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 12, 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	**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

ITP Press Release

On June 12, 2020, Principia Biopharma Inc. (the "***Company***") issued a press release announcing the presentation at a virtual session of the European Hematology Association of positive data on durability of response from its adaptive, open-label, dose-finding Phase 1/2 clinical trial of its proprietary drug candidate, rilzabrutinib, for the treatment of immune thrombocytopenia (ITP).

The analysis presented included 47 heavily pre-treated (median of six prior therapies) adult patients enrolled with a median follow-up of 18 weeks. The primary endpoint was the proportion of patients able to achieve two or more consecutive platelet counts, separated by at least five days, of ³ 50,000/µL and an increase of platelet count of ³20,000/µL from baseline, without use of rescue medication.

Rilzabrutinib treatment at 400 mg twice daily led to both a rapid response detectable at the first platelet measurement (day eight), and a durable response. Fifty percent of patients who started at 400 mg twice daily and had at least 12 weeks of treatment (n=26) achieved the primary endpoint (80 percent confidence interval (CI) 38, 62). In the overall patient population, the primary endpoint was met by 43 percent of patients (80 (CI) 34, 52), irrespective of dose and duration of treatment. Among the patients who started on 400 mg twice daily, 53 percent achieved a clinically significant platelet count of ³30,000/µL on day eight. Among the patients that achieved the primary endpoint, 79 percent had a platelet count ³30,000/µL by day eight, and these patients had sustained responses ³50,000/µL for 71 percent of the time. In addition, responders achieved platelet counts ³20,000/µL above baseline 88 percent of the time. To date rilzabrutinib has been well tolerated, whether given as a monotherapy or with allowed concomitant ITP therapy (thrombopoietin receptor agonists and corticosteroids), with no reported treatment related bleeding or thrombotic events. Related treatment emergent adverse events were reported in 45% of patients and were all grade 1 or 2.

Based on this data, the Company's goal is to initiate a pivotal Phase 3 trial, assuming no future COVID-19 related impact, by the end of 2020. In addition, the Company believes that a single Phase 3 trial, if successful, will be acceptable for approval in the United States, but can make no assurance thereof.

These results are preliminary in nature and may change as patients progress in the trial and as additional patients may be enrolled. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference.

Pemphigus Data Release

On June 12, 2020, the Company announced the presentation as part of the virtual late-breaker session of the American Academy of Dermatology of positive data from the Phase 2 Part B open-label trial of its proprietary drug candidate, rilzabrutinib, for the treatment of pemphigus.

In the Phase 2 Part B trial of 15 patients with newly diagnosed or relapsed mild-to-severe pemphigus, rilzabrutinib demonstrated a 40% complete remission (CR) rate after 24 weeks of treatment, while the median corticosteroid (CS) dose was reduced significantly. The median CS dose was 18 mg/day (0.201 mg/kg/day) at baseline and in the 14 patients that completed 12 and 24 weeks of treatment the median CS dose decreased to 11 mg/day (0.125 mg/kg/day) at 12 weeks and decreased again to 6 mg/day (0.076 mg/kg/day) at 24 weeks. Additionally, 60 percent and 87 percent of patients achieved control of disease activity (CDA) by weeks 4 and 12, respectively. The results also demonstrated that while patients on 400 mg once-a-day dosing were able to reach CDA, 400 mg twice-a-day dosing is needed to achieve rapid CR rates. Related treatment emergent adverse events were mild-to-moderate and were all grade 1 or 2.

Disclosure Channels to Disseminate Information

The Company disseminates information to the public about the Company, its drug candidates and pipeline, its science and technology and other matters through various channels, including the Company's investor relations website (https://ir.principiabio.com), SEC filings, press releases, public conference calls and webcasts, in order to achieve broad, non-exclusionary distribution of information to the public. The Company encourages investors and others to review the information it makes public through these channels, as such information could be deemed to be material information.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Principia Biopharma Inc. dated June 12, 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: June 12, 2020

By: /s/ Roy Hardiman

Roy Hardiman
Chief Business Officer

Exhibit 99.1

Principia Presents Updated Positive Data of Rilzabrutinib for Immune Thrombocytopenia in Ongoing Phase 1/2 Trial

Oral BTK inhibitor reaches primary endpoint in 50 percent of patients treated ³ 12 weeks; demonstrates fast onset and durable responses

Principia to initiate pivotal Phase 3 trial in ITP

South San Francisco, June 12, 2020 – Principia Biopharma Inc. (Nasdaq: PRNB), a late-stage biopharmaceutical company focused on developing treatments for immune mediated diseases, today announced positive data on durability of response from an ongoing Phase 1/2 trial of its investigational treatment, rilzabrutinib. A total of 47 heavily pre-treated patients (median of six prior therapies) with immune thrombocytopenia (ITP) have been enrolled with a median follow-up of 18 weeks. Data from this trial are being presented by David Kuter, M.D., director of Clinical Hematology at Massachusetts General Hospital and professor of Medicine at Harvard Medical School, at a virtual session of the European Hematology Association (EHA).

"Rilzabrutinib treatment at 400 mg twice daily led to both a rapid response detectable at the first platelet measurement (day eight), and a durable response. These results are significant not only for the speed of onset and sustainability of response, but also for the heavily pretreated nature of the population in which these results were seen," said Dr. Kuter, the trial's Principal Investigator. "It is also important to note that rilzabrutinib continues to be well tolerated and achieved significant reliable responses across subgroups at all doses and treatment times."

In this adaptive, open-label, dose finding Phase 1/2 trial, the primary endpoint was the proportion of patients able to achieve two or more consecutive platelet counts, separated by at least 5 days, of ³ 50,000/µL and an increase of platelet count of ³20,000/µL from baseline, without use of rescue medication.

Fifty percent of patients who started at 400 mg twice daily and had at least 12 weeks of treatment (n=26), achieved the primary endpoint (80 percent confidence interval (CI) 38, 62). In the overall patient population (n=47), the primary endpoint was met by 43 percent of patients (80 (CI) 34, 52), irrespective of dose and duration of treatment.

Among the patients who started on 400 mg twice daily, 53 percent achieved a clinically significant platelet count of ³30,000/µL on day eight. Among the patients that achieved the primary endpoint, 79 percent had a platelet count ³30,000/µL by day eight, and these patients had sustained responses ³50,000/µL for 71 percent of the time. In addition, responders achieved platelet counts ³20,000/µL above baseline 88 percent of the time.

“We are very pleased with the consistency of responses and durability of effect observed among the patient responders. This data provides confidence to move forward to a pivotal Phase 3 trial, and assuming no future COVID-19 related impact, our goal is to initiate the trial by the end of 2020,” said Dolca Thomas, MD, chief medical officer at Principia.

To date rilzabrutinib has been well-tolerated whether given as a monotherapy or with allowed concomitant ITP therapy (thrombopoietin receptor agonists and corticosteroids), with no reported treatment related bleeding or thrombotic events. Related treatment emergent adverse events (TEAEs) were reported in 21 patients (45 percent) and were all grade 1 or 2.

These results are preliminary in nature and may change as patients progress in the trial and as additional patients may be enrolled. A complete analysis of this trial will be presented at a future medical conference.

About ITP and Rilzabrutinib

Immune thrombocytopenia (ITP) is characterized by immune-mediated platelet destruction and impairment of platelet production, leading to downstream thrombocytopenia, a predisposition to bleeding, and adverse impact on patient quality of life. Unmet needs in relapsed or refractory ITP are to improve remission rates and durability by targeting underlying disease mechanisms. Rilzabrutinib is an oral, small molecule, reversible covalent inhibitor of Bruton’s tyrosine kinase (BTK) that modulates immune-mediated processes in ITP. Rilzabrutinib was designed based on Principia’s proprietary Tailored Covalency® platform to optimize rilzabrutinib’s safety and efficacy profile, resulting in prolonged and reversible action at the target site while being rapidly eliminated from the body. Principia believes this approach limits systemic exposure of rilzabrutinib and enables rapid clinical reversibility of effects on the immune system and is thus designed for use as a chronic therapy in immune-mediated diseases.

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 clinical 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 PRN2246/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, Principia's expectations regarding the Principia pipeline of product candidates, the initiation, progress of, and timing of, its clinical trials, including the planned commencement of the Phase 3 trial in ITP in 2020, the timing, scope and success of additional clinical results, and the planned presentation of rilzabrutinib efficacy and safety data in its ongoing Phase 1/2 clinical trial in ITP. 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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