



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

August 14, 2023

Strong start for Omisirge® (omidubicel-only) launch with significant payer coverage and number of transplant centers onboarded exceeding expectations

Company continues to pursue strategic partnership to further support Omisirge launch

Cash runway extended into Q2 2024; balance sheet strengthened with \$9 million reduction in debt

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

BOSTON--(BUSINESS WIRE)--Aug. 14, 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 June 30, 2023.

"Since the approval of Omisirge in April, Gamida Cell has made excellent progress on the launch," said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. "We have rapidly confirmed significant payer coverage and are seeing high interest from transplant centers, exceeding our plans. This is a testament to the unmet needs that Omisirge has the potential to address for patients, as well as the exceptional work of our experienced cell therapy team. We continue to progress our discussions in our efforts to secure a strategic deal to fully resource our Omisirge commercial efforts. We are optimistic that between our progress on the Omisirge launch and our discussions with potential partners, we can accelerate efforts to expand patient access to Omisirge."

The U.S. Food and Drug Administration (FDA) approved Omisirge in April 2023 for use in adult and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation. The Omisirge launch is ahead of expectations in terms of both transplant center onboarding and market access, with 12 transplant centers already onboarded, eight more in the onboarding process, and active engagement with virtually all of the top 70 transplant centers. The company has also confirmed coverage with payers that cover more than 85% of commercial lives, as well as confirmed coverage and reimbursement with Medicare from the Centers for Medicare and Medicaid Services (CMS). All documents are in place for coverage under the Department of Veterans Affairs, Department of Defense and Medicaid.

"We are very encouraged by the strong interest we have received from transplant centers to date, including centers that did not participate in our clinical studies," said Michele Korfin, Chief Operating and Chief Commercial Officer of Gamida Cell. "The enthusiasm for Omisirge is consistent with expectations from the market research we conducted both pre- and post-approval, supporting our assertion that Omisirge has the potential to capture approximately 20% peak market share. We anticipate this peak share will include patients who might have been otherwise transplanted with a different donor source, as well as patients who historically would not have been able to find an appropriate donor. We have onboarded more centers at this point in our launch than we initially anticipated and are ahead of our expectations in terms of payer coverage. We look forward to engaging with and onboarding additional transplant centers in the coming months to provide more access to Omisirge for patients."

Second Quarter Highlights and Recent Developments

Omisirge

- **Commercial progress:**
 - The company is seeing strong demand from transplant centers and is ahead of its goal of onboarding 10-15 transplant centers in 2023. As of the morning of August 14, 2023, 12 transplant centers have been onboarded and eight additional transplant centers are in the onboarding process.
 - Patients are enrolled in the company's Gamida Cell Assist program, which means that their transplanter has the intent to utilize Omisirge as the patient's donor source.
 - The company has confirmed coverage with payers who cover more than 85% of commercial lives and is in ongoing discussions with additional commercial payers.
 - CMS coverage and reimbursement has been confirmed for patients covered by Medicare. All required documentation is in place for patients who are covered under Medicaid, Department of Defense and Veterans Affairs.
 - The company is ready to reliably deliver Omisirge within 30 days from the start of manufacturing.
- **Publication:** The company announced the publication of a prospective sub-study of the Phase 3 clinical trial for Omisirge titled "Immune Reconstitution Profiling Suggests Antiviral Protection After Transplantation with Omidubicel: A Phase 3 Substudy." The publication is available [online](#) on the *Transplantation and Cellular Therapy* journal website.

Corporate Developments

- **Strategic review:** The company continues to work with Moelis & Company LLC to engage and advance discussions with

multiple parties as part of its efforts to explore alternatives to support a fully resourced launch.

- **Terry Coelho, MBA, appointed Chief Financial Officer:** In May 2023, Gamida Cell announced the appointment of Terry Coelho as Chief Financial Officer. Ms. Coelho, a seasoned finance executive with more than 35 years of experience across all areas of finance and business development at emerging growth companies and established global companies, is positioned to support Gamida Cell's transition into a commercial-phase company and its pursuit of a strategic partnership.
- **Jeremy Blank appointed to Board of Directors:** In August 2023, the company's Board of Directors appointed Jeremy Blank, Chief Investment Officer of Community Fund, to the Board, where he will serve on the Transactions Committee. "Having closely followed Gamida Cell for over a decade, it is a privilege to join the Board of Directors," said Mr. Blank. "I have high confidence in Gamida's team and technology and our firm invested in both of Gamida's most recent equity offerings. I look forward to supporting Gamida's strategic process which is a great opportunity to create shareholder value." Mr. Blank will provide a valuable perspective to the Board as it aids the company in executing its corporate strategy. From 2005 to 2020, Mr. Blank also served as a partner at York Capital Management, a \$15 billion global investment fund. Before that, he was a Vice President and credit analyst at Morgan Stanley. Mr. Blank currently serves as a Director on the boards of Insightec Ltd. and Advanced Emissions Solutions, Inc. (NASDAQ: ADES). Community Fund is a significant shareholder in Gamida Cell.
- **Strengthened balance sheet:** The company ended the second quarter with \$54.1 million in cash as a result of the net proceeds of \$29.8 million from both the April equity offering and the at-the-market offering (ATM), thereby extending cash runway into the second quarter of 2024. Additionally, the company reduced its outstanding principal balance in the quarter by \$9.0 million, from \$94.0 million to \$85.0 million.
- **Investor Day:** Gamida Cell hosted an [Investor Day](#) on June 29, 2023. The event was attended by over 180 participants, both in-person and virtual, and included an update on the commercial launch of Omisirge as well as discussions with industry thought leaders. Steven Devine, M.D., Chief Medical Officer at the National Marrow Donor Program® (NMDP)/Be The Match®, discussed the unmet needs and barriers to care in stem cell transplant, and explained how Omisirge can help address some of these issues. Usama Gergis, M.D., MBA, Professor of Oncology & Director of Transplant and Cellular Therapy, Sidney Kimmel Cancer Center, Thomas Jefferson University, discussed the implications of a health outcomes economics research model developed in partnership with Gamida Cell that showed that a 20% peak market share of Omisirge may increase transplant access for eligible patients, particularly those from racially and ethnically diverse groups that are currently underserved.

GDA-201

- **Phase 1 study:** Gamida Cell's GDA-201, an intrinsic natural killer (NK) cell therapy candidate being investigated for the treatment of hematologic malignancies, is being evaluated in an ongoing Phase 1 study for treatment of non-Hodgkin lymphoma. The study is continuing to enroll patients at six sites in the U.S. Data are expected in the first quarter of 2024.
- **Data presented at International Society for Cell and Gene Therapy (ISCT) 2023 Annual Meeting:** GDA-201 [data presented at ISCT](#) on June 2, 2023 demonstrated the robustness of cryopreserved GDA-201 and continued to support signs of strong lymphoid homing and decreased exhaustion of GDA-201 cells.
- **New data on nicotinamide (NAM) mechanism of action:** [Data published](#) in *Science Translational Medicine* in the July 19 edition demonstrated that culturing NK cells with NAM, which the company uses to enhance and expand cells, and IL-15 increases metabolic fitness, energy charge and glucose flux within NK cells, providing a pathway for resistance to oxidative stress and increased potency compared to NK cells cultured with IL-15 but without NAM. Through preventing degradation of the protein FOXO1, the presence of NAM was found to increase levels of CD62L, an important lymph node homing marker. This expression cascade provides evidence for the strong lymph node homing, direct killing and antibody dependent cell-mediated cytotoxicity capabilities of NK cells cultured with NAM. The publication also includes outcome data from the Phase 1 dose escalation clinical trial for Gamida Cell's NK cell therapy candidate GDA-201 in patients with non-Hodgkin lymphoma as well as translational data from biopsy specimens.

Second Quarter 2023 Financial Results

- **Research and development expenses** were \$8.7 million in the second quarter of 2023, compared to \$10.6 million in the same quarter in 2022. The decrease of \$1.9 million was primarily due to a \$1.6 million reduction associated with the discontinuation of development of our engineered NK cell therapy pipeline, and \$0.7 million in lower Omisirge Phase 3 spend, including a decrease in payments for manufacturing services, partially offset by a decrease of \$0.4 million in IIA (Israeli Innovation Authority) income.
- **Commercial expenses** were \$3.9 million in the second quarter of 2023, compared to \$3.2 million in the second quarter of

2022. The increase of \$0.7 million was attributable to an increase in launch readiness activities.

- **General and administrative expenses** were \$6.3 million in the second quarter of 2023, compared to \$4.3 million in the same period in 2022. The increase of \$2.0 million was associated with higher professional services expenses, in part due to the April 2023 follow on offering and business development activities.
- **Financial expenses, net**, were \$12.9 million in the second quarter of 2023, compared to \$0.5 million in the same period of 2022. The increase of \$12.4 million was primarily due to non-cash expenses totaling approximately \$10.4 million, including the fair value impact on our warrants liability of \$4.9 million, the fair value impact on the 2022 convertible note of \$4.3 million, and a decrease in capitalization of finance costs to fixed assets of \$0.6 million. In addition, the increase was due to higher cash expenses of \$2.0 million, including \$1.7 million in issuance costs from our April 2023 underwritten public offering and an increase of \$1.0 million in interest expenses associated with the 2022 convertible notes, partially offset by increased interest income of \$0.5 million.
- **Net loss** was \$31.7 million in the second quarter of 2023, compared to a net loss of \$18.6 million in the second quarter of 2022, driven primarily by the increase in financial expenses of \$12.4 million.
- **Cash Position:** As of June 30, 2023, Gamida Cell had total cash and cash equivalents of \$54.1 million compared to \$64.7 million as of December 31, 2022. The decrease of \$10.4 million is due primarily to net cash used in operating activities of \$44.3 million partially offset by \$34.7 million in net cash proceeds from the issuance of shares and warrants from our underwritten public offering and the issuance of shares via the ATM facility. Subsequent to the quarter close and through August 9th, the company raised an additional \$14.0 million in net proceeds via the ATM facility. The company expects its current cash and cash equivalents, including the funds raised subsequent to the close of the second 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 June 30, 2023, the company had reduced its principal balance on the 2022 secured convertible note by \$15.0 million, from \$25.0 million as of December 31, 2022, to \$10.0 million at the end of the second quarter. The company also holds a 2021 convertible senior note with an aggregate principal amount of \$75.0 million.

Conference Call Information

Gamida Cell will host a conference call today, August 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](#) and be advised to do so at least 10 minutes prior to joining the call. A live conference call webcast can be accessed [here](#) and also 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[®] (omidubicel-only), 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](#).

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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), expectations regarding the commercial launch of Omisirge and potential to capture market share, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 14, 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.

	June 30, 2023	December 31, 2022
	(Unaudited)	
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	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
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Trade payables	\$ 2,440	\$ 6,384
Employees and payroll accruals	5,545	5,300
Operating lease liabilities	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	86,117	96,450
Warrants liability	25,629	-
Accrued severance pay	1,403	1,914
Long-term operating lease liabilities	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:		
Ordinary shares of NIS 0.01 par value	305	211
Treasury ordinary shares of NIS 0.01 par value	*	*
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

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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
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

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

	<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Cash flows from operating activities:		
Net Income (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
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
Payment of 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, cash equivalents and restricted cash at end of period	\$ 54,213	\$ 37,890

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