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

Conference Call and Live Audio Webcast Scheduled for Today at 8:30 a.m., ET

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Q3 2018 and Recent Corporate Highlights:

- Completed $63.9 million upsized initial public offering
- Announced co-development agreement with Amgen and in-licensing of PRV-015 (Amgen's AMG-714), a novel anti-IL-15 monoclonal antibody for the treatment of gluten-free diet non-responsive celiac disease (NRCD)
- Completed enrollment of Phase 1b clinical trial of PRV-300 in moderate-to-severe ulcerative colitis patients
- Appointed Avery (Chip) W. Catlin to Board of Directors and hired leading T1D Expert, Dr. Mark Rigby, as Vice President, Clinical Development

Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today reported financial results for the third quarter ended September 30, 2018, and provided a business update.

"Provention has continued to build momentum since completing our initial public offering in July. Our just-announced co-development agreement with Amgen and in-licensing of AMG-714 (PRV-015), is a clear indication that our strategic vision of intercepting and preventing immune-mediated disease is compelling and resonates with industry leaders and innovators," stated Ashleigh Palmer, CEO of Provention Bio. "In just eighteen months since our founding financing, we have been able to build a deep and diversified pipeline that now includes six programs targeting the interception and prevention of chronic autoimmune diseases including type 1 diabetes, Crohn's disease, ulcerative colitis, lupus, and celiac disease. In so doing, we have demonstrated a unique ability to customize strategically aligned relationships that leverage the strengths, expertise, resources, and even manufacturing capabilities of technology originators, licensors and partners, including Janssen Pharmaceuticals and, now, Amgen."

Mr. Palmer concluded, "Looking ahead, we expect the fourth quarter and 2019 to be a period of continued growth and momentum for Provention as we advance our clinical programs targeting upstream processes that could substantially improve the lives of patients and their families who must endure the suffering and bear the burden of immune-mediated disease."

Third Quarter 2018 and Recent Activities:

- **Announced Co-Development Agreement with Amgen and In-Licensing of AMG-714 (PRV-015) in Celiac Disease**

  On November 5, 2018, Provention and Amgen announced a licensing and co-development agreement for PRV-015 (Amgen's AMG 714), a novel anti-IL-15 monoclonal antibody being developed for the treatment of gluten-free diet non-responsive celiac disease (NRCD). Co-development efforts at Provention will be led by researchers with previous experience developing AMG 714. Under the terms of the agreement, Provention will conduct and fund a Phase 2b trial in NRCD and lead the next phase of development and regulatory activities for the program. Amgen has agreed to make an equity investment of $20 million in Provention coincident with Provention's next financing event or the receipt of non-dilutive funding, subject to certain terms and conditions. Amgen is also responsible for the manufacturing of AMG 714. Upon completion of the Phase 2b trial, Amgen has the right to reacquire the rights to PRV-015 for a $150 million payment to Provention, plus an additional regulatory milestone payment, and royalties on future sales.

- **Completed Enrollment of Phase 1b Clinical Trial of PRV-300 in Moderate-to-Severe Ulcerative Colitis**

  On October 23, 2018, Provention announced that it completed enrollment of its Phase 1b clinical trial of PRV-300, enrolling a total of 37 patients with moderate-to-severe ulcerative colitis (UC). Provention is developing PRV-300, an anti-TLR3 monoclonal antibody, to intercept upstream disease processes in UC patients. The Phase 1b clinical trial of PRV-300 (Provention Ulcerative colitis Safety, pharmacokinetic and pharmacodynamic Evaluation, or PULSE) was initiated in the first quarter of 2018. The primary endpoint of the study is safety, with secondary endpoints designed to evaluate the effect of PRV-300 on endoscopic and histologic endpoints, and a biopsy-based mucosal gene expression signature. Top-line data from PULSE are expected in the second quarter of 2019.

- **Appointed Accomplished Biotech Executive, Chip Catlin, to its Board of Directors and Hired Leading T1D Expert, Dr. Mark Rigby, as Vice President, Clinical Development**

  On September 5, 2018, Provention announced the appointment of Avery (Chip) W. Catlin, a seasoned and accomplished corporate financial executive, to its Board of Directors. Mr. Catlin brings more than 22 years of experience as a senior financial officer of public biopharmaceutical companies to Provention. He served previously as Senior Vice President and Chief Financial Officer of Celldex Therapeutics, Inc. Prior to Celldex, Mr. Catlin held senior financial and operational positions with biopharma companies Endogen, Inc., and Repligen Corporation. He currently sits on the Board of Corbus Pharmaceutical Holdings, Inc. Mr. Catlin earned a B.A. in Psychology from the University of Virginia and an MBA from Boston College. He is also a certified public accountant.

  Additionally, on July 31, 2018, Provention announced the appointment of Mark Rigby, MD, PhD, FAAP, FCCM, to the role of Vice President, Clinical Development. A key opinion leader in T1D research and development, Dr. Rigby joined Provention after more than 25 years of clinical and research experience in academics and industry. Most recently he served as Director, Immunology Early Development and Translational Medicine for Janssen Pharmaceuticals, a Johnson and Johnson Company, where he led multiple clinical and research programs including clinical trials focused on T1D interception in new onset and pre-symptomatic disease.

Financial Highlights:

As of September 30, 2018, Provention had cash and cash equivalents of $64.3 million. In July 2018, the Company completed its initial public offering which generated approximately $59.3 million in net proceeds after deducting commissions and expenses.

Net loss for the second quarter 2018 was $5.4 million, or $0.17 per basic and diluted share, compared to a net loss of $1.5 million, or $0.15 per basic and diluted share, for the same period in 2017. The increase in net loss year-over-year is primarily attributable to an increase in research and development costs of $3.3 million associated with the clinical development of PRV-6527 and PRV-300, the development of PRV-101, and costs for PRV-031, which was acquired from MacroGenics in May 2018, as well as an increase in general and administrative costs of $0.8 million.

Net loss for the nine months ended 2018 was $21.1 million, or $1.21 per basic and diluted share, compared to a net loss of $5.7 million, or $0.62 per basic and diluted share, for the same period in 2017. The increase in net loss year-over-year is primarily attributable to an increase in research and development costs of $13.1 million associated with clinical development of PRV-6527 and PRV-300, the development expenses related to PRV-101, and costs related to the expansion of our clinical pipeline with two additional assets from MacroGenics in May 2018, as well as an increase in general and administrative costs of $2.1 million.

Conference Call Information:
Provention will host a conference call and live audio webcast on Thursday, November 8, 2018, at 8:30 a.m. ET, to discuss its corporate and financial results for the third quarter of 2018. Interested participants and investors may access the conference call by dialing either:

- (877) 870-4263 (U.S.)
- (412) 317-0790 (international)

An audio webcast will be accessible via the Investors section of the Provention website http://investors.proventionbio.com/home. An archive of the webcast will remain available for 90 days beginning later today, November 8, 2018, at approximately 9:30 a.m. ET.

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. Provention's 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, celiac disease, 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 listed under "Risk factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2018 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.

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Financial Tables to Follow

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 4,140	$ 887	$ 17,684	$ 4,618
General and administrative	1,272	488	2,929	788
Total operating expenses	5,412	1,375	20,613	5,406
Operating loss	(5,412)	(1,375)	(20,613)	(5,406)
Other income (expense):				
Interest income	237	50	339	80
Change in fair value of warrant liability	(217)	(37)	(520)	(123)
Net loss	(5,392)	(1,362)	(20,794)	(5,449)
Accretion on Series A Convertible Redeemable Preferred Stock	(25)	(127)	(276)	(217)
Net loss attributable to common stockholders	$ (5,417)	$ (1,489)	$ (21,070)	$ (5,666)
Net loss per common share, basic and diluted	$ (0.17)	$ (0.15)	$ (1.21)	$ (0.62)
Weighted average common shares outstanding, basic and diluted	32,000	10,000	17,414	9,158

	September 30, 2018	December 31, 2017
Balance Sheet Data:		
Cash and cash equivalents	$ 64,297	$ 21,834
Total assets	$ 66,322	$ 22,428
Total liabilities	$ 1,234	$ 2,276
Series A Convertible Redeemable Preferred Stock	$ -	$ 26,185
Accumulated deficit	$ (30,092)	$ (9,298)
Total stockholders' equity (deficit)	$ 65,088	$ (6,033)

SOURCE Provention Bio, Inc.

https://investors.proventionbio.com/2018-11-08-Provention-Bio-Reports-Third-Quarter-2018-Financial-Results-and-Provides-Business-Update