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): April 26, 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.)

5 Nahum Heftsadie Street Givaat Shaul, Jerusalem, Israel	91340
(Address of principal executive offices)	(Zip Code)

+972 (2) 659-5666
(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 8.01 Other Events.

On April 26, 2022, Gamida Cell Ltd. issued a press release entitled "Gamida Cell Announces FDA Clearance of IND and Removal of Clinical Hold for 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated April 26, 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: April 26, 2022

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

Exhibit 99.1

Gamida Cell Announces FDA Clearance of IND and Removal of Clinical Hold for NK Cell Therapy Candidate GDA-201

Company advancing plans to begin Phase 1/2 study in patients with follicular and diffuse large B-cell lymphomas

BOSTON--(BUSINESS WIRE) – April 26, 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 announced that the U.S. Food and Drug Administration (FDA) cleared its investigational new drug (IND) application and removed the clinical hold for a cryopreserved formulation of GDA-201. GDA-201 is an off-the-shelf cell therapy candidate for the treatment of patients with follicular and diffuse large B cell lymphomas. Gamida Cell expects to initiate a company-sponsored Phase 1/2 clinical study in patients with follicular and diffuse large B-cell lymphomas in 2022.

"FDA clearance of our IND for the cryopreserved formulation of GDA-201 represents a significant milestone for the company and reflects our team's expertise in the development of NAM-enabled cell therapies," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "Previously announced data from an investigator-sponsored (IS) study evaluating the fresh formulation of GDA-201 demonstrated durable complete responses in heavily pretreated patients with relapsed or refractory lymphoma. We are pleased to advance our plans to begin the company sponsored Phase 1/2 study and progress our novel cryopreserved formulation of GDA-201 with objective to address the unmet need that exists for patients with follicular and diffuse large B cell lymphomas."

GDA-201 leverages Gamida Cell's proprietary NAM 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%. At the December 2021 Annual Meeting of American Society of Hematology, two-year follow-up data were reported on outcomes and cytokine biomarkers associated with survival. The 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 the IS 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 was no incidents of cytokine release syndrome (CRS), neurotoxic events, GvHD or marrow aplasia.

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 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 antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells.

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 NAM Technology

Our NAM-enabling technology, supported by positive Phase 3 data, 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 therapies 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 therapies 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, the clinical trials of Gamida Cell's product candidates (including GDA-201), anticipated regulatory filings and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including GDA-201). 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, and including the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; 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, and in 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 Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 24, 2022, as amended, 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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