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): December 11, 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 8.01. Other Events.

On December 11, 2021, Precision BioSciences, Inc. (the "Company") issued a press release to announce program updates for its allogeneic chimeric antigen receptor T cell ("CAR T") cell therapy pipeline, including updated data for the Company's Phase 1/2a clinical study of PBCAR0191 with enhanced lymphodepletion[1] ("eLD") presented at the 63rd American Society of Hematology ("ASH") Annual Meeting.

PBCAR0191

The updated data from the Company's PBCAR0191 Phase 1/2a study targeting CD19 for the treatment of Relapsed/Refractory ("R/R") non-Hodgkin lymphoma ("NHL") or R/R B-cell precursor acute lymphoblastic leukemia ("B-ALL") included 22 (17 NHL, 5 B-ALL) heavily pre-treated R/R subjects with predominantly advanced or aggressive B-cell malignancies who were evaluable as of November 16, 2021. Evaluable subjects received a median 5 lines of prior treatment, including 27% (6/22) who previously received a CD19-directed autologous CAR T.

For patients that received treatment of PBCAR0191 following eLD as of November 16, 2021:

- PBCAR0191 showed no ≥ Grade 3 cytokine release syndrome ("CRS"), one Grade 3 immune effector cell-associated neurotoxicity syndrome ("ICANS") with resolution to ≤ Grade 2 in 72 hours, no evidence of graft-versus-host disease, and one infectious death at Day 54 deemed possibly related to treatment[2]
- PBCAR0191 yielded overall response rate of 73% and complete response rate of 59% using a 3 x 10^6 cells/kg cell dose
- Four responders among the 17 evaluable NHL subjects reached Day 180 durability assessment

Most notably, a potential signal for PBCAR0191 was observed among six subjects that previously received an autologous CAR T:

- 100% of these patients responded and 66% experienced a complete response at ≥ Day 28
- More than half of these patients had a longer duration of response on PBCAR0191 than with the prior autologous CAR T treatment

Currently, there are no U.S. Food and Drug Administration ("FDA") approved therapeutics for lymphoma patients who have relapsed following autologous CAR T therapy. PBCAR0191 has the potential to be developed as a salvage treatment for this growing population with high unmet need. The Company is actively enrolling additional patients in this relapse setting to further evaluate this observed activity.

PBCAR19B

The Company's Phase 1 clinical study of PBCAR19B is actively enrolling subjects with R/R NHL. Flat doses of PBCAR19B CAR T cells following standard lymphodepletion[3] ("sLD") are administered starting at Dose Level 1 (2.7×10^8 CAR T cells). The Company has dosed the first three subjects at Dose Level 1 and expects to share initial results from the PBCAR19B program in mid-2022.

PBCAR19B is a novel immune-evading stealth cell candidate employing a single-gene edit to knock-down beta-2 microglobulin designed for evading T cell rejection, while also inserting an HLA-E transgene to further evade rejection from natural killer cells. The Company's CAR T cell candidates are the only allogeneic CAR T cells in human clinical trials made with a single gene editing step designed to specifically avoid the potentially deleterious effects of making multiple edits to T cells.

PBCAR269A

PBCAR269A is an investigational allogeneic CAR T immunotherapy targeting B-cell maturation antigen for the treatment of R/R multiple myeloma. The following has been observed among 14 patients that have been evaluated for clinical activity and safety across four dose levels of PBCAR269A[4] monotherapy following sLD.

- No Grade ≥ 3 CRS or ICANS
- Dose-dependent increase in PBCAR269A peak expansion

Overall, the PBCAR269A monotherapy response observed in the Phase 1/2a trial was not comparable with autologous CAR T profiles. Therefore, the Company is continuing to enroll subjects with PBCAR269A in combination with nirogacestat, a gamma secretase inhibitor developed by SpringWorks Therapeutics, in pursuit of a potential therapeutic index comparable with or better than autologous CAR T. Initial clinical data from the combination cohort is expected to be presented in mid-2022.

The Company's balance of cash and cash equivalents was approximately $152 million as of November 30, 2021. The Company continues to expect that existing cash and cash equivalents, expected operational receipts, and available credit will be sufficient to fund its operating expenses and capital expenditure requirements into 2023.

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 further development and potential of our CAR T cell therapy pipeline. 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, 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.

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[1] eLD = Fludarabine (30 mg/m^2/day × 4 days) and cyclophosphamide (1000 mg/m^2/day × 3 days)

[2] One death among subjects in ongoing complete response deemed potentially related to treatment by investigator (as previously disclosed); three deaths

among subjects in ongoing complete response deemed unrelated to treatment

[3] sLD = Fludarabine (30 mg/m^2/day × 4 days) and cyclophosphamide (1000 mg/m^2/day × 3 days)

[4] Dose Level 1= 0.6×10^6 cells/kg; Dose Level 2 = 2×10^6 cells/kg; Dose Level 3 = 6×10^6 cells/kg; Dose Level 4 = 960 $x10^6$ cells flat dose

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: December 13, 2021

By: /s/ John Alexander Kelly
John Alexander Kelly
Chief Financial Officer