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 10, 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 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 7.01 Regulation FD Disclosure.

On August 10, 2022, Gamida Cell Ltd. (the "***Company***") issued a press release entitled "Gamida Cell Announces Dosing of First Patient in Company-Sponsored Phase 1/2 Study of NK Cell Therapy Candidate GDA-201". The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.10 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

Gamida Cell Ltd. today announced the dosing of the first patient in a company-sponsored Phase 1/2 study evaluating a cryopreserved, readily available formulation of GDA-201 for the treatment of follicular and diffuse large B cell lymphomas.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated August 10, 2022.

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 10, 2022

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

Gamida Cell Announces Dosing of First Patient in Company-Sponsored Phase 1/2 Study of NK Cell Therapy Candidate GDA-201

-The company-sponsored Phase 1/2 study is evaluating a cryopreserved, readily available formulation of GDA-201 for the treatment of follicular and diffuse large B cell lymphomas -

Boston, Mass. – August 10, 2022 – Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapy candidates for patients with hematologic and solid cancers and other serious diseases, announces dosing of the first patient in a company-sponsored Phase 1/2 study evaluating a cryopreserved, readily available formulation of GDA-201 for the treatment of follicular and diffuse large B cell lymphomas (NCT05296525).

"We are excited to further advance the development of GDA-201, a NAM-enabled natural killer (NK) cell therapy candidate which we believe has the potential to be a new readily available, cryopreserved treatment option for cancer patients with relapsed/refractory lymphoma," said Ronit Simantov, M.D., chief medical and scientific officer of Gamida Cell. "Our NK cells elicited an adaptive immune response in patients in the previous investigator-sponsored study with the fresh formulation of GDA-201, potentially leading to durable remissions. We are truly grateful for the contribution of all the participants and clinical collaborators who will allow us to continue studying GDA-201 in this multi-center open label trial."

The Phase 1 portion of the study is a dose escalation phase, designed 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, 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 cohorts of patients with either FL or 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.

"Interest in NK cell therapies has increased in recent years as a potential alternative to current cell therapies, as NK cells have the potential to be effective in hematological and solid tumors while avoiding common safety issues," said Veronika Bachanova, M.D., Ph.D., University of Minnesota. "We are particularly excited about Gamida's cryopreserved formulation of GDA-201, which has potential as a new treatment option for patients."

GDA-201 leverages Gamida Cell's proprietary NAM (nicotinamide) technology platform to expand the number and functionality of NK cells to direct tumor cell killing properties and antibody-dependent cellular cytotoxicity (ADCC). In an investigator-sponsored Phase 1/2 study in patients with relapsed or refractory lymphoma, treatment with the fresh formulation of GDA-201 with rituximab demonstrated significant clinical activity. Of the 19 patients with non-Hodgkin lymphoma (NHL), 13 complete responses and one partial response were observed, with an overall response rate of 74% and a complete response rate of 68%. Two-year data on outcomes and cytokine biomarkers associated with survival data demonstrated a median duration of response of 16 months (range 5-36 months) and an overall survival at two years of 78% (95% CI, 51%–91%). In this study, GDA-201 was well-tolerated and no dose-limiting toxicities were observed in 19 patients with NHL and 16 patients with multiple myeloma. The most common Grade 3/4 adverse events were thrombocytopenia, hypertension, neutropenia, febrile neutropenia, and anemia. There were no incidents of cytokine release syndrome, neurotoxic events, graft versus host disease or marrow aplasia.

About NAM Technology

Our NAM-enabled technology, supported by positive Phase 3 data for omidubicel, 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, we can expand and metabolically modulate multiple cell types — including stem cells and NK 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 GDA-201

Gamida Cell applied the capabilities of its NAM-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy candidate for the 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 trial results. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation in the bone marrow and lymphoid organs. Furthermore, GDA-201 improves 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 therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

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: the timing of initiation of the expansion portion of the currently ongoing Phase 1/2 clinical trial of GDA-201, as well as the progress of, and data reported from, this clinical trial; the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including omidubicel and GDA-201); and Gamida Cell's expectations for the expected clinical development milestones set forth herein. Any statement describing Gamida Cell's goals, expectations, 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 statements related to: the impact that the COVID-19 pandemic could have on our business; 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.

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