
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 July 2023
Commission File Number: 001-37643

PURPLE BIOTECH LTD.
(Translation of registrant's name into English)

4 Oppenheimer Street, Science Park, Rehovot 7670104, 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 ☐

On July 11, 2023, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “*Purple Biotech Reports PDAC Part A results of CM24 Dose Escalation in Advanced Pancreatic Cancer Patients*”, which is attached hereto as Exhibit 99.1.

Exhibit

99.1 [Purple Biotech Reports PDAC Part A results of CM24 Dose Escalation in Advanced Pancreatic Cancer Patients](#)

Incorporation by Reference

This Report on Form 6-K, including all exhibits attached hereto, is hereby incorporated by reference into each of the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on May 20, 2016 (Registration file number 333-211478), the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on June 6, 2017 (Registration file number 333-218538), the Registrant’s Registration Statement on [Form F-3](#), as amended, originally filed with the Securities and Exchange Commission on July 16, 2018 (Registration file number 333-226195), the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on March 28, 2019 (Registration file number 333-230584), the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on September 16, 2019 (Registration file number 333-233795), the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on December 2, 2019 (Registration file number 333-235327), the Registrant’s Registration Statement on [Form F-1](#) filed with the Securities and Exchange Commission on December 27, 2019 (Registration file number 333-235729), the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on May 13, 2020 (Registration file number 333-238229), the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on May 18, 2020 (Registration file number 333-238481), each of the Registrant’s Registration Statements on Form F-3 filed with the Securities and Exchange Commission on July 10, 2020 (Registration file numbers [333-239807](#) and [333-233793](#)), the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on April 4, 2022 (Registration file number 333-264107) and the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on March 23, 2023 (Registration file number 333-270769) and the Registrant’s Registration Statement on [Form F-3](#), as amended, originally filed with the Securities and Exchange Commission on December 8, 2022 (Registration file number 333-268710), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

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.

July 11, 2023

PURPLE BIOTECH LTD.

By: /s/ Lior Fhima
Lior Fhima
Chief Financial Officer

Purple Biotech Reports Positive Results of CM24 Dose Escalation in Advanced Pancreatic Cancer Patients

- *Purple's innovative immuno-oncology, chemotherapy-free regimen reports encouraging Overall Survival data in 3rd line PDAC patients*
- *Randomized Phase 2 study is enrolling as expected with initial Phase 2 data expected by the end of 2023*

REHOVOT, Israel, July 11, 2023 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that harness the power of the tumor microenvironment to overcome tumor immune evasion and drug resistance, today announced the completion and data maturity of its Phase 1 dose escalation study of CM24, a first-in-class anti-CEACAM1 monoclonal antibody addressing multiple tumor types.

In the dose escalation part of the study, 11 refractory, pancreatic ductal adenocarcinoma (PDAC) patients whose cancer progressed following two lines of prior therapies were treated with CM24 at 10, 15 and 20mg/kg once every two weeks (q2w) and nivolumab at 480mg once every four weeks (q4w).

The investigational immunotherapy combination was well tolerated across all dose levels with no recorded Drug Limiting Toxicities (DLTs). Grade 3 adverse events were reported in 6 of the patients and none was considered related to the study drugs. No Grade 4 or deaths were reported.

Overall Survival (OS) data across all dose levels from this study with Purple's chemo free CM24 in combination with nivolumab, demonstrated comparable OS rate in comparison to historical data of third line patients treated with chemotherapy, which demonstrates an OS median rate in a range of 3 to 4 months¹.

Among the patients who demonstrated a response or disease control from the CM24 + nivolumab treatment, one third line patient has survived for 14.6 months. The patient had Microsatellite Stable (MSS) and PDL-1 IHC 2+ and 5% staining, features not expected to respond to immuno-oncology therapy.

Based on the study's safety, tolerability, efficacy, pharmacokinetic and pharmacodynamic data, the recommended Phase 2 dose of CM24 in combination with nivolumab was determined to be 20mg/kg. We believe that these encouraging and confirmed final results provide additional support to the rationale for conducting the already initiated Phase 2 randomized study of CM24 in combination with nivolumab and standard of care chemotherapy vs. standard of care chemotherapy alone, in the second line PDAC setting. This randomized Phase 2 study (NCT04731467) is being conducted as part of Purple Biotech's clinical collaboration with Bristol Myers Squibb.

"We are highly encouraged by these latest Phase 1 data and plan to provide further details from this study at an upcoming medical conference," said Isaac Israel, Purple Biotech's Acting Chief Executive Officer. "As we continue the Phase 2, which is enrolling as planned across multiple sites in the U.S., Europe, and Israel, we expect to share initial Phase 2 data by the end of 2023 and topline results later in 2024."

¹ Efficacy of the third-line chemotherapy in patients with advanced pancreatic cancer.

About Purple Biotech

Purple Biotech Ltd. (NASDAQ/TASE: PPBT) is a clinical-stage company developing first-in-class therapies that seek to overcome tumor immune evasion and drug resistance. The Company's oncology pipeline includes NT219, CM24 and IM1240. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. In a Phase 1/2 study of NT219, the Company is currently advancing it in a dose escalation as a monotherapy treatment of solid tumors, and in a dose escalation in combination with cetuximab for the treatment of recurrent and metastatic squamous cell carcinoma of the head and neck (SCCHN) or colorectal adenocarcinoma (CRC). These studies will be followed by an expansion phase of NT219 at its recommended Phase 2 level in combination with cetuximab in patients with recurrent and metastatic SCCHN. CM24 is a humanized monoclonal antibody that blocks CEACAM1, an immune checkpoint protein that supports tumor immune evasion and survival through multiple pathways. The Company is advancing CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in a Phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC). The Company has entered into a clinical collaboration agreement with Bristol Myers Squibb for the Phase 2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab in addition to chemotherapy. IM1240 is a preclinical, conditionally-activated tri-specific antibody that engages both T cells and NK cells to mount a strong, localized immune response within the tumor microenvironment. The third arm specifically targets the Tumor Associated Antigen (TAA) 5T4 that is expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. IM1240 has a cleavable capping technology that confines the compound's therapeutic activity to the local tumor microenvironment, and thereby potentially increases the anticipated therapeutic window in patients. The Company's corporate headquarters are located in Rehovot, Israel. For more information, please visit <https://purple-biotech.com/>.

Forward-Looking Statements and Safe Harbor Statement

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements that are not statements of historical fact, and may be identified by words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. You should not place undue reliance on these forward-looking statements, which are not guarantees of future performance. Forward-looking statements reflect our current views, expectations, beliefs or intentions with respect to future events, including (without limitation) our belief and expectation relating to the survival outcome rates for patients treated with CM24 in combination with nivolumab and our expected timeline to share data and topline results from the CM24 dose escalation study, and are subject to a number of assumptions, involve known and unknown risks, many of which are beyond our control, as well as uncertainties and other factors that may cause our actual results, performance or achievements to be significantly different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause or contribute to such differences include, among others, risks relating to: the plans, strategies and objectives of management for future operations; product development for NT219, CM24 and IM1240; the process by which such early stage therapeutic candidates could potentially lead to an approved drug product is long and subject to highly significant risks, particularly with respect to a joint development collaboration; the fact that drug development and commercialization involves a lengthy and expensive process with uncertain outcomes; our ability to successfully develop and commercialize our pharmaceutical products; the expense, length, progress and results of any clinical trials; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals necessary in order to commercialize our products; the difficulty of predicting actions of the U.S. Food and Drug Administration or any other applicable regulator of pharmaceutical products; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; the uncertainty surrounding the actual market reception to our pharmaceutical products once cleared for marketing in a particular market; the introduction of competing products; patents obtained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents; the commencement of any patent interference or infringement action against our patents, and our ability to prevail, obtain a favorable decision or recover damages in any such action; and the exposure to litigation, including patent litigation, and/or regulatory actions, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2022 and in our other filings with the U.S. Securities and Exchange Commission ("SEC"), including our cautionary discussion of risks and uncertainties under "Risk Factors" in our Registration Statements and Annual Reports. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those we have listed could also adversely affect us. Any forward-looking statement in this press release speaks only as of the date which it is made. We disclaim any intention or obligation to publicly update or revise any forward-looking statement or other information contained herein, whether as a result of new information, future events or otherwise, except as required by applicable law. You are advised, however, to consult any additional disclosures we make in our reports to the SEC, which are available on the SEC's website, <https://www.sec.gov>.

Company Contact:

Lior Fhima
Chief Financial Officer
IR@purple-biotech.com
