

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 10, 2020

PRINCIPIA BIOPHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38653

(Commission File Number)

26-3487603
(IRS Employer
Identification No.)

220 East Grand Avenue,
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 416-7700

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.0001 Per Share	PRNB	The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2020, Principia Biopharma Inc. (the “*Company*”) issued a press release announcing our financial results for the fourth quarter and full year ended December 31, 2019. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, and shall not be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by Principia Biopharma Inc. dated March 10, 2020.

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.

PRINCIPIA BIOPHARMA INC.

Date: March 10, 2020

By: _____ /s/ Christopher Y. Chai
Christopher Y. Chai
Chief Financial Officer



Principia Biopharma Reports Fourth Quarter and Full Year 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., March 10, 2020 – Principia Biopharma Inc. (Nasdaq: PRNB), a late-stage biopharmaceutical company focused on developing treatments for immune-mediated diseases, today announced financial results for the fourth quarter and full year ended December 31, 2019.

“Our significant achievements in 2019 lay a strong foundation for us to advance our corporate strategy and the promise of our drug discovery platform. Including our program partnered with Sanofi, we now have proof of concept in three immune-mediated diseases: pemphigus, immune thrombocytopenia and multiple sclerosis. As a result of these clinical milestones, we are now well positioned to progress our clinical programs this year,” said Martin Babler, president and chief executive officer of Principia.

Full Year 2019 and Recent Program Highlights

- Rilzabrutinib for the treatment of pemphigus (pemphigus vulgaris (PV) and pemphigus foliaceus (PF))
 - Presented positive data from Phase 2 Part A trial at 2019 American Academy of Dermatology Late-Breaking session
 - Announced confirmatory preliminary data from Phase 2 Part B trial
 - Announced accelerated enrollment of Phase 3 pivotal trial-- anticipating results in second half of 2021
 - Anticipated Upcoming Milestones:
 - 1H20 – Presentation of data from Phase 2 Part B trial
 - Rilzabrutinib for the treatment of Immune Thrombocytopenia (ITP)
 - Presented positive data from ongoing Phase 1/2 trial in highly treatment-resistant and refractory patients at 61st American Society of Hematology Annual Meeting
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- Anticipated Upcoming Milestones:
 - 2H20 – Presentation of ITP data from Phase 1/2 trial
 - Rilzabrutinib for the treatment of IgG4-Related Disease (RD)
 - Announced expansion into IgG4-RD, an immune-mediated disease of chronic inflammation and fibrosis
 - Anticipated Upcoming Milestones:
 - 1H20 – Initiation of Phase 2 trial for IgG4-RD
 - PRN473 Topical for the treatment of immune-mediated diseases
 - Initiated a third BTK inhibitor clinical program, a Phase 1, randomized, double blind, placebo-controlled, single and multiple dose clinical trial
 - Anticipated Upcoming Milestones:
 - 2020 – Phase 1 trial results
 - PRN2246/SAR442168 for the treatment of Multiple Sclerosis (MS)
 - Presented positive Phase 1 data at Americas Committee for Treatment and Research in Multiple Sclerosis Forum 2019
 - In February 2020, Sanofi announced PRN2246/SAR442168 met its primary endpoint and was well tolerated in the Phase 2b trial with no new safety findings. Sanofi also announced it expects to initiate four Phase 3 clinical trials in relapsing and progressive forms of MS in the middle of 2020
 - PRN1371 for the treatment of bladder cancer
 - Suspended clinical program to focus our portfolio on immune-mediated diseases
 - General Corporate Updates
 - Raised \$242 million through a public offering of 8,625,000 shares of common stock
 - Announced generic name for PRN1008 – rilzabrutinib
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Fourth Quarter and Full Year 2019 Financial Results

Cash Position: Cash, cash equivalents, and marketable securities were \$367.8 million as of December 31, 2019, compared to \$180.6 million as of December 31, 2018. The increase in Principia's cash position is mainly due to net proceeds of \$226.5 million from our follow-on offering completed in the fourth quarter of 2019.

Revenues: We did not recognize any collaboration revenue for the three months ended December 31, 2019, compared to \$26.1 million for the same period in 2018. Collaboration revenue for the full year of 2019 was \$35.2 million, compared to \$69.1 million for the full year of 2018. The decrease was due to the revenue recognition for portions of an upfront payment of \$40.0 million received in 2017 and milestone payments totaling \$25.0 million received in 2018 from Sanofi and an upfront payment of \$15.0 million received in June 2017 from AbbVie Biotechnology Limited, which were fully recognized as of year-end 2018. The revenue recognized for the year ended 2019 was primarily for the achievement of a milestone in our Sanofi collaboration.

R&D Expenses: Total research and development expenses were \$21.5 million for the three months ended December 31, 2019, including stock-based compensation expense of \$1.9 million, compared to \$13.7 million for the same period in 2018, including stock-based compensation expense of \$0.8 million. For the full year of 2019, total research and development expenses were \$74.1 million, including stock-based compensation expense of \$6.6 million, compared to \$40.5 million for full year of 2018, including stock-based compensation expense of \$1.4 million. The increase in total research and development expenses was mainly driven by an increase in rilzabrutinib program costs, attributed to various manufacturing campaigns to supply drug products for our rilzabrutinib clinical trials and the initiation of a global Phase 3 trial in pemphigus in November 2018, as well as an increase in employee-related expenses.

G&A Expenses: General and administrative expenses were \$5.1 million for the three months ended December 31, 2019, including stock-based compensation expense of \$1.3 million, compared to \$4.2 million for the same period in 2018, including stock-based compensation expense of \$0.6 million. For the full year of 2019, general and administrative expenses were \$19.8 million, including stock-based compensation expense of \$5.5 million, compared to \$11.5 million for the full year of 2018, including stock-based compensation

expense of \$1.4 million. The increase in total general and administrative expenses was primarily driven by increased employee-related expenses and facility costs.

Net Income (Loss): For the three months ended December 31, 2019, net loss was \$24.9 million compared to net income of \$9.4 million for the same period in 2018. For the full year of 2019, net loss was \$53.8 million, compared to net income of \$18.2 million for the full year of 2018.

Financial Guidance: The company's current cash position is anticipated to fund operations beyond the Phase 3 data readout in pemphigus, irrespective of any opt-in decision related to the Sanofi agreement, based on the current operating plan.

About Principia Biopharma

Principia is a late-stage biopharmaceutical company dedicated to bringing transformative therapies to patients with significant unmet medical needs in immune-mediated diseases. Through Principia's proprietary Tailored Covalency® platform, our strategy is to build and advance a pipeline of best-in-class drug candidates with significant therapeutic benefits, limit unintended side effects, improve quality of life and over time modify the course of disease. This highly reproducible approach enables the company to pursue multiple programs efficiently, having discovered three drug candidates. Rilzabrutinib, a reversible covalent BTK inhibitor, is being evaluated in a global Phase 3 clinical trial in patients with pemphigus, a Phase 1/2 clinical trial in patients with immune thrombocytopenia (ITP), and the company plans to initiate a Phase 2 clinical trial in patients with IgG4-Related Diseases. PRN2246/SAR442168 is a covalent BTK inhibitor which crosses the blood-brain barrier and is partnered with Sanofi. Sanofi has announced that PRN2246/SAR442168 will be evaluated in four Phase 3 clinical trials in patients with relapsing and progressive forms of multiple sclerosis. PRN473 Topical, a topical reversible covalent BTK inhibitor designed for immune mediated diseases that could benefit from localized application to the skin, is being evaluated in a Phase 1 trial. For more information, please visit www.principiabio.com.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements reflect the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Principia's expectations regarding the Principia pipeline of product candidates, the

initiation, timing, scope and success of additional clinical trials and results, forecasted cash runway and future financial and operating results . Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Principia's actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements. For a description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Principia's business in general, see the risk factors set forth in Principia's reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Principia specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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Principia Biopharma Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,	
	2019	2018
Revenue	\$ -	\$ 26,137
Operating expenses:		
Research and development	21,474	13,678
General and administrative	5,137	4,197
Total operating expenses	26,611	17,875
Income (loss) from operations	(26,611)	8,262
Other income (expense), net	38	2
Interest income	1,649	1,113
Net income (loss)	\$ (24,924)	\$ 9,377
Net income (loss) attributable to common stockholders	\$ (24,924)	\$ 9,377
Net income (loss) per share attributable to common stockholders		
Basic	\$ (0.80)	\$ 0.39
Diluted	\$ (0.80)	\$ 0.37
Weighted-average shares used to calculate net income (loss) per share attributable to common stockholders		
Basic	31,239,371	23,863,193
Diluted	31,239,371	25,552,347

Principia Biopharma Inc.
Summary Consolidated Balance Sheet Data
(Unaudited)
(In thousands)

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Cash, cash equivalents and marketable securities
Total assets
Stockholders' equity