
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 February 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 February 1, 2024, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “*Purple Biotech Reaches Recommended Phase 2 Dose for NT219*” a copy of which is attached hereto as Exhibit 99.1.

Exhibit

99.1 [Purple Biotech Reaches Recommended Phase 2 Dose for NT219](#)

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) and 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), 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.

February 1, 2024

PURPLE BIOTECH LTD.

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

Purple Biotech Reaches Recommended Phase 2 Dose for NT219

REHOVOT, Israel, Feb. 01, 2024 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that harness the power of the tumor microenvironment to overcome tumor immune evasion and drug resistance, today announced it has determined 100mg/kg is the recommended Phase 2 dose (RP2D) for NT219 in combination with cetuximab in the treatment of head and neck cancer based on its Phase 1/2 dose escalation study (NCT04474470). NT219 is a first-in-class small molecule dual inhibitor of IRS1/2 and STAT3.

The RP2D was determined based on data from the open-label dose escalation study designed to assess the safety, pharmacokinetics, pharmacodynamics and efficacy of NT219 in combination with Erbitux® (cetuximab), in previously treated recurrent and/or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN) patients. The Company recently reported that NT219, in combination with cetuximab, demonstrated a dose dependent anti-tumor activity with confirmed partial responses. No dose-limiting toxicities were reported. The additional supporting data used for this determination was pharmacokinetics of NT219 across all dose levels. Further dose optimization is planned for future studies.

The Phase 1 dose escalation study is being concluded and the remaining patients' data are expected to be reported during the first half of 2024. The Company is now advancing its upcoming Phase 2 Proof of Concept study of NT219 for the treatment of R/M SCCHN.

Detailed clinical results from the dose escalation portion of the study are intended to be presented at the European Society of Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Congress 2024 in Paris on February 26, 2024, in an Oral Presentation titled "Interim results of a Phase 1/2 trial of NT219 in combination with cetuximab in patients with advanced/metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)."

"This is a major milestone for the development of NT219 for an indication in need of more effective therapies. As we progress into a Phase 2 study, our goal is to establish NT219 as standard of care for squamous cell carcinoma of the head and neck for patients who have not responded to first line treatments," stated Gil Efron, Chief Executive Officer of Purple Biotech. "We look forward to treating more patients with NT219 in a Phase 2 study."

About NT219

NT219 is a first-in-class, small molecule that promotes Insulin Receptor Substrates 1/2 (IRS) degradation and inhibits Signal Transducer and Activator of Transcription 3 (STAT3) phosphorylation, two major complementary signalling pathways that play a key role in the tumor and its microenvironment. IRS1/2 acts as scaffolds, organizing signalling complexes that mediate mitogenic, metastatic, angiogenic, and anti-apoptotic signals from IGF1R and other oncogenes, consisting of an important driver in multiple cancers and is highly involved in triggering drug resistance. STAT3 is a transcription factor that is broadly hyperactivated in many cancers, promoting proliferation, survival, angiogenesis, metastasis, and tumor immune evasion. Feedback activation of STAT3 plays a prominent role in mediating drug resistance to various anti-cancer therapies. As an inhibitor of both IRS1/2 and STAT3, NT219 has the potential to prevent the development of resistance to multiple approved therapies.

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 2 study of NT219 at its recommended Phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic 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 advancing a preclinical platform of conditionally-activated tri-specific antibody that engages both T cells and NK cells to mount 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, 2022 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>.

CONTACTS:

Company Contact:

Lior Fhima
Chief Financial Officer
IR@purple-biotech.com
