UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of December 2020

Commission File Number 001-38716

GAMIDA CELL LTD.
(Translation of registrant's name into English)

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

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On December 14, 2020, Gamida Cell Ltd. ("**Gamida Cell**" or the "**Company**") issued a Report on Form 6-K, a copy of which is furnished as Exhibit 99.1 to this Report on Form 6-K, announcing that it conducted a Type B Meeting for omidubicel with the U.S. Food and Drug Administration (the "**FDA**") on Friday, December 11, 2020.

During the meeting, the FDA provided encouraging feedback regarding the Phase 3 study of omidubicel pertaining to the pre-specified primary and secondary endpoints. The FDA also recommended that Gamida Cell generate additional manufacturing-related data prior to requesting a pre-Biologics License Application (BLA) meeting. Specifically, the FDA requested that Gamida Cell demonstrate analytical and clinical comparability from the company's planned commercial manufacturing sites. The company believes the clinical comparability requirement will be met if the time to neutrophil engraftment in patients from the company's ongoing expanded access program (EAP) using omidubicel produced at Gamida Cell's planned commercial manufacturing sites is consistent with the results achieved in the Phase 3 clinical trial. Based on the feedback received at the meeting with FDA, Gamida Cell intends to submit a full BLA for omidubicel in the second half of 2021 in lieu of the company's previous plan to initiate a rolling BLA submission by the end of 2020. The revised plan could support a potential commercial launch of omidubicel in the United States as early as mid-2022.

As previously announced, given the encouraging Phase 1 data presented at the 2020 ASH meeting, the company also plans to submit an IND for GDA-201, its expanded natural killer cell investigational therapy, in 2021.

This Report on Form 6-K 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, anticipated regulatory filings including BLA submission, launch readiness and FDA approval, commercialization efforts and Gamida Cell's expectations regarding its projected ongoing operating activities, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, 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. Any forward-looking statements speak only as of the date of this Report on Form 6-K and are based on information available to Gamida Cell as of the date of this release.

This Report on Form 6-K, excluding the exhibits attached hereto, is hereby incorporated by reference into the Company's Registration Statement on Form F-3 (File No. 333-234701).

Exhibit

99.1	Press Release, dated December 14, 2020, Gamida Cell Provides Regulatory Update on Biologics License Application for Omidubicel

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GAMIDA CELL LTD.

December 14, 2020

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

Exhibit 99.1

gamida cell

CONFIDENTIAL DRAFT FOR REVIEW: NOT FOR RELEASE

Gamida Cell Provides Regulatory Update
on Biologics License Application for Omidubicel

-- Feedback from FDA supports proceeding to BLA Submission for omidubicel with additional manufacturing requirements; the company plans to submit full BLA in second half of 2021

BOSTON, MA – December 14, 2020 – Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today announced that the company conducted a Type B Meeting for omidubicel with the U.S. Food and Drug Administration (FDA) on Friday, December 11, 2020.

During the meeting, the FDA provided encouraging feedback regarding the Phase 3 study of omidubicel pertaining to the pre-specified primary and secondary endpoints. The FDA also recommended that Gamida Cell generate additional manufacturing-related data prior to requesting a pre-Biologics License Application (BLA) meeting. Specifically, the FDA requested that Gamida Cell demonstrate analytical and clinical comparability from the company's planned commercial manufacturing sites. The company believes the clinical comparability requirement will be met if the time to neutrophil engraftment in patients from the company's ongoing expanded access program (EAP) using omidubicel produced at Gamida Cell's planned commercial manufacturing sites is consistent with the results achieved in the Phase 3 clinical trial. Based on the feedback received at the meeting with FDA, Gamida Cell intends to submit a full BLA for omidubicel in the second half of 2021 in lieu of the company's previous plan to initiate a rolling BLA submission by the end of 2020. The revised plan could support a potential commercial launch of omidubicel in the United States as early as mid-2022.

"Although we are disappointed by the delay in timing to bring omidubicel to patients after a potential FDA approval, we are encouraged by the FDA's reaction to our Phase 3 data as the pivotal trial of omidubicel achieved pre-specified primary and secondary endpoints. Commercial manufacturing readiness activities are underway, and we believe we will be able to complete all the requirements discussed with FDA," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "With this clarity, we look forward to proceeding towards a full BLA submission in the second half of 2021. We continue to prepare for the commercialization of omidubicel on the revised timeline, as we continue to provide omidubicel to patients in need through our expanded access program."

The planned BLA submission for omidubicel is supported by a Phase 3 study which met its primary and secondary endpoints. The international, multi-center, randomized Phase 3 study was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing a bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. Omidubicel is the first bone marrow transplant cell therapy product to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the U.S. and EU.

As previously announced, given the encouraging Phase 1 data presented at the 2020 ASH meeting, the company also plans to submit an IND for GDA-201, its expanded natural killer cell investigational therapy, in 2021.

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 hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

Omidubicel is an investigational therapy, and its safety and efficacy have not been established by the U.S. Food and Drug Administration or any other health authority.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201, an innate natural killer (NK) cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. 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 of NK cells expanded in culture. GDA-201 is in Phase 1 development through an investigator-sponsored study in patients with refractory non-Hodgkin lymphoma and multiple myeloma.[1] For more information on the clinical study of GDA-201, please visit www.clinicaltrials.gov.

GDA-201 is an investigational therapy, and its safety and efficacy has not been established by the U.S. Food and Drug Administration or any other health authority.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn or Twitter at @GamidaCellTx.

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[1] Clinicaltrials.gov identifier NCT03019666

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, anticipated regulatory filings including BLA submission, launch readiness and FDA approval, commercialization efforts and Gamida Cell's expectations regarding its projected ongoing operating activities, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. 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 February 26, 2020, its Reports on Form 6-K filed with the SEC on May 18, 2020, August 11, 2020 and November 10, 2020, 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. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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