Precision BioSciences Reports First Quarter and 2021 Financial Results and Provides Business Update

May 13, 2021

- Reacquired Global Development and Commercialization Rights to all Servier Partnered CAR T Programs, Including PBCAR0191 and PBCAR19B Stealth Cell

- Expect to Present Updated PBCAR0191 Data in June at ASCO 2021

- Plan to Initiate Phase 1 Study of PBCAR19B Stealth Cell in Patients with R/R NHL by End of May 2021

- Appointed Alan List, M.D. as Chief Medical Officer and Stanley Frankel, M.D. to Board of Directors; Initiated CEO Transition Plan to Support Company's Next Phase of Growth

DURHAM, N.C.--(BUSINESS WIRE)--May 13, 2021-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, today announced financial results for the first quarter ended March 31, 2021 and provided a business update.

"In the first quarter, we have worked diligently to advance our ARCUS-based *in vivo* gene editing and allogeneic CAR T pipelines," commented Matt Kane, CEO and co-founder of Precision BioSciences. "In April, we seized the opportunity to reacquire all global rights previously granted to Servier for our CAR T programs, including PBCAR0191 and PBCAR19B. We believe that this repurchase, alongside our maturing datasets, will allow us to take full advantage of our CAR T programs as they progress through clinical development."

"We are on track to initiate the Phase 1 study of our PBCAR19B this month, our first candidate incorporating immune evading stealth cell technology as an alternative potential path to deeper and more durable responses. This will precede multiple anticipated clinical and research milestones across our portfolio in 2021, including interim updates from all three clinical-stage CAR T programs: PBCAR0191, PBCAR20A, and PBCAR269A. Additionally, we look forward to providing an update on our *in vivo* gene editing pipeline mid-year," concluded Mr. Kane.

Recent Developments and Upcoming Milestones:

Allogeneic CAR T Portfolio:

Reacquired Global Development and Commercialization Rights from Servier: In April 2021, Precision announced that it had entered into a Program Purchase Agreement to reacquire all global development and commercialization rights for all CAR T partnered programs covered under its Development and Commercial License Agreement with Servier. This includes its two CD19-targeting allogeneic CAR T candidates, PBCAR0191 and PBCAR19B stealth cell, plus four additional CAR T targets identified by Servier in 2020.

Under the terms of the Program Purchase Agreement, Precision paid $1.25 million in cash to Servier and agreed to waive earned, but as-yet unpaid milestones totaling $18.75 million that would have otherwise been payable to Precision. Servier is also eligible to receive milestones and low- to mid-single-digit royalties subject to product development achievement.

PBCAR0191: Precision has continued to advance its Phase 1/2a study of PBCAR0191 in patients with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) or R/R B-cell precursor acute lymphoblastic leukemia (B-ALL). Since the December 2020 interim data update, additional patients have been dosed with PBCAR0191 following enhanced lymphodepletion (eLD)[1]. Precision will continue to monitor the results for durability from this eLD regimen and expects to report updated interim results in June at ASCO 2021.

PBCAR19B: Precision has begun adding clinical trial sites for its Phase 1 study of PBCAR19B, the Company's next generation, stealth cell, allogeneic CAR T candidate for patients with CD19-positive malignancies such as those with R/R NHL. The study is expected to begin by the end of May 2021. PBCAR19B will be administered at flat dose levels, beginning at 2.7×10^8 cells, with the ability to dose up to 8.1×10^8 cells per patient, following standard lymphodepletion[2]. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities.

PBCAR20A: Precision continues to enroll patients in its Phase 1/2a clinical trial of PBCAR20A, its anti-CD20 CAR T therapy for patients with R/R NHL, including patients with R/R chronic lymphocytic leukemia or R/R small lymphocytic lymphoma. In February 2021, the study began enrolling patients into dose level 3, a fixed dose of 480×10^6 cells with a max dose of 6.0×10^6 cells/kg. Precision expects to provide an interim update for the PBCAR20A study in 2021.

PBCAR269A: Precision continues to enroll patients in its Phase 1/2a study of PBCAR269A, its CAR T candidate targeting B-cell maturation antigen (BCMA) for the treatment of R/R multiple myeloma, for which Precision has received Fast Track Designation and Orphan Drug Designation from the FDA. In February 2021, the study began enrolling patients into its highest dose cohort, dose level 3 at 6.0×10^6 cells/kg and Precision expects to provide an interim update in 2021. Precision also expects to initiate the combination arm of its ongoing Phase 1/2a clinical study with PBCAR269A and nirogacestat, SpringWorks Therapeutics' investigational gamma secretase inhibitor, in the first half of 2021.

PBCAR269B: In April 2021, Precision introduced PBCAR269B, a next-generation, BCMA-targeted candidate incorporating stealth cell technology, for treatment of R/R multiple myeloma. Precision is conducting IND-enabling studies for PBCAR269B and expects to file an IND application in early 2022.

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

Genome Editing Research Collaboration with Eli Lilly: In January 2021, Precision announced the closing of its agreement with Eli Lilly. Under the agreement, Precision will develop up to six *in vivo* therapies for genetic disorders using ARCUS, with an initial focus on Duchenne muscular dystrophy and two other undisclosed gene targets.

PH1: Pre-clinical research continues to progress with Precision's wholly-owned *in vivo* gene correction program using its ARCUS genome editing technology to knock out the HAO1 gene as a potential one-time treatment for primary hyperoxaluria type 1 (PH1), a rare genetic disease. The Company expects to provide an update in mid-2021.

Corporate:

Executive Leadership: In April 2021, Precision announced that it has initiated a CEO transition plan for Co-Founder and Chief Executive Officer, Matt Kane. Mr. Kane is expected to continue in his current leadership capacity until his successor has been identified. He will also serve as an advisor for a period of time after the next CEO is hired ensuring a smooth transition.

Precision also announced the appointment of Alan List, M.D. as the Company's Chief Medical Officer and a member of the senior leadership team. Dr. List is a world-renowned hematologist with extensive academic and clinical experience in the research and development of hematology and oncology products.

Board of Directors: Precision announced that it has strengthened its Board of Directors with the appointment of Stanley R. Frankel, M.D., a hematologist-oncologist with extensive academic and industry experience in the research, clinical development, and commercialization of immuno-oncology and cellular therapies. Dr. Frankel was most recently the Senior Vice President, Cellular Therapy Development at Bristol-Myers Squibb (BMS). Prior to the BMS acquisition of Celgene, he was Corporate Vice President, Head, Immuno-Oncology & Cellular Therapy, Clinical Research and Development Head, Cell Therapy Clinical Center of Excellence at Celgene.

Elo Life Systems:

Corporate Structure: In January 2021, Precision disclosed its intention to spin out its wholly-owned subsidiary, Elo Life Systems. Precision is continuing to explore its strategic options, and expects to complete any such spinout, sale or other treatment of Elo in 2021.

Quarter Ended March 31, 2021 Financial Results

Cash and Cash Equivalents: As of March 31, 2021, Precision had approximately $193.5 million in cash and cash equivalents, which includes the $100 million upfront cash payment and equity investment of $35 million received from Eli Lilly in January 2021. The Company expects that existing cash and cash equivalents, expected operational receipts, and available credit will be sufficient to fund its operating expenses and capital expenditure requirements into 2023.

Revenues: Total revenues for the first quarter ended March 31, 2021 were $16.3 million, as compared to $7.0 million for the same period in 2020.

Research and Development Expenses: Research and development expenses were $25.6 million for the quarter ended March 31, 2021, as compared to $24.9 million for the same period in 2020.

General and Administrative Expenses: General and administrative expenses were $9.5 million for the quarter ended March 31, 2021, as compared to $9.6 million for the same period in 2020.

Net Loss: Net loss was $18.7 million, or $(0.33) per share, for the quarter ended March 31, 2021, as compared to a net loss of $26.8 million, or $(0.52) per share, for the same period in 2020.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its wholly 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 Eli Lilly

Under the terms of the research collaboration and exclusive license agreement with Eli Lilly, Precision will use its ARCUS genome editing platform for pre-clinical research and IND-enabling activities for up to six *in vivo* gene editing programs, with an initial focus on focus on Duchenne muscular dystrophy and two other undisclosed gene targets. Lilly will assume responsibility for clinical development and commercialization and will have the right to select up to three additional gene targets for this collaboration. Precision can co-fund clinical development of one product in exchange for an increased royalty rate on co-funded product sales.

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 our leadership transition, the expected timing of clinical updates and interim updates related to PBCAR0191, the expected commencement of our Phase 1 study for PBCAR19B, the expected commencement of our Phase 1/2a clinical trial for PBCAR20A, the expected timing of clinical updates and interim updates related to PBCAR269A, the expected IND filing for PBCAR269B, clinical developments related to our *in vivo* gene correction program, developments related to our expected spinout or other treatment of Elo Life Systems and expectations regarding our operational initiatives. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe,"

“could,” “expect,” “should,” “plan,” “intend,” “estimate,” “target,” “mission,” “goal,” “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; effects of tax rules; risks related to ownership of our common stock and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as any such factors may be updated from time to time in our other filings with the SEC, including our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 to be filed with the SEC, 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 have no obligation to 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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[1] Fludarabine (30 mg/m/day for 4 days) and cyclophosphamide (1000 mg/m^2/day for 3 days)

[2] Fludarabine (30 mg/m/day for 3 days) and cyclophosphamide (500 mg/m^2/day for 3 days)

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

	For the Three Months Ended March 31,	
	2021	**2020**
Revenue	$ 16,349	$ 6,998
Operating expenses		
Research and development	25,593	24,879
General and administrative	9,498	9,615
Total operating expenses	35,091	34,494
Loss from operations	(18,742)	(27,496)
Other income:		

Interest income	53	660
Net loss and net loss attributable to common stockholders	$ (18,689)	$ (26,836)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.33)	$ (0.52)
Weighted average shares of common stock outstanding-basic and diluted	56,625,024	51,312,770

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 193,460	$ 89,798
Working capital	155,342	62,735
Total assets	262,316	150,158
Total stockholders' equity	$ 58,822	$ 44,425

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