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 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 March 9, 2023, Precision BioSciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2022. 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 March 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: March 9, 2023

By: /s/ John Alexander Kelly
John Alexander Kelly

Chief Financial Officer

Precision BioSciences Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Update

- *Advanced ARCUS Gene Editing Development for Clinical and Research Programs; In Vivo Gene Editing R&D Day Planned for Mid-2023*

- *Progressed Azer-cel and PBCAR19B Allogenic CAR T Clinical Studies; Program Updates Planned for Azer-cel and PBCAR19B*

- *Advanced Wholly Owned, Preclinical PBGENE-HBV and Partnered DMD, Sickle Cell Disease, and OTC Programs; New Data Expected to be Presented/Published in 2023*

- *Cash Balance Provides Expected 2-Year Runway through Q1 2025*

DURHAM, N.C., March 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 fourth quarter and fiscal year ended December 31, 2022 and provided a business update.

"2022 proved to be a significant year for Precision as we made considerable progress on clinical, manufacturing, research, and collaboration fronts toward building an end-to-end gene editing company. Over the last year, Precision has invested in manufacturing optimization with our allogeneic CAR T therapies, which resulted in improved product candidate attributes in azer-cel, a potential first-in-class allogeneic CAR T treatment for patients who have relapsed following autologous CAR T treatment. In addition, following the platform-wide manufacturing optimization in 2022, we are continuing to dose subjects with PBCAR19B in its Phase 1 clinical study," said Michael Amoroso, Chief Executive Officer of Precision BioSciences. "I'm very proud of our team's work to align with the U.S. Food and Drug Administration (FDA) on the azer-cel chemistry, manufacturing and controls (CMC) package in late 2022 and look forward to providing updates on our allogeneic CAR T therapies as we progress towards key decision points on next steps for azer-cel and PBCAR19B."

Mr. Amoroso continued, "We have continued to leverage the ARCUS gene editing platform in progressing multiple *in vivo* gene editing programs, independently and with select partners such as Novartis, Lilly, and iECURE, with the goal of differentiating ARCUS on safety, high efficiency gene insertion, and complex edits aimed at restoring function for specific genetic diseases. We expect 2023 to be an important year as the first ARCUS nuclease for *in vivo* gene insertion is planned to move towards a Clinical Trial Application (CTA) and/or an Investigational New Drug (IND) application. We look forward to providing progress updates on our *in vivo* gene editing pipeline, including meaningful learnings with our partnered programs, and next steps from our strategic prioritization exercise at the R&D Day planned for mid-2023."

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

Favorable Type C feedback from FDA on azer-cel: In late 2022, the FDA provided supportive Type C feedback on the Company's CMC processes and analytical methods for azer-cel. Responses from the FDA on analytical methods, proposed potency assays, and manufacturing processes are further guiding clinical development. Regulatory dialogue is ongoing as the Company progresses azer-cel.

Trials Progressing for azer-cel and PBCAR19B: The Company plans to progress azer-cel to a decision point for a Phase 2 trial in non-Hodgkin lymphoma (NHL) subjects who have relapsed following

autologous CAR T treatment. Precision expects to complete the Phase 1b cohort for azer-cel to identify a dosing schedule for further study and plans to seek feedback from the FDA on the azer-cel clinical program once more data become available. The Company also plans to complete Phase 1 dose escalation for PBCAR19B in the earlier line NHL setting.

CAR T Portfolio Update: Precision plans to provide a CAR T update once investigators complete enrollment of the current azer-cel cohort of six CAR T relapsed subjects with sufficient follow-up to support a meeting with the FDA to discuss clinical plans. Subjects are being treated with optimized azer-cel product at the planned final dose level (500 million CAR T cells following a lymphodepletion regimen consisting of 3 days of fludarabine and cyclophosphamide). Based on current enrollment, the update is now expected to occur in the April/May 2023 time frame, once appropriate follow-up from the current cohort is available.

During the CAR T update, the Company plans to provide additional long-term follow up from the azer-cel cohorts presented at ASH 2021 and ASCO 2022, as well as data from subjects in the current cohort. The CAR T update is also expected to include interim efficacy and safety data from the PBCAR19B Phase 1 trial at Dose Level 2 (540 million CAR T cells following 3 days of fludarabine and cyclophosphamide) with an expectation of durability data to follow this year.

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

Precision believes *in vivo* gene editing applications are particularly well suited to ARCUS because they require extremely low levels of off-target editing and efficient delivery. Emerging preclinical data from Precision and partners continue to validate that ARCUS may be particularly advantageous for gene insertion and large gene excisions, both intended to restore function. ARCUS is also unique in its relatively small size which potentially allows delivery to a wider range of cells and tissues using both viral and non-viral gene delivery methods.

Chronic Hepatitis B Virus (HBV): For its *in vivo* gene editing portfolio, Precision is prioritizing nominating the final drug candidate for its wholly owned PBGENE-HBV *in vivo* program, with the goal of submitting a CTA and/or IND in 2024. Preclinical data published in 2022 showed that ARCUS efficiently targeted and degraded HBV cccDNA in HBV-infected primary human hepatocytes and reduced expression of HBV S-antigen ("HBsAg") by as much as 95%. Similar levels of HBsAg reduction were observed in a newly developed mouse model of HBV infection following administration of ARCUS mRNA using lipid nanoparticle delivery. The Company plans to present additional data in 2023.

Novartis Partnered Program: Precision continues to make significant progress in its 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, *in vivo*, a therapeutic transgene 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 that are targeting an *ex vivo* gene editing approach.

Lilly Partnered Programs: The partnered PBGENE-DMD program with Lilly targeting Duchenne muscular dystrophy (DMD) highlights the versatility of ARCUS for complex editing. Joint teams continue to make significant progress against preclinical objectives with the goal of using a pair of ARCUS nucleases to excise an often mutated "hot-spot" region of the dystrophin gene to restore dystrophin expression in DMD patients. In addition, the Company plans to present initial preclinical data for the DMD program in 2023.

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 file a CTA and/or IND in the second half of 2023. If accepted this would be the first ARCUS gene insertion program to be ready for human clinical trials and a major milestone for ARCUS *in vivo* gene editing.

The strategic prioritization exercise for Precision's *in vivo* research pipeline announced in November 2022 remains ongoing to assess diseases with highest unmet need in a dynamic regulatory and competitive gene editing landscape.

Quarter Ended December 31, 2022 Financial Results:

Revenues: Total revenues for the quarter ended December 31, 2022 were $10.6 million, as compared to $6.3 million for the same period in 2021. The increase of $4.3 million in revenue during the quarter ended December 31, 2022 was primarily the result of an increase of $6.0 million in revenue recognized under the Novartis Agreement offset by a decrease of $1.0 million from agriculture partnering collaborations and a timing related decrease of $0.7 million under the Lilly Agreement.

Research and Development Expenses: Research and development expenses were $21.1 million for the quarter ended December 31, 2022, as compared to $26.5 million for the same period in 2021. The decrease of $5.4 million was primarily due to a decrease of $4.0 million related to the iECURE agreement and a decrease of $2.9 million in employee-related and other operational costs driven by the separation of Elo in 2021, offset by an increase of $1.5 million in research costs related to our *in vivo* gene editing preclinical studies.

General and Administrative Expenses: General and administrative expenses were $10.1 million for the quarter ended December 31, 2022, as compared to $10.6 million for the same period in 2021.

Other Income and Expense: Total other expense was $7.9 million for the quarter ended December 31, 2022, as compared to total other income of $8.5 million for the same period in 2021. The increase was primarily driven by a $10.8 million impairment of prepaid expenses related to the iECURE PCSK9 collaboration in the quarter ended December 31, 2022.

Net Loss: Net loss was $28.5 million, or $(0.26) per share (basic and diluted), for the quarter ended December 31, 2022, as compared to net loss of $22.3 million, or $(0.37) per share (basic and diluted), for the same period in 2021. Weighted average shares of common stock outstanding were approximately 111.0 million for the quarter ended December 31, 2022, as compared to approximately 60.7 million for the quarter ended December 31, 2021. 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 the year ended December 31, 2022.

Fiscal Year 2022 Financial Results:

Cash and Cash Equivalents: As of December 31, 2022, Precision had $189.6 million in cash and cash equivalents. The Company expects that existing cash and cash equivalents, continued operational discipline, expected operational receipts, and available credit will be sufficient to fund its operating expenses and capital expenditure requirements through Q1 2025.

Revenues: Total revenues for the year ended December 31, 2022 were $25.1 million, as compared to $115.5 million for the same period in 2021. The decrease of $90.4 million in revenue during the year ended December 31, 2022 was primarily the result of the absence of $72.9 million in revenue recognized under the Servier Agreement and a decrease of $17.9 million under the iECURE agreement subsequent to the full satisfaction of the performance obligations in April 2021 and August 2021, respectively, a decrease of $5.4 million under the Lilly Agreement, and a decrease of $3.7 million from agriculture partnering collaborations that were transferred to Elo Life Systems, Inc. ("Elo") upon separation in 2021. These decreases in revenue were partially offset by an increase of $9.5 million in revenue recognized under the Novartis Agreement.

Research and Development Expenses: Research and development expenses were $83.9 million for the year ended December 31, 2022, as compared to $115.2 million for the same period in 2021. The decrease of $31.3 million was primarily due to a decrease of $11.3 million in expense related to the Servier Program Purchase Agreement, a decrease of $8.9 million in external development costs associated with our allogeneic CAR T product candidates, a decrease of $6.7 million in employee-related and other operational costs driven by the separation of Elo in 2021, and a decrease of $4.5 million in clinical manufacturing organization and research costs related to our preclinical studies.

General and Administrative Expenses: General and administrative expenses were $41.5 million for the year ended December 31, 2022, as compared to $39.7 million for the same period in 2021. The increase of $1.8 million was primarily due to increased share-based compensation expense offset by decreases in insurance, legal, and information technology expenses.

Other Income and Expense: Total other expense was $11.3 million for the year ended December 31, 2022, as compared to total other income of $8.8 million for the same period in 2021. The increase was primarily driven by a $10.8 million impairment of prepaid expenses related to the iECURE PCSK9 collaboration.

Net Loss: Net loss was $111.6 million, or $(1.27) per share (basic and diluted), for the year ended December 31, 2022, as compared to net loss of $30.6 million, or $(0.52) per share (basic and diluted), for the same period in 2021. Weighted average shares of common stock outstanding were approximately 87.9 million for the year ended December 31, 2022, as compared to approximately 58.7 million for the year ended December 31, 2021. 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* "off-the-shelf" CAR T immunotherapy 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. 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 efficacy and benefit of our product

candidates and programs, the expected timing of updates regarding programs in our allogeneic CAR T and in vivo portfolio and ARCUS research, 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 and expectations regarding our liquidity and capital resources. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should," "target," "will," "would," 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; 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 key executives and other qualified 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 and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period

ended September 30, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	For the Three Months Ended December 31,	
	2022	**2021**
Revenue	$ 10,598	$ 6,339
Operating expenses		
Research and development	21,072	26,470
General and administrative	10,073	10,616
Total operating expenses	31,145	37,086
Loss from operations	(20,547)	(30,747)
Other (expense) income, net:		
Impairment charges	(11,438)	-
Loss on disposal of assets	(48)	(3)
(Loss) gain from changes in fair value	(510)	2,281
Gain on deconsolidation of subsidiary	-	5,985
Income from equity method investment	2,604	184
Interest expense	(486)	(53)
Interest income	1,937	63
Total other (expense) income, net	(7,941)	8,457
Net loss	$ (28,488)	$ (22,290)
Net loss per share - basic and diluted	$ (0.26)	$ (0.37)
Weighted average shares of common stock outstanding - basic and diluted	110,957,493	60,674,925

	For the Years Ended December 31,	
	2022	**2021**
Revenue	$ 25,098	$ 115,529
Operating expenses		
Research and development	83,939	115,238
General and administrative	41,525	39,667
Total operating expenses	125,464	154,905
Loss from operations	(100,366)	(39,376)
Other (expense) income, net:		
Impairment charges	(11,438)	-
Loss on disposal of assets	(106)	(26)
(Loss) gain from changes in fair value	(510)	2,555
Gain on deconsolidation of subsidiary	-	5,985
(Loss) income from equity method investment	(1,579)	184
Interest expense	(1,111)	(132)
Interest income	3,473	208
Total other (expense) income, net	(11,271)	8,774
Net loss	$ (111,637)	$ (30,602)
Net loss per share - basic and diluted	$ (1.27)	$ (0.52)
Weighted average shares of common stock outstanding - basic and diluted	87,898,498	58,688,102

Precision BioSciences, Inc.
Consolidated Balance Sheets Data
(In thousands, except share amounts)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 189,576	$ 143,663
Working capital	$ 139,441	$ 125,774
Total assets	$ 238,169	$ 211,498
Total liabilities	$ 177,736	$ 120,330
Total stockholders' equity	$ 60,433	$ 91,168
Common stock outstanding	110,964,035	60,902,105

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