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): June 22, 2020

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** **(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 8.01 Other Events.

On June 22, 2020, Principia Biopharma Inc. (the "***Company***") issued a press release announcing that its partner Genzyme Corporation ("***Sanofi***") had enrolled the first patient in Sanofi's Phase 3 clinical trial of SAR442168, formerly known as PRN2246, in patients with relapsing multiple sclerosis. Pursuant to the License Agreement by and between the Company and Sanofi dated as of November 8, 2017, and as amended on May 24, 2018, upon dosing of the first patient, Principia will be entitled to a $50.0 million milestone payment from Sanofi.

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 June 22, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

PRINCIPIA BIOPHARMA INC.

By: /s/ Roy Hardiman
Roy Hardiman
Chief Business Officer

Dated: June 26, 2020

Exhibit 99.1

Principia Announces First Patient Enrolled in Sanofi's Phase 3 Trial of SAR442168 in Relapsing Multiple Sclerosis

Dosing of Patient Will Trigger $50 Million Milestone Payment

SOUTH SAN FRANCISCO, Calif., June 22, 2020 – Principia Biopharma Inc. (Nasdaq: PRNB), a late-stage biopharmaceutical company focused on developing treatments for immune-mediated diseases, today announced that the first patient has been enrolled in its partner Sanofi's Phase 3 clinical trial (GEMINI 1) of SAR442168 in patients with relapsing multiple sclerosis (RMS). Upon dosing, Principia will be entitled to a $50 million milestone payment. SAR442168, discovered by Principia and 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 central nervous system (CNS), which shows promise for the potential treatment of CNS diseases.

"We are delighted that Sanofi has initiated a Phase 3 trial in patients with relapsing MS," said Roy Hardiman, chief business officer at Principia. "Our partnership with Sanofi, a company with a long track record of bringing novel therapies to the multiple sclerosis community, is highly collaborative. We continue to evaluate our Phase 3 co-funding option that could increase Principia's economic rights."

About this Phase 3 Trial of SAR442168

As part of a broad Phase 3 clinical program in MS, Sanofi has initiated a global, randomized, double-blind efficacy and safety trial comparing SAR442168 to teriflunomide (Aubagio®) in 900 participants with relapsing forms of MS. The trial will assess efficacy of daily SAR442168 compared to a daily dose of 14 mg teriflunomide measured by annualized adjudicated relapse rate (ARR) in participants with relapsing forms of MS. Secondary objectives will assess efficacy of SAR442168 compared to teriflunomide on disability progression, MRI lesions, cognitive performance and quality of life.

About SAR442168

SAR442168 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 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.

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 participants with pemphigus, a Phase 1/2 clinical trial in participants with immune thrombocytopenia (ITP), and the company plans to initiate a Phase 2 clinical trial in participants with IgG4-Related Diseases and a Phase 3 trial in ITP. PRN2246/SAR442168 is a covalent BTK inhibitor which crosses the blood-brain barrier and is partnered with Sanofi. Sanofi has announced that SAR442168 will be evaluated in four Phase 3 clinical trials in participants 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, the initiation, timing, scope and success of Sanofi's Phase 3 clinical trial program, Principia's expectations regarding the Principia pipeline of product candidates, the potential patient benefits of Principia's pipeline, including of rilzabrutinib to rapidly and effectively treat

pemphigus while significantly reducing the exposure to moderate to high CS doses, the safety and efficacy of rilzabrutinib, the planned patient enrollment for the Phase 3 PEGASUS trial, the initiation and timing of Principia's Phase 2 clinical trial in participants with IgG4-Related Diseases and Phase 3 clinical trial in ITP, and the initiation, timing, scope and success of additional clinical trials and 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 the 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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