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): February 9, 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 91340 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 February 9, 2022, Gamida Cell Ltd. issued a press release entitled “Gamida Cell Initiates Rolling Submission of Biologics License Application for Omidubicel”. 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 February 9, 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: February 9, 2022

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

Exhibit 99.1

Gamida Cell Initiates Rolling Submission of Biologics License Application for Omidubicel

On track to complete the BLA submission in the first half of 2022

BOSTON – February 9, 2022 – Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, today announced that it has initiated the Biologics License Application (BLA) rolling submission process with the U.S. Food and Drug Administration for omidubicel, a potentially life-saving treatment for patients with blood cancers in need of stem cell transplant. The company remains on track to complete the BLA submission in the second quarter of 2022.

"We are pleased to reach this important milestone for omidubicel and bring this potential therapy one step closer to reaching patients in need," said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. "In the Phase 3 study, omidubicel achieved a statistically significant reduction in time to neutrophil engraftment, reduced hospitalization time, decreased risk of infection and shorter time to platelet engraftment. Based on this positive data, we believe omidubicel has the potential to address the existing unmet needs in allogeneic transplant, offering a new standard of care and the opportunity to treat even more patients."

Omidubicel has the potential to be the first FDA approved advanced cell therapy product for allogeneic stem cell transplant. For patients with hematologic malignancies that are deemed eligible for an allogeneic stem cell transplant, the procedure is their best chance for a potential cure. In the U.S., there are approximately 8,000 patients above the age of 12 with hematologic malignancies who undergo an allogeneic stem cell transplant each year and we believe that number of patients may grow over time[1]. Unfortunately, there are approximately 1,000 patients each year, who are above the age of 12 and are deemed eligible for an allogeneic stem cell transplant but cannot find an appropriate donor[2]. Based on its encouraging clinical data and less stringent matching criteria, omidubicel has the potential to improve outcomes for allogeneic stem cell transplant patients compared to other donor sources and expand access for patients who cannot find a suitable donor.

About Omidubicel

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with blood cancers. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the U.S. FDA and has also received Orphan Drug Designation in the U.S. and EU. Gamida Cell has completed an international, multi-center, randomized Phase 3 study (NCT0273029) evaluating the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing allogeneic bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. That study achieved its primary endpoint, demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in a patient's recovery from a stem cell transplant. The Phase 3 study also achieved its secondary endpoints of reduced time to platelet engraftment, reduced infections and shorter days of hospitalization. For more information about omidubicel, please visit https://www.gamida-cell.com.

Omidubicel is an investigational therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

[1] CIBMTR 2019 – allogenic transplants in patients 12+ years with hematological malignancies.

[2] Gamida Cell market research.

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 (including the timing of submission of the BLA for omidubicel to the FDA), commercialization planning efforts, and the potentially life-saving or curative therapeutic and commercial potential of omidubicel, and Gamida Cell's expectations for the expected clinical development milestones set forth herein. 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 20-F, filed with the Securities and Exchange Commission (SEC) on March 9, 2021, 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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