Provention Bio Reports Second Quarter 2022 Financial Results and Provides Business Update

-Teplizumab Biologics License Application (BLA) user fee goal date extended to November 17, 2022-

-Company completes $60.0 million private placement-

RED BANK, N.J., Aug. 4, 2022 /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, 2022, and provided a business update.

"Throughout the second quarter we remained sharply focused on teplizumab's potential approval for the delay of clinical type 1 diabetes in at-risk individuals and our plans and preparations for the potential commercial launch," stated Ashleigh Palmer, Chief Executive Officer & Co-Founder, Provention Bio. "While the extension to our action date is extremely frustrating for the Company and our stakeholders, especially the patients and families we serve who have waited so long for a disease modifying option to delay the onset of insulin dependent disease, we remain optimistic about the prospect of ultimate approval. We also remain committed to collaborating closely with the FDA in support of its ongoing review."

Second Quarter 2022 and Recent Corporate Highlights:

Company Completes $60.0 Million Private Placement

On July 7, 2022, the Company entered into a Securities Purchase Agreement with certain institutional purchasers, pursuant to which the Company sold, in a private placement, 13,318,535 shares of common stock and 13,318,535 warrants to acquire additional shares of common stock for aggregate gross proceeds of approximately $60.0 million, based on an offering price of $4.505 for each share plus one warrant (the July 2022 Private Placement). The warrants will expire five years from the closing date of the transaction, have an exercise price of $6.00 per share and are immediately exercisable upon issuance, subject to other limitations on exercise as described in the warrants. Net proceeds from the transaction are estimated to be approximately $57.2 million after deducting fees for the placement agent and other offering expenses.

FDA Extends User Fee Goal Date to November 17, 2022 for the Biologics License Application (BLA) Resubmission for Teplizumab for the Delay of Clinical Type 1 Diabetes in At-Risk Individuals

On June 30, 2022, the Company announced that the U.S. Food and Drug Administration (FDA) extended its review period by three months for the BLA for teplizumab. The extended user fee goal date is November 17, 2022. As part of its ongoing review and communications, the FDA informed the Company that its timely responses to an additional information request, related to updating the PK model to include additional anti-drug antibody data and re-evaluating the proposed modeling regimens made earlier in June 2022, is considered to be a Major Amendment to the BLA resubmission, requiring additional time for the FDA's review.

The Company was also informed that if no major deficiencies are identified during the review period, the FDA plans to communicate proposed labeling and, if necessary, any post-marketing requirement or commitment requests by October 17, 2022.

During the first quarter of 2022, the Company announced that the resubmitted BLA for teplizumab for the delay of clinical type 1 diabetes (T1D) in at-risk individuals has been considered a complete, class 2 response to the July 2021 action letter by the FDA. The FDA had originally assigned a user fee goal date of August 17, 2022.

In February 2022, the Company had resubmitted the BLA for teplizumab for the delay of clinical type 1 diabetes (T1D) in at-risk individuals following the completion of a Type B pre-BLA resubmission meeting during which the FDA proposed, and the Company agreed, to use PK modeling to adjust the 14-day dosing regimen for the planned commercial product to match the exposure of clinical material used in prior clinical trials.

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

The Company is currently evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D in the Phase 3 PROTECT study. The Company reached target enrollment during the third quarter of 2021 and currently expects to report top-line data from the study in the second half of 2023.

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

In the first quarter of 2022, the Company initiated a Phase 2a trial of PRV-3279 in Systemic Lupus Erythematosus, an investigational DART® (bispecific antibody-based molecule) targeting the B-cell surface proteins CD32B and CD79B.

The PREVAIL-2 study is a Phase 2a proof-of-concept (POC) study in moderate-to-severe SLE patients induced into response with a short course of corticosteroids, and then monitored for relapse, after randomization to either PRV-3279 or placebo treatment. This design enables the withdrawal of most concomitant medications and clear POC evaluation. The study will be conducted in the US and Hong Kong. Enrollment has commenced in the US with the goal of identifying and enrolling approximately 100 patients to 6 monthly infusions of PRV-3279 or placebo, with primary efficacy readout at 24 weeks. PRV-3279 was well-tolerated in a prior single ascending dose Phase 1 study and a multiple ascending dose Phase 1b study, PREVAIL-1, establishing proof of mechanism with long-lasting inhibition of B cell function as shown by reduction in IgM production 8 weeks post last dose of PRV-3279. These results, together with observations that CD32B genetic variants are associated with SLE, and PRV-3279 inhibition of B cells isolated from SLE patients, support evaluation in SLE.

The ongoing effects of the COVID-19 pandemic have affected the PREVAIL-2 study enrollment, primarily due to resource constraints at the clinical site level and subdued patient interest in participating in clinical trials of immune modulatory agents. The Company now

expects to report top-line results of the PREVAIL-2 study in the second half of 2024.

PROACTIVE Phase 2b Study of Ordesekimab (AMG 714/PRV-015) in Non-Responsive Celiac Disease

The Company is conducting a Phase 2b dose-finding, placebo-controlled study of ordesekimab (AMG 714/PRV-015), an investigational anti-interleukin-15 monoclonal antibody in adults with non-responsive celiac disease. The study currently expects to enroll 220 adult celiac patients not responding to gluten-free diet.

The Company announced that it expects top-line results from this study by the end of 2023.

PRV-101 Coxsackievirus B Vaccine (CVB)

In the first quarter of 2022, the Company announced results from the final analysis of the PROVENT (PROtocol for coxsackievirus VaccinE in healthy voluNTeers) study, a first-in-human PROVENT study of PRV-101, a polyvalent inactivated coxsackievirus B (CVB) vaccine candidate targeting all key CVB strains associated with type 1 diabetes autoimmunity. Provention is developing PRV-101 for the prevention of CVB-triggered autoimmune damage to pancreatic beta cells that may progress to T1D and damage to intestinal cells that may lead to celiac disease.

In this final analysis, 6 months following the final administered dose of the vaccine, PRV-101 met the primary endpoint confirming the tolerability observed in the previously reported interim analysis, with no treatment-emergent serious adverse events, adverse events of special interest, or adverse events leading to study drug discontinuation or study withdrawal.

The results also showed durability of viral neutralizing antibody (VNT) responses. Six months following the final dosing, the percentages of subjects in the high-dose PRV-101 arm who maintained high titers of VNT were 100% for the majority of serotypes included in the vaccine and no less than 90% for all serotypes.

The Company continues to seek and evaluate partnership opportunities to further the clinical development of PRV-101.

Second Quarter 2022 Financial Results:

- **Cash Position:** Provention ended the second quarter of 2022 with $96.1 million of cash, cash equivalents and marketable securities.
- **2021 At-the-market (ATM) Program:** Provention sold 2,663,063 shares of its common stock for aggregate net proceeds of approximately $11.1 million, net of $0.3 million in sales commissions, under the Company's 2021 ATM Program during the second quarter of 2022. As of June 30, 2022, the Company had $135.6 million of available capacity under the 2021 ATM Program.
- **Collaboration Revenue:** The Company recognized collaboration revenue of $0.7 million under its License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. during the second quarter of 2022.
- **Research & Development (R&D):** R&D expenses were $16.6 million for the second quarter of 2022, compared to $17.0 million for the second quarter of 2021. The decrease in R&D costs was driven by lower costs for the Company's teplizumab program, including the PROTECT study as target enrollment was reached in August 2021, and lower costs for regulatory activities compared to the prior year period, which included costs related to the initial teplizumab BLA submission. R&D cost decreases were partially offset by increased costs for the PROACTIVE Phase 2b study (PRV-015) and, the PREVAIL-2 Phase 2a study (PRV-3279) as well as increased manufacturing costs for commercial batches of teplizumab.
- **General & Administrative (G&A):** G&A expenses were $14.0 million for the second quarter of 2022, compared to $13.2 million for the second quarter of 2021. The increase in G&A expenses related primarily to an increase in the Company's pre-commercial activities and associated costs following the FDA's acceptance of the Company's BLA resubmission in March 2022.
- **Net Loss:** Net loss for the second quarter of 2022 was $29.7 million, or $0.46 per basic and diluted share, compared to a net loss of $29.1 million, or $0.46 per basic and diluted share, for the second quarter of 2021.
- **Cash Based Operating Expense:** Cash-based operating expense for the second quarter of 2022 was $27.2 million, which excludes non-cash, stock-based compensation expense of $3.2 million and depreciation expense of $0.2 million.

Financial Guidance:

The Company expects its cash-based operating expenses to be in the range of $27.0 million to $31.0 million for the third quarter of 2022.

Based on the Company's current business plans, management believes that its cash, cash equivalents and marketable securities on hand as of June 30, 2022, together with the approximately $57.2 million in net proceeds from the July 2022 Private Placement, will be sufficient to fund the Company's operating requirements for at least the next 12 months from the issuance of the Company's financial statements for the quarter ended June 30, 2022. If the Company's teplizumab BLA resubmission is approved by the FDA, factors that could impact its cash runway include, but are not limited to, changes to estimated costs of commercialization and potential milestone payments that may be triggered under the Company's current agreements, including with MacroGenics.

Conference Call and Webcast Information:

Provention Bio will discuss these business updates and second 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; the Company's planned regulatory interactions; the medical need in at-risk T1D patients, the potential approval of teplizumab and therapeutic effects and safety of teplizumab in at-risk T1D patients; the FDA's review and potential approval of teplizumab and potential regulatory and commercialization timeline; the potential impact of FDA decisions on PK comparability and the BLA resubmission for at-risk patients on the PROTECT study; anticipated timing for the Phase 2a trial of PRV-3279; 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 current operating requirements for at least the next 12 months; and expected cash-based operating expenses for the third quarter of 2022. These statements may be identified by the use of forward-looking words such as "will," "may," "believe," "plans," 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 additional delays in or failure to obtain FDA approvals for teplizumab or in the development plans for the Company's other Company product candidates and the potential for noncompliance with FDA regulations and requirements; any inability to successfully work with the FDA to find a satisfactory solution to address its concerns in a timely manner or at all, including during the FDA's review of the teplizumab BLA resubmission; any inability of the BLA resubmission or our response to FDA requests to satisfactorily address other matters cited in the CRL including relating to PK comparability, product quality, the safety update required by the 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 second quarter ended June 30, 2022 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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Financial Tables to Follow

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Statement of Operations Data:				
Collaboration revenue	$ 746	$ —	$ 1,326	$ —
Operating expenses:				
Research and development	16,577	16,968	33,932	36,655
General and administrative	14,002	13,205	26,308	25,986
Total operating expenses	30,579	30,173	60,240	62,641
Loss from operations	(29,833)	(30,173)	(58,914)	(62,641)
Interest income, net	146	31	203	59
Loss before income tax benefit	(29,687)	(30,142)	(58,711)	(62,582)
Income tax benefit	—	1,000	7,056	1,000
Net loss	$ (29,687)	$ (29,142)	$ (51,655)	$ (61,582)
Net loss per common share, basic and diluted	$ (0.46)	$ (0.46)	$ (0.81)	$ (0.98)
Weighted average common shares outstanding, basic and diluted	64,716	63,375	64,062	62,822

	June 30,	December 31,

	2022 (unaudited)	2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 96,136	$ 127,132
Total assets	$ 104,353	$ 135,621
Total liabilities	$ 25,672	$ 24,887
Accumulated deficit	$ (343,729)	$ (292,074)
Total stockholders' equity	$ 78,681	$ 110,734

SOURCE Provention Bio, Inc.

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https://investors.proventionbio.com/2022-08-04-Provention-Bio-Reports-Second-Quarter-2022-Financial-Results-and-Provides-Business-Update