Provention Bio Reports Second Quarter 2018 Financial Results and Provides Business Update

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Recent Corporate Highlights:

- Closed initial public offering of common stock on July 19, 2018, generating $63.9 million in gross proceeds
- Expanded pipeline with two additional clinical-stage assets in type 1 diabetes (T1D) and systemic lupus erythematosus (SLE); pipeline now consists of five programs targeting the interception and prevention of immune-mediated disease
- Appointed Wayne Pisano, former President of Sanofi Pasteur, to board of directors
- Recruited Dr. Mark Rigby and additional clinical development and operations expertise to lead T1D and SLE programs

Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today reported financial results for the second quarter ended June 30, 2018 and provided a business update. These results mark the first quarterly reporting period for Provention as a publicly traded company.

On July 19, 2018, Provention closed its initial public offering ("IPO") of shares of its common stock at a price to the public of $4.00 per share. The shares began trading on The Nasdaq Capital Market under the ticker symbol "PRVB" on July 24, 2018. Gross proceeds from the upsized offering were $63.9 million, prior to deducting underwriting commissions and expenses.

"We are delighted to provide our first quarterly results and business update as a publicly traded company," stated Ashleigh Palmer, CEO of Provention Bio. "The successful completion of our IPO was a transformative event for Provention. In the short period of time from our founding financing in April 2017 to our recent IPO, we've built a diverse clinical-stage pipeline that now consists of five novel therapeutics that were acquired or in-licensed because of their potential to interrupt, delay, reverse or prevent the onset or progression of life-threatening or debilitating immune-mediated disease. Our unique focus on disease intervention and prevention, as well as our deep understanding of immune-related pathophysiology, translational medicine, and clinical trial design and execution, set Provention apart, and are fundamental to our strategic intent."

Mr. Palmer continued, "Our current development pipeline consists of a Phase 3 candidate for the interception of type 1 diabetes (T1D), two Phase 2 candidates for inflammatory bowel diseases (IBD), a Phase 1 candidate for systemic lupus erythematosus (SLE), and a pre-investigational new drug (IND)-stage vaccine for acute coxsackievirus B (CVB) infection and the potential prevention or delay in onset of T1D. These assets were obtained from industry-leading pharmaceutical companies, such as Janssen Pharmaceuticals and MacroGenics, as well as innovative, development-stage companies such as Vactech, Ltd., a Finnish biotechnology company."

"In recent months we have also continued to build a talented team with significant experience and expertise in autoimmune diseases. Most recently, we added Mark Rigby, M.D., Ph.D., to support the advancement of our pipeline as Vice President, Clinical Development, bringing his significant expertise in T1D interception to Provention. Earlier in the second quarter we added Wayne Pisano, former President of Sanofi Pasteur, to our Board of Directors. Wayne's vast industry experience will be invaluable as we continue to progress and develop our programs."

Mr. Palmer concluded, "With the proceeds from the IPO and our leadership team in place, we believe we are well positioned to move our clinical candidates forward efficiently and in accordance with our rapid go/no-go clinical development strategy. We plan to initiate a number of clinical studies and other development activities over the 12-18 months that we expect to showcase the potential of our pipeline assets to intercept and prevent immune-mediated diseases and substantially improve the lives of patients around the world, as well as to continue to enhance shareholder value."

Pipeline Summary:

PRV-031 (anti-CD3 antibody for type 1 diabetes)

Provention's most advanced product candidate is PRV-031 (also known as teplizumab), which is a Phase 3 anti-CD3 monoclonal antibody (mAb) and is being developed for the interception of type 1 diabetes (T1D). PRV-031 was acquired from MacroGenics, Inc. and has been the subject of multiple clinical studies involving more than 1,000 subjects (823 patients received PRV-031).

Provention expects to commence a randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial of PRV-031 in the second half of 2019 – the PROTECT (PROvention T1D trial Evaluating C-peptide with Teplizumab) study, which is expected to enroll between 300 and 350 pediatric and adolescent T1D patients in North America and Europe.

PRV-6527 (oral CSF-1R inhibitor for Crohn's disease)

PRV-6527 was developed by Janssen Pharmaceuticals and has undergone clinical testing in 178 subjects to date. It is a highly potent and selective small-molecule oral inhibitor of CSF-1R, which Provention is developing to intercept the progression of Crohn's disease before it becomes a chronic, life-altering condition.

PRV-6527 is currently the subject of a randomized, double-blinded, placebo-controlled Phase 2a proof-of-concept (PoC) clinical trial – the PRINCE (PRovention INvestigation in Crohn's DiseasE) study, which the Company initiated in the first quarter 2018. Provention expects to report top line data from this study in the second half of 2019.

PRV-300 (anti-TLR3 antibody for ulcerative colitis)

PRV-300, also developed by Janssen Pharmaceuticals, is a first-in-class, fully human, IgG4κ monoclonal antibody (mAb) that binds the extracellular domain of toll-like receptor 3 (TLR3) with high specificity and affinity. Provention is developing PRV-300 to intercept the progression of ulcerative colitis (UC) before it becomes a chronic, life-altering condition.

PRV-300 is currently in a randomized, double-blind, placebo-controlled Phase 1b clinical trial – the PULSE (Provention ULcerative Colitis Study Evaluation) study, which Provention initiated in the first quarter 2018. Top-line data is expected to be available in the second half of 2019.

PRV-3279 (dual affinity biologic for lupus and other autoimmune diseases)

PRV-3279 is a humanized CD32B x CD79B (DART®) protein developed by MacroGenics, which Provention is developing to intercept the pathophysiology of systemic lupus erythematosus (SLE) before it becomes a chronic, life-altering condition.

Provention plans to initiate a randomized, double-blind, placebo-controlled Phase 1b/2a clinical study in the second half of 2019. The study will begin with an evaluation of multiple ascending doses of PRV-3279 in healthy volunteers, followed by expansion into an SLE patient cohort. Based on the outcome, Provention may choose to pursue lupus nephritis (a possible orphan indication) and/or the broader SLE indication.

PRV-101 (coxsackievirus B vaccine for CVB infection and T1D)

PRV-101 is a polyvalent coxsackievirus B (CVB) vaccine licensed from Vactech, Ltd., which Provention is developing as a vaccine for acute CVB infection and for the potential prevention of up to 50% of worldwide type 1 diabetes (T1D) cases.

PRV-101 is currently in investigational new drug (IND)-enabling studies focused on safety and immunogenicity. Provention plans to complete these studies and file an IND application for PRV-101 in 2019, prior to initiating a first-in-human Phase 1 clinical study in 2020.

Financial Highlights:

As of June 30, 2018, Provention had cash and cash equivalents of $10.2 million. In July 2018, the Company completed its initial public offering and received approximately $59.3 million in net proceeds after deducting commissions and expenses.

Net loss for the second quarter 2018 was $10.5 million, or $1.05 per basic and diluted share, compared to a net loss of $4.1 million, or $0.44 per basic and diluted share, for the same period in 2017. The increase in net loss year-over-year is primarily attributable to costs associated with the clinical development of PRV-6527 and PRV-300, development of PRV-101, and the expansion of our clinical pipeline with two additional assets from MacroGenics in May 2018.

Net loss for the six months ended 2018 was $15.7 million, or $1.57 per basic and diluted share, compared to a net loss of $4.2 million, or $0.48 per basic and diluted share, for the same period in 2017. The increase in net loss year-over-year is primarily attributable to costs associated with clinical development of PRV-6527 and PRV-300, development expenses related to PRV-101, and the expansion of our clinical pipeline with two additional assets from MacroGenics in May 2018.

About Provention Bio, Inc.
Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy that is focused on the prevention or interception of immune-mediated disease. Our diverse portfolio was assembled with product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. Provention's mission is to in-license, transform and develop clinical-stage, or nearly clinical-stage, therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), Crohn's disease, ulcerative colitis, lupus, and certain life-threating viral diseases. For more information on Provention Bio, please visit www.proventionbio.com.

Forward Looking Statements
Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. 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 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 detailed in Provention's prospectus filed with the Securities and Exchange Commission as well as in quarterly and annual reports and other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. 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.

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Financial Tables to Follow

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 9,161	$ 3,731	$ 13,544	$ 3,731
General and administrative	1,004	256	1,657	299
Total operating expenses	10,165	3,987	15,201	4,030
Operating loss	(10,165)	(3,987)	(15,201)	(4,030)
Other income (expense):				
Interest income	45	30	102	30
Change in fair value of warrant liability	(219)	(86)	(303)	(86)
Net loss	(10,339)	(4,043)	(15,402)	(4,086)
Accretion on Series A Convertible Redeemable Preferred Stock	(126)	(90)	(251)	(90)
Net loss attributable to common stockholders	$ (10,465)	$ (4,133)	$ (15,653)	$ (4,176)
Net loss per common share, basic and diluted	$ (1.05)	$ (0.44)	$ (1.57)	$ (0.48)
Weighted average common shares outstanding, basic and diluted	10,000	9,473	10,000	8,740

	June 30, 2018	**December 31, 2017**
Balance Sheet Data:		
Cash and cash equivalents	$ 10,209	$ 21,834
Total assets	$ 12,236	$ 22,428
Total liabilities	$ 2,994	$ 2,276
Series A Convertible Redeemable Preferred Stock	$ 26,436	$ 26,185
Accumulated deficit	$ (24,700)	$ (9,298)
Total stockholders' deficit	$ (17,194)	$ (6,033)

SOURCE Provention Bio, Inc.

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http://investors.proventionbio.com/2018-08-13-Provention-Bio-Reports-Second-Quarter-2018-Financial-Results-and-Provides-Business-Update