
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 September 2024
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 September 18, 2024, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release titled “*Purple Biotech Reports Additional Positive Interim Data from its Randomized Phase 2 Study with its Lead Oncology Therapeutic Candidate CM24*,” a copy of which is attached hereto as Exhibit 99.1.

Exhibit

99.1 *Press Release issued by Purple Biotech Ltd. on September 18, 2024*

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-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), 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), the Registrant’s Registration Statement on [Form F-1](#), as amended, originally filed with the Securities and Exchange Commission on October 30, 2023 (Registration file number 333-275216) and the Registrant’s Registration Statement on [Form F-1](#), filed with the Securities and Exchange Commission on July 22, 2024 (Registration file number 333- 280947), 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.

September 18, 2024

PURPLE BIOTECH LTD.

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

Purple Biotech Reports Additional Positive Interim Data from its Randomized Phase 2 Study with its Lead Oncology Therapeutic Candidate CM24

- *High CEACAM1 and low PDL1 expression in tumors, as well as their combination identified as potential biomarkers associated with improved overall survival (OS) of pancreatic ductal adenocarcinoma (PDAC) patients (HR=0.1 and prolongation of 4.1 months in median OS, p value 0.01, for the combination), which support the CM24/nivolumab combined treatment.*
- *Improved OS is demonstrated for patients with serum neutrophil extracellular trap (NET) marker myeloperoxidase (MPO) (HR=0.38 and prolongation of 3.3 months in median OS, p value 0.1), similar trend for NET positive tumors.*
- *The results presented in the poster propose NETs as a novel MoA and a potential biomarker for CM24-based therapy.*
- *New biomarker data supports the potential for future biomarker-led studies and exploration of CM24's efficacy in other cancers where the CEACAM1 novel target plays a key role in cancer progression and immune evasion*

REHOVOT, Israel, Sept. 18, 2024 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that overcome tumor immune evasion and drug resistance, today reported new positive biomarker findings for its lead oncology therapeutic candidate CM24. These data were presented yesterday at the American Association for Cancer Research® (AACR) Special Conference on Advances in Pancreatic Cancer Research currently ongoing in Boston, in a poster titled, "Exploratory biomarker evaluation of the randomized Phase 2 cohort of CM24 in combination with nivolumab and chemotherapy in advanced/metastatic pancreatic cancer".

"We are excited to present additional positive data from our Phase 2 study with CM24. CEACAM1 as a novel target in oncology continues to be supported by these data, underscoring its potential given its high expression on cancer cells, tumor infiltrating leucocytes and on NETs, suggesting the potential multiple roles of CM24 in overcoming immune evasion," stated Purple Biotech CEO Gil Efron. "Moreover, these data enable us to potentially design biomarker-guided studies for CM24 for the treatment of pancreatic ductal adenocarcinoma (PDAC), as well as other cancers."

Purple Biotech's Phase 2 study is evaluating CM24 in combination with Bristol Myers Squibb's PD-1 inhibitor nivolumab plus standard of care (SoC) chemotherapy as a second line treatment of patients with PDAC and compared to SoC chemotherapy alone. Sixty-three patients have been enrolled in the randomized study across 18 centers in the U.S., Spain, and Israel.

The following is a summary of findings presented in the poster:

Mechanism of Action

CM24 blocks CEACAM1 interactions, which have key roles in cancer progression, immune escape and metastasis. CEACAM1 is part of the NET complex, involved in tumor immune evasion, metastasis and cancer-associated thrombosis, affecting patient survival. Purple Biotech has previously presented data that demonstrates that CM24 binds to CEACAM1 on NETs, suppresses NET-induced migration of cancer cells and inhibits *in-vivo* tumor metastasis. In the poster, Purple Biotech presents data that demonstrates that CM24 also inhibits NET-induced platelet aggregation, an *in-vitro* assay imitating the thrombosis process.

CM24+nivolumab+Nal-IRI/5FU/LV treatment of PDAC patients reduced serum levels of the NET marker, MPO, and showed potential overall survival (OS) benefit to patients with reduced post-dose MPO as compared to the control arm.

NET Marker MPO as a Potential Serum Biomarker for Patient Selection for CM24-Based Therapy

An analysis of patients with serum MPO levels < 350 ng/mL, demonstrated a potential 62% reduction in risk of death (HR=0.38) for CM24+nivolumab+Nal-IRI/5FU/LV therapy in PDAC patients, and prolongation of 3.3 months in median OS. This compared to an analysis of all patients which demonstrated a potential 25% reduction in risk of death (HR=0.75) and prolongation of 2.1 months in median OS.

High Tumor CEACAM1 & Low PDL1 as Potential Biomarkers for CM24-Based Therapy

An analysis of patients with high CEACAM1⁺tumor cells (H-score > 115) or low PDL1 (CPS ≤ 1) demonstrated a potential 45% and 65% reduction in risk of death (HR=0.55 and 0.35), respectively.

Combining these two potential biomarkers, suggests augmented outcome of 90% reduction in risk of death (HR=0.1) for CM24+nivolumab+Nal-IRI/5FU/LV therapy in PDAC patients, and prolongation of 4.1 months in median OS (*p value 0.01*).

“A serum biomarker for patient selection is a major advantage for cancer patients in general and PDAC patients in particular. The additional interim data suggesting serum NET levels as a potential biomarker for improving the outcome of CM24-based therapy, together with the ability of this therapy to reduce serum NET levels in PDAC patients and to inhibit NET-related activities in vitro, add supporting evidence for NETs as a new mechanism of action (MoA) and potential biomarker for CM24-based therapy,” said Dr. Hadas Reuveni, VP R&D of Purple Biotech. “Additional encouraging results suggesting that the CM24/ nivolumab/chemotherapy effect is most pronounced among patients with high CEACAM1 expression and low PDL1 also relate to the CM24/nivolumab MoA and support the CM24/nivolumab combined treatment. This may open a new opportunity for patients who are not eligible for anti-PD1 therapy in various indications. A larger sample size is required to confirm the results and better define the cutoff values.”

Interim data from Purple Biotech’s Phase 2 study presented in June at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated improvement in OS, progression free survival (PFS), objective response rate (ORR) and all other efficacy endpoints in the CM24+nivolumab+Nal-IRI/5FU/LV experimental arm as compared with the SoC control arm. Topline data are expected in the fourth quarter of 2024.

The poster is available on the Publications section of Purple Biotech’s website and in the following link: <https://purple-biotech.com/pipeline/#1Publications>

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 CM24, NT219 and IM1240. CM24 is a humanized monoclonal antibody that blocks CEACAM1, that supports tumor immune evasion and survival through multiple pathways. CEACAM1 on tumor cells, immune cells and neutrophils extracellular traps is a novel target for the treatment of multiple cancer indications. As a proof of concept of these novel 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. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. A Phase 1 dose escalation study was concluded as a monotherapy and in combination with cetuximab in which NT219 demonstrated anti-tumor activity in combination with cetuximab in second line patients with recurrent and/or metastatic SCCHN (R/N SCCHN). The Company is advancing CAPTN-3, a preclinical platform of conditionally-activated tri-specific antibody that engages both T cells and NK cells to induce a strong, localized immune response within the tumor microenvironment. The cleavable capping technology confines the compound's therapeutic activity to the local tumor microenvironment, and thereby potentially increases the anticipated therapeutic window in patients. The third arm specifically targets the Tumor Associated Antigen (TAA). The technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems to mount an optimal anti-tumoral immune response. IM1240 is the first tri-specific antibody in development that targets 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. 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, 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, 2023 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>.

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