Precision BioSciences Reports Third Quarter 2019 Financial Results and Highlights Ongoing Operational Progress Including Initial Data from PBCAR0191 Phase 1/2a Clinical Trial

November 12, 2019

DURHAM, N.C., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL) (“Precision”), a genome editing company dedicated to improving life through the application of its pioneering, proprietary ARCUS® platform, today announced financial results for the third quarter ended September 30, 2019 and provided a corporate update.

Key Highlights

- After quarter end, announced publication of an abstract accepted for presentation at the upcoming 61st Annual Meeting of the American Society of Hematology (ASH) in Orlando, Florida, December 7-10, 2019, supporting the safety and clinical activity of Precision BioSciences’s lead CD19-targeted off-the-shelf (allogeneic) chimeric antigen receptor (CAR) T product candidate, PBCAR0191. Abstract reports initial data from first three patients treated at Dose Level 1 as of August 1, 2019. Trial is ongoing and updated data, including from patients treated at Dose Level 2, will be presented during the ASH annual meeting on December 9, 2019 at 6:00 pm ET.
- Announced an investigator update event during ASH meeting to discuss the PBCAR0191 data presented, starting at 8:15pm ET on December 9, 2019, with accompanying live webcast.
- Received acceptance from US Food and Drug Administration (FDA) of investigational new drug (IND) application for second and wholly-owned allogeneic CAR T therapy candidate PBCAR20A, targeting CD20. Phase 1/2a clinical trial to begin in the fourth quarter of 2019.
- Further enhanced senior leadership team with appointment of David Thomson, PhD, as Chief Operating Officer, and Nicholas Riddle, MD, PhD, as Vice President, Financial Strategy and Investor Relations.
- Ended the quarter with $206.3 million in cash and cash equivalents, which is expected to fund operating expenses and capital expenditure requirements into 2021.

“We reached a transformative moment for Precision BioSciences this quarter; it is very exciting to report initial data from our first clinical trial with a product candidate that leverages our unique approach to allogeneic CAR T therapy,” commented Matt Kane, Chief Executive Officer and Co-Founder of Precision BioSciences. “These data bring the reality of a true off-the-shelf CAR T therapy a step closer for patients in need of new and improved treatment options. While preliminary and from a limited number of patients, the safety profile, *in vivo* cell expansion and early evidence of clinical activity we have demonstrated with PBCAR0191 in the absence of biologic lymphodepletion is very encouraging and gives us confidence in the approach we have taken to allogeneic CAR T. We are looking forward to sharing updated results from patients treated at both Dose Level 1 and Dose Level 2 at ASH. The team at Precision is committed to advancing our pipeline of differentiated CAR T product candidates as rapidly as possible to bring these potentially transformative therapies to patients.”

Recent Developments and Upcoming Milestones

Program updates

- On November 6, 2019, Precision announced that initial results from the ongoing Phase 1/2a trial of its lead investigational allogeneic CAR T cell therapy candidate, PBCAR0191, will be presented during the 61st Annual Meeting of the American Society of Hematology in Orlando, Florida, December 7-10, 2019. PBCAR0191, which is being developed in collaboration with Servier, is Precision’s first allogeneic CAR T therapy candidate in clinical trials and targets the well characterized cancer cell surface protein CD19. The Phase 1/2a trial includes adult patients with relapsed or refractory (R/R) non-Hodgkin’s lymphoma (NHL) or R/R B-cell precursor acute lymphoblastic leukemia (B-ALL). The abstract outlining initial data from patients treated with PBCAR0191 at Dose Level 1 can be accessed on the ASH conference website. Data in the abstract include results as of the cutoff date of August 1, 2019 for three patients with advanced NHL treated at Dose Level 1. No significant toxicities were observed, including no serious adverse events and no dose-limiting toxicities. All patients had a minimum follow-up of 28 days (median 60 days). Two of the three patients experienced an objective tumor response by Lugano criteria, at day 14 and day 28, respectively. The third patient, who had previously progressed following treatment with axicabtagene ciloleucel (Yescarta®), an approved anti-CD19 autologous CAR T therapy, had not met the definition of response, but demonstrated evidence of central necrosis, decreased tumor size, and decreased PET-avidity at day 28, in the context of post-infusion tumor site pain and mild CRS symptoms. Peripheral blood analysis for CAR T cell expansion has identified preliminary evidence of cell expansion.

- The PBCAR0191 Phase 1/2a trial is ongoing and updated results from patients treated at Dose Level 1 and Dose Level 2 will be presented at the ASH annual meeting on December 9, 2019 starting at 6:00 p.m. ET. Precision will host a live webcast of an investigator update event during the ASH meeting to discuss the presented data, beginning at 8:15 p.m. ET on December 9, 2019. The webcast will be accessible from the "Events & Presentations" page within the Investors & Media section of the Precision website and a replay will be available for 30 days following the call.

- On September 16, 2019, Precision announced that the FDA accepted its IND application for PBCAR20A. Wholly-owned by Precision, PBCAR20A is an allogeneic anti-CD20 CAR T therapy candidate in development for the treatment of patients with NHL, chronic lymphocytic leukemia (CLL), and small lymphocytic lymphoma (SLL). Precision plans to initiate a Phase 1/2a clinical trial in the fourth quarter of 2019, with initial data expected in 2020.

Senior leadership appointments

- On September 30, 2019, Precision announced that Nicholas Riddle, MD, PhD, joined as Vice President, Financial Strategy and Investor Relations. Dr. Riddle joined Precision from J.P. Morgan where he was an Executive Director in the global healthcare investment banking group.

- On September 23, 2019, Precision appointed David Thomson, PhD, to the position of Chief Operating Officer. Dr. Thomson previously served as Precision's Chief Development Officer since 2017.

Upcoming Corporate Presentations

Precision's senior management team will be presenting and meeting with investors at the following upcoming conferences:

- Barclays Gene Editing and Gene Therapy Summit, New York, NY, November 13, 2019
- Stifel Healthcare Conference, New York, NY, November 20, 2019
- Jefferies London Healthcare Conference, London, UK, November 20, 2019
- Piper Jaffray Annual Health Care Conference, New York, NY, December 3–5, 2019
- J.P. Morgan Healthcare Conference, San Francisco, CA, January 13-16, 2020

Third Quarter 2019 Financial Results

Cash and Cash Equivalents: As of September 30, 2019, Precision had approximately $206.3 million in cash and cash equivalents. We expect that existing cash and cash equivalents will be sufficient to fund operating expenses and capital expenditure requirements into 2021.

Revenues: Total revenues for the quarter ended September 30, 2019 were $4.9 million, compared to $2.5 million for the quarter ended September 30, 2018. This increase was primarily due to research funding from a collaboration partner, offset by a decrease in license fees.

Research and Development Expenses: Research and development expenses were $19.8 million for the quarter ended September 30, 2019, as compared to $9.7 million for the same period in 2018. This increase of $10.1 million was primarily due to platform development and early-stage research expenses.

General and Administrative Expenses: General and administrative expenses were $7.1 million for the quarter ended September 30, 2019, as compared to $3.3 million for the same period in 2018. The increase of $3.8 million was primarily due to increased employee-related costs for additional personnel and facility costs associated with our growing infrastructure needs.

Net Loss: Net loss was $20.7 million, or $(0.41) per share, for the quarter ended September 30, 2019, compared to a net loss of $9.8 million, or $(0.62) per share, for the same period in 2018.

About Precision BioSciences, Inc.
Precision BioSciences is dedicated to improving life (DTIL) through its proprietary genome editing platform, ARCUS. Precision leverages ARCUS in the development of its product candidates, which are designed to treat human diseases and create healthy and sustainable food and agriculture solutions. Precision is actively developing product candidates in three innovative areas: allogeneic CAR T immunotherapy, *in vivo* gene correction, and food. For more information regarding Precision, please visit www.precisionbiosciences.com.

Forward-Looking Statements

Information contained in or accessible through this press release contains forward-looking statements. All statements other than statements of present and historical facts contained in this prospectus, including without limitation, statements regarding the success of our allogeneic CAR T therapy product candidate PBCAR0191 and the timing of the Phase 1/2a clinical trial for our allogeneic CAR T therapy candidate PBCAR20A, may be forward-looking statements. Without limiting the foregoing, the words "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "may," "will," "would," "potential," the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements reflect various assumptions of Precision's management that may or may not prove to be correct. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding; our limited operating history; our ability to identify, develop and commercialize our product candidates; our dependence on our

ARCUS technology; the initiation, cost, timing, progress and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; our or our collaborators' ability to identify, develop and commercialize product candidates; our or our collaborators' ability to advance product candidates into, and successfully complete, clinical or field trials; our or our collaborators' ability to obtain and maintain regulatory approval of future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the regulatory landscape that will apply to our and our collaborators' development of product candidates; our ability to achieve our anticipated operating efficiencies as we commence manufacturing operations at our new facility; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; the success of our existing collaboration agreements; our ability to enter into new collaboration arrangements; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; potential manufacturing problems associated with any of our product candidates; potential liability lawsuits and penalties related to our technology, our product candidates and our current and future relationships with third parties; and other important factors discussed under the caption "Risk Factors" in our quarterly report on Form 10-Q for the quarterly period ended June 30, 2019, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at www.sec.gov.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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Precision Biosciences, Inc.
Condensed Consolidated Statement of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 4,865	$ 2,541	$ 15,716	$ 5,943
Operating expenses				
Research and development	19,791	9,737	62,512	28,723
General and administrative	7,052	3,251	18,547	9,027
Total operating expenses	26,843	12,988	81,059	37,750
Loss from operations	(21,978)	(10,447)	(65,343)	(31,807)
Other income (expense), net:				
Change in fair value of convertible note payable	—	—	(9,758)	—
Interest expense	—	—	(182)	—
Interest income	1,236	691	3,322	1,213
Total other income (expense), net	1,236	691	(6,618)	1,213
Net loss and net loss attributable to common stockholders	$ (20,742)	$ (9,756)	$ (71,961)	$ (30,594)
Net loss per share attributable to common stockholders- basic and diluted	$ (0.41)	$ (0.62)	$ (1.85)	$ (1.94)
Weighted average shares of common stock outstanding- basic and diluted	50,623,665	15,816,748	39,002,304	15,751,091

Precision Biosciences, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

(Unaudited)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 206,265	$ 103,193
Working capital	195,775	101,600
Total assets	260,298	138,600
Total stockholders' equity	$ 155,788	$ 39,960

Source: Precision Biosciences