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): May 09, 2023

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)**

Registrant's Telephone Number, Including Area Code: 919 314-5512

(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.

On May 9, 2023, Precision BioSciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Precision BioSciences, Inc. dated May 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 9, 2023

By: /s/ John Alexander Kelly
John Alexander Kelly

Chief Financial Officer

Precision BioSciences Reports First Quarter 2023 Financial Results and Provides Business Update

- *Program Updates Planned for Azer-cel and PBCAR19B in May 2023*

- *Presented data on PBGENE-HBV program at Global Hepatitis Summit 2023; PBGENE-DMD program data update upcoming at ASGCT Conference*

- *In Vivo Gene Editing R&D Day Planned for Mid-2023*

- *Cash Balance Provides Expected Runway through Q1 2025*

DURHAM, N.C., May 9, 2023 -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *ex vivo* allogeneic CAR T and *in vivo* gene editing therapies, today announced financial results for the first quarter ended March 31, 2023 and provided a business update.

"Our progress in the first quarter of 2023 makes it clear that we are focused on the generation of meaningful clinical data from our CAR T programs while working in parallel to advance our broad *in vivo* portfolio into the clinic as soon as possible," said Michael Amoroso, Chief Executive Officer at Precision BioSciences. "We continue to collect data from our latest patient cohorts for both our azer-cel and PBCAR19B programs and anticipate providing an update once we have sufficient follow up from these cohorts. We expect that these data will inform key next steps for development and potential regulatory interactions."

"From our *in vivo* portfolio, we continue to leverage the core features of ARCUS that we believe drive high efficiency gene insertion and the ability to make large gene excisions while advancing programs where we see a clear and rapid path to the clinic. Preclinical data presentations at the Global Hepatitis Summit 2023 on hepatitis B virus (HBV) and an upcoming, late breaker oral presentation on Duchenne muscular dystrophy (DMD) at the American Society of Gene & Cell Therapy Meeting highlight key execution steps that have brought ARCUS closer to the clinic. We look forward to providing further updates across our wholly owned and partnered gene editing programs at our upcoming *in vivo* gene editing R&D Day in the middle of the year," added Mr. Amoroso.

***Ex Vivo* Allogeneic CAR T Portfolio:**

Azer-cel: Precision continues to progress its Phase 1/2a clinical trial of azer-cel, the Company's lead investigational anti-CD19 allogeneic CAR T candidate, in adult subjects with non-Hodgkin lymphoma (NHL) who have relapsed following CAR T treatment. Precision plans to provide an update on the expansion cohort as well as additional long-term follow up from the previously presented azer-cel cohorts in May 2023. As of May 1, 2023, seven patients have been treated in the expansion/Phase 2a cohort with a lower dose lymphodepletion regimen, in addition to the 12 patients who were treated in previous cohorts.

PBCAR19B: Precision continues to progress the ongoing Phase 1 study of PBCAR19B, its second generation, anti-CD19 targeting allogeneic CAR T candidate designed to evade immune rejection by host T cell and natural killer (NK) cells with a single-gene edit to knock-down beta-2 microglobulin and insert an HLA-E transgene. The Company also expects to provide a program update on seven patients treated at Dose Level 2 in May 2023.

***In Vivo* Gene Editing Portfolio:**

Chronic Hepatitis B Virus (HBV): Precision is prioritizing nomination of a development candidate for its wholly owned PBGENE-HBV *in vivo* program, with the goal of submitting a Clinical Trial Application (CTA) and/or Investigational New Drug Application (IND) in 2024. An abstract titled *"Targeting Hepatitis B cccDNA with a Sequence-Specific ARCUS Nuclease to Eliminate Hepatitis B Virus In Vivo"* was presented in April 2023 at the Global Hepatitis Summit 2023. Data showed that ARCUS demonstrated a high degree of on-target antiviral activity, as measured by substantial reductions of both intracellular cccDNA and secretion of HBsAg, with no detectable translocations in ARCUS-treated primary human hepatocytes. These data support the further development of PBGENE-HBV with the goal of developing a functional cure for HBV. The Company plans to present additional data in 2023.

Novartis Partnered Program: Precision continues to advance its gene editing program with Novartis to develop a custom ARCUS nuclease for patients with sickle cell disease and beta thalassemia. The collaborative intent is to insert, *in vivo*, a therapeutic anti-sickling gene as a potential one-time transformative treatment administered directly to the patient that would overcome many of the hurdles present today with other therapeutic technologies, including those targeting an *ex vivo* gene editing approach.

Prevail, a wholly-owned subsidiary of Lilly, Partnered Programs: Precision continues its *in vivo* gene editing collaboration with Prevail Therapeutics, a wholly-owned subsidiary of Eli Lilly and Company (Lilly), in applying ARCUS nucleases to three initial targets, including DMD in muscle, a central nervous system directed target, and a liver directed target. The goal of the PBGENE-DMD program is to utilize a pair of ARCUS nucleases, delivered by a single AAV, that are designed to excise an approximately 500,000 base pair mutation "hot spot" region from the dystrophin gene to generate a variant of the dystrophin protein that is functionally competent.

In April 2023, Precision announced that a late-breaking abstract featuring preclinical data from its PBGENE-DMD program for the potential treatment of DMD was selected for an oral presentation at the American Society of Gene & Cell Therapy (ASGCT) 26th Annual Meeting being held May 16-20, 2023 in Los Angeles, CA.

Ornithine Transcarbamylase (OTC) Deficiency: Led by iECURE, an ARCUS-mediated gene insertion approach is being pursued as a potential treatment for neonatal onset ornithine transcarbamylase (OTC) deficiency. Non-human primate (NHP) data presented by researchers from the University of Pennsylvania's Gene Therapy Program demonstrated sustained gene insertion of a therapeutic OTC transgene one-year post-dosing in newborn and infant NHP with high efficiency. iECURE is targeting to submit a CTA and/or IND in the second half of 2023.

Other ARCUS Research: Preclinical data presented at the Keystone Symposium in March 2023 demonstrated the unique potential of ARCUS nucleases to achieve high frequency gene insertion in nondividing primary hepatocytes. These data highlight the potential advantage of ARCUS for use in developing therapeutics for gene addition, for which Precision believes ARCUS is highly differentiated given the need for extremely low levels of off-target editing and high insertion efficiency.

Corporate:

Intellectual Property (IP) Update: In February 2023, the U.S. Patent and Trademark Office issued Precision a Notice of Allowance for an application with composition of matter claims covering a PCSK9-specific

ARCUS nuclease. This ARCUS nuclease has been used preclinically for both gene deletion approaches for cardiovascular diseases such as familial hypercholesterolemia as well as a viable and safe site to insert a functional copy of a specific gene to restore function addressing other diseases requiring gene addition. This patent further builds on the Company's IP portfolio that cover the ARCUS platform and its use developing novel *ex vivo* and *in vivo* gene editing therapies.

Quarter Ended March 31, 2023 Financial Results:

Cash and Cash Equivalents: As of March 31, 2023, Precision had approximately $158 million in cash and cash equivalents. In line with the same period for 2022, net cash used in operating activities for the quarter ended March 31, 2023 are expected to be higher in the first fiscal quarter than the remainder of 2023 primarily due to the timing of the Company's annual compensation cycle. 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 through the first quarter of 2025.

Revenues: Total revenues for the quarter ended March 31, 2023 were $8.8 million, as compared to $3.3 million for the same period in 2022. The increase of $5.5 million in revenue during the quarter ended March 31, 2023 was primarily driven by revenue recognized under the Novartis agreement as work thereunder began in the third quarter of 2022.

Research and Development Expenses: Research and development expenses were $22.2 million for the quarter ended March 31, 2023, as compared to $20.0 million for the same period in 2022. The increase of $2.2 million was primarily due to an increase in direct research and development expenses related to our azer-cel and PBCAR19B product candidates as well as consulting fees related to our increased focus on quality management, partially offset by a decrease in expenses related to manufacture of materials for use in preclinical studies, PBCAR20A external development costs, and share-based compensation expense from recent forfeitures.

General and Administrative Expenses: General and administrative expenses were $11.1 million for the quarter ended March 31, 2023, as compared to $10.7 million for the same period in 2022. The increase of $0.4 million was primarily related to consulting fees related to *in vivo* program competitive landscape analyses, partially offset by a decrease in insurance expense.

Net Loss: Net loss was $25.1 million, or $(0.23) per share (basic and diluted), for the quarter ended March 31, 2023, as compared to a net loss of $28.2 million, or $(0.46) per share (basic and diluted), for the same period in 2022. Weighted average shares of common stock outstanding were approximately 111.3 million for the quarter ended March 31, 2023, as compared to approximately 61.0 million for the quarter ended March 31, 2022. The increase in weighted average shares of common stock outstanding was primarily due to a $50 million underwritten offering of common stock and Novartis' $25 million equity investment in 2022.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform. ARCUS is a highly precise 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 ex vivo clinical candidates and several *in vivo* gene

editing candidates designed 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. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. 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, clinical development and expected efficacy and benefit of our product candidates and programs; timing and content of program and data updates; the expected timing of regulatory submissions and other communications; planned development activities with our collaboration partners; expectations about our operational initiatives, our business strategy and portfolio review; expectations regarding our liquidity and capital resources; the expected safety, efficacy, and benefit of our gene editing approaches including editing efficiency and differentiating aspects; and the suitability of ARCUS nucleases for gene insertion, large gene deletion, and other complex gene editing approaches and the utilization of safe harbor site strategies for therapeutic gene insertion. The words “aim,” “anticipate,” “approach,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “goal,” “intend,” “look,” “may,” “mission,” “plan,” “possible,” “potential,” “predict,” “project,” “promise,” “pursue,” “should,” “target,” “will,” “would,” and other similar words or expressions, or the negative of these words or similar words or expressions, are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions.

Forward-looking statements are based on management’s current expectations, beliefs and assumptions and on information currently available to us. These statements are neither promises nor guarantees, but involve 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; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators’ ability to identify, develop and commercialize product candidates; pending and potential product 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 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; our ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; 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; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of the COVID-19 pandemic and variants thereof, or any pandemic, epidemic, or outbreak of an infectious disease; 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; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price, and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the annual period ended December 31, 2022, as any such factors may be updated from time to time in our other filings with the SEC, including, but not limited to, our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, to be filed with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors page of our website under SEC Filings 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.

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

	For the Three Months Ended March 31,	
	2023	**2022**
Revenue	$ 8,780	$ 3,317
Operating expenses		
Research and development	22,158	19,972
General and administrative	11,086	10,680
Total operating expenses	33,244	30,652
Operating loss	(24,464)	(27,335)
Other (loss) income:		
Loss from equity method investment	(1,341)	(952)
Change in fair value of investment	(769)	—
Interest expense	(522)	(42)
Interest income	2,043	172
Loss on disposal of assets	(7)	(11)
Total other loss	(596)	(833)
Net loss and net loss attributable to common stockholders	$ (25,060)	$ (28,168)
Net loss per share attributable to common stockholders- basic and diluted	$ (0.23)	$ (0.46)
Weighted average shares of common stock outstanding- basic and diluted	111,301,409	61,031,775

Precision Biosciences, Inc.
Condensed Balance Sheets Data
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2023	**December 31, 2022**
Cash and cash equivalents	$ 158,132	$ 189,576
Working capital	122,158	139,441
Total assets	204,502	238,169
Total liabilities	164,325	177,736
Total stockholders' equity	$ 40,177	$ 60,433

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