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

November 14, 2023

Company continues to advance launch, reports initial revenue from Omisirge® (omidubicel-onlv)

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

BOSTON, Nov. 14, 2023 (GLOBE NEWSWIRE) -- Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today reported financial results for the quarter ended September 30, 2023, and provided a business update.

"The third quarter marked the first patients receiving Omisirge following FDA approval and the point at which Gamida Cell truly transitioned to a commercial-stage company with our first revenue reported," said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. "Our lean launch prioritized two key performance indicators – transplant center onboarding and market access – both of which have surpassed our expectations, ahead of schedule. We anticipate continuing to onboard additional transplant centers, leading to a ramp-up of patients and Omisirge deliveries in the coming months."

To date, a total of 17 transplant centers have been onboarded, exceeding the company's 2023 target range of 10 to 15. Transplant center onboarding is a critical step in the process of making Omisirge available to patients, as it is required in order for transplant center teams to select Omisirge as a donor source. The company reported revenue for the delivery of two units of Omisirge in the third quarter of 2023 and projects revenue from a total of four to six units for full year 2023.

The company also provided an update on its market access efforts, reporting confirmed coverage with U.S. payers covering more than 90% of commercial lives, exceeding the full year goal of 70%. This includes confirmed coverage with all 20 of the top U.S. commercial payers. Omisirge also has confirmed coverage and reimbursement with Medicare from the Centers for Medicare and Medicaid Services (CMS).

Looking to 2024, the company will continue to maintain a lean launch effort due to resource constraints. Contingent on additional funding to extend its cash runway, the company anticipates onboarding more than 40 transplant centers by the end of 2024, including at least half of the top 70 transplant centers in the U.S.

Michele Korfin, Chief Operating and Chief Commercial Officer of Gamida Cell, said, "The strong interest for transplant centers to be onboarded and excellent feedback from transplanters as they are evaluating patients for Omisirge are encouraging indicators of its potential. We are excited about the opportunity for Omisirge to capture up to 20% market share at peak, provided we are able to secure the necessary funding to support fully resourced commercialization. We are proud of what our team has accomplished to date with limited resources to deliver Omisirge to patients in need of a donor source for allogenic stem cell transplant."

Additionally, Jenkins provided an update on the company's operations in Israel, noting that Gamida Cell's manufacturing facility in Kiryat Gat has remained operational amid the ongoing Israel-Hamas war. "The dedication, courage and resilience demonstrated by our employees in Israel is an inspiration to us all. Despite the horror of terrorist attacks, they have continued to put patients first and have shown incredible strength and commitment to ensuring we can reliably deliver Omisirge to patients in need."

Gamida Cell will hold a fireside chat with 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. UCLA Health was a clinical trial site for the Phase 3 study of omidubicel in patients with hematologic malignancies and is one of the 17 transplant centers where patients can currently access Omisirge. Dr. Schiller will discuss 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. The virtual event will take place on Monday, December 4 from 4:30-5:15pm ET.

Third Quarter Highlights and Recent Developments

Corporate Developments

- **Annual shareholders meeting**: Gamida Cell held its Annual General Meeting of Shareholders in New York City on October 19. At the meeting, shareholders approved six proposals relating to the company's business, including:
  - The reappointment of Directors Ken Moch and Jeremy Blank
  - The reappointment of Kost, Forer, Gabbay & Kaiserer as the company's independent auditors for the fiscal year ending December 31, 2023, until the 2024 Annual General Meeting of Shareholders
  - Amendments to the company's compensation policy, and CEO and non-executive directors' compensation
  - An increase in Gamida Cell's authorized share capital to 325,000,000 ordinary shares
- **Corporate presentation and panel discussion at Cell & Gene Meeting on the Mesa**: Abbey Jenkins, President and Chief Executive Officer, presented corporate highlights, including commercial launch updates for Omisirge and an overview of market opportunity at the annual Cell & Gene Meeting on the Mesa held October 10-12 in Carlsbad, CA and livestreamed globally. Jenkins also participated in a panel discussion titled "A record setting year for cell and gene therapies – how do we keep the momentum going?"
- **Strategic review**: Efforts to identify a strategic partner are ongoing. The company reported it has received considerable

interest from multiple potential partners during the process, which has been supported by the leading global independent investment bank, Moelis & Company LLC, and has resulted in oral and written proposals. However, according to the company, it has not identified a partnership that will adequately address strategic needs. Gamida Cell intends to continue the business development process in 2024.

Scientific Publications and Medical Meetings

- **Publication in *Transplantation and Cellular Therapy***: The company announced the publication of a secondary analysis of the Phase 3 clinical trial for Omisirge titled "Hospitalization and Healthcare Resource Utilization of Omidubicel-onlv Versus Umbilical Cord Blood Transplantation for Hematologic Malignancies: Secondary Analysis from a Pivotal Phase 3 Clinical Trial." The publication is available online on the *Transplantation and Cellular Therapy* website.
- **Data presented at Society for Immunotherapy of Cancer's (SITC) Annual Meeting**: Gamida Cell presented data further characterizing the mechanism of the company's proprietary nicotinamide (NAM) technology on the expansion and enhancement of cells at SITC November 1-5 in San Diego, California. The full press release is available here.
    - **Omidubicel**: Researchers used immunophenotyping to evaluate and characterize the cellular populations in the cultured fraction (CF) and non-cultured fraction (NF) of omidubicel compared to standard umbilical cord blood (UCB). The data indicated that omidubicel is characterized by a significantly increased number of myeloid cells compared to UCB. The results provide a potential mechanism for the rapid engraftment and immune reconstitution observed in patients transplanted with omidubicel.
    - **GDA-201**: Researchers sought to better understand the impact of Gamida Cell's NAM technology on natural killer (NK) cell kinetics. The data presented showed increased survival of feeder cells and prolonged support in NK cell expansion, resulting in higher fold expansion in NK cells expanded with NAM. In addition, NK cells expanded with NAM showed significantly higher cytotoxicity and an active phenotype. These data provide further evidence for the unique cell culture kinetics of NAM-NK cells.
- **Upcoming participation in the American Society of Hematology (ASH) Annual Meeting and Exposition**: Members of the Gamida Cell team will attend the upcoming ASH Annual Meeting December 9-12 in San Diego, California. A product theater will be presented on Omisirge.

GDA-201

- **Preliminary data from Phase 1 study**: On October 16, the company announced data in 10 patients with CD20 positive non-Hodgkin lymphoma enrolled in the first three cohorts in an ongoing multicenter Phase 1 study of GDA-201. The study is designed to evaluate safety and determine the maximum tolerated dose. Preliminary results showed marked shrinkage of target lesions in five patients; efficacy evaluation showed two patients with complete response, two with partial response and one with stable disease. No dose-limiting toxicities were reported in the 10 patients treated with doses up to $1x10^8$ cells/kg GDA-201 in combination with rituximab. Activity appears to be dose dependent with two of the three patients in Cohort 3 responding. The fourth and final cohort of the study, at the target dose level of $2x10^8$ cells/kg, is currently enrolling at six sites in the U.S. Full Phase 1 data are expected in the first quarter of 2024. Solely for financial reasons, we do not plan to conduct the Phase 2 portion of the GDA-201 Phase 1/2 study.

Third Quarter 2023 Financial Results

- **Net Revenue** for the third quarter 2023 was $0.7 million, resulting from the delivery of two units of Omisirge. Cost of sales, including costs of direct manufacturing and quality in addition to royalty expenses, was $0.6 million in the quarter. Over time we expect the cost of sales, and therefore the company's gross margin, to improve measurably if production volumes scale to capacity.
- 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, 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 $4.2 million in the third quarter of 2023, compared to $9.9 million in the same quarter in 2022. The $5.7 million decrease was primarily due to the aforementioned reporting transition, along with reduced omidubicel clinical spend relating to the Phase 3 clinical trial.
- **SG&A expenses** were $13.8 million in the third quarter of 2023, an increase of $6.6 million compared to $7.2 million in the third quarter of 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 $4.4 million to the increase in the quarter. Additionally, excess capacity costs of $2.2 million associated with our manufacturing facility were recorded in SG&A in the third quarter. Selling and marketing expenses increased by $1.3 million compared to the prior year quarter, due to commercial launch activities.

- **Financial income/expenses, net,** were $16.5 million of income in the third quarter of 2023, compared to $0.7 million of expenses in the same period of 2022. The $17.2 million change in financial income was primarily due to $14.0 million of income related to the valuation of warrants liability and $3.2 million of income related to the valuation of the Company's secured convertible senior notes issued in December 2022.
- **Net loss** was $1.5 million in the third quarter of 2023, compared to a net loss of $17.8 million in the third quarter of 2022, driven primarily by the $17.2 million change in financial income referenced in the financial income/expenses, net above.
- **Cash position**: As of September 30, 2023, Gamida Cell had total cash and cash equivalents of $60.4 million compared to $64.7 million as of December 31, 2022. The decrease of $4.3 million is due primarily to $59.2 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 $39.4 million in net proceeds from the issuance of ordinary shares via the at-the-market (ATM) facility, offset by $1.1 million in principal payments of the Company's 2022 convertible senior note, and $62.9 million of net cash used in operating activities. The company expects its current cash and cash equivalents, including the $0.5 million in funds raised through its ATM facility subsequent to the close of the third quarter, to support its ongoing operating activities into the second quarter of 2024, based on Gamida Cell's current operational plans and excluding commercialization activities beyond the initial launch of Omisirge as well as any additional financing activities that may be undertaken.
- **Debt position:** As of September 30, 2023, the company had reduced its principal balance on the December 2022 secured senior convertible note by $16.7 million, from $25.0 million as of December 31, 2022, to $8.3 million at the end of the third quarter of 2023. 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, November 14, 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 13741024. 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, including with respect to the potentially life-saving or curative therapeutic and commercial potential of Omisirge® (omidubicel-onlv), the Company's cell therapy candidate, GDA-201, expectations regarding the commercial launch of Omisirge and potential to capture market share or generate revenue, Gamida Cell's plans for commercial or strategic partnerships to support the launch of Omisirge, Gamida Cell's financial runway, Gamida Cell's ability to keep its Israel facilities open, the state of its workforce, and future developments that may adversely impact Gamida Cell's Israel operations. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 14, 2023, 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.

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

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 60,431	$ 64,657
Short-term restricted deposit	2,723	-

Inventory	2,324	-
Accounts Receivable	676	-
Prepaid expenses and other current assets	2,355	1,889
Total current assets	68,509	66,546
NON-CURRENT ASSETS:		
Restricted deposits	377	3,668
Property, plant and equipment, net	42,667	44,319
Operating lease right-of-use assets	3,706	7,024
Severance pay fund	1,288	1,703
Other long-term assets	1,201	1,513
Total non-current assets	49,239	58,227
Total assets	**$ 117,748**	**$ 124,773**
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Trade payables	$ 1,664	$ 6,384
Employees and payroll accruals	6,058	5,300
Operating lease liabilities	1,497	2,648
Accrued interest of convertible senior notes	710	1,652
Accrued expenses and other current liabilities	10,725	8,891
Total current liabilities	20,654	24,875
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	81,419	96,450
Warrants liability	11,610	-
Accrued severance pay	1,381	1,914
Long-term operating lease liabilities	2,302	4,867
Other long-term liabilities	-	4,690
Total non-current liabilities	96,712	107,921
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares of NIS 0.01 par value	357	211
Treasury ordinary shares of NIS 0.01 par value	*	*
Additional paid-in capital	471,012	408,598
Accumulated deficit	(470,987)	(416,832)
Total shareholders' equity (deficit)	382	(8,023)
Total liabilities and shareholders' equity (deficit)	**$ 117,748**	**$ 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)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Net Revenue	$ 673	-	$ 673	-
Cost of Sales	626	-	626	-
Research and development expenses, net	$ 4,248	$ 9,864	$ 21,776	$ 31,732
Selling, general and administrative	13,837	7,197	34,691	22,698
Total operating expenses	18,085	17,061	56,467	54,430

Total operating loss	18,038	17,061	56,420	54,430
Financial (income) expenses, net	(16,519)	741	(2,265)	2,149
Net Loss	**$ 1,519**	**$ 17,802**	**$ 54,155**	**$ 56,579**
Net loss per share attributable to ordinary shareholders, basic and diluted	0.01	0.29	0.53	0.95

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

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net Income (Loss)	$ (54,155)	$ (56,579)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,024	391
Financing expense (income), net	61	(2,461)
Share-based compensation	4,297	3,829
Change in Fair Value of Warrants liability	(9,143)	-
Change in Fair Value of convertible senior note	1,039	-
Warrants Issuance Costs	1,733	-
Amortization of loan issuance costs	625	582
Change in assets and liabilities:		
Inventory	(92)	-
Operating lease right-of-use assets	2,020	1,922
Operating lease liabilities	(2,417)	(2,395)
Increase in Accounts Receivable	(676)	-
Increase (decrease) in accrued severance pay, net	(118)	23
Increase (decrease) in prepaid expenses and other assets	(239)	1,719
Decrease in trade payables	(4,720)	(6,355)
Increase (decrease) in accrued expenses and other liabilities	(2,096)	5,079
Net cash used in operating activities	**(62,857)**	**(54,245)**
Cash flows from investing activities:		
Purchase of property, plant and equipment	(833)	(2,865)
Purchase of marketable securities	-	(4,557)
Proceeds from maturity of marketable securities	-	37,972
Proceeds from restricted deposits	294	500
Net cash provided by (used in) investing activities	**$ (539)**	**$ 31,050**
Cash flows from financing activities:		
Proceeds from exercise of warrants liability	$ 45	-
Proceeds from exercise of options	-	76
Principal payments of convertible senior note	(1,142)	-
Proceeds from share issuance and warrants liability, net	60,267	22,298
Net cash provided by financing activities	**59,170**	**22,374**
Decrease in cash and cash equivalents	(4,226)	(821)
Cash and cash equivalents at beginning of period	64,657	55,892
Cash and cash equivalents at end of period	**$ 60,431**	**$ 55,071**

Source: Gamida Cell, Ltd