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): March 10, 2020

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 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 March 10, 2020, Precision BioSciences, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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.

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 March 10, 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.

PRECISION BIOSCIENCES, INC.

Date: March 10, 2020

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

Precision BioSciences Reports Fourth Quarter and Fiscal Year 2019 Financial Results and Provides Business Update

-Presented initial clinical data for lead allogeneic CAR T program PBCAR0191 for the treatment of NHL and B-ALL-

-Implemented amendment to PBCAR0191 Phase 1/2a trial focused on optimizing clinical activity, CAR T cell expansion and persistence-

-Received FDA IND clearance and Orphan Drug Designation for two additional wholly-owned allogeneic CAR T programs targeting CD20 and BCMA; expect clinical trials to begin in 2020-

-Announced first wholly-owned in vivo gene correction program targeting primary hyperoxaluria type 1 (PH1), a rare genetic disease; expect clinical candidate to be selected in 2020-

-Achieved proof-of-concept for Elo Life Systems' ZeroMelon™ zero calorie watermelon-based sweetener program; expect to move to greenhouse trials in 2020-

DURHAM, NC, March 10, 2020 -- Precision BioSciences, Inc. (Nasdaq: DTIL) ("Precision"), a life sciences company dedicated to improving life through the application of its pioneering, proprietary ARCUS® genome editing platform, today announced financial results for the fourth quarter and fiscal year ended December 31, 2019, and provided a business update.

"The considerable progress we made in 2019, our first year as a public company, positions Precision BioSciences to further accelerate development across all areas of our portfolio," commented Matt Kane, CEO and co-founder of Precision BioSciences. "We now have three clinical-stage allogeneic CAR T candidates in development for the treatment of NHL, B-ALL, CLL/SLL and multiple myeloma, and have the clinical team and resources to focus on rapidly advancing these programs. We look forward to providing meaningful updates on their progress during 2020. Over the past year, we also built and opened our first-in-class cGMP-compliant manufacturing facility, advanced our partnered and wholly-owned *in vivo* gene-correction programs, and achieved validating milestones at our food-focused subsidiary, Elo Life Systems. I am very proud of the achievements of the entire Precision team in 2019 and am excited to continue this impressive pace of progress in 2020."

Recent Developments and Upcoming Milestones

Allogeneic CAR T portfolio

Presented initial clinical data for lead CD19-targeted allogeneic CAR T candidate PBCAR0191; dose escalation continuing on-track with further updates expected during 2020. IND applications cleared for wholly-owned CD20 and BCMA targeted CAR T programs. PBCAR20A clinical trial set to begin at higher dose level, accelerating development

- On December 9, 2019, Precision presented initial results from the ongoing Phase 1/2a trial of its lead allogeneic chimeric antigen receptor (CAR) T product candidate, PBCAR0191. Data included adult patients with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) or R/R B-cell precursor acute lymphoblastic leukemia (B-ALL) treated at the lowest two dose levels (Dose Level 1, $3x10^5$ cells/kg; Dose Level 2, $1x10^6$ cells/kg). No dose-limiting toxicities or cases of graft-versus-host disease were observed. Early evidence of dose dependent, cell-mediated anti-cancer activity was observed. In the NHL cohort, four out of six patients treated across Dose Levels 1 and 2 achieved an objective response at day 28+, for an objective response rate of 67%. Two of three NHL patients treated at Dose Level 1 achieved partial responses at day 28+. Responses at day 28+ were seen to deepen in the three NHL patients treated at Dose Level 2, with one patient achieving a complete response and one patient achieving a partial response. In the B-ALL cohort, one of three patients treated at Dose Level 2 achieved a complete response at day 28+; the remaining two B-ALL patients with progressive disease had high disease burden and poor prognostic indicators on entry into the trial.
- The PBCAR0191 trial is ongoing and dosing is progressing as planned. Based on the data observed at Dose Levels 1 and 2, and after discussion with the U.S Food and Drug Administration (FDA), Precision recently implemented an amendment to the PBCAR0191 trial protocol designed to further optimize clinical activity. The amended trial design is intended to specifically address key clinical questions. These include assessing the impact of higher total doses of cells on clinical activity and/or the impact of modified lymphodepletion on the ability to achieve durable clinical benefit with associated CAR T cell expansion and persistence.
    - The most important modification is the inclusion of two additional dose levels: Dose Level 4 ($6x10^6$ cells/kg) and Dose Level 5 ($9x10^6$ cells/kg). These higher doses will employ a split dosing strategy following a single lymphodepletion, with the intention of optimizing clinical activity, while preserving a favorable safety profile. Dose Level 4 will comprise two infusions of $3x10^6$ cells/kg, and Dose Level 5 will comprise three such infusions.
    - In addition, Precision now has the option to increase or decrease the doses of fludarabine and cyclophosphamide used in the lymphodepletion protocol if data suggest that CAR T cell rejection limits efficacy.
    - The final modification allows for the option to re-dose patients following evidence of clinical response but with subsequent disease progression.
- Precision expects to announce additional clinical data from the PBCAR0191 trial for both the NHL and B-ALL cohorts during 2020. PBCAR0191 is being developed in collaboration with Servier, an international pharmaceutical company.
- In September 2019, the FDA cleared the Investigational New Drug (IND) application for PBCAR20A, Precision's second and wholly-owned CAR T therapy candidate, which is expected to enter the clinic in Q1 2020. Based on the safety profile so far observed for PBCAR0191, the FDA has permitted Precision to begin dosing with PBCAR20A at Dose Level 2 ($1x10^6$ cells/kg), which is expected to accelerate the trial. PBCAR20A is an allogeneic anti-CD20 CAR T therapy candidate in development for the treatment of (1) NHL and (2) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). PBCAR20A has received Orphan Drug Designation from the FDA for the treatment of mantle cell lymphoma.
- In January 2020, the FDA also cleared Precision's IND application for its third CAR T therapy candidate, PBCAR269A, which is also wholly-owned by Precision and which targets BCMA for the treatment of patients with multiple myeloma. PBCAR269A has received Orphan Drug Designation from the FDA, and dosing of patients in a Phase 1/2a clinical trial is expected to begin in 2020.

***In vivo* gene correction portfolio**

Lead in vivo gene correction program identified, clinical candidate selection expected in 2020

- In January 2020, Precision announced that it expects to advance its first wholly-owned *in vivo* gene correction program for the treatment of primary hyperoxaluria type 1 (PH1), a rare genetic disease. In collaboration with Dr. Jim Wilson's group at the University of Pennsylvania, Precision has generated encouraging preclinical data demonstrating that one-time administration of an ARCUS nuclease can efficiently knock out the validated target gene HAO1 in hepatocytes of non-human primates, and can reduce urine oxalate, a known PH1 biomarker, by up to 70% in a mouse model. In 2020, Precision expects to select a clinical candidate for this program to advance into human trials.
- In partnership with Gilead, Precision is developing an *in vivo* gene correction program to potentially cure chronic infection with the hepatitis B virus. Submission of an IND for this product candidate is currently targeted for 2021.

Elo Life Systems

Advanced Elo Life Systems' key food and agriculture programs

- Elo's partnered program with Cargill focuses on developing canola oil with ultra-low saturated fatty acids. In 2019, the partnership was able to demonstrate progress towards the goal of achieving a product with <2.5% saturate levels. The program remains ongoing to further reduce saturate levels.
- In 2020, Elo expects to advance its ZeroMelon™ program to develop sustainable and scalable alternatives for zero-calorie sweeteners.

Corporate activities

In-house cGMP-compliant manufacturing facility opened and operational. Enhanced leadership team, Board of Directors and Scientific Advisory Board

- In July 2019, Precision announced the opening of its in-house Current Good Manufacturing Practice (cGMP) compliant manufacturing facility, located in Research Triangle Park, North Carolina. The Manufacturing Center for Advanced Therapeutics (MCAT) is designed to manufacture clinical trial material for Precision's planned Phase 1/2 clinical trials starting in 2020, beginning with its BCMA CAR T program. In the longer term, Precision believes MCAT has the potential to be a commercial launch facility. MCAT is expected to provide various operational and strategic advantages to the company as its CAR T and gene correction portfolios continue to progress.
- Precision made key appointments to its leadership team in 2019, including Chris Heery, MD, Chief Medical Officer; Dario Scimeca, General Counsel; and Nicholas Riddle, MD, PhD, Vice President, Financial Strategy and Investor Relations. In addition, David Thomson, PhD, was appointed to the position of Chief Operating Officer after serving as Precision's Chief Development Officer since 2017.
- Precision added new members to its Board of Directors in 2019, including Kevin J. Buehler, former CEO of Alcon Laboratories, and Raymond Schinazi, PhD, Hon DSc, the Frances Winship Walters Professor of Pediatrics and Director of the Laboratory of Biochemical Pharmacology at Emory University.
- Precision formed a Scientific Advisory Board of leading experts in immuno-oncology and infectious disease, including Raymond Schinazi, PhD; Kenneth C. Anderson, MD, the program director of the Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics at the Dana-Farber Cancer Institute; Hagop Kantarjian, MD, Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center; and Cameron Turtle, MBBS, PhD, Associate

Member at Fred Hutchinson Cancer Research Center and Associate Professor at the University of Washington.

Upcoming Corporate Presentations
Precision's senior leadership team will be participating in the following upcoming conferences:

- Barclays Global Healthcare Conference, March 12, 2020
- H.C. Wainwright Global Life Sciences Investor Conference, April 21, 2020 in London, UK
- Jefferies 7th Annual Cell Therapy Summit, April 30, 2020 in New York, NY

Fiscal Year 2019 Financial Results

Cash and Cash Equivalents: As of December 31, 2019, Precision had approximately $180.9 million in cash and cash equivalents. The Company expects that existing cash and cash equivalents will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2021.

Revenues: Total revenues for the year ended December 31, 2019 were $22.2 million, compared to $10.9 million for the year ended December 31, 2018. This increase was primarily due to research funding from Precision's joint development collaboration partners.

Research and Development Expenses: Research and development expenses were $82.4 million for the year ended December 31, 2019, as compared to $45.1 million for the same period in 2018. This increase of $37.3 million was primarily due to increases in platform development and early stage research expenses, including increases in personnel costs, laboratory supplies and services and expenses to support Precision's technology platform development and manufacturing capabilities.

General and Administrative Expenses: General and administrative expenses were $27.0 million for the year ended December 31, 2019, as compared to $13.7 million for the same period in 2018. The increase of $13.3 million was primarily due to an increase in employee-related costs for additional personnel and facility costs associated with the Company's growing infrastructure needs.

Net Loss: Net loss was $92.9 million, or $(2.21) per share, for the year ended December 31, 2019, compared to a net loss of $46.0 million, or $(2.92) per share, for the same period in 2018.

About Precision BioSciences, Inc.
Precision BioSciences is dedicated to improving life (DTIL) through its proprietary genome editing platform, ARCUS. Precision leverages ARCUS in the development of its product candidates, which are designed to treat human diseases and create healthy and sustainable food and agriculture solutions. Precision is actively developing product candidates in three innovative areas: allogeneic CAR T immunotherapy, *in vivo* gene correction, and food. For more information regarding Precision, 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

Information contained in this press release contains forward-looking statements. All statements other than statements of present and historical facts contained in this press release, including without limitation: the timing of trials and results from clinical studies of our CAR T product candidates and our *in* vivo gene correction program; the efficacy of our ARCUS® genome editing technology; the capabilities of our cGMP manufacturing facility; and the timing of Elo's ZeroMelon™ program and greenhouse trials, and expectations regarding our liquidity and ability to fund operating expenses and capital expenditure requirements may be forward looking statements. Without limiting the foregoing, the words "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "may," "will," "would," "potential," the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements reflect various assumptions of Precision's management that may or may not prove to be correct. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's 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 factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding; our limited operating history; our ability to identify, develop and commercialize our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; our or our collaborators' ability to identify, develop and commercialize product candidates; our or our collaborators' ability to advance product candidates into, and successfully complete, clinical or field trials; our or our collaborators' ability to obtain and maintain regulatory approval of future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the regulatory landscape that will apply to our and our collaborators' development of product candidates; our ability to achieve our anticipated operating efficiencies as we commence manufacturing operations at our new facility; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; the success of our existing collaboration agreements; our ability to enter into new collaboration arrangements; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; potential manufacturing problems associated with any of our product candidates; potential liability lawsuits and penalties related to our technology, our product candidates and our current and future relationships with third parties; and other important factors discussed under the caption "Risk Factors" in our quarterly report on Form 10-Q filed for the quarterly period ended September 30, 2019, as such factors may be updated from time to time in our other filings with the SEC, including, but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, 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 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.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	For the Years Ended December 31,	
	2019	2018
Revenue	$ 22,238	$ 10,883
Operating expenses		
Research and development	82,416	45,122
General and administrative	27,026	13,673
Total operating expenses	109,442	58,795
Loss from operations	(87,204)	(47,912)
Other income (expense), net:		
Change in fair value of convertible note payable	(9,758)	—
Interest expense	(182)	—
Interest income	4,267	1,875
Total other income (expense), net	(5,673)	1,875
Net loss and net loss attributable to common stockholders	$ (92,877)	$ (46,037)
Net loss per share attributable to common stockholders-basic and diluted	$ (2.21)	$ (2.92)
Weighted average shares of common stock outstanding-basic and diluted	41,991,162	15,775,541

Precision Biosciences, Inc.
Consolidated Balance Sheets Data
(In thousands)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 180,886	$ 103,193
Working capital	166,740	101,600
Total assets	235,233	138,600
Total stockholders' equity	$ 138,314	$ 39,960