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): August 12, 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 Operation and Financial Condition.

On August 12, 2021, Precision BioSciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021. 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.

Item 7.01. Regulation FD Disclosure.

The Company has updated its corporate deck, which is available in the "Investors & Media" portion of the Company's website at https://investor.precisionbiosciences.com.

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 August 12, 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: August 12, 2021

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

Exhibit 99.1

Precision BioSciences Reports Second Quarter 2021 Financial Results and Provides Business Update

- *Presented Interim Data Showing PBCAR0191 with Enhanced Lymphodepletion Yielded Overall Response Rate of 75% and Complete Response Rate of 50% at Day ≥ 28*

- *Dosed First Patient in CD19-Targeted Phase 1 Clinical Trial with PBCAR19B Immune-Evading Stealth Cell*

- *Precision to Host First In Vivo Gene Editing Event on September 9, 2021*

DURHAM, N.C., August 12, 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 financial results for the second quarter ended June 30, 2021 and provided a business update.

"In the second quarter of 2021, we continued to execute on our ARCUS-edited allogeneic CAR T programs, including our anti-CD19 studies. We continue to monitor for durability of response for our PBCAR0191 dosing protocol with enhanced lymphodepletion following the interim results presented in
June 2021. We also dosed the first patient in our Phase 1 study of PBCAR19B, our next-generation anti-
CD19 candidate designed to evade the immune system by avoiding both T and NK cell rejection," said Matt Kane, Chief Executive Officer at Precision BioSciences. "This quarter we also advanced our preclinical *in vivo* gene editing programs and look forward to sharing more about our development strategy and plans to advance select *in vivo* programs into the clinic at our upcoming gene editing event in September."

Recent Developments and Upcoming Milestones:

Allogeneic CAR T Portfolio:

PBCAR0191: In June 2021, Precision reported updated data for its lead anti-CD19 CAR T candidate,
PBCAR0191. As of May 21, 2021, 18 subjects with Relapsed/Refractory (R/R) non-Hodgkin lymphoma (NHL) completed Day 28 evaluation and received either enhanced lymphodepletion (eLD, n=12) or standard lymphodepletion (sLD, n=6) with Dose Level 3 (3.0×10^6 cells per kg) of PBCAR0191. After a single dose of PBCAR0191 following eLD, overall response rates and complete response rates were 75% and 50%, respectively, at Day ≥ 28. Five of nine responding patients (56%) who received PBCAR0191 cells following eLD remained progression-free, including 4/9 evaluable subjects with responses lasting greater than 4 months. PBCAR0191 with eLD continues to show acceptable tolerability with no evidence of graft versus host disease (GvHD) and with a similar frequency of immune effector cell-associated neurotoxicity syndrome (ICANS) and cytokine release syndrome (CRS) compared to patients who received sLD. A subset of this data set was presented at ASCO 2021.

PBCAR19B: In July 2021, Precision announced that the first patient in the Phase 1 study of PBCAR19B, the Company's anti-CD19 immune-evading stealth cell candidate for patients with R/R NHL. PBCAR19B is being administered at flat dose levels, with the first dose level (2.7×10^8 CAR T cells per patient) comparable to Dose Level 3 of PBCAR0191. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities.

PBCAR20A: Precision has completed Dose Level 3 (4.8×10^8 cells per patient given as a fixed dose) of its Phase 1/2a anti-CD20 study of PBCAR20A and has paused the study until PBCAR0191 and PBCAR19B durability is demonstrated. Precision expects to provide an interim update for PBCAR20A in 2021.

PBCAR269A: Precision continues to enroll patients in its Phase 1/2a study of PBCAR269A targeting B-cell maturation antigen (BCMA) for patients with R/R multiple myeloma. In June 2021, Precision announced that it dosed the first patient in its combination arm with PBCAR269A and nirogacestat, a gamma secretase inhibitor (GSI) being developed by SpringWorks. Emerging preclinical and clinical data suggest that a GSI may increase antitumor efficacy of BCMA-targeted autologous CAR T therapy in patients with relapsed or refractory multiple myeloma. Precision expects to provide an interim update on the monotherapy arm of the study in 2021.

PBCAR269B: In April 2021, Precision announced it started conducting IND-enabling studies for PBCAR269B, its next-generation immune-evading stealth cell candidate targeting BCMA.

***In Vivo* Gene Correction Portfolio:**

ARCUS to Target Mitochondrial DNA: In June 2021, Precision announced a paper was published in *Nature Communications* and highlighted the use of ARCUS genome editing to target mutant mitochondrial DNA. Led by Carlos T. Moraes, Ph.D., Esther Lichtenstein Professor in Neurology at the University of Miami Miller School of Medicine, with Ugne Zekonyte as first author, researchers reported effective use of a mitochondrial-targeted ARCUS nuclease (mitoARCUS) to edit mutant mtDNA. This is the first time ARCUS has been used to edit outside the nuclear genome and has done so with encouraging safety and efficacy in this mouse model. These results were also discussed during the United Mitochondrial Disease Foundation's Mitochondrial Medicine 2021 Virtual "Meet the Scientific Program Faculty" in June 2021.

Gene Editing Event: Precision will host its first *in vivo* focused gene editing event on Thursday, September 9, 2021. The virtual event will include presentations on the Company's *in vivo* gene editing business strategy, including pipeline development plans and timelines to the clinic for certain gene editing programs such as its wholly-owned PH1 program. The virtual event is expected to last approximately two hours and will be a live video webcast available through the Company's website. Additional details for the event will follow.

Corporate:

Executive Leadership: In May 2021, Precision announced that Alex Kelly had been appointed as Chief Financial Officer, a role in which he had served in an interim capacity since January 2021. Alex oversees Precision's finance, corporate communications, investor relations, IT, facilities and operations functions. Shane Barton, the Company's Vice President and Corporate Controller, had been serving as interim principal accounting officer and will now serves as principal accounting officer.

Elo Life Systems:

Corporate Structure: Precision continues to explore strategic options and expects to complete any such spinout, sale or other treatment of Elo in 2021.

Quarter Ended June 30, 2021 Financial Results

Cash and Cash Equivalents: As of June 30, 2021, Precision had approximately $173.9 million in cash and cash equivalents. The Company expects 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.

Revenues: Total revenues for the second quarter ended June 30, 2021 were $68.8 million, as compared to $1.1 million for the same period in 2020. The increase of $67.7 million in revenues during the three months ended June 30, 2021 was primarily the result of a $62.0 million increase in revenue recognized under the Servier Agreement, as the performance obligation was deemed fully satisfied upon the execution of the Program Purchase Agreement. In the second quarter, the Company also recognized $5.3 million in revenue under the Lilly Agreements, compared to no revenue for the same period in 2020, as work commenced in 2021.

Research and Development Expenses: Research and development expenses were $37.2 million for the quarter ended June 30, 2021, as compared to $25.2 million for the same period in 2020. The increase of $12.0 million in research and development expenses was primarily the result of $11.3 million in expense related to the Servier Program Purchase Agreement that was recognized in the quarter ended June 30, 2021.

General and Administrative Expenses: General and administrative expenses were $9.9 million for the quarter ended June 30, 2021, as compared to $8.7 million for the same period in 2020.

Net Income (loss): Net income was $21.7 million, or $0.38 per share (basic) and $0.36 per share (diluted), for the quarter ended June 30, 2021, as compared to a net loss of ($32.7 million), or $(0.63) per share (basic and diluted) for the same period in 2020. Weighted average common shares outstanding for the quarter ended June 30, 2021 were 57,739,622 (basic) and 59,841,638 (diluted), compared to 51,909,240 (basic and diluted) for the same period in 2020.

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 the clinical development of our product candidates, including the expected timing of an interim update regarding our PBCAR20A program, the expected timing of an IND filing for PBCAR269B, the expected timing of an update regarding our *in vivo* gene correction program, the potential clinical benefit of our allogeneic CAR T product candidates, the further development of our ARCUS platform, developments related to our expected spinout or other treatment of Elo Life Systems and expectations regarding our operational initiatives and our gene editing event. 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 March 31, 2021, as any such factors may be updated from time to time in our other filings with the SEC, including our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 to be filed with the SEC, and 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
Chief Financial Officer
Alex.Kelly@precisionbiosciences.com

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

Precision Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(unaudited)

	For the Three Months Ended June 30,	
	2021	**2020**
Revenue	$ 68,805	$ 1,078
Operating expenses		
Research and development	37,235	25,183
General and administrative	9,938	8,703
Total operating expenses	47,173	33,886
Operating income (loss)	21,632	(32,808)
Other income (expense):		
Interest expense	(24)	—
Interest income	48	107
Total other income, net	24	107
Net loss and net loss attributable to common stockholders	$ 21,656	$ (32,701)
Net income (loss) per share attributable to common stockholders		
Basic	$ 0.38	$ (0.63)
Diluted	$ 0.36	$ (0.63)
Weighted average common shares used in calculation of net income (loss) per share		
Basic	57,739,622	51,909,240
Diluted	59,841,638	51,909,240

	For the Six Months Ended June 30,	
	2021	**2020**
Revenue	$ 85,154	$ 8,076
Operating expenses		
Research and development	62,828	50,062
General and administrative	19,436	18,318
Total operating expenses	82,264	68,380
Operating income (loss)	2,890	(60,304)
Other income (expense):		
Interest expense	(24)	—
Interest income	101	767
Total other income, net	77	767
Net loss and net loss attributable to common stockholders	$ 2,967	$ (59,537)
Net income (loss) per share attributable to common stockholders		
Basic	$ 0.05	$ (1.15)
Diluted	$ 0.05	$ (1.15)
Weighted average common shares used in calculation of net income (loss) per share		
Basic	57,185,402	51,611,005
Diluted	59,647,367	51,611,005

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 173,943	$ 89,798
Working capital	152,053	62,735
Total assets	230,114	150,158
Total stockholders' equity	100,553	44,425