



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 OF
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of **May 2024**

Commission File Number: **001-36187**

EVOGENE LTD.

(Translation of Registrant's Name into English)

**13 Gad Feinstein Street, Park Rehovot
Rehovot 7638517, Israel**

(Address of principal executive offices)

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

Form 20-F ☒ Form 40-F ☐

CONTENTS

Evogene Ltd., or Evogene, today announces that its subsidiary, Biomica Ltd., or Biomica, presents positive initial clinical data update from ongoing Phase 1 trial of microbiome-based therapeutic, BMC128, in patients with non-small cell lung cancer (NSCLC), melanoma, or renal cell carcinoma (RCC). A copy of the press release is attached as Exhibit 99.1 to this Report of Foreign Private Issuer on Form 6-K, or this Form 6-K.

The content of Exhibit 99.1 to this Form 6-K, excluding the statements of Prof. Gal Markel and of Biomica's CEO, is incorporated by reference in the registration statements on [Form F-3](#) (Securities and Exchange Commission ("SEC") File No. [333-277565](#)), and Form S-8 (SEC File Nos. [333-193788](#), [333-201443](#), [333-203856](#) and [333-259215](#)) of Evogene, and will be a part thereof from the date on which this Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibits No.	
---------------------	--

99.1	Biomica Presents Positive Clinical Data Update from Ongoing Phase 1 Trial of Microbiome-Based Therapeutic, BMC128, for Refractory RCC, NSCLC & Melanoma
----------------------	---

Signature

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.

EVOGENE LTD.
(Registrant)

By: /s/ Yaron Eldad
Yaron Eldad
Chief Financial Officer

Date: May 23, 2024



**Biomica Presents Positive Clinical Data Update from
Ongoing Phase 1 Trial of Microbiome-Based Therapeutic,
BMC128, for Refractory RCC, NSCLC & Melanoma**

*Preliminary Phase 1 results show promising trends for BMC128 in combination
with nivolumab in refractory cancer patients. Data will be showcased at the 2024
American Society of Clinical Oncology (ASCO) annual meeting*

REHOVOT, Israel, May 23, 2024. Biomica Ltd., a clinical-stage biopharmaceutical company developing innovative microbiome-based therapeutics and a subsidiary of **Evogene Ltd.** (Nasdaq: EVGN, TASE: EVGN), today announced encouraging initial findings from an ongoing Phase 1 clinical trial. In the study, Biomica is investigating the safety and tolerability of its microbiome-based immuno-oncology candidate, BMC128, in combination with nivolumab, an anti-PD1 immune checkpoint inhibitor, in patients with non-small cell lung cancer (NSCLC), melanoma, or renal cell carcinoma (RCC).

All trial participants, 11 patients, had experienced disease progression in prior immunotherapy treatment before joining the trial. These preliminary findings represent some of the initial positive evidence emerging from the burgeoning field of clinical research on cancer therapies leveraging gut microbiota. While these results are preliminary and subject to further validation, they suggest potential benefits for patients facing advanced stages of these malignancies.

ASCO 2024 Presentation Details:

Title: Preliminary results from a First-in-Human (FIH), open-label Phase 1 study with BMC128, a rationally designed live bacterial consortium, in combination with nivolumab.

Session Type: Poster Session

Abstract Number: 8631

Date and Time: June 3, 2024, 1:30 PM – 4:30 PM (CDT)

Key observations from the study include:

- **Safety Profile:** As of the data cutoff date, the safety profile of BMC128 has been exceptional, with no major safety events potentially associated with BMC128 reported during the course of BMC128 monotherapy or combination treatment, indicating a favorable safety profile for the investigational therapy.

- **Clinical Responses:** As of the data cutoff date, among the patients included in the study, 72% of refractory cases exhibited positive clinical signals, indicating a potential efficacy for the BMC128 and nivolumab combination.
- **Response Rates:** As of the data cutoff date, one patient demonstrated partial response (PR) upon imaging and RECIST v1.1 assessment and remains actively responding to treatment. Additionally, 64% of patients' disease stopped progressing following the combination treatment, and they displayed stable disease (SD) and sustained benefits beyond the first imaging assessment, suggesting additional important potential clinical benefit.
- **Durability of Response:** As of the data cutoff date, 55% of patients showed sustained clinical benefit, with notable durations of response of over 16 weeks and with one patient exceeding 80 weeks.
- **Cross-Cancer Effectiveness:** 100% of RCC patients and 60% of NSCLC patients in the study demonstrated positive clinical outcomes, indicating potential efficacy across different cancer types.

With these encouraging early results, it is important to note that the study remains ongoing. Further data will become available and analyzed through the next few months to gain a deeper understanding of the therapeutic potential of BMC128 in combination with nivolumab in cancer treatment.

Prof. Gal Markel, Director of the Davidoff Cancer Center, Rabin Medical Center and Biomica's Scientific Advisory Board member, said: "The positive trends emerging from the ongoing Phase 1 trial of BMC128, particularly in combination with nivolumab, underscore the transformative potential of microbiome-based therapeutics in oncology. These findings bring hope to patients contending with refractory RCC, NSCLC, and melanoma, envisioning a future where innovative treatments like BMC128 could provide meaningful solutions to longstanding challenges in cancer care. Additionally, the observed cross-cancer effectiveness hints at BMC128's broad applicability across different cancer types, further solidifying its significance in the field of oncology. The demonstrated safety profile thus far, alongside the encouraging clinical benefits including response rate and notable durability, accentuates the potential efficacy of BMC128 in addressing the unmet needs of patients grappling with these malignancies. These initial results mark a significant advancement, reflecting our steadfast commitment to pioneering innovative solutions that address critical unmet needs in oncology."

Dr. Elran Haber, Biomica CEO, stated, "The preliminary results from this Phase 1 study show positive evidence of BMC128's superior safety profile and potential efficacy when combined with anti-PD1 checkpoint inhibitor immunotherapy. This suggests potential benefits for patients with refractory NSCLC, melanoma, or RCC who have not responded to, or developed resistance to previous immunotherapy treatments. We believe BMC128 has the promise to be a potential therapy for patients fighting cancer, and we look forward to continuing to evaluate BMC128's beneficial activity in subsequent phases of clinical development. Furthermore, these results underscore the strength of Biomica's computational platform for microbiome drug discovery, developed with Evogene, validating our approach to innovative therapeutic solutions."

Additional information about the trial, can be found at:

<https://clinicaltrials.gov> (ClinicalTrials.gov Identifier: NCT05354102).

About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to the principle that knowledge conquers cancer. Together with the Association for Clinical Oncology, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of high quality, equitable patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. The ASCO Annual Meeting is a unique and unparalleled opportunity to connect with one of the largest, most diverse audiences in global cancer care as well as global cancer experts and professionals, to discover the latest innovations in cancer research and education.

About BMC128:

BMC128 is a rationally-designed microbial consortium identified and selected through a detailed functional microbiome analysis using PRISM, a proprietary high-resolution microbiome analysis platform powered by Evogene's MicroBoost ^{AI} platform.

Developed as a Live Bacterial Product (LBP), BMC128 is an LBP consortium comprised of four unique bacterial strains, natural inhabitants of the human intestinal tract, that harbour specific functional capabilities with the potential to enhance immunological therapeutic responses and facilitate anti-tumor immune activity through multiple biological processes.

Rationally-designed consortia are multi-strain products designed to restore diversity and specific functionality to a host's microbial community with individually selected, cultured bacteria.

About Biomica Ltd.:

Biomica is a clinical stage biopharmaceutical company developing innovative microbiome-based therapeutics utilizing PRISM system, a proprietary computational platform powered by Evogene's *MicroBoost AI* tech-engine. licensed from Evogene. Biomica aims to identify and characterize disease-related microbiome entities and to develop novel therapeutics based on these understandings. The company is focused on the development of therapies for antibiotic resistant bacteria, immuno-oncology, and microbiome-related gastrointestinal (GI) disorders. Biomica is a subsidiary of Evogene Ltd. (Nasdaq: EVGN, TASE: EVGN).

For more information, please visit www.biomicaed.com

About Evogene Ltd.:

Evogene (Nasdaq: EVGN, TASE: EVGN) is a computational biology company aiming to revolutionize the development of life-science-based products by utilizing cutting-edge technologies to increase the probability of success while reducing development time and cost. Evogene established three unique tech-engines - *MicroBoost AI*, *ChemPass AI*, and *GeneRator AI* – leveraging Big Data and Artificial Intelligence and incorporating deep multidisciplinary understanding in life sciences. Each tech-engine is focused on the discovery and development of products based on one of the following core components: microbes (*MicroBoost AI*), small molecules (*ChemPass AI*), and genetic elements (*GeneRator AI*).

Evogene uses its tech-engines to develop products through subsidiaries and strategic partnerships. Evogene's subsidiaries currently utilize the tech-engines to develop human microbiome-based therapeutics by Biomica, ag-biologicals by Lavie Bio, ag-chemicals by AgPlenus, medical cannabis products by Canonic and castor varieties, for the biofuel and other industries, by Casterra.

For more information, please visit www.evogene.com.

Forward-Looking Statements:

This press release contains "forward-looking statements" relating to future events. These statements may be identified by words such as "will", "may", "could", "expects", "intends", "anticipates", "plans", "believes", "scheduled", "estimates", "demonstrates", or words of similar meaning. For example, Evogene and Biomica are using forward-looking statements in this press release when they discuss the safety and potential efficacy of BMC128 and its potential benefits for patients with refractory NSCLC, melanoma, or RCC who have not responded to or developed resistance to previous immunotherapy treatments. Such statements are based on current expectations, estimates, projections and assumptions, describe opinions about future events, and involve certain risks and uncertainties which are difficult to predict and are not guarantees of future performance. Therefore, actual future results, performance or achievements of Evogene and its subsidiaries may differ materially from what is expressed or implied by such forward-looking statements due to a variety of factors, many of which are beyond the control of Evogene and its subsidiaries, including, without limitation, the current war between Israel Hamas and Hezbollah and any worsening of the situation in Israel such as further mobilizations or escalation in the northern border of Israel and those risk factors contained in Evogene's reports filed with applicable securities authorities. Evogene and its subsidiaries disclaim any obligation or commitment to update these forward-looking statements to reflect future events or developments or changes in expectations, estimates, projections, and assumptions.

Contacts

Rachel Pomerantz Gerber

Head of Investor Relations at Evogene

rachel.pomerantz@evogene.com

Tel: +972-8-9311901
