# 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): April 9, 2021**

# Precision BioSciences, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-38841** | **20-4206017** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(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 1.01 Entry into a Material Definitive Agreement.**

On April 9, 2021, Precision BioSciences, Inc. (the "Company") entered into a Program Purchase Agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "Servier") (the "Program Purchase Agreement"), pursuant to which the Company is reacquiring all of its global development and commercialization rights previously granted to Servier pursuant to the Development and Commercial License Agreement by and between Servier and the Company, dated February 24, 2016, as amended (the "Servier Agreement"), and terminating the Servier Agreement by mutual agreement pursuant to the terms described herein.

The Program Purchase Agreement terminates the Servier Agreement, pursuant to which the Company has developed certain allogeneic CAR T candidates, including PBCAR0191 and the stealth cell PBCAR19B, each targeting CD19, and four other programs for four targets nominated by Servier in 2020. Pursuant to the termination and reacquisition, the Company has regained full global rights to research, develop, manufacture and commercialize products resulting from such programs, with sole control over all activities. With respect to products directed to CD19, Servier has certain rights of negotiation, which may be exercised during a specified time period if the Company elects to initiate a process or entertain third party offers for partnering such products.

The Program Purchase Agreement requires the Company to pay an upfront payment of $20 million in a combination of cash ($1.25 million) and the waiver of earned, but as-yet unpaid milestones that would have otherwise been payable to the Company ($18.75 million). The Program Purchase Agreement also requires the Company to make certain payments to Servier based on the achievement of regulatory and commercial milestones for each product, and a low- to mid-single-digit percentage royalty (subject to certain reductions) based on net sales of approved products, if any, resulting from any continued development and commercialization of the programs by the Company, for a period not to exceed ten years after first commercial sale of the applicable product in the United States or certain countries in Europe. If the Company enters into specified product partnering transactions, the Program Purchase Agreement requires the Company to pay to Servier a portion of certain consideration received pursuant to such product partnering transactions in lieu of the foregoing milestones (with the exception of a one-time clinical phase development milestone) and royalties.

The foregoing description of the Program Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the Program Purchase Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, with certain confidential portions redacted. For additional information regarding the terms of the Servier Agreement, see the section captioned "Item 1. Business—License and Collaboration Agreements—Servier" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission on March 18, 2021.

**Item 1.02 Termination of Material Definitive Agreement.**

The information regarding the termination of the Servier Agreement set forth under Item 1.01 of this Current Report on Form 8-K is hereby incorporated into this Item 1.02 by reference.

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

Although it has not finalized its full financial results for the quarter ended March 31, 2021, the Company expects to report that it had $193 million in cash and cash equivalents as of March 31, 2021. This estimate is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of March 31, 2021 and its results of operations for the three months ended March 31, 2021. The review of the Company's financial statements for the three months ended March 31, 2021 by the Company's independent registered public accounting firm is ongoing and could result in changes to the information set forth above.

The information contained in this Item 2.02 of the Form 8-K 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 7.01. Regulation FD Disclosure.**

On April 15, 2021, the Company issued a press release announcing it has entered into the Program Purchase Agreement and provided a clinical update. A copy of this press release is furnished as Exhibit 99.1 to this Form 8-K and incorporated into this Item 7.01 by reference.

As described in the accompanying press release, the Company will be hosting a conference call at 5:00 p.m., Eastern Time, on April 15, 2021 to review the clinical update. Access to the live webcast and the accompanying presentation materials will be available in the "Investors & Media" portion of the Company's website at https://investor.precisionbiosciences.com/events-and-presentations.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it deemed to be incorporated by reference in any filing of the Company under the Securities Act, except as expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On April 15, 2021, subsequent to the Company's December 2020 interim Phase 1/2a study data update for PBCAR0191, its lead CAR T candidate, the Company announced enrollment in the study has continued with a focus on dose level 3 ($3x10^6$ cells/kg) following enhanced lymphodepletion. Initial response rates are consistent with the high response rates reported by the Company in December 2020, and the safety profile continues to be acceptable. The Company intends to monitor the results for durability from this enhanced lymphodepletion regimen and report updated interim results in mid-2021.

The Company expects to dose the first patient with PBCAR19B, its second CD19 allogenic CAR T candidate engineered with the Company's proprietary stealth cell technology, by the end of May 2021.

**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 regarding the expected benefits of the Program Purchase Agreement, the potential milestone, royalty and other payments the Company may make thereunder and statements regarding the expected timing of clinical updates and interim data reports related to PBCAR0191 and the commencement of clinical studies for PBCAR19B. Forward-looking statements may be identified by words such as "anticipates," "believe," "continue," "expect," "intend," "may," "plan to," "potential," "projects," "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 the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as such factors may be updated from time to time in the Company's other filings with the Securities and Exchange Commission ("SEC"), which filings are accessible on the SEC's website at *www.sec.gov* and the Investors & Media page of the Company's 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, the Company has 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.

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

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Precision BioSciences Press Release, dated April 15, 2021. |

**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.

PRECISION BIOSCIENCES, INC.

Date: April 15, 2021

By: /s/ Dario Scimeca
Dario Scimeca
General Counsel

**Precision BioSciences Reacquires Global Rights to its Allogeneic CAR T Programs**

*- Precision Reacquires from Servier its Global Development and Commercialization Rights and Control of All Partnered CAR T Programs, Including PBCAR0191 and PBCAR19B Stealth Cell*

*- Servier Eligible to Receive Milestones and Royalties Based on Program Success*

*- Precision to Host Conference Call and Webcast Today at 5:00 p.m. ET*

DURHAM, N.C., April 15, 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 it has 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 clinical stage CD19-targeting allogeneic CAR T candidates, PBCAR0191 and PBCAR19B stealth cell, as well as four additional product targets.

“We are excited about the potential of our allogeneic CAR T pipeline to deliver off-the-shelf treatments for patients with cancer,” said Matt Kane, CEO and Co-Founder of Precision BioSciences. “We believe we are in a unique position with multiple near-term opportunities to achieve success with allogeneic CAR T cells targeting CD19. Our lead candidate, PBCAR0191, continues to look promising when paired with our enhanced lymphodepletion regimen, and our immune-evading PBCAR19B stealth cell candidate is poised to enter the clinic soon. We seized the opportunity to reacquire these two CD19 programs, as well as four additional targets that were selected by Servier in 2020 to regain global commercial rights and full control of our clinical programs, allowing us to focus our resources and enable rapid decision making.”

Under the terms of the Program Purchase Agreement, Servier will receive $1.25 million in cash and Precision has 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. With respect to products directed to CD19, Servier has certain rights of negotiation if Precision elects to re-partner the programs.

“Precision was a very good partner for us, and we continue to believe their proprietary, single-step cell engineering technology has the potential to open the door to an off-the-shelf approach for addressing cancer,” said Patrick Therasse, Deputy Head of R&D Oncology at Servier. “While we have made the strategic decision to refocus our R&D activities and we will no longer be taking an active role in the Precision programs, we continue to believe they have multiple opportunities, including the stealth cell approach, to benefit patients with hematologic malignancies and solid tumors, so we are pleased to be able to participate in the potential future success of these programs.”

Subsequent to Precision’s December 2020 interim Phase 1/2a study data update for PBCAR0191, enrollment in the study has continued, with a focus on dose level 3 (3 x $10^6$ cells/kg) following enhanced lymphodepletion (eLD)[1]. Initial response rates are consistent with the high response rates reported by Precision in December 2020, and the safety profile continues to be acceptable. Precision intends to monitor the results for durability from this eLD regimen and report updated interim results by mid-2021.

By the end of May 2021, Precision expects to dose the first patient with PBCAR19B, its second CD19 allogeneic CAR T candidate that is engineered with Precision’s proprietary stealth cell technology.
Although it has not finalized its full financial results for the first quarter ended March 31, 2021, Precision BioSciences had cash and cash equivalents of approximately $193 million as of March 31, 2021 and continues to expect that cash and cash equivalents, expected operational receipts, and available credit will allow the Company to continue its operations into 2023.

**Company-Hosted Conference Call and Webcast Information**
Precision's management team will host a conference call and webcast at 5:00 p.m. ET, Thursday, April 15, 2021 to discuss today’s announcement. The dial-in conference call numbers for domestic and international callers are (866) 996-7202 and (270) 215-9609, respectively. The conference ID number for the call is 8170529. Participants may access the live webcast and the accompanying presentation materials on Precision's website https://investor.precisionbiosciences.com/events-and-presentations in the Investors and Media section under Events and Presentations. An archived replay of the webcast will be available on Precision's website for approximately 30 days.

**About PBCAR0191 (Clinical Trials Study Identifier: NCT03666000)**
PBCAR0191 is an investigational allogeneic CAR T in a Phase 1/2a clinical trial for the treatment of patients with R/R NHL and R/R B-ALL. PBCAR0191 was designed using Precision BioSciences’ novel and proprietary ARCUS® genome editing platform. It has been granted Fast Track Designation by the FDA for the treatment of R/R B-ALL. Precision also holds Orphan Drug Designation from the FDA for this program in mantle cell lymphoma, an aggressive subtype of NHL.

In December 2020, Precision BioSciences reported positive interim results from this study, in which 27 patients with R/R NHL or R/R B-ALL were dosed with PBCAR0191 CAR T therapy and showed no graft versus host disease, no grade ≥ 3 cytokine release syndrome, and no grade ≥ 3 neurotoxicity. For those NHL and B-ALL patients dosed with PBCAR0191, when combined with eLD, objective response rates reached 83% (5/6).

**About PBCAR19B (Clinical Trials Study Identifier: NCT04649112)**
PBCAR19B is a next-generation, stealth cell candidate for patients with CD19-positive malignancies such as R/R NHL. PBCAR19B is designed to improve the persistence of allogeneic CAR T cells following infusion by reducing rejection by T cells and NK cells. In addition to the CAR gene, the PBCAR19B stealth cell vector carries a short hairpin RNA that suppresses expression of beta-2 microglobulin, a component of Class I Major Histocompatibility Complex (MHC) molecules found on the cell surface. Reducing or

[1] Fludarabine (30 mg/$m^2$/day for 4 days) and cyclophosphamide (1000 mg/$m^2$/day for 3 days)

knocking-down Class I MHC expression on allogeneic CAR T cells has been shown to reduce CAR T cell killing by cytotoxic T cells. The PBCAR19B vector also carries an HLA-E gene intended to reduce rejection of CAR T cells by NK cells that can be stimulated as a result of reduced MHC molecule expression on the cell surface.

**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.

**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 potential milestone payments under the purchase agreement with Servier, the expected timing of trials and results from clinical studies of CAR T product candidates and in vivo gene editing programs, and expectations regarding our liquidity, anticipated cash payments and our ability to fund operations. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe," "could," "eligible," "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 year ended December 31, 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 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.

**Investor Contact:**
Alex Kelly
Interim Chief Financial Officer
Alex.Kelly@precisionbiosciences.com

**Media Contact:**
Maurissa Messier
Senior Director, Corporate Communications
Maurissa.Messier@precisionbiosciences.com