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 04, 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 August 4, 2023, Precision BioSciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 4, 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: August 4, 2023

By: /s/ John Alexander Kelly
John Alexander Kelly

Chief Financial Officer

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

- *FDA Advice Provides Clarity on Future Development for Lead CAR T Program Candidate Azer-Cel; CAR T Partnering Discussions Ongoing*

- *Presented Preclinical Data Demonstrating Potential of ARCUS for Treatment of Duchenne Muscular Dystrophy and Chronic Hepatitis B*

- *Company plans to host In Vivo Gene Editing R&D Day on September 12, 2023*

- *Cash Balance Provides Expected Runway Through Q1 2025*

DURHAM, N.C., August 4, 2023 -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *in vivo* gene editing and *ex vivo* allogeneic CAR T therapies, today announced financial results for the second quarter ended June 30, 2023 and provided a business update.

“The first half of 2023 has been a busy time at Precision. Key updates have continued to elucidate the development and potential regulatory pathway for our ex vivo portfolio as well as demonstrate the potential of our proprietary ARCUS® genome editing platform as a differentiated technology for high efficiency in vivo gene insertion and excision,” said Michael Amoroso, Chief Executive Officer at Precision BioSciences. “Following our recent CAR T data update in May 2023 and subsequent Type B End of Phase 1 meeting with the U.S. Food and Drug Administration (FDA), we are actively engaging with potential partners to advance azer-cel and PBCAR19B to the next stage of development. As we prioritize organic development of our in vivo portfolio, we continue to generate supportive preclinical data to leverage the core features of ARCUS and advance differentiated programs to the clinic. We look forward to providing further updates across our in vivo programs at our upcoming gene editing R&D event in September.”

***Ex Vivo* Allogeneic CAR T Platform**

In July 2023, Precision received final meeting minutes from its June 2023 Type B meeting with the FDA for azer-cel. The objective of the meeting was to gain further clarity on the potential registration path for azer-cel including study design, endpoints, and the recommended phase 2 dose in the CAR T relapsed patient setting. The discussion with the FDA provided clarity on azer-cel development, including a potential pathway toward registration. Based on the advice received from the FDA and clinical data shared during the May 2023 CAR T update, Precision is currently advancing discussions with multiple potential strategic partners for its cell therapy assets, including hematologic and non-hematologic applications.

***In Vivo* Gene Editing Platform**

ARCUS may have broad utility in many diseases and the Company believes ARCUS is uniquely suited for *in vivo* gene editing, including the potential to produce a profound impact on diseases that are best treated by therapeutic gene insertion or excision of large defective gene sequences.

Chronic Hepatitis B: Precision is developing PBGENE-HBV for the treatment of patients with chronic hepatitis B with the goal of submitting a clinical trial application (CTA) and/or investigational new drug (IND) application in 2024. Hepatitis B virus (HBV) causes inflammation and damage to the liver, which can lead to chronic infection and increased risk of death from liver cancer or cirrhosis. There is no cure for chronic hepatitis B and current treatments rarely result in a functional cure, primarily due to persistence of viral DNA in the liver. In patients with chronic HBV infection, genetic material of the virus is converted

within infected liver cells into covalently closed circular DNA (cccDNA) that acts as a template to make HBV copies. HBV also inserts its DNA into the human genome of infected liver cells. This integrated HBV DNA is a primary source of the viral protein, hepatitis B surface antigen (HBsAg), which is secreted in the blood. The presence of HBsAg is associated with poorer outcomes, and elimination of HBsAg, along with loss of circulating HBV DNA, is necessary for achieving a functional cure of chronic hepatitis B. Using ARCUS, Precision scientists have generated a highly specific nuclease designed to eradicate chronic HBV infection. The Company believes PBGENE-HBV is the only approach designed to inactivate and immediately eliminate cccDNA with direct edits as well as to inactivate integrated HBV DNA with the goal of long-lasting reductions in HBsAg and HBV DNA.

In June 2023, the Company presented data at the European Association for Study of the Liver (EASL) Congress. In an episomal adeno-associated virus (AAV) mouse model, Company researchers demonstrated that administration of lipid nanoparticles containing mRNA encoding an HBV-targeted ARCUS nuclease resulted in a 96% reduction in serum HBsAg. In a follow-on experiment, treatment of HBV-infected primary human hepatocytes with the HBV-targeted ARCUS nuclease resulted in a 90% reduction of cccDNA and high specificity. The Company plans to present additional data during its in vivo gene editing R&D event in September and at subsequent scientific conferences in 2023.

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

Prevail Partnered Programs: Precision continues to progress its *in vivo* gene editing collaboration with Prevail Therapeutics, a wholly-owned subsidiary of Eli Lilly and Company, in applying ARCUS nucleases to three initial targets, including Duchenne muscular dystrophy (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 May 2023, the Company presented *in vivo* proof-of-concept data in preclinical models at the American Society of Gene & Cell Therapy (ASGCT) 26th Annual Meeting demonstrating the therapeutic potential of PBGENE-DMD, including excision and repair of large sections of DNA. Precision scientists observed the edited dystrophin variant in multiple tissue types frequently involved in progression of DMD, including skeletal muscle, heart, and diaphragm, enabling significant functional muscle improvement.

In June 2023, Precision and Prevail entered into an amended and restated development and license agreement to continue to collaborate on developing the Company’s ARCUS nucleases for potential in vivo therapies for genetic disorders. Precision will continue to oversee creation, selection, in vitro development, and optimization of ARCUS nucleases with respect to the gene targets subject to the collaboration. Prevail will oversee and fund preclinical research and IND-enabling activities which were previously to be conducted by the Company at its expense. Prevail retains responsibility for conducting clinical development and commercialization activities for products from the collaboration. The Company will be eligible to receive milestone payments of up to an aggregate of $390 million to $395 million per licensed product, a decrease from $420 million as provided in the Original Agreement. This change reflects Prevail’s increased involvement in pre-clinical activities.

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

Quarter Ended June 30, 2023 Financial Results:

Cash and Cash Equivalents: As of June 30, 2023, Precision had approximately $137.8 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 through the first quarter of 2025.

Revenues: Total revenues for the quarter ended June 30, 2023 were $19.8 million, as compared to $3.8 million for the same period in 2022. The increase of $16.0 million was the result of a $11.2 million increase in revenue recognized from Prevail, $10.7 million of which was the result of a cumulative catch -up adjustment under the amended development and license agreement, and an increase of $4.8 million in revenue recognized under the Novartis Agreement.

Research and Development Expenses: Research and development expenses were $21.9 million for the quarter ended June 30, 2023, as compared to $22.9 million for the same period in 2022. The decrease of $1.0 million was primarily due to decreases in PBCAR19B external development, outsourced research and development, employee-related costs, and contract manufacturing organization expenses partially offset by increases in *in vivo* external development and azer-cel external development costs.

General and Administrative Expenses: General and administrative expenses were $9.8 million for the quarter ended June 30, 2023, as compared to $10.4 million for the same period in 2022. The decrease of $0.6 million was primarily driven by a decrease in share-based compensation expense and expense management, including a reduction in director and officer insurance premiums.

Net Loss: Net loss was $11.9 million, or $(0.10) per share (basic and diluted), for the quarter ended June 30, 2023, as compared to a net loss of $31.0 million, or $(0.46) per share (basic and diluted), for the same period in 2022. Weighted average shares of common stock outstanding were approximately 114.1 million for the quarter ended June 30, 2023, as compared to approximately 68.0 million for the quarter ended June 30, 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 several *in vivo* gene editing candidates designed to cure genetic and infectious diseases where no adequate treatments exist and multiple *ex vivo* clinical candidates. 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 of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 and expected safety, efficacy and benefit of our product candidates and gene editing approaches including editing efficiency and differentiating aspects; 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 expected timing of updates regarding our allogenic CAR T and *in vivo* programs; the expected timing of regulatory processes; expectations about our operational initiatives and business strategy; expectations around partnership opportunities; expectations about achievement of key milestones; and expectations regarding our liquidity and capital resources. 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 to advance our programs; risks associated with raising additional capital and requirements under our current debt instruments and effects of restrictions thereunder; 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 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, as any such factors may be updated from time to time in our other filings with the Securities and Exchange Commission ("SEC"), including, but not limited to, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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 June 30,	
	2023	**2022**
Revenue	$ 19,789	$ 3,820
Operating expenses		
Research and development	21,946	22,936
General and administrative	9,830	10,438
Total operating expenses	31,776	33,374
Operating loss	(11,987)	(29,554)
Other income (expense):		
Loss from equity method investment	(1,369)	(1,448)
Interest expense	(553)	(178)
Interest income	1,946	192
Gain (loss) on disposal of assets	72	(47)
Total other income (expense)	96	(1,481)
Net loss and net loss attributable to common stockholders	$ (11,891)	$ (31,035)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.10)	$ (0.46)
Weighted average shares of common stock outstanding-basic and diluted	114,099,594	67,954,688

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

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 137,794	$ 189,576
Working capital	91,465	139,441
Total assets	181,697	238,169
Total liabilities	147,656	177,736
Total stockholders' equity	$ 34,041	$ 60,433

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