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): April 23, 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

Sanofi Press Release

On April 23, 2020, Sanofi S.A. ("***Sanofi***") announced that PRN2246/SAR442168, a Bruton Tyrosine Kinase (BTK) inhibitor licensed exclusively from Principia Biopharma Inc. (the "***Company***") by Genzyme Corporation, a wholly-owned subsidiary of Sanofi, for development for development in relapsing and progressive multiple sclerosis (MS) and other diseases of the central nervous system, significantly reduced disease activity in Sanofi's Phase 2b clinical trial in MS. Sanofi also reiterated that it will be initiating four Phase 3 clinical trials in relapsing and progressive forms of MS.

As announced by Sanofi, PRN2246/SAR442168, an oral, brain-penetrant, selective small molecule achieved both the primary and secondary endpoints in a Phase 2b trial evaluating efficacy and safety in participants with relapsing forms of multiple sclerosis. PRN2246/SAR442168 significantly reduced disease activity associated with MS as measured by magnetic resonance imaging (MRI), with 85% or greater relative reduction achieved in the number of new gadolinium-enhancing (Gd-enhancing) T1 and new or enlarging T2 hyperintense lesions, as measured by MRI. The trial evaluated four doses ranging from 5mg to 60 mg QD (once daily) and used placebo data obtained at four weeks. In the study, PRN2246/SAR442168 demonstrated a dose-response relationship in reducing the number of new gadolinium-enhancing T1-hyperintense brain lesions and in reducing the number of new or enlarging T2-hyperintense brain lesions after 12 weeks of treatment.

For the primary endpoint measuring the number of new Gd-enhancing T1 hyperintense lesions, Sanofi applied a multiple comparison procedure with modeling to the dose-response data and the exponential model provided the best fit ($p=0.03$), in Sanofi's determination. For the secondary endpoint measuring the number of new or enlarging T2 hyperintense lesions, Sanofi applied the linear model ($p<0.0001$). At the 60mg dose, for the primary endpoint the treatment effect was 85% relative reduction of new Gd-enhancing T1 hyperintense lesions, and for the secondary endpoint the treatment effect was 89% relative reduction of new or enlarging T2 hyperintense lesions.

Sanofi identified no new safety signals, with one single serious adverse event (MS relapse) reported over 12 weeks. The most frequent adverse events were headache (3 to 13%), upper respiratory tract infection (3 to 6%) and nasopharyngitis (3 to 9%). 123 of 129 participants who completed the trial have enrolled into a long-term safety follow-up study to assess safety and tolerability of PRN2246/SAR442168. During Sanofi's April 23, 2020 investor call on its Phase 2b trial results, Sanofi publicly disclosed that the end of Phase 2 meeting with the Food and Drug Administration had occurred on April 22, 2020.

Additional details regarding Sanofi's Phase 2b results can be found in the press release issued by Sanofi on April 23, 2020 and in its presentation materials posted on Sanofi's investor relations website on April 23, 2020. Further information regarding the license agreement between the Company and Genzyme Corporation, a wholly-owned subsidiary of Sanofi, can be found in the Company's prior filings with the Securities and Exchange Commission.

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: April 24, 2020

By: /s/ Roy Hardiman

Roy Hardiman
Chief Business Officer