
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 2022
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): ☐

Purple Biotech Ltd. (the “Company” or the “Registrant”) is announcing the following:

1) Initiation of Phase 2 Study for CM24:

On May 18, 2022 the Company issued a press release, “*Purple Biotech Announces the Initiation of Phase 2 Study for CM24 in 2L PDAC Patients*”, a copy of which is attached hereto as Exhibit 99.1.

Exhibit

99.1 [Purple Biotech Announces the Initiation of Phase 2 Study for CM24 in 2L PDAC Patients](#)

2) Dismissal of the BIRAD Lawsuit

The Company is announcing that on May 16, 2022, the Tel Aviv District Court fully dismissed with prejudice the lawsuit filed by Bar Ilan University and BIRAD Research& Development Company Ltd. (the “University” and “BIRAD”, respectively) on December 21, 2020 against the Company’s subsidiary TyrNovo Ltd. (“TyrNovo”), a TyrNovo officer and others, alleging that the University is the rightful owner of one of the patents owned by TyrNovo resulting from experiments performed under a services agreement between BIRAD and TyrNovo, as described under “Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings” in the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2021, filed with the SEC on March 9, 2022 (the “Patent”, the “Services Agreement”, the “BIRAD Lawsuit”, and the “Annual Report on Form 20-F”, respectively).

The Court’s full dismissal of the BIRAD Lawsuit is based on a mediation arrangement signed between TyrNovo, all other defendants in the BIRAD Lawsuit, the University and BIRAD on May 16, 2022. Under the terms of such mediation arrangement, TyrNovo retains ownership of its patent and other intellectual property rights as stipulated in the Services Agreement.

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, 2021 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>.

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 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](#)) and 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), 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.

May 18, 2022

PURPLE BIOTECH LTD.

By: /s/ Isaac Israel
Isaac Israel
Chief Executive Officer

Purple Biotech Announces the Initiation of Phase 2 Study for CM24 in 2L PDAC Patients

Decision based on positive interim Phase 1b data in pancreatic ductal adenocarcinoma (PDAC)

REHOVOT, Israel, May 17, 2022 -- Purple Biotech Ltd. ("Purple Biotech", or the "Company") (NASDAQ/TASE: PPBT), a clinical-stage company focused on developing first-in-class, effective and durable therapies by harnessing the power of the tumor microenvironment to overcome tumor immune evasion and drug resistance, today announced the initiation of the Phase 2 portion of its ongoing study of CM24, a first-in-class monoclonal antibody with the potential to treat multiple cancers. The Phase 2 is an open-label, multicenter study in subjects with metastatic pancreatic cancer (PDAC) to evaluate the safety and tolerability of CM24 in combination with the PD-1 inhibitor Opdivo® (nivolumab) and chemotherapy. The primary study endpoint is to evaluate preliminary efficacy in 2nd line PDAC.

The phase 2 portion of the study (NCT04731467) is being conducted as part of Purple Biotech's clinical collaboration with Bristol Myers Squibb. The companies together made the determination to prioritize PDAC over non-small cell lung cancer (NSCLC) based on the positive interim data. Accordingly, this decision will allow an increase in the number of subjects that will be participating, and will accelerate this part of the study, and the updated timeline to complete this trial is within 2023.

"Pancreatic ductal adenocarcinoma, or pancreatic cancer, has one of the highest mortality rates of all cancers and affects tens of thousands of patients each year. While progress has been made in understanding and treating pancreatic cancer, more effective treatments are needed. It is exciting to have CM24 and Opdivo® showing a confirmed partial response in a patient with pancreatic cancer with an MSS tumor, where other immune checkpoint inhibitors have failed to show response to date. In addition, the safety profile of CM24 in combination with nivolumab and the positive efficacy signals in advanced patients with very poor prognosis in the study are encouraging, and support the advancement of the clinical study in patients with pancreatic cancer," said Erkut Borazanci, MD, Deputy Director Oncology and Clinical Investigator at HonorHealth Research Institute, Scottsdale, AZ.

"We are thrilled at the progress being made to help move this treatment forward in the clinical trial process for the potential benefit of patients with pancreatic cancer," said Gil Efron, President and CFO of Purple Biotech. "We are thankful for our partners at BMS for collaborating with us on this study and their support. Importantly, the decision to prioritize the PDAC study will extend the cash runway of Purple Biotech through the end of 2024," added Efron.

This announcement follows the release of interim safety and efficacy results from the Phase 1b portion of the study of CM24 in combination with Opdivo® shared at the American Association for Cancer Research (AACR) Annual Meeting in April. Information shared demonstrated a favorable safety profile. Six Grade 3 adverse events (AEs) that were unrelated to CM24 or nivolumab and no Grade 4 AEs or deaths were reported. Encouraging signals of efficacy in advanced patients with PDAC were reported (n=8, ORR=12%, DCR=37%), with one confirmed partial response in a patient with metastatic pancreatic cancer, as well as three patients with stable disease, including two patients with pancreatic cancer and one patient with papillary thyroid cancer. All patients but one received two prior lines of treatment for their metastatic disease.

OPDIVO® is a trademark of Bristol-Myers Squibb Company.

About Purple Biotech

Purple Biotech Ltd. is a clinical-stage company developing first-in-class therapies designed to overcome 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 dose in combination with cetuximab in patients with recurrent and/or 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 selected cancer indications. The Company initiated a phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC). The Company has entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo®) in addition to chemotherapy. The Company's corporate headquarters are located in Rehovot, Israel. For more information, please visit <https://purple-biotech.com>.

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