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): May 14, 2019

Principia Biopharma Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38653**	**26-3487603**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
220 East Grand Avenue South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(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 8.01 Other Events.

On May 14, 2019, Principia Biopharma Inc. (the "***Company***") issued a press release announcing the achievement of a clinical development milestone related to its proprietary drug candidate, PRN2246, also known as SAR442168. As a result, pursuant to the License Agreement by and between the Company and Genzyme Corporation ("***Sanofi***") dated as of November 8, 2017, as amended on May 24, 2018, Sanofi is obligated to make a $30.0 million milestone payment to the Company.

A copy of this press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Principia Biopharma Inc. dated May 14, 2019

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.

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

Dated: May 15, 2019

Exhibit 99.1

Principia Biopharma Announces First Patient Dosed in Sanofi's Phase 2b Trial of SAR442168 in Multiple Sclerosis, Triggering $30 Million Milestone

SOUTH SAN FRANCISCO, Calif., May 14, 2019 – Principia Biopharma Inc. (Nasdaq: PRNB), a late-stage biopharmaceutical company dedicated to bringing transformative oral therapies to patients with significant unmet medical needs in immunology and oncology, today announced that the first patient has been dosed in its partner Sanofi's Phase 2b clinical trial of SAR442168 in patients with relapsing multiple sclerosis (MS), triggering a $30 million milestone payment to Principia. SAR442168, formerly known as PRN2246, is a Bruton's tyrosine kinase (BTK) inhibitor that crosses the human blood-brain barrier and modulates immune cell function in both the periphery and in the brain, which shows promise for the potential treatment of central nervous system (CNS) diseases.

"We are delighted that the first patient has been dosed in Sanofi's Phase 2b dose-finding trial in patients with relapsing multiple sclerosis," said Martin Babler, president and chief executive officer of Principia. "One challenge in developing medicines for CNS disorders has been achieving sufficient blood–brain barrier penetration. We are very enthusiastic about the potential of our CNS-penetrating BTK inhibitor, especially because in a Phase 1 clinical trial, we demonstrated exposure of SAR442168 in the CNS as well as BTK occupancy in peripheral blood."

About the Phase 2b Clinical Trial of SAR442168

Sanofi is conducting a global, randomized, double-blind, placebo-controlled, Phase 2b clinical trial that will enroll approximately 120 patients with MS to evaluate SAR442168. The trial will include adult patients diagnosed with relapsing MS (RMS) with at least 1 relapse during the previous year, or 2 or more relapses during the previous 2 years, or 1 or more active Gadolinium (Gd)-enhancing brain lesion on magnetic resonance imaging (MRI) scan in the past 6 months prior to screening. The trial will evaluate the dose response of SAR442168, once daily, for the treatment of RMS based on MRI assessments.

About SAR442168

SAR442168, formerly known as PRN2246, is being developed to potentially treat MS and other CNS diseases, in part by penetrating the blood-brain barrier and modulating B cells and other immune cells in the CNS. During neuro-inflammation, the number of B cells in the brain increases, which is thought to play a central role in the pathology of MS and other CNS diseases. This provides the potential of targeting the adaptive and innate immunity in both the periphery and also within the CNS. In late 2017, Principia formed a collaboration with Sanofi under which Principia granted Sanofi an exclusive, worldwide license to develop and commercialize SAR442168. Principia completed Phase 1 activities. Key findings from the Phase 1 trial included confirming that SAR442168 was well tolerated in the trial, that BTK occupancy increased in a dose dependent manner, and that cerebral spinal fluid exposure was achieved in all subjects who underwent lumbar puncture. Phase 2b and any further development will be conducted by Sanofi, a global biopharmaceutical company committed to discovering and developing new treatment options for people living with serious diseases, including MS.

About Principia Biopharma

Principia is a late-stage biopharmaceutical company dedicated to bringing transformative oral therapies to patients with significant unmet medical needs in immunology and oncology. Principia's proprietary Tailored Covalency® platform enables the Company to design and develop reversible and irreversible covalent, small molecule inhibitors with potencies and selectivities that have the potential to rival those of injectable biologics yet maintain the convenience of a pill. PRN1008, a reversible covalent BTK inhibitor, is being evaluated in a Phase 3 clinical trial in patients with pemphigus, an orphan autoimmune disease, and in a Phase 2b clinical trial in patients with immune thrombocytopenia, a rare hematological disease. SAR442168 (formerly PRN2246), a covalent BTK inhibitor which crosses the blood-brain barrier, is in a Phase 2b clinical trial in patients with multiple sclerosis, and has been partnered with Sanofi for development in multiple sclerosis and, potentially, for other diseases of the central nervous system. PRN1371, a covalent inhibitor of Fibroblast Growth Factor Receptor (FGFR) is being evaluated in a Phase 1 trial in patients with bladder cancer. For more information, please visit www.principiabio.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical fact contained herein are forward-looking statements reflecting 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, Principia's receipt of a milestone payment from Sanofi pursuant to its license agreement regarding SAR442168; the potential for SAR442168 to treat CNS diseases, including MS; the ability of SAR442168 to target the adaptive and innate immunity in both the periphery and within the CNS; the exposure of SAR442168 in the CNS and the peripheral BTK occupancy of SAR442168; and the safety and tolerability of SAR442168. 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 any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties of the clinical development process and of clinical trial recruitment; risks and uncertainties about the efficacy, safety and tolerability of our product candidates; risks that early research or clinical results may be materially different from future clinical results; risks and uncertainties regarding Principia's reliance on third-party organizations, such as contract research organizations, contract manufacturing organizations, and partners such as Sanofi; risks of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Principia's patents or proprietary rights; and the risk that Principia's proprietary rights may be insufficient to protect its technologies and product candidates. For a further 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 the Principia's business in general, see the risk factors set forth in Principia's reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the period ending December 31, 2018. 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.

Investor Contact
Christopher Chai, CFO
ir@principiabio.com

Media Contact
Paul Laland, VP of Corporate Communications
paul.laland@principiabio.com
415.519.6610