Provention Bio Reports First Quarter 2020 Financial Results and Provides Business Update

- Company on Track to Complete Submission of Rolling Biologics License Application for Teplizumab in Q4 2020 -

OLDWICK, N.J., May 7, 2020 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical-stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today reported financial results and provided a business update for the first quarter ended March 31, 2020.

"Public health and clinical research conditions have changed dramatically in recent months. As an agile, virtual company, Provention has adapted quickly and seamlessly to this challenging new operating environment," said Ashleigh Palmer, CEO of Provention Bio.

"We continue to execute on our strategy to advance our lead candidate, teplizumab, as the first disease modifying therapy for patients who are at-risk of progressing to clinical-stage type 1 diabetes (T1D). To that end, last month we announced the first module of our rolling biologics license application (BLA) was submitted on schedule, and we remain on track to complete the submissions of all modules in Q4 2020. In parallel with these regulatory efforts, we are building a commercial team and laying the foundations to support a US launch if teplizumab is approved."

"Additionally, we have reported progress on our development pipeline with positive Phase 1b study results for PRV-3279, highlighting this therapeutic candidate's potential to intercept the pathophysiology of lupus and other B cell-mediated autoimmune diseases, as well as prevent or reduce the immunogenicity associated with certain biotherapeutics, including gene therapy products."

"Our team remains highly focused on fulfilling the potential of our portfolio of clinical-stage assets targeting life-impacting and life-threatening autoimmune diseases, and we look forward to building on our success during the remainder of 2020," concluded Ashleigh Palmer.

First Quarter 2020 and Recent Corporate Highlights:

Initiation of Provention's Rolling Submission of BLA for Teplizumab

In April, the Company submitted the first module of its rolling BLA to the U.S. Food and Drug Administration (FDA) for teplizumab (PRV-031), an anti-CD3 monoclonal antibody, for the delay or prevention of clinical T1D in at-risk individuals, as indicated by the presence of two or more T1D-related autoantibodies. Rolling submission allows for completed modules of the BLA to be submitted and reviewed by the FDA on an ongoing basis. Provention submitted the non-clinical module and expects to submit the clinical module in Q3 and the chemistry, manufacturing and controls (CMC) module in Q4 of 2020. Once the final module of the BLA has been submitted, FDA will make a filing acceptance decision and set a Prescription Drug User Fee Act (PDUFA) goal date.

Completed First GMP Run of Teplizumab; Manufacturing on Track

During the first quarter, AGC Biologics, the Company's contract manufacturer, completed a cGMP production run of teplizumab. The Company continues to expect to proceed with three commercial-scale process performance qualification (PPQ) batches this summer, supporting the CMC module and enabling the completion of the rolling BLA submission as planned. The Company has not experienced any interruption in its supply chain or manufacturing efforts due to the COVID-19 pandemic at this time.

Conducted Initial PRIME Meeting with the EMA

In the first quarter, the Company held a kick-off meeting with the EMA to discuss teplizumab. The Company believes it will be able to file a marketing authorization application (MAA) with the data from the At-Risk clinical study along with supplemental data from historical clinical studies of teplizumab. Provention plans to have additional meetings with the EMA and expects to file the MAA for teplizumab in the second half of 2021.

Temporarily Paused Randomization of PROTECT Study Due to the Impact of COVID-19

In March, Provention announced a temporary pause in the randomization of patients with newly diagnosed T1D into its global Phase 3 PROTECT study of PRV-031 (teplizumab). This pause was taken proactively, to protect patients, caregivers, clinical site staff, company employees and contractors at this critical juncture in the

collective global efforts to combat the COVID-19 pandemic. Patients currently undergoing study therapy will be allowed to complete their course, as recommended by the PROTECT study's Data Safety Monitoring Board, which was recently expanded to include infectious diseases expertise.

Announced Positive data From Phase 1b PREVAIL Study of PRV-3279

In March, Provention announced positive top-line results from the Phase 1b portion of the PREVAIL (PRV-3279 EVAluation In Lupus) study evaluating PRV-3279 in healthy volunteers. PRV-3279 is a humanized diabody targeting the B-cell surface proteins, CD32B and CD79B, and has the potential to intercept the pathophysiology of systemic lupus erythematosus (SLE) and other B cell-mediated autoimmune diseases and prevent or reduce the immunogenicity of biotherapeutics, including gene therapy products. Based on the results, Provention plans to commence the Phase 2a portion of the PREVAIL study in lupus patients in the first half of 2021. These Phase 1b results will also enable a second development pathway for the prevention of immunogenicity of biotherapeutics such as gene therapy products.

Received $0.5 million from the Sale of NJ Net Operating Losses

In April, Provention received $0.5 million from the sale of a portion of the Company's New Jersey State net operating losses (NOLs). A program administered by the New Jersey Economic Development Authority allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs for cash.

Financial Highlights:

Net loss for the first quarter 2020 was $12.6 million, or $0.26 per basic and diluted share, compared to a net loss of $11.0 million, or $0.29 per basic and diluted share, for the same period in 2019. The increase in net loss was primarily attributable to an increase in general and administrative costs, including the initial build out of our commercial organization and other aspects of our corporate infrastructure.

As of March 31, 2020, Provention had cash, cash equivalents and marketable securities of $76.6 million. Cash-based operating expenses were $11.6 million for the three months ended March 31, 2020. Provention expects to utilize $24 million to $29 million of cash for its operating needs in the first six months of 2020. Provention expects its current cash, cash equivalents and marketable securities will be sufficient to fund projected operating requirements for at least the next 12 months.

Conference Call and Webcast Information:

Provention Bio will discuss these results via conference call today at 4:30 pm ET. To access the call, please dial 1-877-870-4263 (domestic) or 1-412-317-0790 (international) five minutes prior to the start time and ask to be connected to the "Provention Bio Call". An audio webcast will also be available on the "Events and Webcasts" page of the Investors section of the Company's website, www.proventionbio.com. An archived webcast will be available on the Company's website approximately two hours after the conference call and will be available for seven days following the call.

About Provention Bio, Inc.:

Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy focused on the prevention or interception of immune-mediated disease. Provention's mission is to source, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune diseases. Provention's diversified portfolio includes PRV-031 (teplizumab), a pre-commercial-stage candidate that has been shown to delay the onset of end-stage type one diabetes (T1D) in at-risk individuals with pre-symptomatic disease. The Company's portfolio includes additional clinical-stage product development candidates that have demonstrated proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus.

Forward Looking Statements:

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including statements related to timing of submission of the BLA. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Provention's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties surrounding the COVID-19 pandemic, including the impact to our clinical trial programs, risks related to failure to obtain FDA approvals or clearances and noncompliance with FDA regulations; uncertainties of patent protection and litigation; limited research and development efforts and dependence upon third parties; substantial competition; our need for additional financing and the risks listed under "Risk factors" in our annual report on Form 10-K for the year ended December 31, 2019 and any subsequent filings with the

Securities and Exchange Commission (SEC). As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Provention does not undertake an obligation to update or revise any forward-looking statement. The information set forth herein speaks only as of the date hereof.

Investors:
Sam Martin, Argot Partners
sam@argotpartners.com
212-600-1902

Media:
Lori Rosen, LDR Communications
lori@ldrcommunications.com
917-553-6808

PROVENTION BIO, INC.
SELECTED FINANCIAL DATA (unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2020	**2019**
Statement of Operations Data:		
Operating expenses:		
Research and development	$ 9,090	$ 10,022
General and administrative	3,775	1,237
Total operating expenses	12,865	11,259
Loss from operations	(12,865)	(11,259)
Interest income	283	287
Loss before income tax benefit	(12,582)	(10,972)
Income tax benefit	—	—
Net loss	$ (12,582)	$ (10,972)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.29)
Weighted average common shares outstanding, basic and diluted	47,699	37,362

	March 31, 2020	**December 31, 2019**
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 76,629	$ 85,373
Total assets	$ 78,117	$ 85,996
Total liabilities	$ 6,903	$ 3,840
Accumulated deficit	$ (91,643)	$ (79,061)
Total stockholders' equity	$ 71,214	$ 82,156

SOURCE Provention Bio, Inc.

---

http://investors.proventionbio.com/2020-05-07-Provention-Bio-Reports-First-Quarter-2020-Financial-Results-and-Provides-Business-Update