Provention Bio Reports Second Quarter 2021 Financial Results and Provides Business Update

RED BANK, N.J., Aug. 5, 2021 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today reported financial results for the second quarter ended June 30, 2021 and provided a business update.

"The significant steps we've made during this past quarter highlighted by the supportive FDA briefing documents, the positive vote from the advisory committee, and the lack of any clinical efficacy or safety review deficiencies noted in the Complete Response Letter issued by the FDA, draw us much closer to realizing our vision of delivering a therapeutic option to intervene in a serious autoimmune disease and positively alter the course of thousands of lives with teplizumab," stated Ashleigh Palmer, co-founder and CEO of Provention Bio. "The remaining steps that we need to complete to obtain approval for teplizumab are very clear, most notably obtaining the pharmacokinetic data from the PROTECT substudy, which we expect later this quarter, to address the FDA's observations related to drug comparability."

Palmer continued, "In addition to all of the progress for teplizumab in the at-risk type 1 diabetes patient population, we also continue to make strong progress advancing the rest of our autoimmune disease focused development pipeline, positioning Provention to deliver numerous key catalysts throughout the course of the next 24 months."

Second Quarter 2021 and Recent Corporate Highlights:

FDA Advisory Committee Votes in Favor of the Benefits of Teplizumab Outweighing the Risks in Support of Approval to Delay Clinical Type 1 Diabetes (T1D)

In May, Provention Bio announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. Food and Drug Administration (FDA) voted 10 yes and 7 no on the question, "Does the information provided in the background documents and presentations by the Applicant and FDA show that the benefits of teplizumab outweigh the risks in support of approval to delay clinical type 1 diabetes mellitus?".

The EMDAC based its recommendation on safety and efficacy data from the pivotal TN-10 Study in which a single 14-day course of teplizumab delayed insulin-dependent, clinical-stage disease by a median of at least two years in presymptomatic patients with Stage 2 T1D compared to placebo. Acknowledging the significant unmet medical need facing early-stage T1D patients, the Committee Members discussed the strengths and limitations of the clinical data and provided opinions on the proposed indication statement and potential post-marketing studies.

FDA Issues Complete Response Letter (CRL) to Biologics License Application (BLA) for Teplizumab for the Delay of Clinical Type 1 Diabetes in At-risk Individuals

In July, Provention Bio announced that the U.S. Food and Drug Administration had issued a Complete Response Letter (CRL) for the Company's Biologics License Application for teplizumab for the delay of clinical type 1 diabetes in at-risk individuals.

In the CRL, the FDA stated that a single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study in healthy volunteers to compare planned commercial product with drug product originating from drug substance manufactured for historic clinical trials had failed to show PK comparability.

The Company expects relevant additional PK/PD data being, or to be, collected from a PK/PD substudy in patients receiving 12-days of therapy in the ongoing Phase 3 PROTECT trial in newly diagnosed T1D patients later this quarter. These data will be analyzed by independent, unblinded third-parties to maintain the integrity of this placebo-controlled trial. Upon review of the results from this substudy, the Company will determine whether to submit these data to the FDA for its review, along with any other relevant data and analyses based on our ongoing discussions with FDA, to support PK comparability or otherwise justify why PK comparability is not necessary.

In the CRL, the FDA cited several additional considerations related to product quality, which the Company believes have either been addressed in amendments already submitted to the BLA or can be addressed in the short-term. The CRL acknowledged that the FDA had not reviewed several amendments already submitted by the Company in response to certain Chemistry, Manufacturing and Controls (CMC) information requests.

The FDA also stated that certain deficiencies conveyed during a recent general inspection, not specific to teplizumab, at a fill/finish manufacturing facility used by the Company will need to be resolved before approval.

The CRL did not cite any clinical deficiencies related to the efficacy and safety data packages submitted to the BLA and confirmed the acceptability of the proposed proprietary name for teplizumab. The FDA requested that the Company provide a safety update as part of its BLA resubmission. The CRL contained other comments and recommendations that do not impact approvability, as well as general guidance regarding the resubmission process.

Teplizumab Awarded Innovation Passport in the United Kingdom (UK) for the Delay of Onset of Clinical Type 1 Diabetes in At-risk Individuals

In July, Provention Bio announced that teplizumab, an anti-CD3 monoclonal antibody (mAb), was awarded an Innovation Passport for the delay of clinical type 1 diabetes in at-risk individuals. Teplizumab is one of the first investigational medicines to receive this designation under the United Kingdom's (UK) Innovative Licensing and Access Pathway (ILAP) launched by The Medicines and Healthcare products Regulatory Agency (MHRA) in January 2021.

ILAP was launched to accelerate the development and access to promising medicines in the UK, thereby facilitating and improving patient access to new medicines. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with the MHRA and other stakeholders, including the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). The decision to award the Innovation Passport to the teplizumab program was made by the ILAP Steering Group, which is comprised of representatives from MHRA, NICE, and SMC. The process is also supported by such bodies as the National Health Service (NHS) England, the NHS Improvement, Health Research Authority and the National Institute for Health Research.

PROTECT Phase 3 Trial Evaluating Teplizumab in Patients with Recent Onset Type 1 Diabetes

Provention Bio is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D in the Phase 3 PROTECT study and expects to complete enrollment of the study in the third quarter of this year.

PREVAIL Phase 2a Trial Evaluating PRV-3279 in Systemic Lupus Erythematosus

Provention Bio remains on track to initiate a Phase 2a trial of PRV-3279, an investigational DART® (bispecific antibody-based molecule) targeting the B cell surface proteins CD32B and CD79B in the fourth quarter of 2021.

PROACTIVE Phase 2b study of PRV-015 in Non-responsive Celiac Disease

Provention Bio is conducting a Phase 2b dose-finding, placebo-controlled study of PRV-015, an investigational anti-interleukin-15 monoclonal antibody in adults with non-responsive Celiac Disease. The study expects to enroll 220 adult Celiac patients not responding to gluten-free diet. Provention Bio expects top-line results from this study in 2022.

PROVENT Phase 1 Healthy Volunteer study of PRV-101 Coxsackievirus B Vaccine

Provention Bio completed enrollment of the PROVENT (PROtocol for coxsackievirus VaccinE in healthy voluNTeers) study in April of this year, a first-in-human study of its polyvalent inactivated coxsackievirus B (CVB) vaccine candidate, PRV-101. Provention Bio is developing PRV-101 for the prevention of acute CVB infection and the potential delay or prevention of T1D and celiac disease. The Company expects top-line first-in-human data in the fourth quarter of this year.

Financial Highlights:

As of June 30, 2021, Provention Bio had cash and cash equivalents and marketable securities of $176.4 million.

Net loss for the second quarter 2021 was $29.1 million, or $0.46 per basic and diluted share, compared to a net loss of $22.1 million, or $0.45 per basic and diluted share, for the same period in 2020. The increase in net loss was attributable to an overall increase in research and development expenses of $2.0 million, driven primarily by costs for our teplizumab program, including the PROTECT study, regulatory activities, and the build out of our medical affairs infrastructure and medical education programs as well as grants to support the screening of potential T1D patients. This increase in research and development costs was offset by lower teplizumab manufacturing costs compared to the prior year period, as the Company incurred significant costs for production of GMP and PPQ batches of drug supply and drug product during the second quarter of 2020. Also contributing to the net loss was $5.4 million increase in general and administrative expenses, including $2.1 million in pre-commercial expenses and $3.3 million in other corporate costs as we continue to build out our infrastructure.

Cash-based operating expenses were $26.8 million for the three months ended June 30, 2021. The Company expects our cash-based operating expenses to be in the range of $31 to $36 million in the third quarter of 2021. Provention Bio 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 business updates and first quarter financial results via conference call today at 8:00 am ET. To access the call, please dial 1-888-347-7861 (domestic) or 1-412-902-4247 (international) ten 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.

About Provention Bio, Inc.:

Provention Bio, Inc. (Nasdaq: PRVB) is a biopharmaceutical company focused on advancing the development of investigational therapies that may intercept and prevent debilitating and life-threatening immune-mediated disease. The Company's pipeline includes clinical-stage product

candidates that have demonstrated in pre-clinical or clinical studies proof-of-mechanism and/or proof-of-concept in autoimmune diseases, including type 1 diabetes, celiac disease and lupus. Visit www.ProventionBio.com for more information and follow us on Twitter: @ProventionBio.

Internet Posting of Information:

Provention Bio, Inc. uses its website, www.proventionbio.com, as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation F.D. Such disclosures will be included on the Company's website in the "News" section. Accordingly, investors should monitor this portion of the Company's website, in addition to following its press releases, SEC filings and public conference calls and webcasts.

Forward Looking Statements:

Certain statements in this press release are forward-looking, including but not limited to, statements relating to our product pipeline and delivery of key catalysts throughout the course of the next 24 months; regulatory review of and potential approval of teplizumab; the potential therapeutic effects and safety of teplizumab; the timing and ability of the Company to obtain additional PK/PD data from a PK/PD substudy in the ongoing Phase 3 PROTECT trial and other data and analysis relevant to PK comparability; the potential for these data to address the FDA's PK comparability considerations; the FDA review of such data if submitted by the Company; the Company's belief that the remaining product quality issues cited in the CRL are addressed or can be addressed in the short-term; the need for resolution of deficiencies identified at a fill/finish manufacturer used by the Company; the Company's plans to address the other matters raised in the CRL including plans to continue working collaboratively with FDA to hopefully secure teplizumab approval; anticipated timing for the Phase 2a trial of PRV-3279; anticipated timing for completing enrollment in the Phase 3 PROTECT study; anticipated enrollment in the PROACTIVE study; anticipated timing of top-line results for our product candidates; our current expectations regarding the ability of our cash, cash equivalents and marketable securities to fund our projected operating requirements for at least the next 12 months; and expected cash-based operating expenses for the third quarter of 2021. These statements may be identified by the use of forward-looking words such as "will," "may," "believe," and "expect," among others. These forward-looking statements are based on the Company'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 delays in or failure to obtain FDA approvals for teplizumab or other Company product candidates and the potential for noncompliance with FDA regulations; any inability to successfully work with FDA to find a satisfactory solution to address its concerns in a timely manner or at all, including any inability to provide the FDA with PK/PD data from our ongoing Phase 3 PROTECT study or other data or information sufficient to support approval of teplizumab; any inability to satisfactorily address other matters cited in the CRL including relating to product quality, fill/finish manufacturer deficiencies identified in a general inspection, the safety update required by FDA or any other FDA requirements for an approval of teplizumab; the potential impacts of COVID-19 on our business and financial results; changes in law, regulations, or interpretations and enforcement of regulatory guidance; uncertainties of patent protection and litigation; the Company's dependence upon third parties; substantial competition; the Company's need for additional financing and the risks listed under "Risk Factors" in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021 and any subsequent filings 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, whether as a result of new information, future developments or otherwise, except as may be required by applicable law. The information set forth herein speaks only as of the date hereof.

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Provention Bio, Inc.
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 16,968	$ 15,032	$ 36,655	$ 24,122

General and administrative	13,205	7,764	25,986	11,539
Total operating expenses	30,173	22,796	62,641	35,661
Loss from operations	(30,173)	(22,796)	(62,641)	(35,661)
Interest income, net	31	151	59	434
Loss before income tax benefit	(30,142)	(22,645)	(62,582)	(35,227)
Income tax benefit	1,000	523	1,000	523
Net loss	$ (29,142)	$ (22,122)	$ (61,582)	$ (34,704)
Net loss per common share, basic and diluted	$ (0.46)	$ (0.45)	$ (0.98)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	63,375	49,199	62,822	48,449

	June 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 176,378	$ 121,824
Total assets	$ 183,308	$ 128,519
Total liabilities	$ 25,288	$ 17,445
Accumulated deficit	$ (239,224)	$ (177,642)
Total stockholders' equity	$ 158,020	$ 111,074

SOURCE Provention Bio, Inc.

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http://investors.proventionbio.com/2021-08-05-Provention-Bio-Reports-Second-Quarter-2021-Financial-Results-and-Provides-Business-Update