

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 15, 2023

Gamida Cell Ltd.

(Exact name of registrant as specified in its Charter)

Israel

(State or other jurisdiction
of incorporation)

001-38716

(Commission File Number)

Not Applicable

(IRS Employer
Identification No.)

116 Huntington Avenue, 7th Floor
Boston, Massachusetts

(Address of principal executive offices)

02116

(Zip Code)

(617) 892-9080

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2023, Gamida Cell Ltd. (the “**Company**”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2023. A copy of the press release is furnished with this report as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (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 of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 15, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Gamida Cell Ltd.

Dated: May 15, 2023

By: /s/ Josh Patterson
Josh Patterson
General Counsel



Gamida Cell Reports First Quarter 2023 Financial Results and Provides Company Update

Company reports positive feedback and continued progress on transplant center on-boarding and payer coverage around launch of Omisirge® (omidubicel-only), a new cell therapy for allogeneic stem cell transplant approved April 17 by the FDA

Company successfully completed public offering, raising gross proceeds of \$22.8 million

Company reports positive momentum on two-pronged corporate strategy: executing commercial plan and pursuing strategic partnerships to support Omisirge launch

Company to host conference call today at 4:30 p.m. ET

BOSTON – May 15, 2023 - Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today provided a business update and reported financial results for the quarter ended March 31, 2023.

Gamida Cell recently announced that the U.S. Food and Drug Administration (FDA) has approved Omisirge® (omidubicel-only) for patients with hematologic malignancies who are planned for allogeneic hematopoietic stem cell transplantation. Please see full **Prescribing Information**, including the Boxed Warning.

“With the recent approval of Omisirge and the funds raised via our public offering, Gamida Cell is making progress on our two-pronged strategy: executing our commercial plan while seeking partnerships to accelerate patient access and product uptake,” said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. “Our team was launch-ready by April 15, which allowed us to move swiftly to initiate onboarding of transplant centers and secure payer coverage to make Omisirge available to patients in need of stem cell transplant.”

First Quarter and Recent Developments

Omisirge® (omidubicel-only)

- **FDA approval of Omisirge:** On April 17, the company announced that the FDA approved Gamida Cell’s allogeneic cell therapy, Omisirge, as a new donor source for allogeneic stem cell transplant. Omisirge had previously received orphan drug, breakthrough therapy and priority review designations. Omisirge is the first enhanced and expanded cell therapy approved for stem cell transplant.
-

- **Commercial progress:** The company continues to advance efforts throughout the organization to execute the launch of Omisirge. As of May 15, 2023:
 - The company is on target to complete the goal of onboarding 10-15 of the top 70 transplant centers in 2023.
 - The company has confirmed coverage with commercial payers that cover 65% of targeted lives and has discussions ongoing with other commercial payers and the Centers for Medicare & Medicaid Services.

Corporate developments

- **Public offering of securities:** The company announced a \$22.8 million public offering of its securities. The underwritten public offering consisted 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 \$22.8 million, before deducting underwriting discounts and commissions and estimated offering expenses. The warrants have an exercise price of \$1.35 per share, are exercisable immediately upon issuance, and will expire five years following the date of issuance. The net proceeds from the offering will be used to support the launch of Omisirge, the continued development of GDA-201 and for general corporate purposes.
- **Debt reduction:** The company announced that between January and May 2023, Highbridge Capital Management, LLC, which issued Gamida Cell a \$25 million senior secured convertible term loan in December 2022, voluntarily exchanged an aggregate of \$11.5 million in principal of that loan for ordinary shares in Gamida Cell. The share redemptions were priced at \$1.91 per share. In addition, the company repaid an additional \$1 million of principal through an ordinary share issuance. As a result, the outstanding principal balance of this loan has been reduced from \$25 million to \$12.5 million.
- **Special shareholders meeting:** The company will hold a special shareholders meeting May 19 to vote on an amendment to the company's articles of incorporation that increases the number of ordinary shares authorized for issuance from 150,000,000 to 225,000,000. The purposes of this increase — which include providing the company with the flexibility to issue ordinary shares in connection with a commercial or strategic partnership, to pay down debt or to fund operations — are outlined in the company's proxy statement. Following the increase, if approved, all ordinary shares issuable from the company's authorized share capital would have the same voting rights and rights to any dividends or other distributions by the company as the ordinary shares currently issuable from its share capital.
- **Strategic partnerships:** The company continues to explore partnerships or broader strategic alternatives that would provide additional resource to support the launch of Omisirge and associated commercial activities in the United States and the rest of the world. The company recently announced it has hired Moelis & Company LLC to support these efforts.

First Quarter 2023 Financial Results

- Research and development expenses were \$8.8 million in the first quarter of 2023, compared to \$11.3 million in the same quarter in 2022. The decrease was attributable mainly to a \$2.4 million decrease in payments to Lonza for manufacturing services, a \$1.3 million decrease in clinical activities relating to the conclusion of our Phase 3 clinical trial, offset by an increase of \$1.2 million in the GDA-201 clinical program.
- Commercial expenses were \$5.6 million in the first quarter of 2023, compared to \$3.9 million in the first quarter of 2022. The increase was attributable mainly to an increase in launch readiness activities. We anticipate that our commercial expenses will increase over time due to the recent FDA approval of Omisirge.
- General and administrative expenses were \$5.2 million in the first quarter of 2023, compared to \$4.1 million in the same period in 2022. The increase was primarily due to professional services expenses.
- Finance expenses, net, were \$1.4 million in the first quarter of 2023, compared to \$0.9 million in the same period in 2022. The increase was attributable to interest due on the convertible notes issued in 2022, offset by interest income from cash management.
- Net loss was \$21.0 million in the first quarter of 2023, compared to a net loss of \$20.2 million in the first quarter of 2022.

2023 Financial Guidance

As of March 31, 2023, Gamida Cell had total cash and cash equivalents of \$46.8 million. This amount does not include the approximately \$25 million in net proceeds from its April 2023 underwritten public offering of securities and sales through its ATM facility. The company expects its current cash and cash equivalents to support its ongoing operating activities into 2024. This guidance is based on Gamida Cell's current operational plans and excludes commercialization activities beyond the initial launch of Omisirge and any additional financing activities that may be undertaken.

Conference Call Information

Gamida Cell will host a conference call today, May 15, 2023, at 4:30 p.m. ET to discuss these financial results and company updates. To access the conference call, please register here and be advised to do so at least 10 minutes prior to joining the call. A live conference call webcast can be accessed in the "Investors & Media" section of Gamida Cell's website at www.gamida-cell.com. A webcast replay will be available approximately two hours after the event for approximately 30 days.

About Gamida Cell

Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company's proprietary nicotinamide (NAM) technology leverages the properties of NAM to enhance and expand cells, creating allogeneic cell therapy products and candidates that are potentially curative for patients with hematologic malignancies. These include Omisirge[®], an FDA-approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy, and GDA-201, an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on **LinkedIn**, **Twitter**, **Facebook** or **Instagram**.

Omisirge[®] is a registered trademark of Gamida Cell Inc. © 2023 Gamida Cell Inc. All Rights Reserved.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to the potentially life-saving or curative therapeutic and commercial potential of Omisirge[®] (omidubicel-only), the company's plans for commercial or strategic partnerships to support the launch of Omisirge and the company's anticipated financial runway. Any statement describing Gamida Cell's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to a number of risks, uncertainties and assumptions including those related to clinical, scientific, regulatory and technical developments and those inherent in the process of developing and commercializing product candidates that are safe and effective for use as human therapeutics. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section and other sections of Gamida Cell's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 31, 2023, and other filings that Gamida Cell makes with the SEC from time to time (which are available at <http://www.sec.gov>), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Although Gamida Cell's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Gamida Cell. As a result, you are cautioned not to rely on these forward-looking statements.

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 46,763	\$ 64,657
Prepaid expenses and other current assets	1,404	1,889
Total current assets	48,167	66,546
NON-CURRENT ASSETS:		
Restricted deposits	3,680	3,668
Property, plant and equipment, net	45,644	44,319
Operating lease right-of-use assets	4,726	7,024
Severance pay fund	1,649	1,703
Other long-term assets	1,266	1,513
Total non-current assets	56,965	58,227
Total assets	\$ 105,132	\$ 124,773
	March 31, 2023	December 31, 2022
	(unaudited)	
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Trade payables	\$ 4,398	\$ 6,384
Employees and payroll accruals	4,333	5,300
Operating lease liabilities	2,082	2,648
Accrued interest of convertible senior notes	986	1,652
Accrued expenses and other current liabilities	10,474	8,891
Total current liabilities	22,273	24,875
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	90,646	96,450
Accrued severance pay	1,862	1,914
Long-term operating lease liabilities	2,976	4,867
Other long-term liabilities	2,742	4,690
Total non-current liabilities	98,226	107,921
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY (DEFICIT):		
Share capital - Ordinary shares of NIS 0.01 par value	222	211
Treasury ordinary shares of NIS 0.01 par value	*	*
Additional paid-in capital	422,203	408,598
Accumulated deficit	(437,792)	(416,832)
Total shareholders' deficit	(15,367)	(8,023)
Total liabilities and shareholders' equity	\$ 105,132	\$ 124,773

	Three months ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Research and development expenses, net	\$ 8,840	\$ 11,305
Commercial expenses	5,576	3,879
General and administrative expenses	5,164	4,139
Total operating loss	19,580	19,323
Financial expenses, net	1,380	900
Net Loss	\$ 20,960	\$ 20,223
Net loss per share attributable to ordinary shareholders, basic and diluted	0.27	0.34

	Three months ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
<u>Cash flows from operating activities:</u>		
Net Loss	\$ (20,960)	\$ (20,223)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	106	112
Financing expense (income), net	(464)	(1,172)
Share-based compensation	1,499	1,194
Amortization of debt discount and issuance costs	196	191
Changes in operating assets and liabilities:		
Operating lease right-of-use assets	527	562
Operating lease liabilities	(686)	(613)
Accrued severance pay, net	2	33
Decrease (increase) in prepaid expenses and other assets	607	(889)
Decrease in trade payables	(1,986)	(3,927)
Decrease in accrued expenses and current liabilities	(1,125)	(996)
Net cash used in operating activities	(22,284)	(25,728)
<u>Cash flows from investing activities:</u>		
Purchase of property, plant and equipment	(830)	(723)
Purchase of marketable securities	-	(2,086)
Proceeds from maturity of marketable securities	-	14,126
Proceeds from restricted deposits	-	500
Net cash provided by (used in) investing activities	\$ (830)	\$ 11,817
<u>Cash flows from financing activities:</u>		
Proceeds from exercise of options	\$ -	\$ 76
Proceeds from share issuance, net	5,217	-
Net cash provided by financing activities	5,217	76
Decrease in cash and cash equivalents	(17,894)	(13,835)
Cash and cash equivalents at beginning of period	64,657	55,892
Cash and cash equivalents at end of period	\$ 46,763	\$ 42,057

###

Investor and Media Contact:

Dan Boyle
OrangeFiery
media@orangefiery.com
1-818-209-1692