
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 March 2021
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 ☐

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On March 19, 2021, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “**Purple Biotech Appoints Announces Initiation of Phase 1b/2 Clinical Trial of CM24 for Treatment of Multiple Advanced Cancers**”, which is attached hereto as Exhibit 99.1.

Exhibits

99.1 [Press Release](#)

Incorporation by Reference

This 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-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 28, 2020 (Registration file number 333-238481) and 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](#)), 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.

March 19, 2021

PURPLE BIOTECH LTD.

By: */s/ Isaac Israel*

Isaac Israel
Chief Executive Officer

Purple Biotech Announces Initiation of Phase 1b/2 Clinical Trial of CM24 for Treatment of Multiple Advanced Cancers

Study Being Conducted in Clinical Collaboration with Bristol Myers Squibb

Preliminary Data from First Part of Study Expected to be Available in Second Half of 2021

REHOVOT, Israel, March 19, 2021 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class, effective and durable therapies by overcoming tumor immune evasion and drug resistance, today announced the initiation of a Phase 1b/2 clinical trial evaluating CM24, a monoclonal antibody blocking CEACAM1, in advanced cancer patients, with expansion cohorts in subjects with non-small cell lung cancer (NSCLC) and pancreatic cancer. The trial will be conducted in clinical collaboration with Bristol Myers Squibb.

"The initiation of this Phase 1b/2 clinical trial represents an important milestone for our CM24 development program," said Michael Schickler, Ph.D., Head of Clinical Operations and Regulatory Affairs of Purple Biotech. "In a Phase 1a monotherapy study, CM24 demonstrated good safety and a signal of efficacy, with a 33% disease control rate with up to 10mg/kg dosing. Moreover, pharmacokinetic (PK) and pharmacodynamic modelling demonstrated target saturation expected at higher doses of CM24 on a two-week schedule. The Phase 1b/2 study will be conducted in multiple countries, with sites anticipated in the U.S., E.U. and Israel, and we expect preliminary data from the first part of the study in the second half of this year."

"CEACAM1 levels are prognostic in a number of cancers, and relate to multiple mechanisms of action in neoplastic disease, from oncogenesis to influencing the tumor microenvironment," said Bertrand Liang, M.D., Ph.D., Chief Medical Officer of Purple Biotech. "Based on its profile and the compelling Phase 1a data, we believe this study, which will evaluate CM24 at higher doses in combination with nivolumab in NSCLC patients and in combination with nab-paclitaxel and nivolumab in pancreatic cancer patients, will provide important data on blocking CEACAM1 in these critical unmet medical needs."

CM24 will be dose escalated from 10mg/kg, targeting the 20mg/kg dose, in combination with nivolumab in Phase 1b, in patients with NSCLC, pancreatic cancer, ovarian carcinoma, colorectal adenocarcinoma, melanoma or thyroid carcinoma, with the primary objective of evaluating safety, PK and determining the recommended Phase 2 dose. In the Phase 2 component, patients with NSCLC will be treated with CM24 and nivolumab after first-line immuno-oncology failure, and patients with metastatic pancreatic adenocarcinoma will be treated with CM24, nivolumab and nab-paclitaxel after first-line therapy failure, with study endpoints being safety and preliminary efficacy. CEACAM1 level of expression, as well as a number of other immune and adhesion-related molecules, will be evaluated as potential biomarkers in the study.

About Purple Biotech

Purple Biotech Ltd. (f/k/a Kitov Pharma Ltd.) (the "Company"; NASDAQ/TASE: KTOV) is a clinical-stage company developing first-in-class therapies by overcoming tumor immune evasion and drug resistance. The Company's oncology pipeline includes NT219 and CM24. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. The Company is currently advancing NT219 as a monotherapy treatment of solid tumors, followed by a dose escalation of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer (SCCHN) or colorectal adenocarcinoma in a phase 1/2 study, and an expansion phase 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. 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 selected cancer indications in a phase 1 study followed by a phase 2 for the treatment of non-small cell lung cancer and pancreatic cancer. The Company has entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the planned phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo®) in patients with non-small cell lung cancer and in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE®) in patients with pancreatic cancer. The Company is also the owner of Consensi®, an FDA-approved fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension that was approved by the FDA for marketing in the U.S. Consensi® is being sold in the U.S. by Burke Therapeutics, the marketing partner of the Company's U.S. distributor, Coeptis Pharmaceuticals. The Company has also partnered to commercialize Consensi in China and South Korea. The Company has recently relocated its corporate headquarters imminently to Rehovot, Israel. For more information, please visit <http://www.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 and CM24; the process by which early stage therapeutic candidates such as NT219 and CM24 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, 2019 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, <http://www.sec.gov>.

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