
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 2023
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 May 16, 2023, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “*Purple Biotech Reports First Quarter 2023 Financial Results*” . A copy of this press release, together with the Company’s Consolidated Unaudited Financial Results as of March 31, 2023, and for the three months then ended, are furnished herewith as Exhibits 99.1 and 99.2, respectively.

Exhibit

99.1	Press Release
99.2	The Registrant’s Consolidated Unaudited Financial Results as of March 31, 2023, and for the three months then ended

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-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 16, 2023

PURPLE BIOTECH LTD.

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

Purple Biotech Reports First Quarter 2023 Financial Results and Provides Business Update

*Expands pipeline with acquisition of new tri-specific antibodies
Data readouts for two lead clinical programs expected in 2023*

REHOVOT, Israel, May 16, 2023 – (GLOBE NEWSWIRE) Purple Biotech Ltd. (“Purple Biotech” or “the Company”) (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class, effective and durable therapies that harness the power of the tumor microenvironment to overcome tumor immune evasion and drug resistance, today announced financial results for the three months ended March 31, 2023.

“We are optimistic about Purple Biotech’s prospects during 2023 and beyond, as the year started off with an important acquisition that brings us a powerful new platform for tri-specific antibodies, complementing our two ongoing clinical programs, both of which are expected to read out during 2023,” said Isaac Israel, Acting Chief Executive Officer of Purple Biotech.

“We saw significant progress with both of our ongoing investigational compounds. For CM24, we expanded the Phase 2 clinical trial while maintaining the anticipated enrollment rate. We completed the enrollment of patients in the safety run-in arms and dosed the first patients in the randomized arms, which we anticipate will allow us to obtain further meaningful clinical data this year. We also made significant advancements in our efforts to develop a biomarker that may identify which PDAC patients would be most appropriately treated with CM24. For NT219, we are about to complete the enrollment of patients in both dose-escalation study arms, monotherapy, and in combination with cetuximab, and plan to announce the top-line results at one of the upcoming medical conferences.”

“Purple’s team and I look forward to continuing to execute on our plans and pursuing our mission to bring hope and to transform the lives of many cancer patients in need.”

Corporate Updates

- ***Immunorizon Acquisition Expands Company Pipeline***

Purple Biotech expanded its product pipeline through the acquisition of Immunorizon Ltd. This acquisition brings a portfolio of potential multi-specific T and NK cell engager oncology therapies that selectively activate the immune response within the tumor microenvironment (TME). The lead asset targets the antigen 5T4, activating both T and NK cells to mount a powerful immune system response against cancer cells; importantly, the compound includes a cleavable capping technology that confines the compound’s therapeutic activity to the local TME, thereby potentially increasing the anticipated therapeutic index in patients. The acquisition provides Purple Biotech with a technology platform for tri-specific antibody compounds and offers the potential to further expand to additional targets. The Company anticipates initiating clinical trials evaluating the first of these assets in 2025.

- ***First Patient Dosed in Open Label, Randomized Arm of CM24 Phase 2 Clinical Trial***

Purple Biotech announced on February 14, 2023, that the first patient had been dosed in the randomized arm of the open label Phase 2 clinical trial evaluating CM24 in the treatment of advanced metastatic pancreatic adenocarcinoma (PDAC).

The ongoing Phase 2 trial is investigating CM24, a novel, first-in-class monoclonal antibody that targets CEACAM1, an immune checkpoint protein that promotes tumor immune evasion. The study design compares, in a randomized fashion, treatment with CM24 combined with the PD-1 immune checkpoint inhibitor nivolumab and standard-of-care (SoC) chemotherapy vs. SoC chemotherapy in second-line PDAC patients. Purple Biotech has now treated the first patient in this randomized Phase 2 study that is designed to include approximately 30 patients in the experimental cohort and an additional approximately 30 patients in the control cohort. The Company has completed the enrollment of patients in the safety run-in arms, during which no dose-limiting toxicities (DLTs) have been observed to date and dosed the first patients in the study's randomized arms. The primary endpoint of this randomized part of the trial is overall survival. We expect to share initial data from this study by the end of 2023 and a topline report by the end of 2024.

- ***Biomarker Data from CM24 Phase 1 Dose Escalation Study***

On March 16, 2023, Purple Biotech shared new results from exploratory analyses from a Phase 1 dose escalation study that assessed the safety and tolerability of CM24 plus nivolumab (NCT04731467). The study enrolled 14 patients with advanced cancers, including 11 patients with PDAC, two with colorectal adenocarcinoma (CRC) and one with papillary thyroid cancer. The analyses conducted in eight evaluable PDAC patients demonstrate clinically meaningful and durable reductions in serum myeloperoxidase, a biomarker for neutrophil extracellular traps (NETs), which promote immune evasion, tumor progression and metastases. These reductions in NET biomarkers followed treatment with CM24 plus nivolumab, both immediately and 15 days after the first administration. In addition, analyses of tumor samples derived from the evaluable PDAC patients suggest that patient survival may be positively associated with higher levels of CEACAM1+ tumor-infiltrating lymphocytes in the TME. These results, along with additional data from this clinical study, are part of the Company's effort aimed at identifying and evaluating the potential utility of a biomarker to optimize future patient selection.

- ***New Preclinical Data on Potential of NT219 to Re-sensitize Resistant Tumors to Immune Checkpoint Inhibitors***

On April 19, 2023, Purple Biotech announced research findings at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando. The study, conducted by researchers at The University of Texas MD Anderson Cancer Center, showcased the potential of Purple Biotech's NT219, a novel small molecule dual inhibitor, to enhance the effectiveness of Immune Checkpoint Blockage (ICB) therapies. Results demonstrated that NT219, in combination with anti-PD1 or anti-CTLA4 drugs, effectively reprogrammed the immune profile within the TME, converting resistant tumors into responders. In vivo studies using immunocompetent mice demonstrated that the combination of NT219 with either anti-PD1 or anti-CTLA4 therapies significantly increased the presence of activated CD8 cytotoxic T cells and NK cells in the TME, while reducing immunosuppressive populations. Furthermore, the synergistic effect of NT219 and anti-PD1 therapy resulted in significant tumor growth inhibition of ICB-resistant tumors. The study also revealed that NT219 effectively diminished the activation of IRS1 and STAT3, two proteins associated with drug resistance, in both ICB-resistant and ICB-sensitive melanoma cells. These findings may provide a promising avenue for improving the efficacy of ICB therapies in treating resistant tumors.

- ***Debuts Scientific Advisory Board***

Purple Biotech announced on April 25, 2023, the inauguration of its Scientific Advisory Board (SAB). Purple Biotech anticipates conducting regular SAB meetings to advise and assist management with significant scientific judgements regarding its clinical trials as well as to perform external scientific review of pre-clinical and R&D activities.

Financial Results for the three Months Ended March 31, 2023

Research and Development Expenses were \$3.5 million, a decrease of \$2.5 million, or 41.7%, compared to \$6 million in the same period of 2022. The decrease was mainly due to batch manufacturing in 2022 to support our clinical studies.

Sales, General and Administrative Expenses were \$1.6 million, compared to \$1.4 million in the same period of 2022, an increase of \$0.2 million.

Operating Loss was \$5.1 million, a decrease of \$2.2 million, or 30.1%, compared to \$7.3 million in the same period of 2022.

Adjusted operating loss (as reconciled below) was \$4.4 million, a decrease of \$2.6 million, compared to \$7 million in the same period of 2022, mainly due to a decrease in R&D expenses.

Net Loss for the first three months ended March 31, 2023, was \$4.9 million, or \$0.25 per basic and diluted ADS, compared to a net loss of \$7.3 million, or \$0.41 per basic and diluted ADS, in the same period of 2022. The decrease in net loss was mainly due to a decrease of \$2.2 million in operating expenses.

Adjusted net loss (as reconciled below) for the first three months ended March 31, 2023, was \$4.1 million, a decrease from \$7 million in the first three months ended March 31, 2022.

During the three months ended March 31, 2023, the Company sold, under the Open Market Sale AgreementSM with Jefferies LLC, approximately 208,000 ADSs, at an average price of \$1.926 per ADS. Net proceeds to the Company were approximately \$380,000, net of issuance expenses.

Non-IFRS Financial Measures.

This press release includes information about certain financial measures that are not prepared in accordance with International Financial Reporting Standards (“IFRS”), including adjusted operating loss and adjusted net loss. These non-IFRS measures are not based on any standardized methodology prescribed by IFRS and are not necessarily comparable to similar measures presented by other companies. Adjusted operating loss and adjusted net loss adjust for share-based compensation expenses. The Company’s management and board of directors utilize these non-IFRS financial measures to evaluate the Company’s performance. The Company provides these non-IFRS measures of the Company’s performance to investors because management believes that these non-IFRS financial measures, when viewed with the Company’s results under IFRS and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, these non-IFRS measures are not measures of financial performance under IFRS and, accordingly, should not be considered as alternatives to IFRS measures as indicators of operating performance. Further, these non-IFRS measures should not be considered measures of the Company’s liquidity. A reconciliation of certain IFRS to non-IFRS financial measures has been provided in the tables included in this press release.

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. In a Phase 1/2 study of NT219, the Company is currently advancing it in a dose escalation as a monotherapy treatment of solid tumors, and in a dose escalation in combination with cetuximab for the treatment of recurrent and metastatic squamous cell carcinoma of the head and neck (SCCHN) or colorectal adenocarcinoma (CRC). These studies will be followed by an expansion phase of NT219 at its recommended Phase 2 level in combination with cetuximab in patients with recurrent and 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 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. IM1240 is a preclinical, 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 third arm specifically targets the Tumor Associated Antigen (TAA) 5T4 that is expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. IM1240 has a cleavable capping technology that confines the compound’s therapeutic activity to the local tumor microenvironment, and thereby potentially increases the anticipated therapeutic window in patients. 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

Media Inquiries:

Harriet Ullman
Vice President, Public Relations and Product Communications
LaVoieHealthScience
hullman@lavoiehealthscience.com

###

Purple Biotech Ltd.

Consolidated Unaudited Statements of Financial Position as of:

	March 31 2023 USD thousands	December 31 2022 USD thousands
Assets		
Cash and cash equivalents	21,883	15,030
Short term deposits	849	16,652
Other investments	386	431
Other current assets	1,292	1,143
Total current assets	24,410	33,256
Non-current assets		
Right to use assets	430	467
Fixed assets, net	198	215
Intangible assets	28,044	20,684
Total non – current assets	28,672	21,366
Total assets	53,082	54,622
Liabilities		
Lease liability – short term	189	194
Accounts payable	2,451	2,132
Other payables	2,977	4,732
Total current liabilities	5,617	7,058
Non-current liabilities		
Lease liability	278	321
Post-employment benefit liabilities	141	145
Total non–current liabilities	419	466
Equity		
Share capital, no par value	-	-
Share premium	130,721	126,407
Receipts on account of warrants	28,017	28,017
Capital reserve for share-based payments	10,702	10,164
Capital reserve from transactions with related parties	761	761
Capital reserve from hedging	(7)	(6)
Capital reserve from transactions with non-controlling interest	(859)	(859)
Accumulated loss	(122,451)	(117,573)
Equity attributable to owners of the Company	46,884	46,911
Non-controlling interests	162	187
Total equity	47,046	47,098
Total liabilities and equity	53,082	54,622

Consolidated Unaudited Statement of Operations for the three months ended

	March 31 2023 USD thousands	March 31 2022 USD thousands
Research and development expenses	3,498	5,952
Sales, general and administrative expenses	1,624	1,379
Operating loss	5,122	7,331
Finance expenses	59	41
Finance income	(278)	(56)
Finance income, net	(219)	(15)
Loss for the period	4,903	7,316
Other Comprehensive Loss:		
Items that will be transferred to profit or loss:		
Loss from cash flow hedges	(1)	-
Total comprehensive loss for the period	4,902	-
Loss attributable to:		
Owners of the Company	4,878	7,297
Non-controlling interests	25	19
	4,903	7,316
Total comprehensive loss attributable to		
Owners of the Company	4,877	-
Non-controlling interests	25	-
	4,902	-
Loss per share data		
Basic and diluted loss per ADS – USD	0.25	0.41
Number of ADSs used in calculating basic and diluted loss per ADS	19,838,608	17,812,673

Reconciliation of Adjusted Operating Loss for the three months ended

	March 31	March 31
	2023	2022
	USD thousands	USD thousands
Operating loss for the period	5,122	7,331
Less ESOP expenses	(752)	(309)
	4,370	7,022

Reconciliation of Adjusted Net Loss for the three months ended

	March 31	March 31
	2023	2022
	USD thousands	USD thousands
Net loss for the period	4,903	7,316
Less ESOP expenses	(752)	(309)
	4,151	7,007

3