
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 December 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 December 6, 2021, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “**Purple Biotech Announces Initiation of Part 2 of Ongoing Phase 1/2 Clinical Trial Evaluating NT219 for Treatment of Multiple Cancers Supporting Potential Expansion of Clinical Program**”, a copy of this press release is furnished herewith as Exhibit 99.1.

Exhibit

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.

December 6, 2021

PURPLE BIOTECH LTD.

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

**Purple Biotech Announces Initiation of Part 2 of Ongoing Phase 1/2 Clinical Trial Evaluating NT219 for Treatment of Multiple Cancers
Supporting Potential Expansion of Clinical Program**

Part 2 is a Dose Escalation Study of NT219, in Combination with cetuximab (ERBITUX®), in Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of Head and Neck Cancer or Colorectal Adenocarcinoma

Monotherapy Study (Part 1) Continues to Progress Well, with good Safety and Promising Signals of Efficacy Supporting Potential Expansion of Clinical Program

REHOVOT, Israel, December 6, 2021 (GLOBE NEWSWIRE) -- 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 Part 2 of its ongoing Phase 1/2 clinical trial of NT219, a novel small molecule inhibiting simultaneously IRS1/2 and STAT3, for the treatment of multiple cancers. Part 2 is a dose escalation study of NT219, beginning with 6mg/kg, in combination with the standard dose of cetuximab (ERBITUX®), in patients with recurrent or metastatic squamous cell carcinoma of head and neck cancer (SCCHN) or colorectal adenocarcinoma.

The monotherapy portion of the study, Part 1, is progressing as planned, and is now dosing patients with advanced solid tumors in the 24mg/kg cohort. To date, no drug limiting toxicities have been observed in the trial, and NT219 has been found to be well-tolerated with minimal serious adverse events.

Initial efficacy data previously reported from the first dose level in Part 1, and additional efficacy signals in the following two cohorts, support the immediate extension of the study to Part 2 of the study, dosing NT219 at its recommended Phase 2 dose in combination with cetuximab in patients with recurrent or metastatic SCCHN, as well as the potential expansion of the clinical program to new indications, which is anticipated to commence during the second half of 2022.

Additional preliminary efficacy data from Part 1 of the trial is expected to be presented at a medical meeting in the first half of 2022.

“The advancement of our ongoing Phase 1/2 clinical trial to Part 2 represents an important achievement for our NT-219 clinical development program,” said Michael Schickler, Ph.D., Head of Clinical and Regulatory Affairs of Purple Biotech. “We are encouraged by the initial signals of efficacy, as well as safety trends, observed in Part 1 of the study to date. We look forward to the availability of additional preliminary efficacy data from Part 1 of the study in the first half of 2022, as well as to the further advancement of our development program to Part 2 of the study, and to the potential expansion of the clinical program into other unmet cancer indications, in the second half of 2022.”

About Purple Biotech

Purple Biotech Ltd. 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, a novel small molecule that simultaneously targets IRS1/2 and STAT3. The Company is currently advancing NT219 as 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 cancer. 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 1b 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's corporate headquarters are located in Rehovot, Israel. For more information, please visit <https://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, 2020 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:

Gil Efron
President & Chief Financial Officer
IR@purple-biotech.com

Investor Relations Contact:

Chuck Padala
chuck@lifesciadvisors.com
+1 646-627-8390

Media Contact:

Megan Humphreys
megan@mlhconsulting.com
