
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 June 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 June 27, 2024, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release titled, “*Purple Biotech Reports Additional Positive Interim Results from its Randomized Phase 2 Pancreatic Cancer Study with CM24 Regarding a Potential Predictive Biomarker for Overall Survival Benefit*” a copy of which is attached hereto as Exhibit 99.1

Exhibit

99.1

[Press Release issued by Purple Biotech Ltd. on June 27, 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) and the Registrant’s Registration Statement on [Form F-1](#) filed with the Securities and Exchange Commission on October 30, 2023 (Registration file number 333-275216), 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.

June 27, 2024

PURPLE BIOTECH LTD.

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

Purple Biotech Reports Additional Positive Interim Results from its Randomized Phase 2 Pancreatic Cancer Study with CM24 Regarding a Potential Predictive Biomarker for Overall Survival Benefit

- *New data suggests that baseline serum myeloperoxidase (MPO) levels below the threshold may predict overall survival (OS) improvement when comparing the CM24+nivolumab+Nal-IRI/5FU/LV vs. Nal-IRI/5FU/LV arms*
- *Data reported at the 2024 ASCO annual meeting demonstrated reduced risk of death and cancer progression, prolongation of OS and progression free survival (PFS) as well as higher objective response rate (ORR) and disease control rate (DCR) and decreasing CA19-9 levels in the CM24+Nivolumab+Nal-IRI/5FU/LV arm*
- *Further data and top line results are expected in the second half of 2024*
- *Company to host virtual key opinion leader (KOL) event to discuss results on July 11, 2024*

REHOVOT, Israel, June 27, 2024 (GLOBE NEWSWIRE) – Purple Biotech Ltd. (“Purple Biotech” or “the Company”) (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class oncology therapies that overcome tumor immune evasion and drug resistance, today reported additional positive interim data from its randomized, controlled, open label, multicenter Phase 2 study (NCT 04731467) of CM24, in combination with Bristol Myers Squibb’s immune checkpoint inhibitor nivolumab and standard of care (SoC) chemotherapy, in second-line metastatic pancreatic ductal adenocarcinoma (PDAC). These results suggest that serum MPO may be a predictive biomarker for survival in the CM24+Nivolumab + Nal-IRI/5FU/LV arm. The company also announced that it will host a virtual KOL event on Thursday, July 11, 2024 at 10:30 AM ET to discuss the results in detail. To register for the event, [click here](#).

Interim results that were presented on June 1, 2024 during a late-breaking abstract poster presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated a 26% reduction in risk of death (HR=0.74) and a 28% risk reduction in progression or death (HR=0.72) in previously-treated patients treated with CM24+nivolumab+Nal-IRI/5FU/LV vs. Nal-IRI/5FU/LV chemotherapy alone (i.e., SoC). Median OS was prolonged by 2.1 months and median PFS was extended by 1.9 months in the CM24+nivolumab+Nal-IRI/5FU/LV regimen vs. SoC. The prolongation of both OS and PFS by the CM-24-nivolumab therapy is further supported by a higher ORR (25% vs 7%), DCR (63% vs 40%), and decrease in CA19-9 level (61% decrease vs. 34% increase).

“The concordant and consistent improvement in primary and all secondary endpoints including OS, PFS, ORR, DCR and CA19-9 are compelling, and the addition of a potential predictive biomarker provides further support for the potential of CM24 in combination with nivolumab plus the SoC chemotherapy regimen Nal-IRI/5FU/LV to improve clinical outcomes for those with advanced metastatic PDAC.” stated Gil Efron, Chief Executive Officer of Purple Biotech. “We plan to report further clinical study data in the second half of 2024.”

New Interim Exploratory Biomarker Data:

This interim biomarker analysis comparing the experimental and control arms suggests measured baseline serum MPO as a potential clinical outcome biomarker for CM24-nivolumab therapy.

- Enhanced MPO levels were measured in >90% of the patients with mean MPO over 6-fold higher than healthy donors. The mean MPO is used as a threshold for evaluating MPO as a potential biomarker.
 - The effect of the CM24-nivolumab therapy in combination with Nal-IRI/5FU/LV is most pronounced among patients with serum MPO levels below the mean MPO and is associated with OS improvement of 3.6 months in median OS of 8.1 months vs. 4.5 months (HR 0.34 (95% CI: 0.099-1.149)).
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While in a small sample size, these findings suggest that serum MPO may be a predictive biomarker for the treatment effect of CM24+Nivo+ Nal-IRI/5FU/LV on OS.

Presentation of the biomarker data is planned at an upcoming medical conference.

The experimental arms of the randomized Phase 2 study administered patients with CM24 plus nivolumab and a choice of one of two SoC chemotherapies used in second-line PDAC, and dependent on prior first line therapy regimen; either gemcitabine/nab-paclitaxel or liposomal irinotecan (Nal-IRI)/5-fluorouracil (5-FU) and leucovorin (LV) (Nal-IRI/5FU/LV), while the control arms administered either respective SoC chemotherapy alone. Interim results are provided for the Nal-IRI/5FU/LV sub study. An analysis of the gemcitabine/nab-paclitaxel sub study will be performed later when the data sufficiently matured.

CM24 is a humanized monoclonal antibody that blocks CEACAM1, an immune checkpoint protein responsible for tumor immune evasion and poor tumor response and/or resistance to immune checkpoint inhibitors. Neutrophil extracellular traps (NETs) which are involved in immune evasion and metastasis known to affect disease progression and patient survival. CM24, a CEACAM1 antibody, was reported¹ to also bind to NET structures and significantly suppresses the NET-induced migration of various cancer cells, as an additional Mechanism of Action. In an earlier part of this study, CM24+nivolumab treatment significantly reduced the level of the NET marker, as represented by measurable MPO in patient serum.

The poster presentation at ASCO 2024 may be viewed on Purple Biotech's website [HERE](#) and the abstract may be accessed on ASCO's website [HERE](#).

Purple Biotech: Interim data from the phase 2 randomized study of CM24 and nivolumab in combination with Nal/IRI in advanced/metastatic PDAC patients, presented at ASCO 2024 annual meeting

Parameter	Experimental (n=16)	Control (n=15)
OS (mo, median; 95% CI)	7.72 (4.00-8.11)	5.62 (3.22 -7.89)
OS HR (95% CI)	0.74 (0.31-1.77)	
6 mo OS (%)	52.7	38.9
PFS (mo, median; 95% CI)	3.8 (1.8-5.0)	1.9 (0.9-3.6)
PFS HR (95% CI)	0.72 (0.33-1.60)	
3 mo PFS (%)	60.0	46.7
6 mo PFS (%)	19.0	10.0
ORR (%)	25.0	6.7
DCR (%)	62.5	40.0

1. Poster presentation at AACR Special Conference: Pancreatic cancer 2023: Phase 1 Study of CM24 in Combination with Nivolumab in Patients with Advanced Pancreatic Cancer - Survival, Exploratory Biomarkers and Effect on Neutrophil Extracellular Traps (NETs)

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. A Phase 1 dose escalation study is being concluded and a Phase 2 study of NT219 at its recommended Phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer (SCCHN) is planned. 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. The Company is also advancing a preclinical platform of conditionally-activated tri-specific antibodies that engage 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 of the antibody specifically targets the Tumor Associated Antigen (TAA). The technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems to induce an optimal anti-tumor immune response. IM1240 is the platform's lead tribody 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; final results from clinical studies, including our NT219 and CM24 studies, may vary from the interim analysis, 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; the impact of the economic, public health, political and security situation in Israel, the U.S. and other countries in which we may operate or obtain approvals for our products or our business, 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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