
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 March 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 March 2, 2021, Purple Biotech Ltd. (the “Company” or the “Registrant”) issued a press release, “**Purple Biotech Provides Corporate Update and Reports Second Half and Full Year 2020 Financial Results**”, which is attached hereto as Exhibit 99.1.

Exhibits

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.

March 2, 2021

PURPLE BIOTECH LTD.

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

Purple Biotech Provides Corporate Update and Reports Second Half and Full Year 2020 Financial Results

Rehovot, Israel, March 01, 2021 (GLOBE NEWSWIRE) – Purple Biotech Ltd. (“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 provided a corporate update and announced financial results for the six and 12-months ended December 31, 2020.

“We have recently achieved substantial progress in multiple key aspects of our business,” said Isaac Israel, Chief Executive Officer. “Most importantly, our promising anti-cancer product development pipeline continues to advance our Phase 1/2 clinical studies for NT219, a dual inhibitor, novel small molecule targeting IRS1/2 and STAT3. We completed patient recruitment of the second dose level in the single agent dose-escalation phase, demonstrating the drug to be safe and well tolerated in the treated patients. We expect to begin imminently our Phase 1b/2 studies for CM24, our monoclonal antibody drug candidate blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Our robust clinical development activities are supported by a strong balance sheet, as we raised \$68.5 million in 2020, ended the year with \$60.8 million in cash, and we believe we are well-funded to support our currently planned corporate initiatives until 2024.”

“As part of the completion of our transformation to a corporate mission dedicated to developing first-in-class oncology therapies, we were honored to ring the Nasdaq stock market opening bell on January 5, 2021 to commemorate the successful evolution of our business and the Company’s name change to Purple Biotech. We are firmly committed to improving the lives of cancer patients globally, and look forward to executing on the opportunities that lie ahead of us in 2021 and beyond,” concluded Mr. Israel.

Recent Corporate Highlights

CM24:

- Expanded the planned Phase 1b/2 clinical trial evaluating CM24 in combination with nivolumab in advanced non-small cell lung cancer (NSCLC) with a new cohort that will evaluate CM24 in combination with both nivolumab and nab-paclitaxel (Abraxane®) in patients with pancreatic cancer under a clinical collaboration agreement with Bristol Myers Squibb.
 - Advanced preparations to initiate the Phase 1b/2 study, which is expected to begin imminently.
 - Received notifications from the U.S. Patent and Trademark Office, European Patent Office and the Chinese Patent Office to grant the patent application entitled “Humanized antibodies against CEACAM1,” covering the humanized antibodies capable of specific binding to human CEACAM1 molecules, pharmaceutical compositions and methods of their use in treating and diagnosing cancer and other condition.
 - Presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program positive results of a Phase 1 study consisting of a monotherapy dose escalating of CM24, as CM24 was found to be safe and well tolerated in all patients. In the study of efficacy evaluable patients (n=24), subjects were highly refractory to prior therapy, having received between two and eight prior therapies (with a median of four). Eight of the evaluable patients (33%) achieved stable disease, with most of these patients treated at the higher dose levels of 3mg/kg and 10mg/kg. Pharmacokinetic analysis revealed non-linearity, and modeling suggested that a higher dose level is required to achieve full saturation of CEACAM1 receptors.
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NT-219:

- Initiated and dosed the first patient in the Phase 1/2 clinical trial of NT219.
- Presented new data supporting the mechanism of action of NT219 at the Epigenetics and Metabolism AACR Special Virtual Conference by researchers at Tel-Aviv University.
- Received notifications from the U.S. Patent and Trademark Office and the Chinese Patent Office to grant a patent application entitled “Combinations of IRS/STAT3 Dual Modulators and Anti-Cancer Agents for Treating Cancer,” covering the various combinations of NT219 with multiple EGFR inhibitors, including cetuximab (Erbix®), which will be administered in combination with NT219 for the treatment of recurrent or metastatic squamous cell carcinoma of the head as well as for neck cancer as part of our ongoing Phase 1/2 study, and osimertinib (TAGRISSO®), a 3rd generation EGFR inhibitor approved in the U.S. for first-line treatment of EGFR-mutated non-small-cell lung carcinoma (NSCLC).

CONSENSI®:

- Growth of sales of Consensi® in the U.S. has been slow primarily due to the COVID-19 environment, with minor sales of the drug in the second half of 2020. In addition, our distribution partner has not fulfilled all of its obligations as per the distribution agreement. We are currently evaluating a re-launch program that will be designed to boost sales and maximize the value of Consensi® post-COVID-19. At this time, we are not able to provide revenue projections for the rest of 2021 and beyond.

Financial Results for the Six Months Ended December 31, 2020

Research and Development Expenses were \$4.4 million, an increase of \$3.4 million, or 342%, compared to \$1.0 million in the same period of 2019. The increase was due to expenses related to the NT219 clinical trials initiated in 2020 and the preparation for the anticipated initiation of the CM24 clinical trials, including manufacturing costs.

Selling, General and Administrative (SG&A) Expenses were \$4.1 million, compared to \$2.8 million in the same period of 2019, an increase of \$1.3 million. The increase was due mainly to a \$0.9 million increase in expenses related to stock options granted to directors and employees in the second and third quarters of 2020 and a \$0.3 million increase in director and officer insurance expenses.

Operating Loss was \$8.3 million, an increase of \$4.7 million, or 131%, compared to \$3.6 million in the same period of 2019.

On a non-IFRS basis (as reconciled below), **adjusted operating loss** was \$6.4 million, an increase of \$3.6 million, compared to \$2.8 million in the same period of 2019.

Net Loss for the second half of 2020 was \$0.3 million, or \$0.48 per diluted share, compared to a net loss of \$3.3 million, or \$1.70 per diluted share, in the second half of 2019. The decrease in net loss was due to \$7.5 million in income from a change in the fair value of derivatives, partially offset by an increase of \$4.5 million in operating expenses.

Financial Results for the Full Year Ended December 31, 2020

Revenues were \$1.0 million for the year ended December 31, 2020, unchanged from the \$1.0 million reported for the year ended December 31, 2019.

Research and Development Expenses were \$7.5 million, an increase of \$4.8 million, or 180%, compared to \$2.7 million for the year ended December 31, 2019. The increase was due to expenses related to the NT219 clinical trials initiated in 2020 and the preparation for the anticipated initiation of the CM24 clinical trials, including manufacturing costs.

SG&A Expenses were \$6.3 million, compared to \$6.1 million for the year ended December 31, 2019.

Operating Loss was \$12.6 million, an increase of \$5.5 million, or 76%, compared to \$7.2 million for the year ended December 31, 2019.

On a non-IFRS basis (as reconciled below), **adjusted operating loss** was \$10.0 million, compared to \$5.9 million, an increase of \$4.1 million, for the year ended December 31, 2019.

Net Loss for the year ended December 31, 2020, was \$28.1 million, or \$2.44 per diluted share, compared to a net loss of \$5.9 million, or \$3.00 per diluted share, in the same period of 2019.

The increase was due to \$17.1 million increase in expenses on account of warrants mainly from a change in the fair value of derivatives and an increase of \$4.8 million in R&D expenses.

As of December 31, 2020, Purple Biotech had cash and cash equivalents and short- and long-term deposits of \$60.8 million, compared to \$4.4 million at December 31, 2019. Purple Biotech believes that its cash position will provide sufficient resources for its currently anticipated ongoing needs until fiscal year 2024.

About Purple Biotech

Purple Biotech Ltd. (the “Company”; NASDAQ/TASE: PPBT) is a clinical-stage company focusing on advancing first-in-class therapies to overcome tumor immune evasion and drug resistance in order to create successful long-lasting treatments for people with cancer. The Company’s oncology pipeline includes NT219 and CM24. NT219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. The Company is currently advancing NT219 as a monotherapy treatment of advanced solid tumors and in combination with cetuximab for the treatment of recurrent or metastatic squamous cell carcinoma of head and neck cancer (SCCHN) in a phase 1/2 study. CM24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. The Company plans to advance CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in selected cancer indications in a phase 1 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 is also the owner of Consensi®, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension that was approved by the FDA for marketing in the U.S. Consensi® is being sold in the U.S. by Burke Therapeutics, the marketing partner of the Company’s U.S. distributor, Coeptis Pharmaceuticals. The Company has also partnered to commercialize Consensi in China and South Korea. The Company has recently relocated its corporate headquarters to Rehovot, Israel. For more information, please visit <http://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, 2019 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 Securities and Exchange Commission, which are available on the SEC’s website, <http://www.sec.gov>.

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Purple Biotech Ltd

Consolidated Unaudited Statements of Financial Position

	As of December 31,	
	2020	2019
	USD thousands	USD thousands
Assets		
Cash and cash equivalents	11,247	4,385
Short term deposits	46,558	10
Trade receivables	500	-
Financial assets	-	2,000
Other current assets	977	1,907
Total current assets	59,282	8,302
Non-current assets		
Right to use assets	790	206
Fixed assets, net	178	38
Long term deposits	3,071	-
Intangible assets	20,482	6,172
Total assets	83,803	14,718
Liabilities		
Lease liability – short term	207	195
Accounts payable	1,198	1,245
Other payables	1,693	2,106
Total current liabilities	3,098	3,546
Non-current liabilities		
Lease liability	688	28
Post-employment benefit liabilities	265	285
Total non-current liabilities	953	313
Equity		
Share capital, no par value	-	-
Share premium	118,909	46,986
Receipts on account of warrants	29,984	9,874
Capital reserve for share-based payments	8,115	3,181
Capital reserve from transactions with related parties	761	761
Capital reserve from transactions with non-controlling interest	(859)	(859)
Accumulated loss	(77,521)	(49,522)
Equity attributable to owners of the Company	79,389	10,421
Non-controlling interests	363	438
Total equity	79,752	10,859
Total liabilities and equity	83,803	14,718

Purple Biotech Ltd.

Consolidated Unaudited Statements of Operations

	For the year ended December 31,		For the six months ended December 31,	
	2020	2019	2020	2019
	USD thousands	USD thousands	USD thousands	USD thousands
Revenues	1,000	1,000	-	-
Research and development expenses	7,488	2,674	4,355	986
Sales, general and administrative expenses	6,306	6,078	4,072	2,773
Reimbursement of legal fees	(182)	(596)	(117)	(166)
Total operating expenses	13,612	8,156	8,310	3,593
Operating loss	12,612	7,156	8,310	3,593
Expenses (income) on account of warrants	15,655	(1,509)	(7,928)	(517)
Finance expenses	61	181	46	73
Finance income	(254)	(151)	(170)	(78)
Finance expenses (income), net	15,462	(1,479)	(8,052)	(522)
Tax expenses	-	216	-	216
Loss for the year	28,074	5,893	258	3,287
Loss attributable to:				
Owners of the Company	27,999	5,850	220	3,275
Non-controlling interests	75	43	38	12
	28,074	5,893	258	3,287
Loss per share data				
Basic loss per ADS – USD	2.44	3.00(*)	0.02	1.70(*)
Diluted loss per ADS – USD	2.44	3.00(*)	0.48	1.70(*)
Number of shares used in calculating basic loss per ADS	11,500,113	1,936,778(*)	16,928,162	1,954,866(*)
Number of shares used in calculating diluted loss per ADS	11,500,113	1,936,778(*)	17,160,018	1,954,866(*)

(*) Restated to reflect a 1:10 reverse ratio of the ADSs, that took place in August 2020.

Purple Biotech Ltd.

Consolidated Unaudited Statements of Cash Flow

	For the year ended December 31,		For the six months ended December 31,	
	2020	2019	2020	2019
	USD thousands	USD thousands	USD thousands	USD thousands
Cash flows from operating activities:				
Loss for the period	(28,074)	(5,893)	(258)	(3,287)
<u>Adjustments:</u>				
Depreciation	235	178	143	84
Finance expense (income), net	15,462	(1,479)	(8,052)	(522)
Share-based payments	2,645	1,273	1,895	773
	(9,732)	(5,921)	(6,272)	(2,952)
Changes in assets and liabilities:				
Changes in trade receivables and other current assets	501	62	880	(891)
Changes in accounts payable	(2,330)	503	(1,437)	361
Changes in other payables	(511)	(77)	(641)	149
Changes in post-employment benefit liabilities	(20)	(148)	19	22
	(2,360)	340	(1,179)	(359)
Net cash used in operating activities	(12,092)	(5,581)	(7,451)	(3,311)
Cash flows from investing activities:				
Cash assumed as part of acquisition of FameWave	69	-	-	-
Investment in financial asset	-	(2,100)	-	(100)
Decrease (increase) in deposits	(49,618)	1,511	(49,618)	5,011
Interest received	110	151	71	121
Acquisition of fixed assets	(156)	(11)	(156)	(3)
Net cash provided by (used in) investing activities	(49,595)	(449)	(49,703)	5,029
Cash flows from financing activities:				
Proceeds from issuance of ADSs	27,925	2,594	-	-
ADS issuance expenses paid	(2,074)	(264)	(34)	-
Proceeds from issuance of warrants	26,574	3,406	-	-
Warrants issuance expenses paid	(3,281)	(347)	150	-
Proceeds from exercise of warrants	19,547	43	5,627	-
Repayment of lease liability	(188)	(171)	(108)	(82)
Interest paid	(15)	(28)	(4)	(14)
Net cash provided by (used in) financing activities	68,488	5,233	5,331	(96)
Net increase (decrease) in cash and cash equivalents	6,801	(797)	(51,823)	1,622
Cash and cash equivalents at the beginning of the period	4,385	5,163	62,995	2,757
Effect of translation adjustments on cash and cash equivalents	61	19	75	6
Cash and cash equivalents at end of the period	11,247	4,385	11,247	4,385

Purple Biotech Ltd. Reconciliation of Non-IFRS Financial Results

Reconciliation of Adjusted Operating Loss

	For the year ended December 31,		For the six months ended December 31,	
	2020	2019	2020	2019
	USD	USD	USD	USD
	thousands	thousands	thousands	thousands
Operating loss for the year	12,612	7,156	8,310	3,593
Less ESOP expenses	(2,645)	(1,273)	(1,895)	(773)
	<u>9,967</u>	<u>5,883</u>	<u>6,415</u>	<u>2,820</u>