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): January 25, 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 2.02. Results of Operations and Financial Condition.

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2020, Precision BioSciences, Inc. (the "Company") expects to report that it had $90 million in cash and cash equivalents as of December 31, 2020.

The information contained in this Item 2.02 of this Current Report on Form 8-K (the "Form 8-K") is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2020 and its results of operations for the three months and year ended December 31, 2020. The audit of the Company's financial statements for the year ended December 31, 2020 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 January 25, 2021, the Company announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application covering PBCAR19B, a next-generation, stealth cell, CD19 allogeneic chimeric antigen receptor T cell ("CAR T") product candidate for patients with relapsed/refractory ("R/R") Non-Hodgkin Lymphoma ("NHL"). 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.

The information contained in this Item 7.01 (including Exhibit 99.1) of the Form 8-K 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 be deemed to be incorporated by reference into any filing of the Company under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On January 19, 2021, the Company announced that the U.S. Federal Drug Administration accepted the Company's Investigational New Drug application for PBCAR19B. This Phase 1 study will be a non-randomized, open-label, single-dose, dose-escalation and dose-expansion study deigned to evaluate the safety and clinical activity of PBCAR19B at increasing flat dose levels (2.7×10^8 - 8.1×10^8 CAR T cells) in patients with R/R NHL. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities.

Additionally, on January 21, 2021, the Company received from Eli Lilly and Company ("Lilly") the upfront cash payment of $100 million pursuant to the previously announced collaboration and exclusive license agreement entered into between Lilly and the Company. The Company believes that its expected cash and cash equivalents as of December 31, 2020, its expected operational receipts, the upfront payment from Lilly and its available credit will enable it to fund its operating expenses and capital expenditure requirements into 2023.

On January 25, 2021, the Company announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application covering PBCAR19B. The allowed composition claims of U.S. Patent Application No. 16/908,030 encompass genetically-modified human T cells comprising the Company's PBCAR19B construct, which is inserted within the T cell receptor alpha constant locus. Once issued, patents arising from this patent family will have standard expiration dates in April 2040.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's expected financial results and

cash runway. Forward-looking statements may be identified 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 September 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 Form 8-K 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Precision BioSciences, Inc. Press Release, dated January 25, 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: January 25, 2021

By: /s/ Dario Scimeca
Dario Scimeca
General Counsel

Precision BioSciences Receives Notice of Allowance for U.S. Patent Application Covering PBCAR19B, a Stealth Cell, CD19 Allogeneic CAR T Candidate for Non-Hodgkin Lymphoma

DURHAM, N.C., January 25, 2021 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL) a clinical stage biotechnology company dedicated to improving life with its wholly proprietary ARCUS® genome editing platform, today announced it has received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application covering PBCAR19B, a next-generation, stealth cell, CD19 product candidate for patients with relapsed/refractory (R/R) Non-Hodgkin Lymphoma (NHL).

The allowed composition claims of U.S. Patent Application No. 16/908,030 encompass genetically-modified human T cells comprising the Company's PBCAR19B construct, which is inserted within the T cell receptor alpha constant (TRAC) locus. Once issued, patents arising from this patent family will have standard expiration dates in April 2040.

"This patent, when issued, will cover important design elements of our PBCAR19B stealth cell candidate, which is engineered to knock down expression of beta-2 microglobulin to reduce killing of CAR T cells by cytotoxic T cells, and to reduce CAR T cell rejection by natural killer cells," said Derek Jantz, Ph.D., Chief Scientific Officer and Co-Founder of Precision BioSciences. "Additionally, PBCAR19B CAR T cells are generated using a single gene editing step by inserting one cassette, encoding all the necessary elements, into the TRAC locus. Not only will this patent strengthen our intellectual property portfolio, it will further distinguish our ARCUS-based allogeneic CAR T development approach."

About PBCAR19B

PBCAR19B is a next-generation, stealth cell candidate for patients with CD19-positive malignancies such as relapsed/refractory Non-Hodgkin Lymphoma. PBCAR19B is designed to improve the persistence of allogeneic CAR T cells following infusion by reducing rejection by T cells and natural killer (NK) cells. In addition to the CAR gene, the stealth vector includes a short hairpin RNA (shRNA) that suppresses expression of beta-2 microglobulin (B2M), a component of Class 1 major histocompatibility complex (MHC) molecules found on the cell surface. Reducing or knocking down Class 1 MHC expression on allogeneic CAR T cells has been shown to reduce CAR T cell killing by cytotoxic T cells. The stealth 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. The U.S. Food and Drug Administration has accepted the Investigational New Drug application for PBCAR19B, and the Phase 1 clinical study is expected to begin by mid-2021.

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 Servier
Under the terms of the agreement with Servier, Precision is solely responsible for early-stage research activities as well as PBCAR0191 Phase 1/2a and PBCAR19B Phase 1 clinical trial execution and clinical supply. 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 expected commencement of a Phase 1 clinical trial for PBCAR19B, expected results from clinical trials involving PBCAR19B, and our patent portfolio and ARCUS-based allogeneic CAR T development approach. 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 September 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 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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