
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 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 May 21, 2024, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “*Purple Biotech Reports First Quarter 2024 Financial Results*” a copy of which is attached hereto as Exhibit 99.1

Exhibit

99.1 [Purple Biotech Reports First Quarter 2024 Financial Results](#)

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) and the Registrant’s Registration Statement on [Form F-1](#) filed with the Securities and Exchange Commission on October 30, 2023 (Registration file number 333-275216), 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 21, 2024

PURPLE BIOTECH LTD.

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

Purple Biotech Reports First Quarter 2024 Financial Results

CM24 Phase 2 Pancreatic Cancer Interim Data Selected for Late Breaking Abstract Poster Presentation at ASCO 2024 – Interim results to be Announced June 1, 2024

REHOVOT, Israel, May 21, 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 financial results for the three months ended March 31, 2024.

"We look forward to presenting compelling interim Phase 2 CM24 data for the treatment of pancreatic cancer at ASCO 2024, where we were selected for a Late Breaking Abstract presentation. These data suggest an exciting medical direction, demonstrating potentially reduced risk of disease progression and death in a very difficult to treat indication. Following the announcement of interim results at ASCO on June 1, 2024, we expect to present topline data before the end of year; these clinical milestones will potentially mark significant catalysts for the value of our development pipeline," stated Gil Efron, Chief Executive Officer of Purple Biotech. "We also continue to make solid progress on NT219, which is headed into a Phase 2 trial in head and neck cancer, as well as on our tri-specific antibody platform following a Pre-IND meeting with the FDA that provided a clear path forward for our development plan through Phase 1."

Q1 2024 and Recent Clinical & Corporate Highlights:

- **CM24 Pancreatic Cancer Study Selected for Late Breaking Abstract Poster Presentation at ASCO 2024**
- **Interim data suggest reduced risk of progression or death in the CM24/nivolumab plus standard of care Nal-IRI/5FU/LV arm of the study supported by higher overall response rate (ORR) and disease control rate (DCR) and decreasing CA19-9 in the experimental arm. Full interim data have been submitted to the ASCO Meeting.**
- **Interim data to be announced on June 1, 2024 in conjunction with the ASCO presentation**
- **Topline data expected Q4 2024**

The American Society of Clinical Oncology (ASCO) selected Purple Biotech's poster titled "Interim results of the Randomized Phase 2 Cohort of Study FW-2020-01 Assessing the Efficacy, Safety and Pharmacodynamics of CM24 in combination with Nivolumab and Chemotherapy in Advanced/metastatic Pancreatic Cancer" for a Late Breaking presentation at ASCO's 2024 Annual Meeting.

The Phase 2 study is evaluating CM24 in combination with Bristol Myers Squibb's PD-1 inhibitor nivolumab plus standard of care (SoC) chemotherapy in second line pancreatic ductal adenocarcinoma (PDAC) patients compared to SoC chemotherapy alone. The experimental arms of the study dosed patients with CM24 plus nivolumab and one of two SoC chemotherapies, gemcitabine/nab-paclitaxel or Nal-IRI/5FU/LV, while the control arms dosed with either respective chemotherapy alone. Approximately 60 patients have been enrolled in the randomized study across 18 centers in the U.S., Spain and Israel. Data from the gemcitabine/nab-paclitaxel arm is not yet mature for analysis.

- **Phase 2 study of NT219 in combination with cetuximab as a 2nd Line treatment for R/M SCCHN is planned to commence in 2024.**
 - **NT219 Positive Efficacy Data in Head & Neck Cancer Presented at ESMO-TAT 2024.**
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- *Posters presented at AACR 2024 demonstrated NT219's efficacy in suppressing cancer stem cells, overcoming resistance to KRAS inhibitors and potential biomarkers for NT219 therapy.*
- *Established Head & Neck Cancer Scientific Advisory Board.*

In a presentation at ESMO-TAT 2024, NT219 in combination with cetuximab demonstrated safety and early activity in patients with Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck (R/M SCCHN) with dose-proportional PK values. Of the 7 evaluable R/M SCCHN patients treated at the maximum doses of 50 and 100mg/kg in which anti-tumor activity was observed, the tumor objective response rate (ORR) was 29% and the disease control rate (DCR) was 71%, both highly encouraging results. 100mg/kg was determined to be the recommended Phase 2 dose for NT219 in combination with cetuximab in the treatment of R/M SCCHN.

Key findings were shared in two poster presentations at the American Association for Cancer Research (AACR) 2024 annual meeting in San Diego, California. NT219 was found to significantly suppress cancer stem cells, suggesting a novel therapy and new mechanism to combat cancer recurrence and overcoming resistance to KRAS(G12C) and KRAS(G12D) inhibitors in NSCLC and PDAC cells, respectively. NT219 reverses acquired resistance to KRAS inhibitors by addressing both cellular escape pathways and cancer stem cell mechanisms. Potential biomarkers for NT219 therapy were presented in an additional poster at AACR 2024, and on-target effects of the therapy were demonstrated in patients' tumors. Analysis of patients' biopsies pre-treatment suggests activated IGF1R and STAT3 as potential biomarkers for this therapy.

In preparation for its upcoming Phase 2 trial of NT219, Purple Biotech convened a Scientific Advisory Board (SAB) specifically focused on the R/M SCCHN indication. The SAB is comprised of head and neck cancer key opinion leaders including oncologists, researchers, and investigators. The SAB has provided valuable guidance on clinical studies for NT219 in combination with cetuximab as a second/third line treatment and potentially in combination with a PD1 inhibitor as a first line treatment.

- **Proof of Concept Achieved for Tri-Specific Antibody Platform Technology**
 - *Platform has potential to produce a pipeline of promising drug candidates across numerous solid cancer tumors*
 - *Lead asset, IM1240, expected to be ready for Phase 1 study by early 2026*

Purple Biotech's tri-specific platform is a T cell engager via the anti-CD3 arm, and an NK cell engager via the anti-NKG2A arm, which also functions as an important immune checkpoint inhibitor of both NK cells and specific subsets of T cells; this tri-specific approach unleashes both innate and adaptive immune systems against the tumor. Preclinical studies demonstrated an anti-tumor response and synergistic effects of the NK cell engager with the conditionally-activated T cell engager. The tri-body platform's cleavable capping technology confines therapeutic activity to the local tumor micro environment, which increases the anticipated therapeutic window in patients.

Financial Results for the Quarter Ended March 31, 2024

Research and Development Expenses were \$3.4 million for the three months ended March 31, 2024, a decrease of \$0.1 million, or 2.8%, compared to \$3.5 million in the same period of 2023.

Sales, General and Administrative Expenses were \$1 million for the three months ended March 31, 2024, compared to \$1.6 million in the same period of 2023, a decrease of \$0.6 million.

Operating Loss was \$4.5 million for the three months ended March 31, 2024, a decrease of \$0.6 million, or 11.8%, compared to \$5.1 million in the same period of 2023, mainly due to the decrease in the sales, general, and administrative expenses.

Adjusted Operating Loss (as reconciled below) was \$4.2 million for the three months ended March 31, 2024, a decrease of \$0.2 million, compared to \$4.4 million in the same period of 2023.

Net Loss was \$3.8 million, or \$0.14 per basic and diluted ADS for the three months ended March 31, 2024, compared to a net loss of \$4.9 million, or \$0.25 per basic and diluted ADS, in the same period of 2023. The decrease in net loss was mainly due to a decrease of \$0.6 million in operating expenses and an increase of \$0.5 million in finance income, net.

Adjusted Net Loss (as reconciled below) for the three months ended March 31, 2024, was \$4.1 million, a decrease from \$4.2 million in the first three months ended March 31, 2023.

As of March 31, 2024, Purple Biotech had cash and cash equivalents and short-term deposits of \$10.8 million. This cash position provides a cash runway into the first quarter of 2025.

During the three months ended March 31, 2024, the Company sold, under the Open Market Sale AgreementSM with Jefferies LLC, approximately 504,000 ADSs, at an average price of \$0.742 per ADS. Net proceeds to the Company were approximately \$358,000, 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 its 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. A Phase 1 dose escalation study is being concluded and 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. Additionally, the Company is advancing a preclinical platform of a conditionally-activated tri-specific antibody that engages 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, 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, which is 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, 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>.

CONTACTS:

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Purple Biotech Ltd.

Consolidated Unaudited Statements of Financial Position as of:

	March 31 2024 USD thousands	December 31 2023 USD thousands
Assets		
Cash and cash equivalents	9,985	14,489
Short term deposits	848	850
Other investments	21	73
Other current assets	548	376
Total current assets	11,402	15,788
Non-current assets		
Right to use assets	278	316
Fixed assets, net	139	154
Intangible assets	28,044	28,044
Total non – current assets	28,461	28,514
Total assets	39,863	44,302
Liabilities		
Lease liability – short term	186	188
Accounts payable	3,477	3,532
Other payables	2,801	3,463
Warrants	2,046	2,518
Total current liabilities	8,510	9,701
Non-current liabilities		
Lease liability	121	163
Post-employment benefit liabilities	141	141
Total non–current liabilities	262	304
Equity		
Share capital, no par value	-	-
Share premium	133,696	133,184
Receipts on account of warrants	28,467	28,467
Capital reserve for share-based payments	10,166	10,088
Capital reserve from transactions with related parties	761	761
Capital reserve from hedging	4	19
Capital reserve from transactions with non-controlling interest	(859)	(859)
Accumulated loss	(141,215)	(137,453)
Equity attributable to owners of the Company	31,020	34,207
Non-controlling interests	71	90
Total equity	31,091	34,297
Total liabilities and equity	39,863	44,302

Purple Biotech Ltd.

Consolidated Unaudited Statement of Operations for the three months ended

	March 31 2024 USD thousands	March 31 2023 USD thousands
Research and development expenses	3,423	3,498
Sales, general and administrative expenses	1,043	1,624
Operating loss	4,466	5,122
Finance expenses	17	59
Finance income	(702)	(278)
Finance income, net	(685)	(219)
Loss for the period	3,781	4,903
Other Comprehensive Loss:		
Items that will be transferred to profit or loss:		
Loss from cash flow hedges	15	1
Total comprehensive loss for the period	3,796	4,904
Loss attributable to:		
Owners of the Company	3,762	4,878
Non-controlling interests	19	25
	3,781	4,903
Total comprehensive loss attributable to		
Owners of the Company	3,777	4,879
Non-controlling interests	19	25
	3,796	4,904
Loss per share data		
Basic and diluted loss per ADS – USD	0.14	0.25
Number of ADSs used in calculating basic and diluted loss per ADS	27,113,434	19,838,608

Reconciliation of Adjusted Operating Loss for the three months ended

	March 31	March 31
	2024	2023
	USD thousands	USD thousands
Operating loss for the period	4,466	5,122
Less ESOP expenses	(266)	(752)
	<u>4,200</u>	<u>4,370</u>

Reconciliation of Adjusted Net Loss for the three months ended

	March 31	March 31
	2024	2023
	USD thousands	USD thousands
Net loss for the period	3,781	4,903
Less ESOP expenses	(266)	(752)
Less finance income from financial instruments	607	-
	<u>4,122</u>	<u>4,151</u>

Consolidated Unaudited Statements of Cash Flow

	For the three months ended	
	March 31,	
	2024	2023
	USD thousands	USD thousands
Cash flows from operating activities:		
Loss for the period	(3,781)	(4,903)
Adjustments:		
Depreciation	48	46
Finance income, net	(685)	(219)
Share-based payments	266	752
	(4,152)	(4,324)
Changes in assets and liabilities:		
Changes in other investments and other current assets	(213)	(329)
Changes in accounts payable	(46)	250
Changes in other payables	(671)	(1,500)
Changes in post-employment benefit liabilities	-	(161)
	(930)	(1,740)
Net cash used in operating activities	(5,082)	(6,064)
Cash flows from investing activities:		
Acquisition of subsidiary, net of cash acquired	-	(3,549)
Proceed from other investments	187	-
Decrease in short term deposits	-	15,803
Interest received	125	352
Acquisition of fixed assets	-	(3)
Net cash provided by investing activities	312	12,603
Cash flows from financing activities:		
Proceeds from issuance of ADSs	374	395
ADS issuance expenses paid	(50)	(75)
Repayment of lease liability	(45)	(42)
Interest paid	(11)	(14)
Net cash provided by financing activities	268	264
Net increase in cash and cash equivalents	(4,502)	6,803
Cash and cash equivalents at the beginning of the period	14,489	15,030
Effect of translation adjustments on cash and equivalents	(2)	50
Cash and cash equivalents at end of the period	9,985	21,883