

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): May 15, 2020**

**Precision BioSciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38841**  
(Commission  
File Number)

**20-4206017**  
(IRS Employer  
Identification No.)

**302 East Pettigrew St., Suite A-100, Durham, North Carolina 27701**  
(Address of principal executive offices) (Zip Code)

**(919) 314-5512**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Exchange Act:**

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, par value \$0.000005 per share	DTIL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operation and Financial Condition.**

On May 15, 2020, Precision BioSciences, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of Precision BioSciences, Inc., dated May 15, 2020</a>

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 15, 2020

PRECISION BIOSCIENCES, INC.

By: /s/ Matthew Kane  
Matthew Kane  
President and Chief Executive Officer



## Precision BioSciences Reports First Quarter 2020 Financial Results and Provides Business Update

*Dosed First Patient in Phase 1/2a Clinical Study of PBCAR20A in Relapsed/Refractory NHL, CLL, and SLL*

*PBCAR0191 Phase 1/2a Trial is Progressing with Updated Interim Data Expected in 2020; Phase 1/2a Trial of PBCAR269A in Patients with Multiple Myeloma Expected to Begin in 2020*

*Expect to Select Clinical Candidate for in vivo Gene Correction Program Targeting PH1 in 2020*

DURHAM, N.C., May 15, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a life sciences company dedicated to improving life through the application of its pioneering, proprietary ARCUS® genome editing platform, today announced financial results for the first quarter ended March 31, 2020, and provided a business update.

“So far in 2020, we have continued to make significant progress across our portfolio. This includes advancing the ongoing Phase 1/2a trial of our lead allogeneic CAR T program candidate, PBCAR0191, in relapsed/refractory (R/R) NHL and B-ALL; dosing the first patient in a Phase 1/2a trial of PBCAR20A in R/R NHL, CLL and SLL; and preparing to launch a Phase 1/2a clinical trial of our third allogeneic CAR T candidate, PBCAR269A, in multiple myeloma,” said Matt Kane, CEO and co-founder of Precision BioSciences. “Amid COVID-19’s impact on the healthcare ecosystem, we believe this progress is not only a testament to our team’s dedication, but also a reminder of the significant disease burden and poor prognosis faced by late-stage cancer patients who have failed previous treatment lines. As evidenced by early data from our Phase 1/2a trial of PBCAR0191, our differentiated, off-the-shelf CAR T approach may offer meaningful clinical benefit for these patients, while potentially avoiding safety and logistical challenges faced by other cell therapies, including autologous CAR T. We continue to look forward to reporting updated data from the PBCAR0191 program later in 2020.”

### Recent Developments and Upcoming Milestones:

#### Allogeneic CAR T Portfolio:

**PBCAR0191:** PBCAR0191 is an investigational allogeneic CAR T candidate targeting CD19, currently being evaluated in a Phase 1/2a study in relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) or R/R B-cell precursor acute lymphoblastic leukemia (B-ALL). The NHL cohort will include patients with mantle cell lymphoma (MCL), an aggressive subtype of NHL, for which Precision has received Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA). In the first quarter of 2020, after discussion with the FDA, Precision implemented an amendment to the PBCAR0191 trial protocol designed to further optimize clinical activity. The amended trial design is intended to specifically address key clinical questions, which include assessing the impact of higher total doses of cells on clinical activity and/or the impact of modified lymphodepletion on the ability to achieve durable clinical benefit with

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associated CAR T cell expansion and persistence. The PBCAR0191 clinical trial continues to progress, and no dose limiting toxicities or serious adverse events have been observed to date. Precision expects to present updated interim clinical data from both the NHL and B-ALL cohorts of this trial during 2020. PBCAR0191 is being developed in collaboration with Servier, an international pharmaceutical company.

**PBCAR20A:** PBCAR20A is a wholly-owned investigational allogeneic CAR T candidate targeting CD20 for the treatment of hematological malignancies. In April 2020, Precision dosed the first patient in its Phase 1/2a clinical trial evaluating PBCAR20A in two patient cohorts: R/R NHL, and R/R chronic lymphocytic leukemia (CLL) or R/R small lymphocytic lymphoma (SLL). Similar to the Phase 1/2a study of PBCAR0191, the NHL cohort for PBCAR20A will include patients with MCL, which has also received ODD from the FDA. Based on the safety profile observed from early dose levels in Precision's ongoing Phase 1/2a study of PBCAR0191, the FDA authorized dosing in this Phase 1/2a study of PBCAR20A to begin at what was originally designed to be Dose Level 2 ( $1 \times 10^6$  cells/kg), with the subsequent dose level expected to be  $3 \times 10^6$  cells/kg.

**PBCAR269A:** PBCAR269A is a wholly-owned investigational allogeneic CAR T candidate targeting B-cell maturation antigen (BCMA) for the treatment of R/R multiple myeloma, for which Precision has also received ODD. In January 2020, the FDA cleared Precision's Investigational New Drug (IND) application for PBCAR269A, and the Company expects to begin dosing patients in a Phase 1/2a clinical trial in 2020.

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

**PH1 Program:** In January 2020, Precision announced that its first wholly-owned *in vivo* gene correction program will apply 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. In 2020, Precision expects to select a clinical candidate for this program to advance into human trials.

**ASGCT 2020:** At the American Society of Gene & Cell Therapy 23<sup>rd</sup> Annual Meeting held May 12-15, 2020, multiple presentations were made by Precision and its collaborators supporting the Company's ARCUS genome editing platform and emerging pipeline applying this technology *in vivo*. Posters and talks included:

- *Engineering a Self-Inactivating Adeno-Associated Virus (AAV) Vector for ARCUS Nuclease Delivery* (Abstract #654)
- *Gene Editing Approach to Eliminate Hepatitis B Virus Using ARCUS Meganucleases* (Abstract #1057)
- *Therapeutic Efficacy of ARCUS Meganuclease Gene Editing - Arrest of Rod Degeneration and Restoration of Rod Function in a Transgenic Pig Model of Autosomal Dominant Retinitis Pigmentosa* (Abstract #2)
- *Evaluation of the Long-term Effects of AAV-Meganuclease Genome Editing of PCSK9 in Macaque Liver* (Abstract #518)

### **Corporate**

**COVID-19:** In April 2020, Precision provided an update regarding its clinical trials and business operations amid the COVID-19 pandemic. This includes steps taken in line with guidance from public

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health officials to protect the health and safety of its employees and to ensure continuity of its clinical trials. Precision's work-from-home policy and restriction of on-site activities to certain manufacturing functions and limited laboratory and support activities remain in effect. To date, Precision has not experienced material delays to its planned or ongoing clinical trials.

**Senior Leadership and Board Appointments:** Precision further strengthened its senior leadership team with the appointment of Dora Alvarado as Senior Vice President, Human Resources. The Company also recently welcomed Geno Germano, President and CEO of Elucida Oncology, and former head of Pfizer's Global Innovative Pharmaceutical business, to its Board of Directors.

### **Quarter Ended March 31, 2020 Financial Results**

**Cash and Cash Equivalents:** As of March 31, 2020, Precision had approximately \$154.2 million in cash and cash equivalents. The Company expects that existing cash and cash equivalents will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2021.

**Revenues:** Total revenues for the quarter ended March 31, 2020 were \$7.0 million, compared to \$5.5 million for the quarter ended March 31, 2019. This increase was due to increases in both Therapeutic and Food segments.

**Research and Development Expenses:** Research and development expenses were \$24.9 million for the quarter ended March 31, 2020, as compared to \$20.0 million for the same period in 2019. This increase of \$4.9 million was primarily due to increases in direct research and development expenses, as well as platform development and early stage research expenses, including increases in personnel costs, laboratory supplies and services and expenses to support Precision's technology platform development and manufacturing capabilities.

**General and Administrative Expenses:** General and administrative expenses were \$9.6 million for the quarter ended March 31, 2020, as compared to \$5.0 million for the same period in 2019. The increase of \$4.6 million was primarily due to an increase in employee-related costs for additional personnel and facility costs associated with the Company's growing infrastructure needs.

**Net Loss:** Net loss was \$26.8 million, or \$(0.52) per share, for the quarter ended March 31, 2020, compared to a net loss of \$31.8 million, or \$(1.99) per share, for the same period in 2019.

### **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](http://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

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activities and Phase 1 execution for PBCAR0191, as well as preparation of clinical supply for any Phase 2 clinical trials. 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 involving PBCAR0191, PBCAR20A and PBCAR269A and our *in vivo* gene correction program and the Company's expectations regarding its liquidity and ability to fund operating expenses and capital expenditure requirements. 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," "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; 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 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 achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data 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 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

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rights; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key scientific and management personnel; market and economic conditions; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as supplemented by the risk factor contained in our Current Report on Form 8-K filed with the SEC on April 6, 2020, as any such factors may be updated from time to time in our other filings with the SEC, including, but not limited to, our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, which are accessible on the SEC’s website at [www.sec.gov](http://www.sec.gov) and the Investors & Media page of our website at [investor.precisionbiosciences.com](http://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.

**Contact:**

Maurissa Messier,  
Senior Director, Corporate Communications  
Tel. (919) 314-5512  
[maurissa.messier@precisionbiosciences.com](mailto:maurissa.messier@precisionbiosciences.com)

Josh Rappaport  
Stern Investor Relations  
Tel. (212) 362-1200  
[josh.rappaport@sternir.com](mailto:josh.rappaport@sternir.com)

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenue	\$ 6,998	\$ 5,462
Operating expenses		
Research and development	24,879	19,961
General and administrative	9,615	4,995
Total operating expenses	34,494	24,956
Loss from operations	(27,496)	(19,494)
Other income (expense), net:		
Change in fair value of convertible notes payable	—	(12,708)
Interest expense	—	(182)
Interest income	660	601
Total other income (expense), net	660	(12,289)
Net loss and net loss attributable to common stockholders	\$ (26,836)	\$ (31,783)
Net loss per share attributable to common stockholders- basic and diluted	\$ (0.52)	\$ (1.99)
Weighted average shares of common stock outstanding- basic and diluted	51,312,770	15,967,036

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

	<b>March 31, 2020</b>	<b>December 31, 2019</b>
Cash and cash equivalents	\$ 154,187	\$ 180,886
Working capital	143,084	166,740
Total assets	214,202	235,233
Total stockholders' equity	\$ 115,034	\$ 138,314