
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 2025
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 18, 2025, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “*Purple Biotech Advances NT219 into Phase 2 Head and Neck Cancer Trial*”, which is attached hereto as Exhibit 99.1.

Exhibit

99.1 [Press Release issued by Purple Biotech Ltd. on February 18, 2025](#)

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), the Registrant’s Registration Statement on [Form F-1](#), as amended, originally filed with the Securities and Exchange Commission on October 30, 2023 (Registration file number 333-275216) and the Registrant’s Registration Statement on [Form F-1](#), filed with the Securities and Exchange Commission on July 22, 2024 (Registration file number 333-280947), 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 18, 2025

PURPLE BIOTECH LTD.

By: /s/ Gil Efron

Gil Efron

Chief Executive Officer

Purple Biotech Advances NT219 into Phase 2 Head and Neck Cancer Trial

NT219, a novel agent designed to overcome tumor resistance to drug therapy, will be evaluated in combination with the standard-of-care head and neck cancer drugs pembrolizumab (Keytruda) or cetuximab (Erbixux)

The study is conducted in collaboration with the University of Colorado Anschutz Medical Campus and is led by Dr. Antonio Jimeno, Professor and Director of the Head and Neck Cancer Program

REHOVOT, Israel, Feb. 18, 2025 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that overcome tumor immune evasion and drug resistance, announced today it is advancing into a Phase 2 study with NT219 in patients with recurrent/metastatic squamous cell carcinoma of the head and neck (R/M SCCHN). Purple Biotech's NT219 is a first-in-class small molecule drug designed to target key cancer resistance mechanisms by degrading IRS1/2 and blocking IGF1R/IRS1 and STAT3 survival pathways, resensitizing refractory tumors to immune checkpoint inhibitors, EGFR blockers, and chemotherapy, as demonstrated in various preclinical models.

The market for products and treatments related to SCCHN is forecast to become a \$5 billion market by 2030, yet only 20% of recurrent/metastatic SCCHN patients respond to pembrolizumab (Keytruda), the world's top-selling oncology drug and only 15%-20% respond to cetuximab (Erbixux). Approximately 175,000 people are diagnosed with SCCHN annually, making it the sixth most common cancer type.

The Phase 2 study will assess the efficacy and safety of NT219 as a combination therapy to further investigate NT219's role in overcoming tumor resistance to standard-of-care checkpoint inhibitors, such as pembrolizumab, and EGFR blockers, such as cetuximab. The study is designed as two single-arm cohorts: one arm will evaluate for the first time the combination of NT219 with pembrolizumab, an anti-PD-1 therapy, and the other arm will evaluate NT219 in combination with cetuximab for the treatment of recurrent/metastatic SCCHN. Additionally, the study will assess potential biomarkers identified in a previous clinical study of NT219. The overall statistical design of each arm follows a Simon 2-stage approach, with an initial enrollment of 10 patients per arm, followed by an expansion cohort of an additional 19 patients per arm in the second stage. The study is an investigator-initiated trial and is led by Dr. Antonio Jimeno, Professor and Director of the Head and Neck Cancer Program at the University of Colorado Anschutz Medical Campus.

Dr. Jimeno focuses his research on achieving durable tumor control for head and neck cancers (SCCHN), with an in-depth view of the cancer and immune cell interaction. He recently demonstrated the central role of STAT3 in the PD1-PDL1 axis and tumor clonogenicity, motility, invasion, as well as resistance to immunotherapy, radiation and chemotherapy.

Dr. Jimeno commented, "NT219 is a novel and unique compound inhibiting both IRS and STAT3 oncogenic pathways, which are complementary and activated in SCCHN. The combination with the standard of care pembrolizumab or cetuximab leverages and moves forward our preclinical research demonstrating that such a combination could benefit patients with SCCHN, and I look forward to the results of this study combination in the near future."

“We are pleased and honored to collaborate with Dr. Jimeno and the University of Colorado Anschutz Medical Campus in support of this important study, which aims to address a significant unmet medical need in SCCHN patients who, despite encouraging results in recent mid-stage clinical studies, still have limited treatment options due to the emergence of tumor resistance to current therapies,” stated Gil Efron, Purple Biotech CEO. “NT219 has the potential to establish a new standard of care in combination with pembrolizumab or cetuximab. Purple Biotech remains committed to advancing novel therapeutic strategies that can improve outcomes for patients with aggressive and treatment-resistant cancers.”

The Phase 2 study builds upon Purple Biotech’s Phase 1 studies, which determined the recommended dose of NT219, demonstrating the drug’s anti-tumor activity and confirmed patient responses. Preclinical models in tumors that developed immune resistance post PD1 therapy demonstrated that the combination of NT219 plus PD1 inhibition (i.e., pembrolizumab) reversed that resistance and resulted in tumor shrinkage, while PD1 therapy alone did not. These findings were due to documented reversal of immunosuppressive tumor microenvironment to an immunoreactive microenvironment, conforming with NT219’s mechanism of action.

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 CM24, NT219, and CAPTN-3. CM24 is a humanized monoclonal antibody that blocks CEACAM1, which supports tumor immune evasion and survival through multiple pathways. CEACAM1 on tumor cells, immune cells and neutrophils extracellular traps is a novel target for the treatment of multiple cancer indications. As proof of concept of these novel pathways, the Company completed a Phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC) with CM24 as a combination therapy with the anti-PD-1 checkpoint inhibitor nivolumab and chemotherapy, demonstrating clear and consistent improvement across all efficacy endpoints and the identification of two potential serum biomarkers. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. A Phase 1 dose escalation study was concluded as a monotherapy and in combination with cetuximab, in which NT219 demonstrated anti-tumor activity in combination with cetuximab in second-line patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/N SCCHN). The Company is advancing NT219 into a Phase 2 study in collaboration with the University of Colorado, to treat R/M SCCHN patients in combination with cetuximab or pembrolizumab. The Company is advancing CAPTN-3, a preclinical platform of conditionally activated tri-specific antibodies, which 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, thereby potentially increasing 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 the 5T4 antigen, which is expressed in a variety of solid tumors and is associated 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, 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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