

**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): August 13, 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.

Item 2.02. Results of Operation and Financial Condition.

On August 13, 2020, Precision BioSciences, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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.

Item 7.01 Regulation FD Disclosure.

The Company has updated its corporate deck, which is available on in the “Investors & Media” portion of the Company’s website at <https://investor.precisionbiosciences.com>.

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

Exhibit No.	Description
99.1	Press release of Precision BioSciences, Inc., dated August 13, 2020

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: August 13, 2020

PRECISION BIOSCIENCES, INC.

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



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

Dosed First Patient in Phase 1/2a Clinical Trial of PBCAR269A, a BCMA-Targeted Allogeneic CAR T Candidate for Multiple Myeloma

PBCAR0191 and PBCAR20A Clinical Studies Progressing; Updated Interim Data Expected from PBCAR0191 No Earlier Than Q4 2020

Expect to Select Clinical Candidate for Wholly-Owned In Vivo Gene Correction Program Targeting PH1 in 2H 2020

Elo Life Systems, a Wholly-Owned Subsidiary, Entered Strategic Collaboration with Dole Food Company Aimed to Develop Banana Varieties Resistant to Panama Disease

DURHAM, N.C., August 13, 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 second quarter ended June 30, 2020 and provided a business update.

“We have continued to make important progress across our clinical portfolio, including the initiation of our Phase 1/2a study of BCMA-targeted PBCAR269A, bringing us to three CAR T candidates now in clinical trials. However, due to study site activation and patient enrollment delays related to the COVID-19 pandemic, we now anticipate reporting updated interim data from our lead candidate, PBCAR0191, targeting CD19 in heavily pretreated patients with R/R NHL or B-ALL, no earlier than the fourth quarter of 2020,” said Matt Kane, CEO and co-founder of Precision BioSciences. “Our pre-clinical work also continued to progress, including our lead gene correction program targeting PH1, for which we look forward to nominating a clinical candidate later this year. We anticipate sharing more about this program as it advances towards the clinic, including what we believe are prudent safety and delivery advantages with ARCUS genome editing that support additional *in vivo* targets of interest.”

Recent Developments and Upcoming Milestones

Allogeneic CAR T Portfolio

PBCAR0191: PBCAR0191 is an investigational allogeneic chimeric antigen receptor (CAR T) candidate targeting CD19 and is 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 includes patients with mantle cell lymphoma (MCL), an aggressive subtype of NHL, for which Precision has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA). The PBCAR0191 clinical trial has continued to progress, although site activation and patient enrollment across all studies, including PBCAR0191, has slowed due to the COVID-19 pandemic. Precision expects to share an update of this trial no earlier than the fourth quarter of this year. 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. Precision's Phase 1/2a clinical trial is evaluating PBCAR20A in two patient cohorts: R/R NHL, and R/R chronic lymphocytic leukemia (CLL) or R/R small lymphocytic lymphoma (SLL). The NHL cohort will include patients with MCL, an aggressive subtype of NHL, for which Precision has received Orphan Drug Designation from the FDA.

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 received Orphan Drug Designation from the FDA. In June 2020, the Company dosed the first patient in a Phase 1/2a study of PBCAR269A, at a starting dose of 6×10^5 CAR T cells/kg body weight. Subsequent cohorts will be treated with escalating doses to a maximum dose of 6×10^6 CAR T cells/kg body weight. This is the first study for which all clinical trial materials will be produced at the Company's in-house manufacturing facility, which is compliant with current Good Manufacturing Practices. In preclinical disease models, PBCAR269A demonstrated potent *in vivo* clearance of BCMA+ tumor cells and overall volume reduction, with no evidence of graft-versus-host disease.

In Vivo Gene Correction Portfolio

PH1 Program: Precision's lead, wholly-owned *in vivo* gene correction program applies 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. Precision expects to select a clinical candidate to advance into human trials for this program during 2020.

HBV Program: In July 2020, Precision announced it will regain full clinical development and commercialization rights and all data it generated for the *in vivo* chronic hepatitis B virus (HBV) program developed under its 2018 collaboration agreement with Gilead Sciences, effective September 4, 2020. The Company is exploring partnership or alternative opportunities that enable the continued development and potential commercialization of ARCUS-based HBV therapies.

Elo Life Systems

Dole Collaboration: On August 4, 2020, Elo Life Systems, a wholly-owned subsidiary of Precision BioSciences, announced its strategic collaboration with Dole Food Company, one of the world's largest food producers of high-quality fresh fruit and vegetables, with the aim to develop banana varieties resistant to Fusarium wilt Tropical Race 4 (TR4). The TR4 strain of the fungal pathogen, *Fusarium oxysporum* threatens the continued cultivation of the Cavendish variety, one of the world's most popular bananas. Under the terms of the collaboration, Dole will fully fund research and development efforts executed by Elo to co-develop banana varieties resistant to a pathogen that is otherwise unresponsive to any control measures. Elo is eligible to receive royalties on any commercialized plant product.

Quarter Ended June 30, 2020 Financial Results

Cash and Cash Equivalents: As of June 30, 2020, Precision had approximately \$126.9 million in cash and cash equivalents. The Company expects that existing cash, cash equivalents and available credit will be sufficient to fund operating expenses and capital expenditure requirements into 2022.

Revenues: Total revenues for the quarter ended June 30, 2020 were \$1.1 million, compared to \$5.4 million for the quarter ended June 30, 2019. This decrease of \$4.3 million was primarily due to a decrease in collaboration revenue recognized from Servier and Gilead.

Research and Development Expenses: Research and development expenses were \$25.2 million for the quarter ended June 30, 2020, as compared to \$22.8 million for the same period in 2019. This increase of \$2.4 million was primarily due to increases in direct research and development expenses related to the commencement of our CD20 and BCMA Phase 1/2a clinical trials and our ongoing CD19 clinical program.

General and Administrative Expenses: General and administrative expenses were \$8.7 million for the quarter ended June 30, 2020, as compared to \$6.5 million for the same period in 2019. The increase of \$2.2 million was primarily due to costs associated with the Company's growing infrastructure needs.

Net Loss: Net loss was \$32.7 million, or \$(0.63) per share, for the quarter ended June 30, 2020, compared to a net loss of \$19.4 million, or \$(0.39) 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 potentially cure genetic and infectious diseases where no known 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 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, results from and information involving the Company's clinical trials involving PBCAR0191, PBCAR20A and PBCAR269A and our *in vivo* gene correction program, the Company's selection of a clinical candidate for its PH1 program and opportunities for continued development of its HBV program, results of research and development relating to TR4 resistant banana varieties, 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 "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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 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 June 30, 2020, 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)

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 1,078	\$ 5,389	\$ 8,076	\$ 10,851
Operating expenses				
Research and development	25,183	22,760	50,062	42,721
General and administrative	8,703	6,500	18,318	11,495
Total operating expenses	33,886	29,260	68,380	54,216
Loss from operations	(32,808)	(23,871)	(60,304)	(43,365)
Other income (expense), net:				
Change in fair value of convertible notes payable	—	2,950	—	(9,758)
Interest expense	—	—	—	(182)
Interest income	107	1,485	767	2,086
Total other income (expense), net	107	4,435	767	(7,854)
Net loss and net loss attributable to common stockholders	<u>\$ (32,701)</u>	<u>\$ (19,436)</u>	<u>\$ (59,537)</u>	<u>\$ (51,219)</u>
Net loss per share attributable to common stockholders- basic and diluted	<u>\$ (0.63)</u>	<u>\$ (0.39)</u>	<u>\$ (1.15)</u>	<u>\$ (1.55)</u>
Weighted average shares of common stock outstanding- basic and diluted	<u>51,909,240</u>	<u>50,035,370</u>	<u>51,611,005</u>	<u>33,095,314</u>

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

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$ 126,886	\$ 180,886
Working capital	103,082	166,740
Total assets	184,192	235,233
Total stockholders' equity	\$ 85,599	\$ 138,314