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): March 27, 2023

Gamida Cell Ltd.

(Exact name of registrant as specified in its Charter)

Israel	001-38716	Not Applicable
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

116 Huntington Avenue,7th Floor Boston, Massachusetts	02116
(Address of principal executive offices)	(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 March 27, 2023, Gamida Cell Ltd. (the "***Company***") issued a press release announcing the Company's financial results for the year ended December 31, 2022. A copy of the press release is furnished with this report as an exhibit pursuant to "Item 2.02. Results of Operations and Financial Condition" of Form 8-K in accordance with SEC Release Nos. 33-8216 and 34-47583.

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 2.05 Costs Associated with Exit or Disposal Activities.

On March 27, 2023, the Company announced a workforce reduction plan (the "***Plan***"), pursuant to which it plans to downsize its current workforce by approximately 17% by the end of the second quarter of 2023. The Plan is being enacted to help extend the Company's financial resources through the third quarter of 2023, during which time the Company intends to allocate the vast majority of its resources to executing a launch of omidubicel, if approved. Affected employees will be offered separation benefits, including severance payments and temporary healthcare coverage assistance, which severance payments, in Israel, are required under applicable law. Each affected employee's eligibility for the separation benefits is contingent upon such employee's execution of a separation agreement that includes a general release of claims against the Company. The Company estimates that the severance and termination-related costs will be approximately $1.1 million and expects to record these charges primarily in the second quarter of 2023. The Company expects that payments of these costs will be made through the end of the second quarter of 2023. The costs that the Company expects to incur in connection with the workforce reduction are subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Plan.

Forward Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements are identified by such words as "believe," "expect," "anticipate" and words of similar import and are based on current expectations that involve risks and uncertainties, such as the Company's plans, objectives, expectations and intentions. All statements other than historical or current facts are forward-looking statements, including, without limitation, statements about the Plan, including the expected timing until completion, magnitude of employee headcount reduction, anticipated cost, and the terms and conditions of any agreements with departing employees. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These statements, like all statements in this report, speak only as of their date. Additionally, these forward-looking statements should be considered in conjunction with the cautionary statements and risk factors described in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (SEC) on November 14, 2022, and our other filings filed from time to time with the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated March 27, 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: March 27, 2023

By: /s/ Josh Patterson
Josh Patterson
General Counsel

Exhibit 99.1

Gamida Cell Reports Full Year 2022 Financial Results and Provides Company Update

Company reports on productive interactions with FDA and preparations for launch of omidubicel, if approved, in advance of May 1 PDUFA date

Company outlines strategic restructuring, plans to prioritize omidubicel launch and reduce operating expenses to extend cash runway

Company to explore strategic options to support a broader launch of omidubicel, including potential US and global partnerships with pharmaceutical companies

Company intends to continue GDA-201 Phase 1 study, discontinue development of natural killer (NK) cell preclinical candidates and consolidate its operations in Israel in Kiryat Gat

Company to host conference call at 8:00 am ET today

BOSTON – March 27, 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 year ended December 31, 2022. Net loss for 2022 was $79.4 million, compared to a net loss of $89.8 million in 2021. As of December 31, 2022, Gamida Cell had total cash and cash equivalents of $64.7 million.

The company highlighted positive data, productive regulatory interactions and progress on commercial readiness activities supporting its lead product candidate, omidubicel, an advanced cell therapy candidate for allogeneic stem cell transplant, as it advances toward its May 1, 2023 target Prescription Drug User Fee Act (PDUFA) action date. The company also announced a strategic restructuring of its operations to prioritize launch of omidubicel to ensure that, if approved, patients who may potentially benefit will have access to therapy. To reduce expenses, the company will discontinue development of its preclinical NK cell therapy candidates while continuing to enroll patients in the GDA-201 Phase 1 clinical trial.

“Our mission is to bring potentially curative therapies to patients,” said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. “We believe we have a clear path to approval and are preparing for the commercial launch of omidubicel, if approved. Given the challenging economic environment, to date, we have not been able to raise adequate funding to support our full pipeline and enable a more robust launch of omidubicel, if approved. As a result, we are taking decisive actions to do three things 1) prioritize resources toward the launch 2) reduce expenses across the board 3) seek potential commercial or strategic partnerships to maximize patient access to omidubicel, a potentially life-saving therapy. Today’s actions are difficult. Especially since our engineered NK cell therapy candidates, which are derived from healthy donors, have demonstrated encouraging pre-clinical data that differentiate them from other NK cell therapy approaches. The science is promising, but these changes are economically necessary to ensure omidubicel reaches as many patients as possible.”

Today Gamida Cell announced it would:

- **Implement a strategic restructuring to focus on omidubicel launch, if approved:** The company intends to allocate the vast majority of its resources to executing a launch of omidubicel, if approved, although with a more limited investment and slower ramp than previously planned in order to manage its financial resources. The company reported productive interactions with the FDA, including a recently completed Late Cycle Meeting and a previously reported Pre-Licensing Inspection of the company's Kiryat Gat, Israel, manufacturing facility, with no 483 observations received to date. Recently presented data continue to support the clinical benefits and safety of omidubicel, which, if approved, may be a valuable new donor source for patients in need of allogeneic stem cell transplant. Commercial readiness activities have made progress as the company prepares to onboard approximately 10-15 of the top 70 transplant centers in the United States in 2023. Omidubicel has received positive feedback from leading transplant centers, including ones that did not participate in the company's clinical trials. The company has met with U.S. payers, including payers that cover more than 90% of commercially covered lives, and reported that payers indicate they anticipate covering a one-time therapy with curative intent.

- **Continue its GDA-201 Phase 1 study**: The company will continue to enroll patients in its GDA-201 Phase 1 dose escalation study.

- **Reduce operating expenses in order to extend its cash runway**: The company will discontinue the development of its engineered NK cell therapy preclinical pipeline, including GDA-301, GDA-501 and GDA-601, while maintaining the IP to these candidates. It will implement a headcount reduction of 17%, with the majority of impacted headcount tied to the discontinuation of the pre-clinical NK cell therapy candidates. The company will also close its operations in Jerusalem and consolidate Israel operations at its state-of-the-art manufacturing facility in Kiryat Gat. These changes are expected to extend the company's cash runway through Q3 2023.

- **Explore strategic options**: The company intends to seek potential commercial or strategic partnerships to maximize patient access to omidubicel, if approved.

Fourth Quarter and Recent Developments

Omidubicel: Advanced Cell Therapy

- **New data presented at ASH and TCT:** The company presented new data characterizing peripheral blood lymphocytes measured in correlation with time to neutrophil and platelet engraftment in omidubicel-transplanted and standard cord blood-transplanted patients at the 2023 Tandem Meetings, Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation & Cellular Therapy and the Center for International Blood and Marrow Transplant Research in February. Seven days post-transplant, omidubicel-transplanted patients showed a statistically significant correlation between CD3+/CD4+ T cell counts and time to neutrophil engraftment. Similar correlations were noted between CD3+/CD8+/CD19+ cell counts and time to platelet engraftment. Patients transplanted with standard cord blood showed no such correlations at Day 7 post-transplant, and only began to show correlations starting at 14 days post-transplant. Data support past findings that omidubicel stimulates a faster immune response than standard cord blood, which may be a contributing mechanism resulting in the lower incidence of serious bacterial, fungal and viral infections for omidubicel-transplanted patients.

- **New publication in press:** The company reported a publication in press in *Transplantation and Cellular Therapy,* now available online, reporting on long-term follow-up of patients transplanted with omidubicel across five clinical trials. The analysis showed a three-year overall survival of 62.5% and disease-free survival of 54%. With up to 10 years of follow-up, omidubicel showed durable hematopoiesis.

- **Manufacturing readiness:** The company's state-of-the-art manufacturing facility in Kiryat Gat, Israel, is ready for commercial launch if omidubicel is approved and is currently producing omidubicel for the company's Extended Access Program (EAP) and its ongoing omidubicel aplastic anemia study. The facility, which has completed its Israeli Ministry of Health and FDA pre-licensure inspections with no 483 observations to date, has the ability to deliver omidubicel back to the transplant center within approximately 30 days from the start of manufacturing.

- **Commercial readiness:** The company continues to advance efforts throughout the organization to prepare for the launch of omidubicel, if approved.

GDA-201: Intrinsic NK Cell Therapy

- **New data presented at Tandem Meetings:** The company presented a poster at the 2023 Tandem Meetings, Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation & Cellular Therapy and the Center for International Blood and Marrow Transplant Research reporting new preclinical data on the cryopreserved formulation of GDA-201, which showed increased potency and enhanced cytotoxicity. GDA-201 cells were tested for viability, phenotyping, function and potency. Previous characterization of GDA-201 showed high levels of CD56, CD16, CD49a and CD62L expression, low levels of CD57, and low levels of immune checkpoints such as LAG3 and CD200R. The new analyses showed that cryopreserved GDA-201 exhibited high viability (>90%) and high purity up to 12 months post-manufacturing and preserved the ability to proliferate post-thaw. GDA-201 maintained high levels of expression of CD16, which mediates antibody-dependent cellular toxicity, and CD62L, which is a homing and retention marker. GDA-201 also demonstrated high potency, based on the intracellular secretion of TNF-alpha & IFN-gamma and extracellular degranulation marker CD107a.

  In addition, external investigator Veronika Bachanova, M.D., Ph.D., Professor at the University of Minnesota Medical School, gave an oral presentation highlighting novel observations of "on treatment" tumor biopsies from eight patients treated with GDA-201 in a Phase 1 study. The microscopic spatial analysis demonstrated that while GDA-201 cells were virtually undetectable in tumors after 14 days, T cells were observed in 50-95% of tumor site cellularity. Most biopsies obtained as early as three to seven days post-infusion showed strong indications of widespread tumor death. These observations suggest that GDA-201 infusions trigger profound immune microenvironment changes, supporting the influx of host T cells early post-GDA-201 infusion. These findings further suggest the engagement of the adaptive immune system and effective tumor elimination.

Corporate Developments

- On March 20, the company announced that Shawn Cline Tomasello was elected Chairwoman of the Board of Directors, succeeding Chairman Robert I. Blum, who resigned. Ms. Tomasello joined the Gamida Cell Board of Directors in June 2019. She has extensive experience in leading successful commercial activities at several pharmaceutical companies and providing key strategic guidance on company boards. Dr. Anat Cohen-Dayag and Dr. Naama Halevi Davidov also resigned from the company's Board of Directors.

- In December, the company and its wholly owned subsidiary, as borrower, closed on a senior secured convertible term loan of $25 million with certain funds managed by Highbridge Capital Management, LLC. The loan has a maturity date of December 12, 2024.

Full Year 2022 Financial Results

- Research and development expenses, net were $42.7 million in 2022, compared to $50.2 million in 2021. The decrease was primarily due to a $9.6 million decrease in clinical and operational activities relating to the conclusion of our Phase 3 study of omidubicel, offset by an increase of $1.1 million in T&E and other expenses as well as a $1.0 million decrease in Israeli Innovation Authority grants.

- Commercial expenses in 2022 were $12.9 million, compared to $20.0 million in 2021. The decrease was primarily due to a $8.2 million decrease in commercial launch readiness expenses, offset by an increase of $1.1 million in headcount related expenses.

- General and administrative expenses were $19.4 million in 2022, compared to $17.0 million in 2021. The increase was mainly driven by an increase of $1.4 million attributed to our corporate headquarters and headcount-related expenses as well as a $1.0 million increase in professional services expenses.

- Financial expenses, net, were $4.4 million for 2022, compared to $2.6 million for 2021. The increase was primarily due to expenses relating to the closing on a senior secured convertible term loan of $25 million with certain funds managed by Highbridge Capital Management, LLC.

- Net loss for 2022 was $79.4 million, compared to $89.8 million in 2021.

2023 Financial Guidance

Gamida Cell expects its current cash and cash equivalents will support the company's ongoing operating activities through the third quarter of 2023. This cash runway guidance is based on the company's current operational plans and excludes any additional funding and any business development activities that may be undertaken.

Conference Call Information

Gamida Cell will host a conference call today, March 27, 2023, at 8:00 a.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 Omidubicel

Omidubicel is an advanced cell therapy candidate for allogeneic hematopoietic stem cell (bone marrow) transplant that, if approved, has the potential to expand access and improve outcomes for patients with blood cancers. Omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment compared to standard umbilical cord blood in an international, multicenter, randomized Phase 3 study (NCT02730299) in patients with hematologic malignancies undergoing allogeneic bone marrow transplant. The Phase 3 study also showed reduced time to platelet engraftment, reduced infections and fewer days of hospitalization. One-year post-transplant data showed sustained clinical benefits with omidubicel as demonstrated by a significant reduction in infectious complications as well as reduced non-relapse mortality and no significant increase in relapse rates nor increases in graft-versus-host-disease (GvHD) rates. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the U.S. and E.U. Omidubicel has a PDUFA target action date of May 1, 2023.

Omidubicel is an investigational stem cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority. For more information about omidubicel, please visit https://www.gamida-cell.com.

About GDA-201

GDA-201 is an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. Preclinical studies have shown that GDA-201 may address key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs. Furthermore, these data suggest GDA-201 may improve antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. A multicenter Phase 1/2 study of GDA-201 for the treatment of non-Hodgkin lymphoma is ongoing.

GDA-201 is an investigational cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

About Gamida Cell

Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company's research and development efforts have produced potentially curative cell therapy candidates for patients with blood cancers. The company applies a proprietary expansion platform leveraging the properties of nicotinamide to cell sources including umbilical cord blood-derived cells and NK cells to create allogeneic cell therapy candidates with the potential to redefine standards of care. These include omidubicel, an advanced cell therapy candidate for allogeneic hematopoietic stem cell transplant that, if approved, has the potential to expand access and improve outcomes for patients with blood cancers, and GDA-201, an intrinsic NK cell therapy candidate being investigated for the treatment of hematological malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, Twitter, Facebook or Instagram at @GamidaCellTx.

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 timing of the FDA's review of the BLA for omidubicel, and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including omidubicel), and the company's anticipated cash 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 November 14, 2022, 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.

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CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 64,657	$ 55,892
Marketable securities	-	40,034
Prepaid expenses and other current assets	1,889	2,688
Total current assets	66,546	98,614
NON-CURRENT ASSETS:		
Restricted deposits	3,668	3,961
Property, plant and equipment, net	44,319	35,180
Operating lease right-of-use assets	7,024	7,236
Severance pay fund	1,703	2,148
Other long-term assets	1,513	1,647
Total non-current assets	58,227	50,172
Total assets	$ 124,773	$ 148,786

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	December 31,	
	2022	**2021**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,384	$ 8,272
Employees and payroll accruals	5,300	4,957
Operating lease liabilities	2,648	2,699
Accrued interest of convertible senior notes	1,652	1,640
Accrued expenses and current liabilities	8,891	7,865
Total current liabilities	24,875	25,433
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	96,450	71,417
Accrued severance pay	1,914	2,396
Long-term operating lease liabilities	4,867	5,603
Other long-term liabilities	4,690	-
Total non-current liabilities	107,921	79,416
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares of NIS 0.01 par value - Authorized: 150,000,000 shares at December 31, 2022 and 2021; Issued: 74,703,030 and 59,970,389 shares at December 31, 2022 and 2021, respectively; Outstanding: 74,583,026 and 59,970,389 shares at December 31, 2022 and 2021, respectively	211	169
Treasury ordinary shares of NIS 0.01 par value; 120,004 and 0 shares at December 31, 2022 and 2021, respectively	*	-
Additional paid-in capital	408,598	381,225
Accumulated deficit	(416,832)	(337,457)
Total shareholders' equity (deficit)	(8,023)	43,937
Total liabilities and shareholders' equity	$ 124,773	$ 148,786

* Represents an amount lower than $1.

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,	
	2022	**2021**
Research and development expenses, net	$ 42,692	$ 50,177
Commercial expenses	12,900	20,013
General and administrative expenses	19,401	16,977
Total operating loss	74,993	87,167
Financial expenses, net	4,382	2,626
Loss	$ 79,375	$ 89,793
Net loss per share attributable to ordinary shareholders, basic and diluted	$ 1.24	$ 1.52
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	63,826,295	59,246,803

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Loss	$ (79,375)	$ (89,793)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	440	431
Financing expense (income), net	(375)	359
Share-based compensation	5,041	4,233
Amortization of debt discount and issuance costs	783	638
Operating lease right-of-use assets	2,494	2,109
Operating lease liabilities	(3,069)	(2,193)
Decrease (increase) accrued severance pay, net	(37)	12
Decrease in prepaid expenses and other assets	224	1,008
Increase (decrease) in trade payables	(1,888)	1,941
Increase (decrease) in accrued expenses and current liabilities	5,339	(505)
Net cash used in operating activities	(70,423)	(81,760)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(6,354)	(15,054)
Purchase of marketable securities	(5,037)	(102,179)
Proceeds from maturity of marketable securities	45,029	61,534
Investment in restricted deposits	-	(5,222)
Proceeds from restricted deposits	406	-
Net cash provided by (used in) investing activities	$ 34,044	$ (60,921)
Cash flows from financing activities:		
Proceeds from exercise of options	$ 76	$ 626
Proceeds from share issuance, net	22,298	-
Proceeds from issuance of convertible senior notes, net	22,770	70,777
Net cash provided by financing activities	45,144	71,403
Increase (decrease) in cash and cash equivalents	8,765	(71,278)
Cash and cash equivalents at beginning of year	55,892	127,170
Cash and cash equivalents at end of year	$ 64,657	$ 55,892