

**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): September 17, 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 Act:

Title of each class	Trading Symbol(s)	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 7.01 Regulation FD Disclosure.

On September 17, 2020, Precision BioSciences, Inc. (the “Company”) issued a press release announcing the expansion of targets under the License and Collaboration Agreement (as defined below). A copy 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 Item 7.01 of 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 8.01 Other Events.

On September 17, 2020, the Company announced that in collaboration with Les Laboratoires Servier (“Servier”), an independent global pharmaceutical company, under the Development and Commercial License Agreement by and between Servier and Precision, dated February 24, 2016, as subsequently amended (the “License and Collaboration Agreement”), the companies have added two additional hematological cancer targets beyond the Company’s CD19 product candidate and two solid tumor targets.

Under the terms of the License and Collaboration Agreement, Servier has selected two hematological and two solid tumor targets beyond those already in Precision’s allogeneic CAR T pipeline. Precision intends to leverage its proprietary ARCUS genome editing platform and CAR T development and manufacturing expertise for early-stage research and development activities, including Investigational New Drug (IND) filing through the manufacturing of initial clinical trial material for a Phase 2 study. Servier has the 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. With the addition of these new targets, Precision expects to receive milestone payments in 2020 and 2021. Precision is also eligible for option fees, clinical, regulatory, and sales milestones in addition to royalties on product sales.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding management’s future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements the Company’s expectations for milestone payments involving the additional targets and the Company’s intent to leverage its proprietary ARCUS genome editing platform and CAR T development and manufacturing expertise for early-stage research and development activities. Forward-looking statements may be identified by words such as “anticipates,” “believe,” “continue,” “expect,” “intend,” “may,” “plan to,” “potential,” “will,” and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including without limitation, the risks referred to under the section “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, as such factors may be updated from time to time in our other filings with the SEC, which filings are accessible on the SEC’s website at www.sec.gov and the Investors & Media page of our website at <https://investor.precisionbiosciences.com>. All forward-looking statements speak only as of the date of this Current Report on Form 8-K 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.

Item 9.01.

Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Precision BioSciences, Inc., dated September 17, 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: September 17, 2020

PRECISION BIOSCIENCES, INC.

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



Precision BioSciences and Servier Expand CAR T Oncology Development Collaboration with Four New Programs Targeting Hematological and Solid Tumors

DURHAM, N.C. and PARIS, France -- September 17, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, in collaboration with Servier, an independent global pharmaceutical company, today announced the companies have added two additional hematological cancer targets beyond CD19 and two solid tumor targets to its CAR T development and commercial license agreement.

“The addition of these new targets will build on the productive multi-year collaboration between Precision and Servier that is driving the development of PBCAR0191, our lead allogeneic CAR T candidate targeting CD19,” said Matt Kane, CEO and Co-Founder of Precision BioSciences. “We are pleased to expand our collaboration with Servier and apply our proprietary single-step cell engineering and unique allogeneic CAR T manufacturing and development strategies to potentially extend the reach of “off-the-shelf” CAR T therapies beyond hematological cancers and into solid tumors.”

Under the terms of the existing development and commercial license agreement between Servier and Precision, Servier has selected two hematological and two solid tumor targets beyond those already in Precision’s allogeneic CAR T pipeline. Precision intends to leverage its proprietary ARCUS genome editing platform and CAR T development and manufacturing expertise for early-stage research and development activities, including Investigational New Drug (IND) filing through the manufacturing of initial clinical trial material for a Phase 2 study. Servier has the 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. With the addition of these new targets, Precision expects to receive milestone payments in 2020 and 2021. Precision is also eligible for option fees, clinical, regulatory, and sales milestones in addition to royalties on product sales.

“At Servier, we partner for a purpose – our patients. We are pleased to add four additional targets beyond CD19 to our collaboration with Precision BioSciences as part of our commitment to oncology,” said Patrick Therasse, Deputy Head of global RD oncology at Servier. “We look forward to utilizing their ARCUS genome editing platform with these new targets to potentially develop several innovative allogeneic CAR T therapies for patients with a range of solid and hematological malignancies.”

About PBCAR0191

PBCAR0191 is an investigational allogeneic chimeric antigen receptor (CAR T) candidate targeting CD19 in a Phase 1/2a multicenter, nonrandomized, open-label, parallel assignment, dose-escalation, and dose-expansion study for the treatment of patients with 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 both Orphan Drug and Fast Track Designations from the U.S. Food and Drug Administration

(FDA). More information about the study is available at www.clinicaltrials.gov, study identifier number NCT03666000.

About Precision's Allogeneic CAR T Platform

Precision is advancing a pipeline of cell-phenotype optimized allogeneic CAR T therapies, leveraging fully scaled, proprietary manufacturing processes. The platform is designed to maximize the number of patients who can potentially benefit from CAR T therapy. Precision carefully selects high-quality T cells derived from healthy donors as starting material, then utilizes its unique ARCUS genome editing technology to modify the cells via a single-step engineering process. By inserting the CAR gene at the T cell receptor (TCR) locus, this process knocks in the CAR while knocking out the TCR, creating a consistent product that can be reliably and rapidly manufactured that is designed to prevent graft-versus-host disease. Precision optimizes its CAR T therapy candidates for immune cell expansion in the body by maintaining a high proportion of naïve and central memory CAR T cells throughout the manufacturing process and in the final product.

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. More information about Precision BioSciences is available at www.precisionbiosciences.com.

About Servier

Servier is a Global pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a total revenue of 4.6 billion euros in 2019, Servier employs 22,000 people worldwide. Entirely independent, the Group invests on average 25% of its total revenue (excluding generics) every year in research and development and uses all its profits for its development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory, and neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development. More information is available at www.servier.com.

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 expectations for milestone payments involving the additional targets identified under its agreement with Servier, targets for the Company's clinical trial involving PBCAR0191 and results of the Company's CAR T therapies, including, without limitation, potential treatment of hematological cancers and solid tumors. 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 June 30, 2020, 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.

Precision BioSciences investor and media contact:

Maurissa Messier

Senior Director, Corporate Communications
maurissa.messier@precisionbiosciences.com

Servier Group press contacts:

Sonia Marques: presse@servier.com