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): September 27, 2023

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 September 27, 2023, Gamida Cell Ltd. (the "***Company***") issued a press release entitled "First Patient Receives Gamida Cell's Omisirge™ (omidubicel-onlv)". 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 7.01 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.

On September 27, 2023, the Company announced that the first patient has received a stem cell transplant with Omisirge (omidubicel-onlv).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated September 27, 2023.
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: September 27, 2023

By: /s/ Josh Patterson
Josh Patterson
General Counsel & Chief Compliance Officer

Exhibit 99.1

Media Contact:
Dan Boyle
Orangefiery
media@orangefiery.com
1-818-209-1692

Investor Contact:
Chuck Padala
LifeSci Advisors
Chuck@lifesciadvisors.com
1-646-627-8390

First Patient Receives Gamida Cell's Omisirge™ (omidubicel-onlv)

Omisirge is the only allogeneic stem cell therapy approved by the U.S. Food and Drug Administration (FDA) on the basis of a global randomized Phase 3 trial

Rapid onboarding of transplant centers and significant payer coverage demonstrate strong launch progress

BOSTON – SEPTEMBER 27, 2023 – Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today announced that the first patient has received a stem cell transplant with Omisirge (omidubicel-onlv).

"This is a significant milestone for Gamida Cell, advancing our mission of delivering potentially curative therapies to patients with cancer," said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. "This patient will be the first of many who have new hope for a cure thanks to the availability of Omisirge as a new stem cell transplant donor source. This is why we do the work that we do – to make a difference for people with cancer."

Omisirge was approved by the U.S. FDA in April 2023 for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Gamida Cell has already exceeded its 2023 launch goals, with 15 transplant centers onboarded across the United States and confirmed coverage with payers that cover 90% of commercial lives. Gamida Cell is actively engaged with more than 90% of the top 70 transplant centers, which conduct approximately 80% of transplants. An increasing number of patients are being enrolled in Gamida Cell Assist®, which signals a transplanter's intent to use Omisirge as the donor source.

"The launch of Omisirge is progressing very well in terms of payer coverage, transplant center onboarding and transplanter interest in using Omisirge as a donor source," said Michele Korfin, Chief Operating and Chief Commercial Officer of Gamida Cell. "We recognize the importance of making sure eligible patients can access Omisirge. To appropriately manage our cash, we launched with a limited investment and field footprint. The positive launch progress and strong interest from transplant centers now warrant expanding that investment and the team from four to eight account managers by the start of 2024. We are encouraged by transplanter feedback that Omisirge may both increase the number of patients able to access an appropriate donor source and address some limitations of other donor sources."

Approximately 8,000 stem cell transplants are performed in the U.S. each year in patients with hematologic malignancies[1] and another 1,700 patients are estimated to be eligible for transplant but unable to find a donor.[2] The ability to find a donor is historically more challenging for racially and ethnically diverse populations than for patients who are white.[3] Gamida Cell market analyses indicate that Omisirge has the ability to capture approximately 20% of allogeneic stem cell transplant market share by ~2028, with the potential to address certain limitations of other donor sources and increase the number of patients able to access a donor source for stem cell transplant.

Omisirge Indication

Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Important Safety Information for Omisirge

BOXED WARNING: INFUSION REACTIONS, GRAFT VERSUS HOST DISEASE, ENGRAFTMENT SYNDROME, AND GRAFT FAILURE

- **Infusion reactions may be fatal. Monitor patients during infusion and discontinue for severe reactions. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin or bovine material.**
- **Graft-versus-Host Disease may be fatal. Administration of immunosuppressive therapy may decrease the risk of GvHD.**
- **Engraftment syndrome may be fatal. Treat engraftment syndrome promptly with corticosteroids.**
- **Graft failure may be fatal. Monitor patients for laboratory evidence of hematopoietic recovery.**

1 Data are of transplants performed from January 1–December 31, 2020. These data were reported to the Center for International Blood and Marrow Transplant Research® (CIBMTR) as of February 4, 2021.

2 Gamida Cell market research.

3 Be The Match® website (accessed 5/30/23); IT-Ideation Department, February 2021 (ethnic background %).

Contraindications

OMISIRGE is contraindicated in patients with known hypersensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine products.

Warnings and Precautions

Hypersensitivity Reactions

Allergic reactions may occur with the infusion of OMISIRGE. Reactions include bronchospasm, wheezing, angioedema, pruritis and hives. Serious hypersensitivity reactions, including anaphylaxis, may be due to DMSO, residual gentamicin, Dextran 40, human serum albumin (HSA) and bovine material in OMISIRGE. OMISIRGE may contain residual antibiotics if the cord blood donor was exposed to antibiotics in utero. Patients with a history of allergic reactions to antibiotics should be monitored for allergic reactions following OMISIRGE administration.

Infusion Reactions

Infusion reactions occurred following OMISIRGE infusion, including hypertension, mucosal inflammation, dysphagia, dyspnea, vomiting, and gastrointestinal toxicity. Premedication with antipyretics, histamine antagonists, and corticosteroids may reduce the incidence and intensity of infusion reactions. In patients transplanted with OMISIRGE in clinical trials, 47% (55/117) patients had an infusion reaction of any severity. Grade 3-4 infusion reactions were reported in 15% (18/117) patients. Infusion reactions may begin within minutes of the start of infusion of OMISIRGE, although symptoms may continue to intensify and not peak for several hours after the completion of the infusion. Monitor patients for signs and symptoms of infusion reactions during and after OMISIRGE administration. When a reaction occurs, pause the infusion and institute supportive care as needed.

Graft-versus-Host Disease

Acute and chronic GvHD, including life-threatening and fatal cases, occurred following treatment with OMISIRGE. In patients transplanted with OMISIRGE Grade II-IV acute GvHD was reported in 58% (68/117). Grade III- IV acute GvHD was reported in 17% (20/117). Chronic GvHD occurred in 35% (41/117) of patients. Acute GvHD manifests as maculopapular rash, gastrointestinal symptoms, and elevated bilirubin. Patients treated with OMISIRGE should receive immunosuppressive drugs to decrease the risk of GvHD, be monitored for signs and symptoms of GvHD, and treated if GvHD develops.

Engraftment Syndrome

Engraftment syndrome may occur because OMISIRGE is derived from umbilical cord blood. Monitor patients for unexplained fever, rash, hypoxemia, weight gain, and pulmonary infiltrates in the peri-engraftment period. Treat with corticosteroids as soon as engraftment syndrome is recognized to ameliorate symptoms. If untreated, engraftment syndrome may progress to multiorgan failure and death.

Graft Failure

Primary graft failure occurred in 3% (4/117) of patients in OMISIRGE clinical trials. Primary graft failure, which may be fatal, is defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplantation. Immunologic rejection is the primary cause of graft failure. Monitor patients for laboratory evidence of hematopoietic recovery.

Malignancies of Donor Origin

Two patients treated with OMISIRGE developed post-transplant lymphoproliferative disorder (PTLD) in the second-year post-transplant. PTLD manifests as a lymphoma-like disease favoring non-nodal sites. PTLD is usually fatal if not treated. The etiology is thought to be donor lymphoid cells transformed by Epstein-Barr virus (EBV). Serial monitoring of blood for EBV DNA may be warranted in patients with persistent cytopenias. One patient treated with OMISIRGE developed a donor-cell derived myelodysplastic syndrome (MDS) during the fourth-year post-transplant. The natural history is presumed to be the same as that for *de novo* MDS. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Gamida Cell at (844) 477-7478.

Transmission of Serious Infections

Transmission of infectious disease may occur because OMISIRGE is derived from umbilical cord blood. Disease may be caused by known or unknown infectious agents. Donors are screened for increased risk of infection, clinical evidence of sepsis, and communicable disease risks associated with xenotransplantation. Maternal and infant donor blood is tested for evidence of donor infection. See full Prescribing Information, Warnings and Precautions, Transmission of Serious Infections for list of testing performed. OMISIRGE is tested for sterility, endotoxin, and mycoplasma. There may be an effect on the reliability of the sterility test results if the cord blood donor was exposed to antibiotics in utero. Product manufacturing includes bovine-derived reagents. All animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. **Test results may be found on the container label and/or in accompanying records.** If final sterility results are not available at the time of use, Quality Assurance will communicate any positive results from sterility testing to the physician. Report the occurrence of transmitted infection to Gamida Cell at (844) 477-7478.

Transmission of Rare Genetic Diseases

OMISIRGE may transmit rare genetic diseases involving the hematopoietic system because it is derived from umbilical cord blood. Cord blood donors have been screened to exclude donors with sickle cell anemia, and anemias due to abnormalities in hemoglobins C, D, and E. Because of the age of the donor at the time cord blood collection takes place, the ability to exclude rare genetic diseases is severely limited.

ADVERSE REACTIONS

The most common adverse reactions (incidence > 20%) are infections, GvHD, and infusion reaction.

Please see full Prescribing Information, including Boxed Warning.

About Gamida Cell

Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company's proprietary nicotinamide (NAM) technology leverages the properties of NAM to enhance and expand cells, creating allogeneic cell therapy products and candidates that are potentially curative for patients with hematologic malignancies. These include Omisirge™ (omidubicel-onlv), an FDA-approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy, and GDA-201, an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, X, Facebook or Instagram.

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 potentially life-saving or curative therapeutic and commercial potential of Omisirge™ (omidubicel-onlv). 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 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. 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 August 14, 2023, and other filings that Gamida Cell makes with the SEC from time to time (which are available at 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.

Omisirge is a trademark of Gamida Cell Inc.

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