



Gamida Cell Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides Company Update

March 27, 2024

Company announces commencement of restructuring process supported by Highbridge Capital Management

Continued progress of launch of Omisirge® (omidubicel-only), with the delivery of six units in 2023, as well as significant transplant center onboarding

Company to host conference call today at 8:30 a.m. ET

BOSTON, March 27, 2024 (GLOBE NEWSWIRE) -- [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 fourth quarter and full year ended December 31, 2023.

The company announced today that it has entered into a Restructuring Support Agreement (RSA) with certain funds managed by Highbridge Capital Management, LLC (collectively, "Highbridge"), the company's principal lender.

Contemplated under the terms of the RSA, and upon closing:

- Highbridge will convert \$75 million of its existing unsecured convertible senior note into equity in the company.
- The company will receive \$30 million of new capital from Highbridge on the effective date of the restructuring. This capital infusion, along with additional capital expected to be invested by Highbridge following the company's emergence, should position the company to meet its goals around the commercialization of Omisirge® (omidubicel-only).
- Gamida Cell will become a private company, wholly owned by Highbridge, and the company's outstanding ordinary shares are expected to be canceled.
- The newly reorganized Gamida Cell will issue contingent value rights with a potential aggregate maximum value of \$27.5 million to holders of Gamida Cell's ordinary shares, subject to the achievement of certain revenue and regulatory milestones within specified time frames.

"Our search for strategic alternatives did not yield an actionable proposal from a partner who could address our financial challenges and support the ongoing commercialization of Omisirge," said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. "This restructuring transaction will enable Gamida Cell to remain a going concern and will support our ongoing efforts to make Omisirge available to more transplant centers and their patients."

Fourth Quarter Highlights and Recent Developments

Omisirge

- **Commercial progress:**
 - In 2023, a total of 17 transplant centers were onboarded. Seven additional transplant centers have been onboarded to date in 2024, for a total of 24 onboarded centers. Transplant center onboarding is a critical step in the process of making Omisirge available to patients, as it is required for transplant center teams to select Omisirge as a donor source.
 - The company has confirmed coverage with payers who cover more than 90% of commercial lives, exceeding the 2023 goal of 70%. This includes confirmed coverage with all 20 of the top U.S. commercial payers and coverage and reimbursement with Medicare from the Centers for Medicare and Medicaid Services (CMS).
 - The company reported revenue for the delivery of six units of Omisirge in 2023, meeting its goal of delivering four to six units for the year. As of March 27, 2024, three units of Omisirge have been delivered in 2024.
- **Expanded Access Program data:** [Expanded access program \(EAP\) data](#) for omidubicel were presented at the 2024 Tandem Meetings, the Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT®) and the Center for International Blood and Marrow Transplant Research (CIBMTR®). EAP data presented were consistent with Phase 3 trial results.
- **Publication in *Advances in Therapy*:** A publication titled "Projected Impact of Omidubicel-only on Racial/Ethnic Disparities in Allogeneic Hematopoietic Cell Transplantation (Allo-HCT) Outcomes in Hematologic Malignancies" is available [online](#) on the *Advances in Therapy* website. The publication is a decision-tree model analyzing the potential effect of omidubicel availability on addressing health disparities in allogeneic hematopoietic stem cell transplant access and outcomes for patients with hematologic malignancies.
- **Publication in *Blood Advances*:** A paper titled "Healthcare Costs Among Patients with Hematologic Malignancies Receiving Allogeneic Transplants: A US Payer Perspective" was published [online](#) in American Society of Hematology's

Blood Advances. The publication quantified costs of care among commercially insured patients with blood cancer undergoing allogeneic hematopoietic stem cell transplant.

- **Thought leader fireside chat:** The company hosted a [fireside chat](#) in December 2023 with industry thought leader Gary Schiller, M.D., Professor, Department of Medicine, Hematology/Oncology and Director, Hematological Malignancies/Stem Cell Transplantation Unit at Ronald Reagan UCLA Medical Center, a part of UCLA Health. Dr. Schiller discussed his experience working with patients in need of allogeneic stem cell transplant, including the patient journey from diagnosis to transplant, decision making around donor source selection and his experience with Omisirge since approval.

GDA-201

- **Data from Phase 1 study:** The company presented preliminary data on GDA-201 at the 2024 Tandem Meetings of ASTCT[®] and CIBMTR[®] for the first 12 patients enrolled in the study. The results of the study announced today share data for all 13 patients with relapsed/refractory B-cell non-Hodgkin lymphoma treated with a single dose up to 2×10^8 cells/kg GDA-201 in combination with rituximab. Patients in this study (median age 65, range: 40-78) were heavily pre-treated; seven patients received prior CAR-T cell therapy and five patients had prior hematopoietic stem cell transplant. Results showed no dose-limiting toxicities and no GDA-201-related grade 3 or 4 adverse events. Efficacy evaluation showed three patients with complete response, two with partial response and two with stable disease. The overall response rate (ORR) at the two higher-dose levels ($1.0 - 2.0 \times 10^8$ cells/kg) was 50%. These data offer positive signals about potential anti-tumor activity for GDA-201. Gamida Cell does not plan to conduct further development of GDA-201 at this time.

Organizational Updates

- Gamida Cell announced it will implement a headcount reduction of 25%.
- Chief Operating and Commercial Officer Michele Korfin will depart the company effective April 1, 2024, and General Counsel and Chief Compliance Officer Josh Patterson will depart the company effective April 26, 2024.
- In addition, as of March 31, 2024, Gamida Cell will finalize the wind-down of its Jerusalem office and consolidate all of its Israel operations in Kiryat Gat.
- The company announced Chief Financial Officer Terry Coelho signed a new agreement to continue in her role through June 30, 2024.

Full Year and Fourth Quarter 2023 Financial Results

- **Net revenue** was \$1.8 million for the 12 months ended December 31, 2023 resulting from the delivery of 6 units of Omisirge. The full year Net Revenue included \$1.1 million of net review for the fourth quarter of 2023.
- **Cost of sales**, including costs of direct manufacturing, quality and manufacturing depreciation, in addition to royalty expenses, was \$1.5 million for full year 2023, resulting in 18.5% gross margin.
- Beginning July 1, 2023, the company's reporting of operating expenses was modified to reflect the company's transition to the commercial stage, with all operating costs now being reported as either research and development expenses, excess capacity costs, or selling, general & administrative (SG&A) expenses. For 2022 and the first two quarters of 2023, previously reported commercial and general & administrative costs were combined into SG&A expenses. Additionally, certain expenses previously reported in research and development are being reported in SG&A beginning in the third quarter of 2023, with no reclassification of prior periods.
- **Research and development expenses** were \$24.3 million for the 12 months ended December 31, 2023, compared to \$42.7 million in 2022. The decrease of \$18.4 million was primarily due to the aforementioned reporting transition, along with reduced omidubicel clinical spend relating to the winding down of the Phase 3 clinical trial and the NK platform clinical and research and development spend.
- **Excess Capacity costs** were \$4.1 million in 2023, reflecting costs associated with labor, manufacturing overheads and manufacturing depreciation above our standard cost of goods which are based on staffed capacity levels.
- **SG&A expenses** were \$44.6 million in 2023, an increase of \$12.3 million compared to 2022. The aforementioned financial reporting transition, which resulted in the inclusion of medical affairs expenses and certain indirect supply chain and quality assurance expenses in SG&A reporting, contributed approximately \$6.9 million to the increase in 2023 as compared to 2022. Selling and marketing expenses increased/decreased by \$4.3 million compared to the prior year, due to commercial launch activities. General and administrative expenses increased by approximately \$1.1 million in 2023 as compared to 2022.
- **Financial income/expenses, net**, were \$10.0 million of income in 2023, compared to \$4.4 million of expense in 2022. The \$14.4 million change in financial income was primarily due to \$17.5 million of non-cash income related to the valuation of warrants liability, partially offset by \$1.9 million of higher interest expenses, \$0.6 million of non-cash loss related to the valuation of the Company's secured convertible senior notes issued in December 2022, and \$0.5 million of lower interest income.
- **Net loss** was \$63.0 million in 2023, compared to a net loss of \$79.4 million in 2022, with the lower Net Loss being driven primarily by the increase in financial income of \$14.4 million together with approximately \$2.0 million of lower Operating

Expenses.

- **Cash position:** As of December 31, 2023, Gamida Cell had total cash and equivalents of \$46.6 million compared to \$64.7 million as of December 31, 2022. The decrease of \$18.1 million is due primarily to \$16.8 million in net cash proceeds from financing activities, comprised of \$21.1 million in net proceeds from the issuance of ordinary shares and warrants from the company's underwritten public offering in April 2023 and \$43.1 million in net proceeds from the issuance of ordinary shares via the at-the-market (ATM) facility, offset by \$2.2 million in principal payments of the company's 2022 convertible senior note and \$79.1 million of net cash used in operating activities. Although it is difficult to predict future liquidity requirements, the company believes that its current total existing funds will not be sufficient to support its ongoing operating activities, including the restructuring process, through the end of the second quarter of 2024.
- **Debt position:** As of December 31, 2023, the company had reduced its principal balance on the December 2022 secured senior convertible note by \$18.4 million, from \$25.0 million as of December 31, 2022. As of March 15, 2024, the company owed approximately \$5.0 million on this note. The company also has outstanding 2021 convertible senior notes with an aggregate principal amount of \$75.0 million.

Conference Call Information

Gamida Cell will host a conference call today, March 27, at 8:30 a.m. ET to discuss these financial results and company updates. To access the conference call by phone, please register [here](#) or dial 1-877-425-9470 for domestic callers or 1-201-389-0878 for international callers and enter the conference ID 13744446. A live conference call webcast can be accessed [here](#). 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[®] (omidubicel-onlv), an FDA-approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy, and GDA-201, an intrinsic natural killer (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](#), [X](#), [Facebook](#) or [Instagram](#).

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. 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, including those with respect to the curative therapeutic and commercial potential of Omisirge[®] (omidubicel-onlv), the consummation of the transactions under the RSA, Gamida Cell's financial runway, commercialization of Omisirge and the contribution of capital by Highbridge to enable continued operations of Gamida Cell, are subject to a number of risks, uncertainties and assumptions. These risks, uncertainties and assumptions include 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, and as to the pursuit of the transactions contemplated under the RSA, the risk that no transaction may result. 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 27, 2024, and other filings that Gamida Cell makes with the SEC from time to time (which are available at 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.

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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)

	December 31,	
	2023	2022

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	\$	46,554	\$	64,657
Short-term restricted deposit		3,056		-
Inventory		1,906		-
Accounts Receivable		1,610		-
Prepaid expenses and other current assets		1,420		1,889
Total current assets		54,546		66,546

NON-CURRENT ASSETS:

Restricted deposits		377		3,668
Property, plant and equipment, net		41,264		44,319
Operating lease right-of-use assets		3,177		7,024
Other long-term assets		2,822		3216
Total non-current assets		47,640		58,227
Total assets	\$	102,186	\$	124,773

LIABILITIES AND SHAREHOLDERS' DEFICIT

CURRENT LIABILITIES:

Trade payables	\$	1,880	\$	6,384
Employees and payroll accruals		5,637		5,300
Operating lease liabilities		1,270		2,648
Accrued interest of convertible senior notes		1,780		1,652
Convertible senior notes		6,505		-
Accrued expenses and other current liabilities		8,129		8,891
Total current liabilities		25,201		24,875

NON-CURRENT LIABILITIES:

Convertible senior notes, net		73,041		96,450
Warrants liability		3,284		-
Long-term operating lease liabilities		2,127		4,867
Other long-term liabilities		1,482		6,604
Total non-current liabilities		79,934		107,921
Total Liabilities		105,135		132,796

CONTINGENT LIABILITIES AND COMMITMENTS

SHAREHOLDERS' DEFICIT:

Ordinary shares of NIS 0.01 par value		391		211
Treasury ordinary shares of NIS 0.01 par value		*		*
Additional paid-in capital		476,488		408,598
Accumulated deficit		(479,828)		(416,832)
Total shareholders' deficit		(2,949)		(8,023)
Total liabilities and shareholders' deficit	\$	102,186	\$	124,773

* Represents an amount lower than \$1

GAMIDA CELL LTD. AND ITS SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars in thousands (except share and per share data)

	Year ended	
	December 31,	
	2023	2022
Net Revenue	\$ 1,784	-
Cost of Sales	1,454	-
Excess Capacity	4,081	-

Research and development expenses, net	24,308	42,692
Selling, general and administrative	44,584	32,301
Other operating expenses	395	-
Total operating expenses	<u>73,368</u>	<u>74,993</u>
Total operating loss	<u>73,038</u>	<u>74,993</u>
Financial (income) expenses	<u>(10,042)</u>	<u>4,382</u>
Net Loss	\$ 62,996	\$ 79,375
Net loss per share attributable to ordinary shareholders, basic and diluted	0.57	<u>1.24</u>

GAMIDA CELL LTD. AND ITS SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands (except share and per share data)
(Unaudited)

	Year ended December 31,	
	<u>2023</u>	<u>2022</u>
Cash flows from operating activities:		
Net Loss	\$ (62,996)	\$ (79,375)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	2,024	440
Financing expense (income), net	829	(375)
Share-based compensation	5,511	5,041
Change in Fair Value of Warrants liability	(17,469)	-
Change in Fair Value in convertible note	611	-
Warrants liability issuance costs	1,733	-
Amortization of debt discount and issuance costs	841	783
Loss from sale of equipment	395	-
Change in assets and liabilities:		
Inventory	326	-
Operating lease right-of-use assets	2,679	2,494
Operating lease liabilities	(2,949)	(3,069)
Increase in Accounts Receivable	(1,610)	-
Decrease in prepaid expenses and other assets	1,001	669
Decrease in trade payables	(4,504)	(1,888)
Decrease (Increase) in accrued expenses and other liabilities	(5,542)	4,857
Net cash used in operating activities	\$ (79,120)	\$ (70,423)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(1,081)	(6,354)
Purchase of marketable securities	-	(5,037)
Proceeds from maturity of marketable securities	-	45,029
Proceeds from restricted deposits	238	406
Proceeds from sale of equipment	33	-
Net cash provided by (used in) investing activities	\$ (810)	\$ 34,044
Cash flows from financing activities:		
Proceeds from exercise of warrants liability	45	-
Proceeds from exercise of options	-	76
Principal payments of convertible senior note	(2,249)	-
Proceeds from share issuance and warrants liability, net	63,976	22,298
Proceeds from issuance of convertible senior notes, net	-	22,270
Net cash provided by financing activities	\$ 61,772	\$ 45,144

Effect of exchange rate changed on cash and cash equivalents	55	-
(Decrease) increase in cash and cash equivalents	(18,103)	8,765
Cash and cash equivalents at beginning of period	64,657	55,892
Cash cash equivalents at end of period	\$ 46,554	\$ 64,657



Source: Gamida Cell, Ltd