Precision BioSciences Reports Third Quarter 2020 Financial Results and Provides Business Update

November 10, 2020 at 7:00 AM EST

Expanded allogeneic CAR T development collaboration with Servier to include four new programs targeting hematological and solid tumors

Advanced CAR T clinical pipeline, including a clinical collaboration with SpringWorks to evaluate PBCAR269A in combination with nirogacestat

Prevailed in U.S. Patent Trial and Appeal Board proceedings upholding allogeneic CAR T patents

Expect to report updated interim data from Phase 1/2a study of PBCAR0191 by YE20

DURHAM, N.C., Nov. 10, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL) a clinical-stage biotechnology company dedicated to improving life with its novel and proprietary ARCUS® genome editing platform, today announced financial results for the third quarter ended September 30, 2020 and provided a business update.

"Our achievements from this past quarter reflect increasing momentum with the ARCUS genome editing platform to develop a novel pipeline of allogeneic CAR T and *in vivo* gene correction therapeutic candidates," said Matt Kane, CEO and co-founder of Precision BioSciences. "For our clinical portfolio, we expanded our existing partnership with Servier by adding four new targets, including two solid tumor and two hematologic programs, and entered a new clinical collaboration with SpringWorks Therapeutics for our multiple myeloma study. The PTAB issued judgements in our favor in both of the patent interferences involving our patented single-step CAR knock-in/T cell receptor (TCR) knock-out approach, which underscores the novelty of this precise editing process for allogeneic CAR T cell therapies as part of the emerging landscape in oncology."

Recent Developments and Upcoming Milestones:

Allogeneic CAR T Portfolio:

Expanded Development Collaboration with Servier: In September 2020, Precision announced, in collaboration with Servier, that the companies had added two additional hematological cancer targets beyond CD19 and two new solid tumor targets to its existing CAR T development and commercial license agreement. With the addition of these new targets, Precision expects to receive milestone payments in the remainder of 2020 and in 2021. Precision may also be eligible to receive option fees, as well as clinical, regulatory and sales milestone payments in addition to royalties on product sales.

PBCAR0191: In August 2020, Precision announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to PBCAR0191 for B-ALL. Precision also holds Orphan Drug Designation from the FDA for this program in mantle cell lymphoma (MCL), an aggressive subtype of non-Hodgkin lymphoma (NHL). PBCAR0191 is being developed in collaboration with Servier. Precision expects to present updated interim clinical data from both the NHL and B-ALL cohorts of this trial before year-end 2020 via a Company-sponsored event.

PBCAR269A: In September 2020, Precision announced that the FDA granted Fast Track Designation for PBCAR269A, Precision's wholly-owned investigational allogeneic CAR T candidate targeting B-cell maturation antigen (BCMA), for the treatment of R/R multiple myeloma. PBCAR269A was also previously granted Orphan Drug Designation for this indication by the FDA.

Also, in September 2020, Precision announced a clinical collaboration with SpringWorks Therapeutics to evaluate PBCAR269A in combination with nirogacestat, SpringWorks' investigational gamma secretase inhibitor. The companies have formed a joint steering committee to oversee the combination arm of Precision's Phase 1/2a clinical study, which is expected to commence in the first half of 2021, pending discussions with regulators.

PBCAR020A: Precision continues to enroll patients in the PBCAR020A, a wholly-owned investigational allogeneic anti-CD20 CAR T therapy, in patients with R/R NHL including patients with R/R chronic lymphocytic leukemia or R/R small lymphocytic lymphoma.

***In Vivo* Gene Correction Portfolio:**

PH1 Program: Pre-clinical research has continued to progress for Precision's wholly-owned primary hyperoxaluria type 1 (PH1) gene correction program, which is designed to use ARCUS to knock-out the HAO1 gene as a potential one-time treatment for this rare genetic disease. The Company expects to provide an update on this program in the first half of 2021.

Corporate:

Intellectual Property Protection: Precision continued to expand its intellectual property portfolio which, to-date, includes over 65 issued patents in the U.S. and other countries directed to the ARCUS platform and its uses. Precision has recently been issued several patents relating to its CAR T programs, including a U.S. patent with composition of matter claims for Precision's proprietary Novel 6 (N6) co-stimulatory domain used in its CAR T cell candidates. Precision also prevailed in two patent interference proceedings before the Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office involving certain CAR T patents owned by Precision. Specifically, the involved patents relate to allogeneic CAR T cells produced by inserting a gene encoding a CAR into the TCR alpha chain locus, as well as methods of using those cells for cancer immunotherapy. In the interference proceedings, a third party argued that it had invented the technology in 2012. The PTAB, however, found that the third-party patent application did not satisfy the written description requirement and rejected these claims, while maintaining the claims in all of Precision's involved

patents.

Alex Kelly Appointed Chief Corporate Affairs Officer: Mr. Kelly joined Precision in October 2020 with extensive leadership experience in communications for biopharmaceutical companies. Most recently he was Executive Vice President, Corporate Affairs and Chief Communications Officer at Allergan where he was also President of the Allergan Foundation. He will oversee all investor relations and corporate communications activities at Precision.

Elo Life Systems:

Alec Hayes, Ph.D. Appointed Vice President of Technology and Products at Elo Life Systems: Dr. Hayes joined Elo in September 2020 from the Coca-Cola Company, where he was Technical Director of Agricultural Technologies, and brings 20 years of technical leadership and industry experience in translational agriculture. He is responsible for Elo's research and development pipeline and strategic expansion of capabilities to accelerate product development.

Quarter Ended September 30, 2020 Financial Results:

Cash and Cash Equivalents: As of September 30, 2020, Precision had approximately $104.1 million in cash and cash equivalents. The Company expects that existing cash, cash equivalents, expected operational receipts, and available credit will be sufficient to fund operating expenses and capital expenditure requirements into 2022.

Revenues: Total revenues for the quarter ended September 30, 2020 were $7.4 million, compared to $4.9 million for the quarter ended September 30, 2019. The increase of $2.5 million in revenue was primarily the result of an increase in collaboration revenue with Servier, offset by a decrease in collaboration revenue from Gilead.

Research and Development Expenses: Research and development expenses were $24.9 million for the quarter ended September 30, 2020, as compared to $19.8 million for the same period in 2019. The increase of $5.1 million was primarily due to increases in direct research and development expenses related to our ongoing CD19 clinical program as well as increases in employee-related costs associated with increased headcount to support our technology platform development and manufacturing capabilities.

General and Administrative Expenses: General and administrative expenses were $8.5 million for the quarter ended September 30, 2020, as compared to $7.1 million for the same period in 2019. The increase of $1.4 million was primarily due to costs associated with the Company's growing infrastructure needs.

Net Loss: Net loss was $26.0 million, or $(0.50) per share, for the quarter ended September 30, 2020, compared to a net loss of $20.7 million, or $(0.41) per share, for the same period in 2019.

About Precision BioSciences, Inc.
Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform. ARCUS is a highly specific and versatile genome editing platform that was designed with therapeutic safety, delivery, and control in mind. Using ARCUS, the Company's pipeline consists of multiple "off-the-shelf" CAR T immunotherapy clinical candidates and several *in vivo* gene correction therapy candidates to cure genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit www.precisionbiosciences.com.

About Precision's Collaboration with Servier
Under the terms of the agreement with Servier, Precision is solely responsible for early-stage research activities as well as PBCAR0191 Phase 1/2a clinical trial execution and clinical supply. Servier has the exclusive right to opt in for late-stage development and commercialization, and Precision has the right to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and co-promotion option in the United States.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the Company's timing of clinical trials and results therefrom, including, without limitation, the expected timing of clinical updates and interim data reports related to PBCAR0191, of the commencement of the expanded Phase 1/2a clinical study for PBCAR269A, of updates regarding the Company's PH1 program and of any potential milestone payments. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "may," "will," "would," "should," "could," "target," "potential," "project," "predict," "contemplate," "potential," or the negative thereof and similar words and expressions.

Forward-looking statements are based on management's current expectations, 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 important factors, including, but not limited to: our ability to become profitable; our ability to procure sufficient funding and requirements under our current debt instruments; and effects of restrictions thereunder; risks associated with raising additional capital; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the success of our programs and product candidates in which we expend our resources; our limited ability or inability to assess the safety and efficacy of our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; pending and potential liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators' development of product candidates; our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; our or our collaborators' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; our ability to obtain an adequate supply of T cells from qualified donors; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; changes in interim "top-line" and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side

effects; risks associated with applicable healthcare, data protection, privacy and security regulations and our compliance therewith; the rate and degree of market acceptance of any of our product candidates; the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with and reliance on third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key executives and personnel; market and economic conditions; effects of system failures and security breaches; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events effects of the outbreak of COVID-19, or any pandemic, epidemic or outbreak of an infectious disease; insurance expenses and exposure to uninsured liabilities; 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, 2020, as updated as updated in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 to be filed with the SEC, and as any 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 and the Investors & Media page of our website at investor.precisionbiosciences.com.

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 Statements 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,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 7,363	$ 4,865	$ 15,439	$ 15,716
Operating expenses				
Research and development	24,873	19,791	74,935	62,512
General and administrative	8,534	7,052	26,852	18,547
Total operating expenses	33,407	26,843	101,787	81,059
Loss from operations	(26,044)	(21,978)	(86,348)	(65,343)
Other income (expense), net:				
Change in fair value of convertible notes payable	—	—	—	(9,758)
Interest expense	—	—	—	(182)
Interest income	28	1,236	795	3,322
Total other income (expense), net	28	1,236	795	(6,618)
Net loss and net loss attributable to common stockholders	$ (26,016)	$ (20,742)	$ (85,553)	$ (71,961)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.50)	$ (0.41)	$ (1.65)	$ (1.85)
Weighted average shares of common stock outstanding-basic and diluted	52,346,715	50,623,665	51,858,032	39,002,304

Precision BioSciences, Inc.
Condensed Consolidated Balance Sheets Data
(In thousands)
(Unaudited)

	September 30, 2020	**December 31, 2019**
Cash and cash equivalents	$ 104,148	$ 180,886
Working capital	80,577	166,740

Total assets		168,687		235,233
Total stockholders' equity	$	63,824	$	138,314