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

May 15, 2023

*Company reports positive feedback and continued progress on transplant center onboarding and payer coverage around launch of Omisirge® (omidubicel-onlv), 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--(BUSINESS WIRE)--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-onlv) 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-onlv)***

- **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**.



**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-onlv), 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)** |
| Cash flows from operating activities: | | |
| Net Loss | $ (20,960) | $ (20,223) |
| Adjustments to reconcile loss to net cash used in operating activities: | | |
| Depreciation of property, plant and equipment | 106 | 112 |
| Financing expense (income), net | (464) | (1,172) |
| Share-based compensation | 1,499 | 1,194 |
| Amortization of debt discount and issuance costs | 196 | 191 |
| Changes in operating assets and liabilities: | | |
| 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) |
| Cash flows from investing activities: | | |
| 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 |
| Cash flows from financing activities: | | |
| Proceeds from exercise of options | $ - | $ 76 |
| Proceeds from share issuance, net | 5,217 | - |
| Net cash provided by financing activities | 5,217 | 76 |
| Decrease in cash and cash equivalents | (17,894) | (13,835) |
| Cash and cash equivalents at beginning of period | 64,657 | 55,892 |
| Cash and cash equivalents at end of period | $ 46,763 | $ 42,057 |

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