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): August 15, 2022

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)

(713) 400-6400
(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 August 15, 2022, Gamida Cell Ltd. (the "***Company***") issued a press release announcing the Company's financial results for the quarter ended June 30, 2022. In addition to disclosing results that are determined in accordance with Generally Accepted Accounting Principles (GAAP), the Company also discloses non-GAAP results of operations, which are adjusted from GAAP to exclude non-cash compensation related to stock awards. The Company is presenting non-GAAP information excluding non-cash compensation related to stock awards because the Company believes it is useful for investors in assessing the Company's operating results. A copy of the 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 the Exhibit 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated August 15, 2022.
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: August 15, 2022

By: /s/ Shai Lankry
Shai Lankry
Chief Financial Officer

Exhibit 99.1

gamida cell

Gamida Cell Reports Second Quarter 2022 Financial Results and Provides Company Update

- Received FDA acceptance of BLA for omidubicel with Priority Review; PDUFA target action date set for January 30, 2023 -

- Dosed first patient in company-sponsored Phase 1/2 study of cryopreserved formulation of GDA-201 for the treatment of follicular and diffuse large B-cell lymphomas -

- Finished second quarter of 2022 with $55.1 million in cash; sufficient funding for the company's operations into mid-2023, excluding the cost of commercializing omidubicel -

- Company to host conference call at 8:00 a.m. ET today -

Boston, Mass. – August 15, 2022 – Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapies for patients with hematologic and solid cancers and other serious diseases, today provided a business update and reported financial results for the quarter ended June 30, 2022. Net loss for the second quarter of 2022 was $18.6 million, compared to a net loss of $23.6 million in the second quarter of 2021. As of June 30, 2022, Gamida Cell had total cash, cash equivalents and investments of $55.1 million.

Recently, Gamida Cell:

- Received acceptance for filing from the U.S. Food and Drug Administration (FDA) with priority review for its Biologics License Application (BLA) for omidubicel. The BLA has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2023. If approved, omidubicel will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers in need of a stem cell transplant.

- Dosed the first patient in a company-sponsored Phase 1/2 study evaluating a cryopreserved formulation of GDA-201, a readily available cell therapy candidate for the treatment of follicular and diffuse large B-cell lymphomas.

- Continued development of the company's proprietary NAM-enabled NK cell pipeline, including genetically modified product candidates GDA-301, GDA-401, GDA-501 and GDA-601, which aim to treat solid-tumor and hematological cancers. These cell therapy candidates utilize CAR, membrane bound- and CRISPR-mediated technologies to increase the NK cell targeting, potency and persistence against hematologic malignancies and solid tumors. Promising new pre-clinical data on GDA-301 and GDA-601 were presented at the International Society for Cell & Gene Therapy Meeting. The data demonstrated that both NAM-enabled cell therapy candidates represented a novel potent and cytotoxic approach in fighting cancer.

- Advanced strategic evaluation for omidubicel commercialization, including assessing whether to commercialize omidubicel ourselves or to pursue strategic alternatives to commercialize omidubicel, upon receipt of regulatory approval. The company currently has sufficient cash to fund the company's operations into mid-2023, excluding the cost of commercializing omidubicel.

"2022 is a potentially transformative year for Gamida Cell as we continue to execute against our clinical and regulatory milestones. We were excited that the FDA accepted our BLA submission with priority review, and if approved, omidubicel will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers in need of a stem cell transplant. We believe that omidubicel has the potential to change the outlook for patients suffering from blood cancers through improved outcomes, quality of life and increased access for patients who are currently eligible for transplant, but cannot find a match," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "In addition, the development of our NAM-enabled NK cell therapy candidate, GDA-201, creates an opportunity to potentially bring a new treatment option to tens of thousands of patients with relapsed/refractory lymphoma worldwide. We continue to execute our mission of advancing our broad pipeline of NAM-enabled cell therapies with a curative approach for patients with solid tumors and blood cancers and other serious blood diseases."

Second Quarter and Recent Developments

Omidubicel: Advanced Cell Therapy

- **BLA accepted by FDA with Priority Review:** In August 2022, the FDA accepted for filing Gamida Cell's BLA for omidubicel for the treatment of patients with blood cancers in need of an allogeneic hematopoietic stem cell transplant. The FDA granted Priority Review for the BLA and has set a PDUFA target action date of January 30, 2023. In parallel, Gamida Cell is preparing for the commercialization of omidubicel in the U.S.

GDA-201: NAM-Enabled NK Cell Therapy

- **Dosed the first patient in Phase 1/2 study of cryopreserved formulation of GDA-201:** In August 2022, Gamida Cell completed the dosing of the first patient in a company-sponsored Phase 1/2 study evaluating a cryopreserved formulation of GDA-201 for the treatment of follicular and diffuse B-cell lymphomas.

    - The Phase 1 portion of the study is designed as a dose escalation phase to evaluate the safety of GDA-201, and will include patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL)/high grade B-cell lymphoma (HGBCL), marginal zone lymphoma or mantle cell lymphoma. The Phase 2 expansion phase is designed to evaluate the safety and efficacy of GDA-201 in 63 patients comprised of two patient cohorts, FL and DLBCL. The study will include patients who have relapsed or refractory lymphoma after at least two prior treatments, which may include CAR-T or stem cell transplant.

NAM-Enabled NK Cell Pipeline Expansion

- **Progressed NAM-enabled genetically modified NK pipeline:** Gamida Cell continues to progress its NAM-enabled genetically modified NK pipeline, which utilizes CAR, membrane bound- and CRISPR-mediated technologies to increase targeting, potency and persistence against hematologic malignancies and solid tumors. The company continues to conduct *in vitro* and *in vivo* preclinical proof-of-concept studies for these genetically modified NK therapeutic targets which are already showing encouraging results and plans to select the next NK pipeline product candidate for IND enabling studies by the end of 2022. These therapeutic targets include:

    - GDA-301: Knockout of CISH (cytokine inducible SH2 containing protein) in NK cells using CRISPR/Cas9 in combination with a membrane-bound IL-15/IL-15Ra;

    - GDA-401: A development candidate with an undisclosed target;

    - GDA-501: Anti HER2 CAR-engineered NK cells to target solid tumors expressing HER2, based on a single-chain variable fragment of the widely used humanized monoclonal antibody trastuzumab; and

    - GDA-601: CRISPR Knockout of CD38 on NK cells combined with anti CD38 CAR. CD38 is an established immunotherapeutic target in multiple myeloma, but its expression on NK cells and its further induction during *ex vivo* NK cell expansion represents a barrier to the development of an anti CD38 CAR-NK cell therapy. Gamida Cell is advancing this program in collaboration with the Dana-Farber Cancer Institute to study the *in vitro* cytotoxicity of GDA-601 in fresh tumor tissue samples from multiple myeloma patients.

Corporate Updates

- **Appointed Ivan M. Borrello, M.D. to Board of Directors:** Dr. Borrello is an Associate Professor of Oncology at the Sydney Kimmel Comprehensive Cancer Center at Johns Hopkins and a renowned physician and author who has made major contributions to better the understanding of immunotherapies and the treatment of hematologic malignancies as well as bone marrow transplant. The Company also announced the resignation of Ofer Gonen from its Board of Directors.

Second Quarter 2022 Financial Results

- Research and development expenses were $10.6 million in the second quarter of 2022, compared to $13.4 million in the same quarter in 2021. The decrease was attributable mainly to a $2.4 million decrease in clinical activities relating to the conclusion of our Phase 3 clinical trial and a decrease of $0.4 million in the GDA-201 clinical program.

- Commercial expenses were $3.2 million in the second quarter of 2022, compared to $5.0 million in the second quarter of 2021. The decrease was attributable mainly to reducing near-term commercial readiness expenses, as we continued to assess strategic approaches for the commercialization of omidubicel.

- General and administrative expenses were $4.3 million in the second quarter of 2022, compared to $3.9 million in the same period in 2021. The increase was mainly due to a $0.9 million increase in professional services expenses, offset by a decrease of $0.5 million in headcount related expenses.

- Finance expenses, net, were $0.5 million in the second quarter of 2022, compared to $1.3 million in the same period in 2021. The decrease was primarily due to $0.6 million in non-cash expenses and an increase of $0.2 million in interest income from cash management.

- Net loss was $18.6 million in the second quarter of 2022, compared to a net loss of $23.6 million in the second quarter of 2021.

2022 Financial Guidance

Gamida Cell expects that its current cash, cash equivalents and investments will support the company's ongoing operating activities into mid 2023, excluding the cost of commercializing omidubicel. If we decide to market omidubicel ourselves, we will require substantial additional funding. This cash runaway guidance is based on the company's current operational plans and excludes any additional funding and any business development activities that may be undertaken. Gamida Cell continues to assess all financing options that support its corporate strategy.

Expected Milestones in 2022 and early 2023

Omidubicel

- PDUFA target action date of January 30, 2023.

NK cell pipeline expansion

- Conduct preclinical proof of concept studies of the NAM-enabled, genetically modified NK therapeutic targets

- Select pipeline candidate for IND-enabling studies

Conference Call Information

Gamida Cell will host a conference call today, August 15, 2022, 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 webcast of the conference call can be accessed in the "Investors & Media" section of Gamida Cell's website at www.gamida-cell.com. A replay of the webcast will be available approximately two hours after the event, for approximately 30 days.

About Omidubicel

Omidubicel is an advanced cell therapy candidate developed as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with blood cancers. Omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment in comparison to standard umbilical cord blood in an international, multi-center, randomized Phase 3 study (NCT0273029) 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 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 US and EU.

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

Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy candidate for the potential treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201, the lead candidate in the NAM-enabled NK cell pipeline, has demonstrated promising initial clinical study data. 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. There are approximately 40,000 patients with relapsed/refractory lymphoma in the US and EU, which is the patient population that will be studied in the currently ongoing GDA-201 Phase 1/2 clinical trial.

For more information about GDA-201, please visit https://www.gamida-cell.com. For more information on the Phase 1/2 clinical trial of GDA-201, please visit www.clinicaltrials.gov.

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 NAM Technology

Our NAM-enabling technology, supported by positive omidubicel Phase 3 results, is designed to enhance the number and functionality of targeted cells, enabling us to pursue a curative approach that moves beyond what is possible with existing therapies. Leveraging the unique properties of NAM (nicotinamide), we can expand and metabolically modulate multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' active phenotype and enhance potency. Additionally, our NAM technology improves the metabolic fitness of cells, allowing for continued activity throughout the expansion process.

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapy candidates for patients with solid tumor and blood cancers and other serious blood diseases. We apply a proprietary expansion platform leveraging the properties of NAM to allogeneic cell sources including umbilical cord blood-derived cells and NK cells to create therapy candidates with potential to redefine standards of care. These include omidubicel, an investigational product with potential as a life-saving alternative for patients in need of bone marrow transplant, and a line of modified and unmodified NAM-enabled NK cells targeted at solid tumor and 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 initiation and progress of, and data reported from, pre-clinical and clinical trials of Gamida Cell's product candidates (including omidubicel and GDA-201), anticipated regulatory filings (including the timing of review of the BLA for omidubicel by the FDA), commercialization planning efforts, the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including GDA-201 and omidubicel), Gamida Cell's expectations for the clinical development milestones set forth herein, and Gamida Cell's expectations regarding its projected cash, cash equivalents and investments to be used for operating activities. 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: the impact that the COVID-19 pandemic could have on our business, including the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; clinical, scientific, regulatory and technical developments; the process of developing and commercializing product candidates that are safe and effective for use as human therapeutics; and the endeavor of building a business around such product candidates. 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 May 12, 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.

Contacts

For investors:
Courtney Turiano
Stern Investor Relations, Inc.
Courtney.Turiano@sternir.com
1-212-362-1200

For media:

Heather DiVecchia
Chief of Staff
Heather@gamida-cell.com
1-617-892-9083