
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 January 2020

Commission File Number 001-38716

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

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 January 13, 2020, Gamida Cell Ltd. (the “Company”) issued a press release (the “Press Release”) announcing its 2020-2021 goals and providing a company update.

Expected 2020-2021 Milestones.

The Company targets achieving the following milestones during 2020-2021:

Omidubicel

- Report topline data from the Phase 3 study in the first half of 2020
- Present data from the Phase 3 study at a medical meeting in the second half of 2020
- Submit the biologics license application to the U.S. Food and Drug Administration (FDA) in the second half of 2020, assuming positive data
- Report additional data from the Phase 1/2 study in patients with severe aplastic anemia in the second half of 2020
- Launch omidubicel in 2021, contingent upon FDA approval

GDA-201

- Present additional data from the Phase 1 study in the first half of 2020
- Submit company-sponsored investigational new drug application to FDA in the second half of 2020
- Initiate a Phase 1/2 clinical study in patients with non-Hodgkin lymphoma in 2021

Except as set forth above, the information furnished in the Press Release, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, except as expressly set forth by specific reference in such a filing.

This report on Form 6-K 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 January 13, 2020, Gamida Cell Announces 2020 Goals and Provides Company Update
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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.

January 13, 2020

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



FOR RELEASE ON MONDAY, JANUARY 13, 2020, AT 8:01 A.M. ET

GAMIDA CELL ANNOUNCES 2020 GOALS AND PROVIDES COMPANY UPDATE

- Topline data from Phase 3 study of omidubicel expected in first half of 2020 –*
- GDA-201 program progressing with additional data expected in first half of 2020 –*
- Jas Uppal, Ph.D., appointed as chief regulatory and quality officer –*

San Francisco, CA. – January 13, 2020 – Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases, today reported its expected milestones for 2020-2021, which highlight the company's progress advancing its clinical development candidates: omidubicel, an advanced cell therapy in Phase 3 clinical development as a potential life-saving treatment option for patients in need of bone marrow transplant, and GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma (NHL) and multiple myeloma.

"This is an incredibly important year for Gamida Cell. With patient enrollment completed, we are expecting topline data from the Phase 3 study of omidubicel in the first half of this year. Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and has the potential to be the first FDA-approved bone marrow transplant graft. Positive data from our study would represent an important step toward bringing potentially curative medicines to patients," stated Julian Adams, Ph.D., chief executive officer at Gamida Cell. "We are also very excited by the progress of GDA-201, an investigational therapy in a class that we believe has the potential to be the next generation of cell therapies to dramatically improve the treatment of blood cancers. GDA-201 has shown promise for the treatment of non-Hodgkin lymphoma, including an aggressive form of lymphoma called diffuse large B cell lymphoma, and we anticipate announcing additional data in the first half of 2020."

Today Gamida Cell also announced the appointment of Jas Uppal, Ph.D. to the newly created role of chief regulatory and quality officer. Dr. Uppal brings more than 25 years of global experience in the pharmaceutical industry, including expertise in hematology, immunology and neurology. During her career, she has played key roles in building regulatory organizations and leading multiple successful product launches.

“We are delighted to welcome Jas to Gamida Cell. Her strategic, global experience in building teams and securing multiple product approvals for novel biologics will be invaluable as we move omidubicel and GDA-201 through critical regulatory milestones,” stated Dr. Adams.

Dr. Uppal most recently served as vice president, global head of regulatory affairs of oncology, endocrinology and rare diseases at Ipsen Biopharmaceuticals, where she held worldwide responsibility for Ipsen’s oncology, endocrinology and rare diseases portfolio. In this role, she led all areas of product development and managed a team of regulatory professionals. Prior to Ipsen, she served as vice president, global head of regulatory affairs at Karyopharm Therapeutics, where she was responsible for developing a global regulatory strategy and approach for multiple Phase 2 and Phase 3 programs that were being developed to treat hematological malignancies and solid tumors. Earlier in her career, Dr. Uppal held several regulatory-related positions over the course of 12 years at Biogen Idec (now Biogen) that culminated in her role as director of global emerging markets and head of development sciences. Dr. Uppal has participated in over 30 new drug approvals worldwide and has more than 30 publications in peer reviewed journals. She holds a Ph.D. in biochemistry from Kings College, University of London.

Expected 2020-2021 Milestones

Gamida Cell targets achieving the following milestones during 2020-2021:

Omidubicel

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- Present data from the Phase 3 study at a medical meeting in the second half of 2020
- Submit the biologics license application to the FDA in the second half of 2020, assuming positive data
- Report additional data from the Phase 1/2 study in patients with severe aplastic anemia in the second half of 2020
- Launch omidubicel in 2021, contingent upon FDA approval

GDA-201

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2020 Financial Outlook

Gamida Cell ended 2019 with cash, cash equivalents and available-for-sale securities of approximately \$56 million (unaudited). The company expects that its current cash, cash equivalents and available-for-sale securities will support the company’s ongoing operating activities into the fourth quarter of 2020. This cash runway guidance is based on the company’s current operational plans and excludes any additional funding that may be received or business development activities that may be undertaken.

About Omidubicel

Omidubicel, the company's lead clinical program, 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). Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration and has also received Orphan Drug Designation in the U.S. and EU. In a Phase 1/2 clinical study, omidubicel demonstrated rapid and durable time to engraftment and was generally well-tolerated.¹ A Phase 3 study evaluating omidubicel in patients with leukemia and lymphoma is ongoing in the U.S., Europe and Asia.² Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia.³ 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.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201 (formerly known as NAM-NK), 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.⁴

Omidubicel and GDA-201 are investigational therapies, and their safety and efficacy have not been evaluated 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 finding cures for 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.

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 patient enrollment in and timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, expectations regarding regulatory filings, approval and commercialization of Gamida Cell's product candidates, and Gamida Cell's expectations regarding its projected operating expenses and cash runway, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress, expansion and results of Gamida Cell's clinical trials and variability, 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 of Gamida Cell's public filing on Form 20-F, filed with the SEC on February 25, 2019, 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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¹Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol*. 2019 Feb 10;37(5):367-374.

²ClinicalTrials.gov identifier NCT02730299.

³ClinicalTrials.gov identifier NCT03173937.

⁴ClinicalTrials.gov identifier NCT03019666.