Principia Biopharma Reports Fourth Quarter and Full Year 2018 Financial Results

March 19, 2019

SOUTH SAN FRANCISCO, Calif., March 19, 2019 (GLOBE NEWSWIRE) -- 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 financial results for the fourth quarter and full year ended December 31, 2018.

“In 2018, we made progress across all of our programs, in addition to completing a successful initial public offering. We continued the momentum into the new year with presentations at both the American Academy of Dermatology and the Americas Committee for Treatment and Research in Multiple Sclerosis,” said Martin Babler, Chief Executive Officer of Principia. “In 2019, we are focusing on the continued clinical development of our assets. We will continue to expand enrollment in our Phase 3 program for PRN1008 around the world. One of our goals this year is to have top-line data from PRN1008 in both the Phase 2 clinical trial in immune thrombocytopenia and the Phase 2 extension trial in pemphigus.”

Full Year 2018 and Recent Program Highlights

- **PRN1008** for the treatment of pemphigus (pemphigus vulgaris (PV) and pemphigus foliaceus (PF))
  - Announced presentation of positive Phase 2 results as late breaker at 2019 American Academy of Dermatology
  - Initiated global, randomized, double-blind, placebo-controlled, pivotal, Phase 3 clinical trial, the PEGASUS study, in approximately 120 patients to evaluate PRN1008, using a background treatment of tapering doses of corticosteroids
  - Initiated Phase 2 extension to the Believe-PV clinical trial increasing the active treatment period from 12 to 24 weeks
  - Potential Pemphigus Milestones
    - Phase 2 extension top-line data: fourth quarter of 2019
    - Phase 3 data: first half of 2022
- **PRN1008** for the treatment of Immune Thrombocytopenia (ITP)
  - Received orphan-drug designation from FDA for treatment of ITP
  - Continued conducting an open-label adaptive Phase 2 trial in up to 24 patients with relapsed primary or secondary ITP
  - Potential ITP Milestone
    - Phase 2 top-line data: fourth quarter of 2019
- **PRN2246/SAR442168** for the treatment of Multiple Sclerosis
  - Presented positive Phase 1 results at 2019 Americas Committee for Treatment and Research in Multiple Sclerosis
  - Received $25 million in 2018 related to numerous successful development activities
  - Potential PRN2246/SAR442168 Milestone
    - Phase 2 initiation by Sanofi
- **PRN1371** for the treatment of bladder cancer
  - Completed Phase 1 dose escalation
  - Initiated Phase 1 expansion cohort in patients with metastatic urothelial carcinoma
  - Potential PRN1371 Milestone
    - Phase 1 dose escalation data: first half of 2019
- **Immunoproteasome**
  - Reacquired rights to oral immunoproteasome program in March 2019

General Corporate Recent Highlights

- Completed initial public offering (IPO) raising approximately $122.2 million in gross proceeds
- Completed Series C crossover round raising approximately $50.0 million in gross proceeds. The transaction was led by Cormorant Asset Management, HBM Healthcare Investments, RTW Investments, and Samsara BioCapital in addition to existing investors
- Appointed Dolca Thomas, M.D. as Chief Medical Officer. Dr. Thomas has approximately 15 years of industry and medical experience, including most recently with Roche, Pfizer, and Bristol-Myers Squibb
- Appointed industry veteran John W. Smither to the Board of Directors and Chairperson of our Audit Committee. Mr. Smither has approximately 20 years of industry and financial experience, and currently serves as CFO of Sienna Biopharmaceuticals, Inc.

Fourth Quarter and Full Year 2018 Financial Results

Cash Position: Cash, cash equivalents, and marketable securities were $180.6 million as of December 31, 2018, compared to $41.1 million as of December 31, 2017. The increase in Principia’s cash position is mainly due to net proceeds of $113.6 million from its IPO and net proceeds of $49.8

million from its Series C financing.

Revenues: Collaboration revenue was $26.1 million for the three months ended December 31, 2018, compared to $3.4 million for the same period in 2017. Collaboration revenue for the full year of 2018 was $69.1 million, compared to $5.2 million for the full year of 2017. The increase was due to the revenue recognition of an upfront payment of $40.0 million received in December 2017 from Sanofi and an upfront payment of $15.0 million received in June 2017 from AbbVie Biotechnology Limited, as well as the revenue recognition of milestone payments totaling $25.0 million received in 2018 from Sanofi, of which $10.0 million were received in the fourth quarter of 2018.

R&D Expenses: Total research and development expenses were $13.7 million for the three months ended December 31, 2018, including stock-based compensation expense of $0.8 million, compared to $7.5 million for the same period in 2017, including stock-based compensation expense of $0.1 million. For the full year of 2018, total research and development expenses were $40.5 million, including stock-based compensation expense of $1.4 million, compared to $25.4 million for full year of 2017, including stock-based compensation expense of $0.5 million. The increase in total research and development expenses was mainly driven by an increase in PRN1008 program costs, attributable to various manufacturing campaigns and the initiation of a global Phase 3 trial in pemphigus in November 2018 and the initiation of an ITP clinical trial in December 2017, as well as an increase in employee related expenses.

G&A Expenses: General and administrative expenses were $4.2 million for the three months ended December 31, 2018, including stock-based compensation expense of $0.6 million, compared to $2.0 million for the same period in 2017, including stock-based compensation expense of $0.2 million. For the full year of 2018, general and administrative expenses were $11.5 million, including stock-based compensation expense of $1.4 million, compared to $6.4 million for the full year of 2017, including stock-based compensation expense of $0.6 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, 2018, net income was $9.4 million compared to a net loss of $2.8 million for the same period in 2017. For the full year of 2018, net income was $18.2 million, compared to a net loss of $28.7 million for the full year of 2017.

Financial Guidance
The Company anticipates its cash, cash equivalents, and marketable securities will fund operations toward the end of 2020, based on existing planned expenditures.

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 Principia 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 2 clinical trial in patients with immune thrombocytopenia, a rare hematological disease. PRN2246/SAR442168, a covalent BTK inhibitor which crosses the blood-brain barrier, has completed a Phase 1 clinical trial in healthy volunteers, 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, the clinical development of Principia's assets, the enrollment of the Phase 3 trial of PRN1008 for pemphigus, the timing of top-line data from the Phase 2 clinical trial of PRN1008 in immune thrombocytopenia and from the Phase 2 extension trial of PRN1008 in pemphigus, the timing of data from the Phase 3 trial of PRN1008 in pemphigus, the initiation by Sanofi of a Phase 2 clinical trial of PRN2246/SAR442168 for multiple sclerosis, the timing of data from the Phase 1 dose escalation of PRN1371, and the length of time that Principia's current cash, cash equivalents, and marketable securities may be able to fund its operations. 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.

Principia Biopharma Inc.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017

Collaboration revenue	$ 26,137	$ 3,375	$ 69,137	$ 5,247
Operating expenses:				
Research and development	13,678	7,543	40,533	25,390
General and administrative	4,197	2,015	11,462	6,443
Total operating expenses	17,875	9,558	51,995	31,833
Income (loss) from operations	8,262	(6,183)	17,142	(26,586)
Other income (expense), net	2	4,994	(653)	5,096
Interest income	1,113	14	1,678	16
Interest expense	—	(1,655)	—	(7,223)
Net income (loss)	$ 9,377	$ (2,830)	$ 18,167	$ (28,697)
Net income (loss) attributable to common stockholders	$ 9,377	$ (2,830)	$ 4,917	$ (28,697)
Net income (loss) per share attributable to common stockholders				
Basic	$ 0.39	$ (4.55)	$ 0.65	$ (50.37)
Diluted	$ 0.37	$ (4.55)	$ 0.57	$ (50.37)
Weighted-average shares used to calculate net income (loss) per share attributable to common stockholders				
Basic	23,863,193	621,945	7,622,602	569,719
Diluted	25,552,347	621,945	8,627,473	569,719

Principia Biopharma Inc.

Summary Balance Sheet Data

(In thousands)

	December 31, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 180,637	$ 41,054
Total assets	195,521	43,503
Stockholders' equity (deficit)	169,860	(143,462)

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Source: Principia Biopharma Inc.