herein) or (b) January 30, 2024.

Should any of the foregoing conditions not be met and you fail to earn the Retention Bonus, you agree to repay the gross amount of the entire Retention Bonus to the Company within ten (10) days after written demand from the Company. The Company may recover its attorneys' fees and costs if you fail to timely repay the Retention Bonus, if applicable. You will not be eligible to earn any portion of the Retention Bonus if your employment terminates for any reason prior to the date the Retention Bonus is earned, excluding the Company or an Acquirer terminating your employment without Cause.

For purposes of this letter, "***Cause***" for termination will mean: (a) your commission of any felony or crime involving dishonesty; (b) your participation in any fraud against the Company or an Acquirer; (c) material breach of your duties to the Company or an Acquirer; (d) your persistent unsatisfactory performance of job duties after written notice from the your supervisor or manager and a reasonable opportunity to cure (if deemed curable); (e) your intentional damage to any property of the Company or an Acquirer; (f) your misconduct, or other violation of Company or Acquirer policy that causes harm; (g) your breach of any written agreement with the Company or an Acquirer; or (h) conduct by you which in the good faith and reasonable determination of the Company or an Acquirer demonstrates gross unfitness to serve.

For purposes of this letter, an "***Acquirer***" shall mean the acquiring company in any Merger/Sale, as such term is defined under the Company's 2017 Share Incentive Plan (as amended).

Special Transaction Bonus

In addition, in recognition of the critical role you will play in the Company's efforts to consummate either (x) an exclusive license agreement with a third party to commercialize Omisirge® (omidubicel-onlv), or (y) a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended)) (each of (x) and (y), a "***Corporate Transaction***"), we are pleased to offer you the opportunity to earn a special transaction bonus of One Hundred Ninety-Two Thousand Two Hundred Eighty Dollars ($192,280.00), less applicable withholdings (the "***Special Transaction Bonus***").

Therefore, if you are employed by the Company in good standing on the date the Company or its affiliate, Gamida Cell Ltd., closes a Corporate Transaction (the "***Closing Date***"), then within 60 days after the Closing Date, the Company or the Acquirer (if applicable) will pay you the Special Transaction Bonus. For the avoidance of doubt, if you resign from the Company or are terminated by the Company for Cause, in each case prior to the Closing Date, then you will not be eligible to receive, and will not be paid, any portion of the Special Transaction Bonus.

Please note that this letter relates only to the terms and conditions under which the Retention Bonus and Special Transaction Bonus may become earned and payable to you and does not constitute a guarantee of employment for any specified period of time or modify any other aspects of your employment terms and conditions, including your at-will employment. This Retention Bonus and Special Transaction Bonus shall not affect any other bonuses for which you are eligible.

Thank you again for your hard work and for continuing to make Gamida Cell a successful company.

Sincerely,

Gamida Cell Inc.

By: /s/ Abigail Jenkins
Abigail Jenkins
President & Chief Executive Officer

By my signature below, I accept all the terms of the Retention Bonus and Special Transaction Bonus offer set forth herein.

/s/ Michele Korfin
Michele Korfin

5/20/2023
Date

Exhibit 10.5

May 19, 2023

Josh Patterson
General Counsel & Chief Compliance Officer
116 Huntington Avenue, 7th Floor
Boston, MA 02116

Re: Retention Bonus and Special Transaction Bonus

Dear Josh:

Retention Bonus

In recognition of the critical role you have played with Gamida Cell Inc. (the "***Company***") and will continue to play, we are pleased to offer you a special retention bonus of One Hundred Eighty Thousand Dollars ($180,000.00), less applicable withholdings (the "***Retention Bonus***"). The Company agrees to advance you the Retention Bonus, prior to it being earned, within the next regularly scheduled payroll cycle after May 31, 2023.

To earn the Retention Bonus, you must remain continuously employed by the Company or an Acquirer (as defined herein) in good standing through the earlier of (a) the date the Company or an Acquirer terminates your employment without Cause (as defined herein) or (b) January 30, 2024.

Should any of the foregoing conditions not be met and you fail to earn the Retention Bonus, you agree to repay the gross amount of the entire Retention Bonus to the Company within ten (10) days after written demand from the Company. The Company may recover its attorneys' fees and costs if you fail to timely repay the Retention Bonus, if applicable. You will not be eligible to earn any portion of the Retention Bonus if your employment terminates for any reason prior to the date the Retention Bonus is earned, excluding the Company or an Acquirer terminating your employment without Cause.

For purposes of this letter, "***Cause***" for termination will mean: (a) your commission of any felony or crime involving dishonesty; (b) your participation in any fraud against the Company or an Acquirer; (c) material breach of your duties to the Company or an Acquirer; (d) your persistent unsatisfactory performance of job duties after written notice from the your supervisor or manager and a reasonable opportunity to cure (if deemed curable); (e) your intentional damage to any property of the Company or an Acquirer; (f) your misconduct, or other violation of Company or Acquirer policy that causes harm; (g) your breach of any written agreement with the Company or an Acquirer; or (h) conduct by you which in the good faith and reasonable determination of the Company or an Acquirer demonstrates gross unfitness to serve.

For purposes of this letter, an "***Acquirer***" shall mean the acquiring company in any Merger/Sale, as such term is defined under the Company's 2017 Share Incentive Plan (as amended).

Special Transaction Bonus

In addition, in recognition of the critical role you will play in the Company's efforts to consummate either (x) an exclusive license agreement with a third party to commercialize Omisirge® (omidubicel-onlv), or (y) a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended)) (each of (x) and (y), a "***Corporate Transaction***"), we are pleased to offer you the opportunity to earn a special transaction bonus of One Hundred Eighty Thousand Dollars ($180,000.00), less applicable withholdings (the "***Special Transaction Bonus***").

Therefore, if you are employed by the Company in good standing on the date the Company or its affiliate, Gamida Cell Ltd., closes a Corporate Transaction (the "***Closing Date***"), then within 60 days after the Closing Date, the Company or the Acquirer (if applicable) will pay you the Special Transaction Bonus. For the avoidance of doubt, if you resign from the Company or are terminated by the Company for Cause, in each case prior to the Closing Date, then you will not be eligible to receive, and will not be paid, any portion of the Special Transaction Bonus.

Please note that this letter relates only to the terms and conditions under which the Retention Bonus and Special Transaction Bonus may become earned and payable to you and does not constitute a guarantee of employment for any specified period of time or modify any other aspects of your employment terms and conditions, including your at-will employment. This Retention Bonus and Special Transaction Bonus shall not affect any other bonuses for which you are eligible.

Thank you again for your hard work and for continuing to make Gamida Cell a successful company.

Sincerely,

Gamida Cell Inc.

By: /s/ Abigail Jenkins
Abigail Jenkins
President & Chief Executive Officer

By my signature below, I accept all the terms of the Retention Bonus and Special Transaction Bonus offer set forth herein.

/s/ Josh Patterson
Josh Patterson

5/19/2023
Date

Exhibit 10.6

May 19, 2023

Ronit Simantov
Medical and Chief Scientific Officer
116 Huntington Avenue, 7th Floor
Boston, MA 02116

Re: Retention Bonus and Special Transaction Bonus

Dear Ronit:

Retention Bonus

In recognition of the critical role you have played with Gamida Cell Inc. (the "***Company***") and will continue to play, we are pleased to offer you a special retention bonus of One Hundred Ninety-Two Thousand Two Hundred Eighty Dollars ($192,280.00), less applicable withholdings (the "***Retention Bonus***"). The Company agrees to advance you the Retention Bonus, prior to it being earned, within the next regularly scheduled payroll cycle after May 31, 2023.

To earn the Retention Bonus, you must remain continuously employed by the Company or an Acquirer (as defined herein) in good standing through the earlier of (a) the date the Company or an Acquirer terminates your employment without Cause (as defined herein) or (b) January 30, 2024.

Should any of the foregoing conditions not be met and you fail to earn the Retention Bonus, you agree to repay the gross amount of the entire Retention Bonus to the Company within ten (10) days after written demand from the Company. The Company may recover its attorneys' fees and costs if you fail to timely repay the Retention Bonus, if applicable. You will not be eligible to earn any portion of the Retention Bonus if your employment terminates for any reason prior to the date the Retention Bonus is earned, excluding the Company or an Acquirer terminating your employment without Cause.

For purposes of this letter, "***Cause***" for termination will mean: (a) your commission of any felony or crime involving dishonesty; (b) your participation in any fraud against the Company or an Acquirer; (c) material breach of your duties to the Company or an Acquirer; (d) your persistent unsatisfactory performance of job duties after written notice from the your supervisor or manager and a reasonable opportunity to cure (if deemed curable); (e) your intentional damage to any property of the Company or an Acquirer; (f) your misconduct, or other violation of Company or Acquirer policy that causes harm; (g) your breach of any written agreement with the Company or an Acquirer; or (h) conduct by you which in the good faith and reasonable determination of the Company or an Acquirer demonstrates gross unfitness to serve.

For purposes of this letter, an "***Acquirer***" shall mean the acquiring company in any Merger/Sale, as such term is defined under the Company's 2017 Share Incentive Plan (as amended).

Special Transaction Bonus

In addition, in recognition of the critical role you will play in the Company's efforts to consummate either (x) an exclusive license agreement with a third party to commercialize Omisirge® (omidubicel-onlv), or (y) a Merger/Sale (as such term is defined under the Company's 2017 Share Incentive Plan (as amended)) (each of (x) and (y), a "***Corporate Transaction***"), we are pleased to offer you the opportunity to earn a special transaction bonus of One Hundred Ninety-Two Thousand Two Hundred Eighty Dollars ($192,280.00), less applicable withholdings (the "***Special Transaction Bonus***").

Therefore, if you are employed by the Company in good standing on the date the Company or its affiliate, Gamida Cell Ltd., closes a Corporate Transaction (the "***Closing Date***"), then within 60 days after the Closing Date, the Company or the Acquirer (if applicable) will pay you the Special Transaction Bonus. For the avoidance of doubt, if you resign from the Company or are terminated by the Company for Cause, in each case prior to the Closing Date, then you will not be eligible to receive, and will not be paid, any portion of the Special Transaction Bonus.

Please note that this letter relates only to the terms and conditions under which the Retention Bonus and Special Transaction Bonus may become earned and payable to you and does not constitute a guarantee of employment for any specified period of time or modify any other aspects of your employment terms and conditions, including your at-will employment. This Retention Bonus and Special Transaction Bonus shall not affect any other bonuses for which you are eligible.

Thank you again for your hard work and for continuing to make Gamida Cell a successful company.

Sincerely,

Gamida Cell Inc.

By: /s/ Abigail Jenkins
Abigail Jenkins
President & Chief Executive Officer

By my signature below, I accept all the terms of the Retention Bonus and Special Transaction Bonus offer set forth herein.

/s/ Ronit Simantov
Josh Patterson

5/21/2023
Date

Exhibit 10.7

Execution Version

AMENDED & RESTATED

OPEN MARKET SALE AGREEMENT[SM]

June 5, 2023

JEFFERIES LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

Gamida Cell Ltd., a limited liability company organized under the laws of the State of Israel (the "**Company**"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "**Agent**"), shares of the Company's ordinary shares with a nominal value of New Israeli Shekel 0.01 per share (the "**Ordinary Shares**"), on the terms set forth in this amended and restated agreement (this "**Agreement**"), which amends and supersedes the Open Market Sale Agreement between the parties entered into on September 10, 2021.

Section 1. DEFINITIONS

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

"**Affiliate**" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first-mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agency Period**" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

"**Commission**" means the U.S. Securities and Exchange Commission.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

"**Floor Price**" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less than $1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

[SM] "Open Market Sale Agreement" is a service mark of Jefferies LLC

"**Issuance Amount**" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

"**Issuance Notice**" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President or Chief Financial Officer.

"**Issuance Notice Date**" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"**Issuance Price**" means the Sales Price less the Selling Commission.

"**Maximum Program Amount**" means Ordinary Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Ordinary Shares registered under the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Ordinary Shares (less Ordinary Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized share capital), (c) the number or dollar amount of Ordinary Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Ordinary Shares for which the Company has filed a Prospectus (as defined below).

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"**Principal Market**" means the Nasdaq Global Market or such other national securities exchange in the United States on which the Ordinary Shares, including any Shares, are then listed.

"**Sales Price**" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"**Selling Commission**" means three percent (3.0%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

"**Settlement Date**" means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"**Shares**" means the Company's Ordinary Shares issued or issuable pursuant to this Agreement.

"**Trading Day**" means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date (as defined below) and (5) as of each Time of Sale (as defined below) (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed with the Commission a shelf registration statement on Form S-3 (File No. 333-259472) that contains a base prospectus. Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "**Registration Statement**," and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "**Prospectus**," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "**Prospectus**" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally was declared effective is herein called the "**Original Registration Statement**." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Original Registration Statement was or will be declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. The Original Registration Statement and any Rule 462(b) Registration Statement have been declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied or will comply in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became effective and at each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "**Time of Sale Information**") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Ineligible Issuer Status. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent's prior consent, prepare, use or refer to, any Free Writing Prospectus.

(d) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(e) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Time of Sale, as the case may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) Due Incorporation; Subsidiaries. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Israel. The Company has full power and authority to conduct all the activities conducted by it, to own or lease all the assets owned or leased by it and to conduct its business as described in the Registration Statement and the Prospectus. The Company is duly licensed or qualified to do business in and in good standing as a foreign corporation in all jurisdictions in which the nature of the activities conducted by it or the character of the assets owned or leased by it makes such licensing or qualification necessary, except where the failure to be so qualified or in such good standing would not, individually or in the aggregate, result in a Material Adverse Change. The memorandum and articles of association and other constitutive or organizational documents of the Company comply with the requirements of applicable Israeli law and are in full force and effect. Each subsidiary (as used in this Section 2, "subsidiary" has the meaning set forth in Rule 405 under the Securities Act) of the Company has been duly incorporated or organized, is validly existing as a corporation in good standing under the laws of the jurisdiction of its organization, has the corporate power and authority to own its property and to conduct its business as described in the Registration Statement and Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued share capital or other equity interests of each subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly by the Company, free and clear of all liens, charges, encumbrances, equities, security interests, restrictions on voting or transfer or any other claims. None of the outstanding capital stock or equity interest in any subsidiary was issued in violation of preemptive or similar rights of any security holder of such subsidiary. The constitutive or organizational documents of each of the subsidiaries comply in all material respects with the requirements of applicable laws of its jurisdiction of incorporation or organization and are in full force and effect. No subsidiary is currently prohibited, directly or indirectly under any agreement or instrument to which it is a party or is subject, from paying any dividends to its shareholders, from repaying the Company or any other subsidiary of the Company any loans or advances to such subsidiary from the Company or such other subsidiary or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in the Company's most recently filed Form 10-K.

(g) Capitalization. The authorized, issued and outstanding share capital of the Company is as set forth in the Registration Statement and Prospectus under the caption "**Capitalization**." The outstanding Ordinary Shares and any other outstanding share capital of the Company have been, and the Shares will be, duly authorized, validly issued, fully paid and non-assessable, issued in compliance with all federal and state securities laws and not be subject to any preemptive, first refusal, or similar right. The description of the Ordinary Shares included in the Registration Statement and Prospectus is complete and accurate in all material respects. Except as set forth in the Registration Statement and Prospectus, the Company does not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or any contracts or commitments to issue or sell, any securities of the Company or any such warrants, convertible securities or obligations. Except as set forth in the Registration Statement and Prospectus, there are no stockholder agreements, voting agreements or other similar agreements with respect to the Company's share capital to which the Company is a party or, to the Company's knowledge, between or among any of the Company's shareholders. Upon the issuance and delivery pursuant to the terms of this Agreement, the Agent will acquire good and marketable title to the Shares, free and clear of any lien, charge, claim, encumbrance, pledge, security interest, defect or other restriction or equity of any kind whatsoever. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights.

(h) Financial Statements. The financial statements of the Company (including the related notes thereto) and schedules included in the Registration Statement and Prospectus present fairly in all material respects the financial condition of the Company and its consolidated subsidiary as of the respective dates thereof and their results of operations and cash flows for the respective periods covered thereby, all in conformity with accounting principles generally accepted in the United States ("GAAP") on a consistent basis throughout the entire period involved. The selected financial data and the summary financial information included in the Registration Statement and Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the financial statements included therein and the books and records of the Company and its consolidated subsidiary. The pro forma financial statements, if any, and the other pro forma financial information included in the Registration Statement and Prospectus present fairly in all material respects the information shown therein, have been prepared in accordance with the Commission's rules and guidelines with respect to pro forma financial statements and have been properly computed on the bases described therein. The assumptions used in the preparation of the pro forma financial statements, if any, and other pro forma financial information included in the Registration Statement and Prospectus are reasonable and the adjustments used therein are appropriate to give effect to the transactions or circumstances referred to therein. No other financial statements, schedules or reconciliations of "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) of the Company are required by the Securities Act to be included in the Registration Statement and Prospectus.

(i) Independent Accountants. Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global (the "**Accountants**"), who certified the financial statements and supporting schedules of the Company and its consolidated subsidiary included in the Registration Statement and Prospectus, are (i) independent accountants as required by the Securities Act and by the rules of the Public Company Accounting Oversight Board (United States) (the "**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act, and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(j) No Material Adverse Changes. Since the respective dates as of which information is given in the Registration Statement and the Prospectus, except as set forth in the Registration Statement and Prospectus, (i) there has not been a material adverse change, or any development that would be expected to result in a material adverse change, (a) in or affecting the business, properties, assets, management, business prospects, earnings, rights, condition (financial or otherwise), results of operations, capitalization or long-term debt of the Company and its subsidiaries, taken as a whole, arising for any reason whatsoever or (b) the ability of the Company to consummate the transactions contemplated by this Agreement or perform its obligations hereunder (any such change being referred to herein as a "**Material Adverse Change**"), (ii) the Company has not incurred, nor will it incur, any material liabilities or obligations, direct or contingent, nor has it entered into, nor will it enter into, any material transactions not in the ordinary course of business, other than pursuant to this Agreement and the transactions referred to herein, (iii) the Company has not and will not have paid, declared, set aside for payment or made any dividends or other distributions of any kind on any class of its share capital, (iv) there has not been any material decrease in the share capital or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries, or any repurchase or redemption by the Company or any of its subsidiaries of any share capital, and (v) the Company has not altered its method of accounting.

(k) Investment Company. Each of the Company and its subsidiaries is not, and, after giving effect to the issuance and sale of the Shares and the use of the proceeds therefrom as described in the Registration Statement or the Prospectus, will not be, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**"), and the rules and regulations of the Commission promulgated thereunder.

(l) Litigation. Except as set forth in the Registration Statement and Prospectus, there are no actions, suits or proceedings pending, or to the Company's knowledge, threatened against or affecting, the Company or any of its subsidiaries or any of their respective officers in their capacity as such, before or by any foreign, federal or state court, commission, regulatory body, including, but not limited to, the Financial Industry Regulatory Authority, Inc. ("**FINRA**") and the Nasdaq Stock Market LLC, administrative agency or other governmental body, domestic or foreign, wherein an unfavorable ruling, decision or finding could reasonably be expected to result in a Material Adverse Change. The Company has not received any written notice of proceedings relating to the revocation or modification of any authorization, approval, order, license, certificate, franchise or permit, where such revocation or modification would reasonably be expected to result in a Material Adverse Change. There are no pending investigations known to the Company involving the Company by any governmental agency having jurisdiction over the Company or its business or operations that would reasonably be expected to result in a Material Adverse Change.

(m) Compliance with Laws and Regulations and Performance of Obligations and Contracts. The Company and its subsidiaries have (i) complied in all material respects with all laws, regulations and orders applicable to it or its business and (ii) performed all obligations required to be performed by it, and is not in default under any indenture, mortgage, deed of trust, voting trust agreement, loan agreement, bond, debenture, note agreement, lease or other agreement or instrument (individually, a "**Contract**" and collectively, "**Contracts**") to which it is a party or by which its property is bound or affected, in any such case which default or event, individually or in the aggregate, would have a Material Adverse Change. To the knowledge of the Company, no other party under any Contract to which it is a party is in default in any respect thereunder or has given written or oral notice to the Company or any of its officers or directors of such other party's intention to terminate, cancel or refuse to renew any Contract. The Company is not in violation of any provision of its articles of association or memorandum of association. The disclosures included in the Registration Statement and Prospectus concerning the effects of federal, state, local and foreign laws, rules and regulations on the business of the Company as currently conducted and as proposed to be conducted are correct in all material respects.

(n) No Consent of Governmental Body Needed. No consent, approval, authorization, license, registration, qualification or order of, or any filing or declaration with, any court or arbitrator or governmental or regulatory authority, agency or body is required in connection with the authorization, issuance, transfer, sale or delivery of the Shares by the Company, in connection with the execution, delivery and performance of this Agreement by the Company or in connection with the taking by the Company of any action contemplated hereby, except as have been obtained under the Securities Act and such as may be required under state securities or blue sky laws or the by-laws and rules of FINRA and the Nasdaq Stock Market LLC in connection with the purchase and distribution by the Agent of the Shares to be sold by the Company except for (a) formal authorization from the Israel Innovation Authority (formerly the Office of the Chief Scientist) of the Israeli Ministry of Economy and Industry, and (b) certain post-closing filings to be filed with the Israeli Registrar of Companies.

(o) Agreement Duly Authorized. The Company has full corporate power and authority to enter into this Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(p) No Conflicts. The execution and delivery by the Company of this Agreement and the performance of this Agreement, the consummation of the transactions contemplated hereby, and the application of the net proceeds from the offering and sale of the Shares to be sold in the manner set forth in the Registration Statement and the Prospectus under "Use of Proceeds" do not and will not (i) violate the memorandum or articles of association of the Company or (ii) result in the creation or imposition of any lien, charge or encumbrance upon any of the assets of the Company or its subsidiaries pursuant to the terms or provisions of, or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or give any other party a right to terminate any of its obligations under, or result in the acceleration of any obligation under any Contract to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries or any of its properties is bound or affected, or violate or conflict with any judgment, ruling, decree, order, law, statute, rule or regulation of any court or other governmental agency or body applicable to the business or properties of the Company or any of its subsidiaries, except, in the case of clause (ii), as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(q) Title to Real and Personal Property. The Company and its subsidiaries have good and marketable title to all properties and assets described in the Registration Statement and Prospectus as being owned respectively by them, in each case, free and clear of all liens, charges, encumbrances or restrictions, except as set forth in the Registration Statement and Prospectus or those where the failure to have such title would not, individually or in the aggregate, result in a Material Adverse Change. The Company and its subsidiaries have valid, subsisting and enforceable leases for the properties material to the Company's operations described in the Registration Statement and the Prospectus as leased by them, with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such properties by the Company and its subsidiaries.

(r) No Untrue Statement; Statistical and Market Data. No statement, representation, warranty or covenant made by the Company in this Agreement or made in any certificate or document required by this Agreement to be delivered to Representatives was or will be, when made, inaccurate, untrue or incorrect. All statistical or market-related data included in the Registration Statement and Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects, and the Company has obtained the written consent to the use of such data from such sources to the extent required.

(s) No Price Stabilization or Manipulation. Neither the Company nor any of its directors, officers or controlling persons has taken, directly or indirectly, any action intended to cause or result in, or which might reasonably be expected to cause or result in, or which has constituted, stabilization or manipulation, under the Securities Act or otherwise, of the price of the Ordinary Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Ordinary Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(t) No Registration Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(u) Stock Exchange Listing. The Ordinary Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and have been approved for listing on the Principal Market. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Ordinary Shares under the Exchange Act or delisting the Ordinary Shares from the Principal Market, nor has the Company received any notification that the Commission or the Nasdaq Global Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Principal Market.

(v) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with FINRA rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct.

(w) Labor Matters. Neither the Company nor any of its subsidiaries is involved in any labor dispute, except where the dispute would not, individually or in the aggregate, have a Material Adverse Effect, nor, to the knowledge of the Company, is any such dispute threatened. The Company is in compliance in all material respects with the labor and employment laws and collective bargaining agreements and extension orders applicable to their employees in the State of Israel, except, where such non-compliance would not, individually or in the aggregate, result in a Material Adverse Change.

(x) No Unlawful Payments. Neither the Company nor any of its subsidiaries, nor any director, officer or employee of the Company or its subsidiaries, nor, to the knowledge of the Company, any agent or representative of the Company or its subsidiaries, affiliate or other person associated with or acting on behalf of the Company or its subsidiaries, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment of corporate funds or benefit to any foreign or domestic government or regulatory official or employee, including, without limitation, of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offense under any other applicable anti-bribery or anti-corruption laws; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company has instituted, maintained and enforced, and will continue to maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(y) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of all jurisdictions in which the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental or regulatory agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(z) No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries, nor any director, officer or employee of the Company or its subsidiaries, nor, to the knowledge of the Company, any agent or representative of the Company or its subsidiaries, affiliate or other person associated with or acting on behalf of the Company or its subsidiaries is currently the subject or target of any sanctions administered or enforced by the U.S. government (including, without limitation, the Office of Foreign Assets Control of the U.S. Treasury Department or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, His Majesty's Treasury or other relevant sanctions authority (collectively, "**Sanctions**"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of comprehensive Sanctions, including, without limitation, Cuba, Iran, North Korea, Syria, the so-called Donetsk People's Republic, the so-called Luhansk People's Republic and the Crimea Region of the Ukraine (each, a "**Sanctioned Country**"); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(aa) Passive Foreign Investment Company. Subject to the qualifications, limitations, exceptions and assumptions set forth in the Registration Statement and Prospectus, the Company does not believe it was a passive foreign investment company, as defined in Section 1297 of the Internal Revenue Code of 1986, as amended, for the taxable year ended on December 31, 2022.

(bb) Taxes. The Company and its subsidiaries have filed all income and franchise tax returns required to be filed by them, have paid all taxes required to be paid by them, and are not aware of any claim asserted in writing against them by any taxing authority in relation to the filing of such tax returns or the payment of such taxes, except for any failure to file or pay or any claim that would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(cc) Insurance. The Company and its subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company believes are deemed adequate for the conduct of their business and the value of their properties and is customary for companies engaged in similar industries, and all such insurance is in full force and effect. The Company has no reason to believe that it and its subsidiaries will not be able to (i) renew their existing insurance coverage as and when such policies expire or (ii) obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct their business as currently conducted or proposed to be conducted and at a cost that would not, individually or in the aggregate, result in a Material Adverse Change. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(dd) Defined Benefit Plans. The Company has not maintained or contributed to a defined benefit plan as defined in Section 3(35) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"). No plan maintained or contributed to by the Company, its subsidiaries or their "**ERISA Affiliates**" (as defined below) that is subject to ERISA (an "**ERISA Plan**") (or any trust created thereunder) has engaged in a "prohibited transaction" within the meaning of Section 406 of ERISA or Section 4975 of the Internal Revenue Code of 1986, as amended (the "**Code**") that could subject the Company to any material tax penalty on prohibited transactions and that has not adequately been corrected. "**ERISA Affiliate**" means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Code. Each ERISA Plan is in compliance in all material respects with all reporting, disclosure and other requirements of the Code and ERISA as they relate to such ERISA Plan, except for any noncompliance which would not result in the imposition of a material tax or monetary penalty. With respect to each ERISA Plan that is intended to be "qualified" within the meaning of Section 401(a) of the Code, either (i) a determination letter has been issued by the Internal Revenue Service stating that such ERISA Plan and the attendant trust are qualified thereunder, or (ii) the remedial amendment period under Section 401(b) of the Code with respect to the establishment of such ERISA Plan has not ended and a determination letter application will be filed with respect to such ERISA Plan prior to the end of such remedial amendment period. The Company has never completely or partially withdrawn from a "multiemployer plan," as defined in Section 3(37) of ERISA.

(ee) Title to Intellectual Property. Except as set forth in the Registration Statement and Prospectus, the Company and its subsidiaries own, have valid and enforceable licenses for or otherwise have adequate rights to use all technology (including but not limited to inventions and proprietary or confidential information, systems or procedures), designs, processes, licenses, patents, trademarks, service marks, trade secrets, trade names, know how, copyrights and other works of authorship, computer programs, technical data and information and all similar intellectual property or proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing, as applicable) (collectively, "**Intellectual Property**") that are or would reasonably be expected to be material to their business as currently conducted or as proposed to be conducted or to the development, manufacture, operation and sale of any products and services sold or proposed to be sold by any of the Company or its subsidiaries, except where the failure to own, license or otherwise have rights to such Intellectual Property would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. The Intellectual Property of the Company and its subsidiaries has not been adjudged by a court or other administrative body of competent jurisdiction to be invalid or unenforceable in whole or in part, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as disclosed in the Registration Statement and Prospectus, (i) there are no third parties who have established or, to the knowledge of the Company, will be able to establish, rights to any Intellectual Property owned by, or licensed to, the Company or its subsidiaries, except for, and to the extent of, the ownership rights of the owners of the Intellectual Property which the Registration Statement and Prospectus disclose is licensed to the Company; (ii) to the knowledge of the Company, there is no infringement, misappropriation or other violation by third parties of any Intellectual Property owned by, or licensed to, the Company or its subsidiaries; (iii) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the Company's or any of its subsidiaries' rights in or to any Intellectual Property and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Intellectual Property owned by, or licensed to, the Company and its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (v) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that (nor has the Company or any of its subsidiaries received any claim from a third party that) the Company or its subsidiaries infringe, misappropriate or otherwise violate, or would, upon the commercialization of any product or service described in the Registration Statement or the Prospectus as under development, infringe, misappropriate or otherwise violate, any Intellectual Property rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (vi) the Company and its subsidiaries have complied with and there has been no material breach or default under the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company and its subsidiaries, and all such agreements are in full force and effect; and (vii) the product candidates described in the Registration Statement or the Prospectus as under development by the Company and its subsidiaries fall within the scope of the claims of one or more patents owned by, or exclusively licensed to, the Company and its subsidiaries except, in each case of (ii) through (vii), as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as set forth in the Registration Statement and Prospectus, the Company and its subsidiaries are not obligated or under any liability whatsoever to make any material payment by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any Intellectual Property, with respect to the use thereof or in connection with the conduct of their respective businesses or otherwise.

(ff) Protection of Intellectual Property. The Company and its subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all their Intellectual Property in all material respects, including, but not limited to complying with all duty of disclosure requirements before the U.S. Patent and Trademark Office and any other non-U.S. Patent Offices as appropriate.

(gg) Compliance with Data Privacy Laws. The Company and its subsidiaries are, and at all times in the prior three (3) years from the execution of this Agreement were, in material compliance with all applicable U.S. state and federal data privacy and security laws and regulations, including without limitation, to the extent applicable, HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation ("**GDPR**") (EU 2016/679) (collectively, the "**Privacy Laws**"). The Company and its subsidiaries have in place, and materially comply with, policies and procedures relating to data privacy and security with respect to the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "**Policies**"). The Company and its subsidiaries have made disclosures to users or customers required by applicable laws, except as would not, individually or in the aggregate, reasonably be expected to be material to the Company and its subsidiaries, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been materially inaccurate or in violation of any applicable laws in any material respect. The Company nor any of its subsidiaries: (i) has received written notice of any actual or alleged liability under or relating to, or actual or alleged violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action to address any material non-compliance with any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability for any non-compliance with any Privacy Law.

(hh) Related Party Transactions. There are no business relationships or related party transactions involving the Company, its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus that have not been described. Without limiting the generality of the immediately preceding sentence, no relationship, direct or indirect, exists between or among the Company on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company on the other hand, that is required to be described in the Registration Statement or the Prospectus and that is not so described. Since inception, the Company has not, directly or indirectly, extended or maintained credit, arranged to extend credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer of the Company, or to or for any family member or affiliate of any director or executive officer of the Company in violation of applicable laws, including Section 13(k) of the Exchange Act.

(ii) Environmental Matters. (a) (i) Each of the Company and its subsidiaries is and has been in compliance with, and is not subject to any pending, or to the knowledge of the Company, threatened costs or liability under, any and all federal, state, local and non-U.S. statutes, laws, rules, regulations, ordinances, codes, other requirements or rules of law (including common law) and judicial or administrative decisions or orders, relating to pollution, the generation, use, handling, transportation, treatment, storage, discharge, disposal or release of hazardous substances, the protection or restoration of the environment, human health and safety, noise or the protection of natural resources, including wildlife, migratory birds, eagles or endangered or threatened species or habitats (collectively, "**Environmental Laws**") and to the knowledge of the Company, there are no facts or circumstances that would reasonably be expected to result in such non-compliance, cost or liability, (ii) neither the Company nor any of its subsidiaries owns, occupies, operates, leases or uses any real property contaminated with hazardous substances, (iii) neither the Company nor any of its subsidiaries is conducting or funding any investigation, remediation, remedial action or monitoring of actual or suspected Hazardous Substances in the environment, (iv) neither the Company nor any of its subsidiaries is liable or allegedly liable for any release or threatened release of Hazardous Substances, including at any off-site treatment, storage or disposal site, (v) neither the Company nor any of its subsidiaries, nor to the knowledge of the Company, any principal supplier, manufacturer or contractor of the Company or any of its subsidiaries, is subject to any claim, action, suit, order, demand or notice by any governmental agency or governmental body or person relating to Environmental Laws or Hazardous Substances, (vi) the Company and its subsidiaries have received and are in compliance with all, and have no liability under any, permits, licenses, authorizations, identification numbers or other approvals required under applicable Environmental Laws to conduct their respective businesses, and (vii) to the knowledge of the Company, there are no requirements proposed for adoption or implementation under any Environmental Law, except in each case covered by clauses (i) – (vii) such as would not individually or in the aggregate reasonably be expected to result in a Material Adverse Change; (b) there are no proceedings that are pending, or known to be contemplated, against the Company or any of its subsidiaries pursuant to any Environmental Laws by a governmental authority, other than such proceedings for which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed; and (c) there are no costs or expenditures (including capital expenditures) under or pursuant to Environmental Laws that would reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries. For purposes of this subsection, "**Hazardous Substances**" means (A) petroleum and petroleum products, by-products or breakdown products, radioactive materials, asbestos-containing materials, polychlorinated biphenyls and mold, and (B) any other chemical, material or substance defined as toxic or hazardous or as a pollutant, contaminant or waste or words of similar import, or regulated or that can form the basis for liability, under Environmental Laws.

(jj) [Reserved].

(kk) Disclosure Controls and Procedures. The Company has established and maintains disclosure controls and procedures (as such term is defined in Rules 13a-15 and 15d-15 under the Exchange Act) that (A) are designed to ensure that material information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and its principal financial officer by others within those entities; (B) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures, commencing as of the end of the period covered by the Company's most recent annual or quarterly report filed with the Commission; and (C) are effective in all material respects to perform the functions for which they were established.

(ll) Internal Control Over Financial Reporting and Internal Accounting Controls. The Company maintains (i) effective "internal control over financial reporting" as defined in, and in compliance with, Rules 13a-15 and 15d-15 under the Exchange Act, and (ii) a system of internal accounting controls sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (E) interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and regulations.

(mm) eXtensible Business Reporting Language. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(nn) No Material Weakness in Internal Controls. Since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness (as defined in Rule 1-02 of Regulation S-X of the Commission) in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of (x) any significant deficiency in the design or operation of its internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in its internal controls, except as disclosed in the Registration Statement or Prospectus, since the end of the Company's most recent audited fiscal year; or (y) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls.

(oo) Off-Balance Sheet Transactions. Except as described in the Registration Statement and Prospectus, there are no off-balance sheet transactions (including, without limitation, transactions related to, and the existence of, "variable interest entities" within the meaning of Financial Accounting Standards Board Accounting Standards Codification Topic 810), arrangements, obligations (including contingent obligations), or any other relationships with unconsolidated entities or other persons, that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses.

(pp) Audit Committee. The Company's Board of Directors has validly appointed an audit committee whose composition satisfies, the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act. Neither the Board of Directors nor the audit committee has been informed, nor is any director of the Company aware, of (i) any significant deficiency in the design or operation of the Company's internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weakness in the Company's internal controls; or (ii) any fraud, whether or not material, that involves management or other employees of the Company who have a significant role in the Company's internal controls.

(qq) Sarbanes-Oxley. The Company is, and after giving effect to the offering and sale of the Shares will be, in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Commission promulgated thereunder that are applicable to the Company as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act (an "**Emerging Growth Company**").

(rr) Accurate Disclosure. The statements included in the Registration Statement and Prospectus under the captions "Material Tax Considerations," "Supplemental Material Tax Considerations," "Description of Share Capital" and "Underwriting," insofar as such statements contain descriptions of the terms of statutes, rules, regulations or legal or governmental proceedings, or contracts or other documents, are fair and accurate in all material respects.

(ss) Clinical Trials. The pre-clinical studies and clinical trials conducted by or, to the knowledge of the Company and its subsidiaries, on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries have participated, that are described in, or the results of which are referred to in, the Registration Statement or the Prospectus were and, if still pending, are being conducted in accordance with protocols filed with the appropriate regulatory authorities for each such study or trial, as the case may be, and with standard medical and scientific research standards and procedures, all applicable statutes, all applicable rules and regulations of the United States Food and Drug Administration (the "**FDA**"), the European Medicines Agency (the "**EMA**"), the Israel Ministry of Health (the "**IMH**") and other comparable regulatory agencies to which they are subject and Good Clinical Practices and Good Laboratory Practices, except to the extent where failure to conduct in such manner would not result in a Material Adverse Change. Each description of the results of such studies and trials contained in the Registration Statement or the Prospectus is accurate and complete in all material respects and fairly presents the data derived from such studies and trials, and the Company or its subsidiaries have no knowledge of any other studies or trials the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement and the Prospectus. The Company and its subsidiaries have not received any written notices, correspondence or other communications from the FDA, the EMA, the IMH or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency (collectively, the "**Regulatory Agencies**") requiring or, to the Company's knowledge, threatening the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement or the Prospectus. The Company and its subsidiaries have operated at all times and currently are in compliance in all material respects with all applicable statutes, rules, regulations and policies of the Regulatory Agencies.

(tt) Regulatory Filings. The Company and its subsidiaries have not failed to file with the Regulatory Agencies any required material filing, declaration, listing, registration, report or submission with respect to any products or product candidates that are described or referred to in the Registration Statement or the Prospectus or any other filing required by any other applicable Regulatory Agency or governmental authority; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable laws when filed; all such filings, declarations, listings, registrations, reports or submissions were timely, complete, accurate and not misleading on the date filed in all material respects (or were corrected or supplemented by subsequent submission); and no deficiencies regarding compliance with applicable law have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions.

(uu) Licenses and Permits. Except as otherwise disclosed in the Prospectus, (i) the Company and its subsidiaries hold, and are operating in compliance in all material respects with, such permits, licenses, franchises, registrations, exemptions, approvals, authorizations and clearances of any other governmental authorities (including, without limitation, the FDA, the EMA and the IMH) required for the conduct of their business as currently conducted and as described in the Registration Statement or the Prospectus (collectively, the "**Permits**"), and all such Permits are in full force and effect; and (ii) the Company and its subsidiaries have fulfilled and performed all of their obligations with respect to the Permits, and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the holder of any Permit. All applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for any and all requests for a Permit from the FDA, the EMA, the IMH or other governmental authority relating to the Company or a subsidiary, its business and its products, when submitted to the FDA, the EMA, the IMH or other governmental authority by or on behalf of the Company or a subsidiary, were true, complete and correct in all material respects. Any necessary or required updates, changes, corrections or modification to such applications, notifications, submissions, information, claims, reports and statistics and other data have been submitted to the FDA, the EMA, the IMH or other governmental authority, except as would not, individually or in the aggregate, result in a Material Adverse Change. The Company and its subsidiaries have not received any notification, correspondence or any other written or oral communication, including notification of any pending or, to the Company's knowledge, threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority including, without limitation, the FDA, the EMA, the IMH or the United States Drug Enforcement Administration ("**DEA**"), of potential or actual material non-compliance by, or material liability of, the Company or a subsidiary under any Permits. To the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to any liability of the Company or a subsidiary under any Permits, except as would not, individually or in the aggregate, result in a Material Adverse Change.

(vv) Compliance with Certain Regulatory Matters. The Company, its subsidiaries, and their respective directors and officers and, to the Company's knowledge, their respective employees and agents have operated and currently are in compliance in all material respects with applicable statutes and implementing regulations administered or enforced by the FDA, EMA, IMH, DEA or any other federal, state, local, or foreign governmental authority, including, without limitation, the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the federal False Statements Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. §1320a-7a), all criminal laws relating to health care fraud and abuse, including, but not limited, to 18 U.S.C. §§ 286 and 287, the exclusion law (42 U.S.C. § 1320a-7), the statutes, regulations and directives of Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and all other government funded or sponsored healthcare programs, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §17921 et seq.), and all other regulations promulgated pursuant to such laws; and any other similar local, state, federal or foreign law or regulation. Neither the Company nor its subsidiaries are a party to, and do not have any ongoing reporting obligations pursuant to, any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental authority. Neither the Company, its subsidiaries nor, to the knowledge of the Company, any of their respective directors, officers, employees or agents has been debarred, excluded or suspended from participation in or receiving payment from any federal, state or local government health care program or is subject to an audit, investigation, proceeding or other similar action by any governmental authority that could reasonably be expected to result in debarment, suspension or exclusion.

(ww) Absence of Certain Regulatory Actions. Except as described in the Registration Statement and Prospectus, the Company has not had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for Company products or product candidates) subject to a governmental authority (including, without limitation, the FDA, the EMA or the IMH) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company products, processes or operations, or similar correspondence or notice from the FDA, EMA, IMH or other governmental authority alleging or asserting material noncompliance with any applicable laws. To the Company's knowledge, none of the FDA, the EMA or IMH nor any other governmental authority have threatened such action. Neither the Company nor its subsidiaries have received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court, arbitrator, Regulatory Agency or other governmental authority or third party alleging that any product operation or activity is in material violation of any health care laws, nor to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened.

(xx) No Broker's Fees. Except as disclosed in the Registration Statement and Prospectus, the Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or the Agent for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(yy) Insolvency. No event of insolvency has occurred in relation to the Company or its subsidiaries, nor is there any act which has occurred or, to the best of the Company's knowledge, is anticipated to occur which is likely to result in an event of insolvency in relation to the Company or its subsidiaries.

(zz) Cybersecurity. (i)(x) Except as disclosed in the Registration Statement and Prospectus, to the knowledge of the Company, there has been no security breach, or other compromise of the Company's information technology and computer systems, networks, hardware, software, data (including the data of the Company's and its subsidiaries' respective customers, employees, suppliers, vendors and any third party maintained by or on behalf of them by the Company and its subsidiaries), computer equipment or technology (collectively, "**IT Systems and Data**"), in each case, that required notification to any Person, and (y) the Company has not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems and Data, except as would not, in the case of this clause (i), individually or in the aggregate, result in a Material Adverse Change; (ii) the Company is presently in material compliance with all applicable judgments, and orders, of any court or arbitrator or governmental or regulatory authority, and all applicable internal policies and contractual obligations, in each case, relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, result in a Material Adverse Change; and (iii) the Company and its subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures and safeguards designed to maintain and protect their confidential information and the integrity, operation, redundancy and security of all IT Systems, Personal Data and confidential data used in connection with their businesses. The Company has implemented reasonable backup and disaster recovery technology practices. To the knowledge of the Company the IT Systems and Data are free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. "Personal Data," used in connection with their businesses. "**Personal Data**" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR, solely if and to the extent applicable to the Company; (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "**HIPAA**"), solely if and to the extent applicable to the Company; and (v) any other piece of information that identifies a natural person.

(aaa) Duties, Transfer Taxes, Etc. No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by the Agent in the United States or any political subdivision or taxing authority thereof or therein in connection with the execution, delivery or performance of this Agreement by the Company or the sale and delivery by the Company of the Shares in the manner contemplated therein.

(bbb) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

(ccc) [Reserved].

(ddd) Submission to Jurisdiction. The Company has the power to submit, and pursuant to Section 8(h) of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each United States federal court and New York state court located in the Borough of Manhattan, in the City of New York, New York, in the United States of America (each, a "**New York Court**"), and the Company has the power to designate, appoint and authorize, and pursuant to Section 8(h) of this Agreement, has legally, validly, effectively and irrevocably designated, appointed and authorized an agent for service of process in any action arising out of or relating to this Agreement or the Shares in any New York Court, and service of process effected on such authorized agent will be effective to confer valid personal jurisdiction over the Company as provided in Section 8(h) hereof.

(eee) Enforceability of Judgement. Subject to the conditions and qualifications set forth in the Registration Statement and Prospectus, any final judgment for a fixed or readily calculable sum of money rendered by a New York Court having jurisdiction under its own domestic laws and recognized by the Israeli courts as having jurisdiction to give such final judgment in respect of any suit, action or proceeding against the Company based upon this Agreement and any instruments or agreements entered into for the consummation of the transactions contemplated herein and therein would be declared enforceable against the Company, without re-examination or review of the merits of the cause of action in respect of which the original judgment was given or re-litigation of the matters adjudicated upon, by the courts of Israel. The Company is not aware of any reason why the enforcement in Israel of such a New York Court judgment would be, as of the date hereof, contrary to public policy of Israel.

(fff) No Rights of Immunity. Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its subsidiaries or their respective properties, assets or revenues has any right of immunity under Israeli, New York or United States law, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any law of Israel, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Agreement. To the extent that the Company, any of its subsidiaries or any of their respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced, the Company waives or will waive such right to the extent permitted by law and has consented to such relief and enforcement as provided in Section 8(h) of this Agreement.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(o) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF ORDINARY SHARES

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in negotiated transactions with the consent of the Company; or (B) by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including block transactions, sales made directly on the Principal Market or sales made into any other existing trading market of the Ordinary Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clauses (A) and (B) above) the method of placement of any Shares by the Agent shall be at the Agent's discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; *provided, however,* that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Ordinary Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares in the manner contemplated therein; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "**Blue Sky Survey**" or memorandum and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; (ix) all fees, expenses and disbursements relating to background checks of the Company's directors, director nominees and executive officers; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of the Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) $95,000 in connection with the original entry into this agreement and (B) $25,000 in connection with each Triggering Event Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 4(o).

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or, in the Company's sole discretion, (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "**Interim Prospectus Supplement**"), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, or any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Ordinary Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Sections 4(d) and 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Sections 4(d) and 4(f). Notwithstanding the foregoing, the Company shall not be required to file such amendment or supplement if there is no pending Issuance Notice and the Company believes that it is in its best interests not to file such amendment or supplement.

(d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Use of Free Writing Prospectus. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

(f) Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; *provided, however,* that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed.

(g) Filing of Agent Free Writing Prospectuses. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

(h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as practicable.

(j) Earnings Statement. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act, which requirement may be satisfied by publicly filing the required information on EDGAR.

(k) Listing; Reservation of Shares. (a) The Company will maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(l) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed annual report on Form 10¬K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) confirming that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurances letter and the written legal opinion of Cooley LLP, counsel to the Company, a written legal opinion of Meitar | Law Offices, Israeli counsel to the Company, and the written legal opinion of Cooley LLP, intellectual property counsel to the Company, each dated the date of delivery, shall be furnished to the Agent, each in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date). The Company shall be required to furnish no more than one set of legal opinions hereunder per annual report on Form 10-K or Form 10-K/A and quarterly report on Form 10-Q or Form 10-Q/A filed by the Company.

(q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent on the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter hereunder per annual report on Form 10-K or Form 10-K/A and quarterly report on Form 10-Q or Form 10-Q/A filed by the Company.

(r) Secretary's Certificate. On or prior to the date of the first Issuance Notice, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Ordinary Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(u) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its Affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall cause each of its Affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

(v) Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, (i) offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Ordinary Shares or securities convertible into or exchangeable for Ordinary Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Ordinary Shares, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice; (ii) effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Ordinary Shares; or (iii) enter into any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Ordinary Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Ordinary Shares, warrants or any rights to purchase or acquire, Ordinary Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company's (i) issuance or sale of Ordinary Shares, options to purchase Ordinary Shares or Ordinary Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Nasdaq rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement, (ii) issuance or sale of Ordinary Shares issuable upon exchange, conversion or redemption of securities or convertible debt, including but not limited to the convertible debt issued pursuant to the Indenture, dated February 16, 2021, by and among the Company, Gamida Cell Inc., and Wilmington Savings Fund Society, FSB or the Loan and Security Agreement, dated December 12, 2022, by and among the Company, Gamida Cell Inc., Wilmington Savings Fund Society, FSB, and Highbridge Tactical Credit Master Fund, L.P. (collectively, the "**Highbridge Convertible Debt**"), or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement (iii) issuance or sale of Ordinary Shares or securities convertible into or exchangeable for Ordinary Shares in connection with strategic transactions including mergers, acquisitions, other business combinations, joint ventures, manufacturing, marketing, sponsored research, collaboration, license or distribution arrangements or strategic alliances which are not issued primarily for capital raising purposes; provided that the aggregate number of Ordinary Shares issued in connection with all such strategic transactions does not exceed 5% of the aggregate number of Ordinary Shares outstanding as of the date of such issuance and (iv) modification of any outstanding options, warrants, rights to purchase or acquire Ordinary Shares, or any existing agreement with respect to convertible debt, including the Highbridge Debt.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

(i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(m), Section 4(q) and Section 4(r).

(ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(iii) Material Adverse Change. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Ordinary Shares; Other Events. The trading of the Ordinary Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Ordinary Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal, New York or Israeli authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Agent Counsel Legal Opinion. Agent shall have received from Latham & Watkins LLP, counsel for Agent, such opinion or opinions, on or before the date on which the delivery of the Company counsel legal opinion is required pursuant to Section 4(p), with respect to such matters as Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and to reimburse the Agent and each such officer, employee and controlling person for any and all expenses (including the fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in subsection (b) below. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption “Plan of Distribution” in the Prospectus, and to reimburse the Company and each such director, officer and controlling person for any and all expenses (including the fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded based on the advice of counsel that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party’s election to so assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section (b) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(b) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(b), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(b) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); *provided, however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(b) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this Section 6(e), the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) Term. Subject to the provisions of this Section 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

(i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.

(ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may furnish to the Commission a Current Report on Form 8-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation,

(b) any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(c) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, (v) the Agent has not provided any legal, accounting, financial, regulatory, investment or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate, and (vi) none of the activities of the Agent in connection with the transactions contemplated herein constitutes a recommendation, investment advice or solicitation of any action by the Agent with respect to any entity or natural person.

(d) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(e) Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC
520 Madison Avenue
New York, NY 10022
Facsimile: (646) 619-4437
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Facsimile: (858) 523-5450
Attention: Michael Sullivan

If to the Company:

Gamida Cell Ltd.
116 Huntington Ave., 7th Fl.
Boston, Massachusetts, 02116
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Cooley LLP
55 Hudson Yards
New York, NY 10001
Facsimile: (212) 479-6275
Attention: Joshua A. Kaufman and Daniel I. Goldberg

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(e).

(f) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(g) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(h) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(i) Judgement Currency. If for the purposes of obtaining judgment in any court it is necessary to convert a sum due hereunder into any currency other than United States dollars, the parties hereto agree, to the fullest extent permitted by law, that the rate of exchange used shall be the rate at which in accordance with normal banking procedures the Agent could purchase United States dollars with such other currency in The City of New York on the business day preceding that on which final judgment is given. The obligation of the Company with respect to any sum due from it the Agent or any person controlling the Agent shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first business day following receipt by the Agent or controlling person of any sum in such other currency, and only to the extent that the Agent or controlling person may in accordance with normal banking procedures purchase United States dollars with such other currency. If the United States dollars so purchased are less than the sum originally due to the Agent or controlling person hereunder, the Company agrees as a separate obligation and notwithstanding any such judgment, to indemnify the Agent or controlling person against such loss. If the United States dollars so purchased are greater than the sum originally due to the Agent or controlling person hereunder, the Agent or controlling person agrees to pay to the Agent an amount equal to the excess of the dollars so purchased over the sum originally due to the Agent or controlling person hereunder.

(j) Appointment for Agent for Service. The Company hereby appoints Gamida Cell Inc. as its agent for service of process (the "**Agent for Service**") in any suit, action or proceeding described in the preceding paragraph and agrees that service of process in any such suit, action or proceeding may be made upon it at the office of such agent. The Company waives, to the fullest extent permitted by law, any other requirements of or objections to personal jurisdiction with respect thereto. The Company represents and warrants that such agent has agreed to act as its agent for service of process, and the Company agrees to take any and all action, including the filing of any and all documents and instruments, that may be necessary to continue such appointment in full force and effect; provided, however, that the Company may (and shall, to the extent the Agent for Service ceases to be able to be served on the basis contemplated herein), by written notice of the Agent, designate such additional or alternative agent for service of process under this Section 8(j) that (i) maintains an office located in the Borough of Manhattan, City of New York, State of New York and (ii) is a corporate service company which acts as agent for service of process for other persons in the ordinary course of its business. Such written notice shall identify the name of such agent for service of process and the address of the office of such agent for service of process in the Borough of Manhattan, City of New York, State of New York.

(k) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof, including that certain Open Market Sale Agreement^{SM} dated September 10, 2021 between the Company and the Agent (the "**Prior Agreement**"), which shall be deemed amended and restated and superseded and replaced in its entirety by this Agreement, and shall be of no further force or effect. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com). This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

GAMIDA CELL LTD.

By: */s/ Terry Coelho*
Name: Terry Coelho
Title: Chief Financial Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By:
Name: Donald Lynaugh
Title: Managing Director

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

GAMIDA CELL LTD.

By: _____
Name: Terry Coelho
Title: Chief Financial Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: */s/ Donald Lynaugh*
Name: Donald Lynaugh
Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

[Date]

Jefferies LLC
520 Madison Avenue
New York, New York 10022

Attn: [_____]

Reference is made to the Open Market Sale Agreement between Gamida Cell Ltd. (the "**Company**") and Jefferies LLC (the "**Agent**") dated as of June 5, 2023. The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)):

_____

Issuance Amount (equal to the total Sales Price for such Shares):

$ _____

Number of days in selling period: _____

First date of selling period: _____

Last date of selling period: _____

Settlement Date(s) if other than standard T+2 settlement:

_____

Floor Price Limitation (in no event less than $1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent's sole discretion): $ ____ per share

Comments: _____

By: _____
Name:
Title:

Schedule A

Notice Parties

The Company

Terry Coelho (terryc@gamida-cell.com)

Josh Patterson (joshp@gamida-cell.com)

The Agent

Donald Lynaugh (dlynaugh@jefferies.com)

Michael Magarro (mmagarro@jefferies.com)

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: August 14, 2023

/s/ Abigail L. Jenkins

President and Chief Executive Officer
(*Principal Executive Officer)*

Exhibit 31.2

CERTIFICATIONS

I, Terry Coelho, 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: August 14, 2023

/s/ Terry Coelho

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 Terry Coelho, 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 June 30, 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: August 14, 2023

In Witness Whereof, the undersigned have set their hands hereto as of the 14th day of August, 2023.

/s/Abigail L. Jenkins	/s/ Terry Coelho
Abigail L. Jenkins	Terry Coelho
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."