

**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 9, 2022**

**Precision BioSciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38841**  
(Commission  
File Number)

**20-4206017**  
(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.

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**Item 2.02. Results of Operation and Financial Condition.**

On May 9, 2022, Precision BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of Precision BioSciences, Inc. dated May 9, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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## 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, 2022

By: /s/ John Alexander Kelly

John Alexander Kelly  
Chief Financial Officer

## Precision BioSciences Reports First Quarter 2022 Financial Results and Provides Business Update

- *PBCAR0191, PBCAR19B and PBCAR269A Allogeneic CAR T Program Updates Planned for June 2022*
- *Three Wholly Owned In Vivo Gene Editing Programs Progressing Toward IND or CTA in the Next Three Years*
- *Preclinical In Vivo Gene Editing Data for Primary Hyperoxaluria Type 1 and Chronic Hepatitis B Accepted for Presentation at the 2022 Annual American Society of Gene and Cell Therapy Meeting*

**DURHAM, N.C., May 9, 2022** -- 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, 2022 and provided a business update.

“We continue to focus on execution and build on the utility of ARCUS as a premier genome editing platform to develop novel treatments for cancer and genetic diseases. We believe the differentiated attributes of ARCUS enable a high degree of specificity, minimal levels of off-target editing and maximum versatility, including gene insertion. These qualities underpin our organic strategy and attract accomplished partners that extend our reach to more patients with serious diseases while also providing capital to advance our core development priorities,” said Michael Amoroso, Chief Executive Officer at Precision BioSciences. “As our programs continue to mature, we will remain nimble and follow the data to prudently manage our portfolio. This will allow us to hone in on the most impactful approaches to develop potential allogeneic CAR T product candidates and pursue optimal strategies for delivery to various tissues for gene editing *in vivo*.”

“As we look ahead, we plan to provide an update across our allogeneic CAR T programs in June 2022 as data matures. On the research front, we have initiated IND-enabling studies for PBGENE-PH1 delivered by LNP as we target advancing three wholly owned *in vivo* gene editing programs towards IND or CTA applications over the next three years,” Mr. Amoroso continued.

### Recent Developments and Upcoming Milestones:

#### Ex Vivo Allogeneic CAR T Portfolio:

- **PBCAR0191:** PBCAR0191 is the Company’s lead investigational anti-CD19 allogeneic CAR T candidate being evaluated in a Phase 1/2a clinical trial of adult subjects with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL). In December 2021, Precision announced a Phase 1 data update, in which a 100% overall response rate (6/6) and a 66% complete response rate (4/6) was observed among patients that previously received an autologous CAR T therapy and progressed. Precision prioritized enrollment of this high unmet need patient population as a potential path for PBCAR0191, and the Company plans to provide a program update on PBCAR0191 in June 2022.
  - **PBCAR19B:** PBCAR19B is a novel, immune-evading stealth cell candidate employing a single-gene edit to knock-down beta-2 microglobulin and insert an HLA-E transgene. We believe PBCAR19B is the first CAR T cell candidate in the clinic designed to evade rejection by host T cells and natural killer (NK) cells. Precision initiated a clinical trial of PBCAR19B in patients with NHL in mid-2021 and plans to commence dosing in the third quarter of 2022 at the next dose level with clinical trial material from an optimized manufacturing process. The Company plans to provide a program update on PBCAR19B in June 2022.
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- **PBCAR269A:** PBCAR269A is an investigational allogeneic CAR T cell candidate targeting B-cell maturation antigen (BCMA) for R/R multiple myeloma. Precision is evaluating PBCAR269A in a Phase 1/2a study in combination with nirogacestat, a gamma secretase inhibitor developed by SpringWorks Therapeutics. The first patient was dosed in the combination arm in June 2021, and Precision expects to provide a program update on PBCAR269A in June 2022.

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

Over the next three years, Precision expects that three of its wholly owned preclinical *in vivo* programs will advance to IND or CTA. This includes:

- **PBGENE-PCSK9:** In 2021, Precision initiated a collaboration with iECURE, pursuant to which Precision's PBGENE-PCSK9 candidate is expected to advance through preclinical activities as well as a Phase 1 study in familial hypercholesterolemia. A CTA filing is expected as early as the end of 2022.
- **PBGENE-PH1:** Precision has initiated IND-enabling activities for its PBGENE-PH1 candidate designed to knock out the well-validated HAO1 gene as a potential one-time treatment for primary hyperoxaluria type 1 (PH1). In the first quarter of 2022, the Company initiated a non-human primate study for PBGENE-PH1 delivered by LNP and expects to submit an IND or CTA in 2023.
- **PBGENE-HBV:** Precision's gene editing program for chronic Hepatitis B applies ARCUS to knock out persistent covalently closed circular DNA (cccDNA) and inactivate integrated hepatitis B genomes, potentially achieving durable HBV S-antigen (HBsAg) loss and viral persistence. Precision plans to pursue clinical development of its PBGENE-HBV candidate using LNP delivery and expects to submit an IND/CTA in 2024.

Precision continues its *in vivo* gene editing collaboration with Lilly and is applying ARCUS nucleases for three initial targets, including Duchenne muscular dystrophy in muscle, a central nervous system directed target and a liver directed target. In addition, Precision continues to engage discussions with potential biotech collaborators to leverage the unique attributes of ARCUS, such as gene insertion, for a variety of disease targets.

As announced on May 2, 2022, preclinical data on Precision's wholly owned PH1 and HBV programs will be presented at the upcoming American Society of Gene and Cell Therapy (ASGCT) meeting, May 16-19, 2022.

- Abstract #239, Optimization of Hydroxyacid Oxidase 1 (HAO1) Targeting ARCUS Nucleases for the Treatment of Primary Hyperoxaluria Type 1
- Abstract #447, Targeting the Hepatitis B cccDNA with a Sequence-Specific ARCUS Nuclease to Eliminate Hepatitis B Virus *In Vivo*

### **Other Research:**

Additional abstracts on ARCUS *in vivo* gene editing have been accepted for presentation at the upcoming ASGCT meeting, including one abstract on Precision's mitochondrial DNA preclinical research and one abstract from a research and license collaboration with iECURE and the company's ornithine transcarbamylase (OTC) deficiency program.

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- Abstract #561, ARCUS Gene Editing to Eliminate MELAS-associated m.3243A>G Mutant Mitochondrial DNA
- Abstract #811, AAV-meganuclease-mediated Gene Targeting Achieves Efficient and Sustained Transduction in Newborn and Infant Macaque Liver

Preclinical research led by the Department of Ophthalmology and Visual Sciences at the University of Louisville using ARCUS genome editing platform for autosomal dominant Retinitis Pigmentosa (adRP) was presented at the recent Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting.

- Abstract #3710318, Successful Late-stage Disease Treatment of P23H Human RHO (hRHO) Using ARCUS Nuclease Gene Editing in a Pig Model of Autosomal Dominant Retinitis Pigmentosa (adRP)
- Abstract #3712152, Characterization of a Humanized Mouse Model of P23H Rhodopsin Autosomal Dominant Retinitis Pigmentosa (adRP)

#### **Corporate:**

- **Intellectual Property (IP) Update:** In March 2022, the U.S. Patent and Trademark Office issued Precision five new U.S. patents further adding to the Company's IP portfolio that cover the ARCUS platform and its use developing novel *ex vivo* and *in vivo* gene editing therapies. The five new patents included: patents relating to methods of using ARCUS nucleases to target sequences in the Hepatitis B virus (U.S. Patent No. 11,274,285); methods for modifying the Factor VIII gene in hemophilia A (U.S. Patent No. 11,278,632); methods for novel co-stimulatory domain used for allogeneic CAR T expansion (U.S. Patent No. 11,286,291); and methods of making allogeneic CAR T cells and T cell receptor alpha chain (TRAC)-targeting ARCUS nucleases useful in such methods (U.S. Patent Nos. 11,268,065 and 11,266,693).

#### **Quarter Ended March 31, 2022 Financial Results:**

**Cash and Cash Equivalents:** As of March 31, 2022, Precision had approximately \$116.2 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 mid-2023.

**Revenues:** Total revenues for the quarter ended March 31, 2022 were \$3.3 million, as compared to \$16.3 million for the same period in 2021. The decrease of \$13.0 million in revenue during the quarter ended March 31, 2022 was primarily the result of a \$10.3 million decrease in revenue recognized under the Servier Agreement subsequent to full satisfaction of the performance obligation under the execution of the Program Purchase Agreement in April 2021, a \$2.1 million decrease in revenue recognized under the Lilly Agreement, and a \$0.6 million decrease in revenue recognized from an agriculture partnering collaboration.

**Research and Development Expenses:** Research and development expenses were \$20.0 million for the quarter ended March 31, 2022, as compared to \$25.6 million for the same period in 2021. The decrease of \$5.6 million was primarily due to decreases of \$2.7 million in external development costs, including clinical research organization and clinical manufacturing organization costs, associated with our PBCAR0191, PBCAR269A, PBCAR20A and PBCAR19B clinical trials, as well as decreases of \$1.1 million in sublicensing royalty payable to Duke on the Lilly upfront payment that was received in 2021 and \$1.4 million in employee-related costs due to reduced headcount driven by the separation of Elo in 2021.

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**General and Administrative Expenses:** General and administrative expenses were \$10.7 million for the quarter ended March 31, 2022, as compared to \$9.5 million for the same period in 2021. The increase of \$1.2 million was primarily due to costs required to meet our growing infrastructure needs, including an increase of \$1.3 million in general and administrative employee-related costs associated with increased wages, share-based compensation, relocation and recruiting costs for key management personnel.

**Net Loss:** Net loss was \$28.2 million, or \$(0.46) per share (basic and diluted), for the quarter ended March 31, 2022, as compared to a net loss of \$18.7 million, or \$(0.33) per share (basic and diluted), for the same period in 2021.

#### **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](http://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, the expected timing of updates regarding our allogenic CAR T and *in vivo* programs, the expected advancement toward and timing of IND and CTA filings, the ability of our product candidates to become best-in-class or first-in-class, the planned development activities with our collaboration partners, our expected participation in future industry events and conferences expectations about our operational initiatives and business strategy, achieving key milestones, additional collaborations, and expectations regarding our liquidity and ability to fund operating expenses and capital expenditures requirements. 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," "potential," "predict," "project," "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; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical studies and clinical trials; 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

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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 COVID-19 pandemic and variants thereof, 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 Annual Report on Form 10-K for the fiscal year ended December 31 2021, 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, 2022, to be filed with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov) and the Investors page of our website under SEC Filings at [investor.precisionbiosciences.com](http://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.

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

	For the Three Months Ended March 31,	
	2022	2021
Revenue	\$ 3,317	\$ 16,349
Operating expenses		
Research and development	19,972	25,593
General and administrative	10,691	9,498
Total operating expenses	30,663	35,091
Loss from operations	(27,346)	(18,742)
Other income:		
Loss from equity method investments	(952)	—
Interest expense	(42)	—
Interest and other income, net	172	53
Total other income, net	(822)	53
Net loss and net loss attributable to common stockholders	\$ (28,168)	\$ (18,689)
Net loss per share attributable to common stockholders- basic and diluted	\$ (0.46)	\$ (0.33)
Weighted average shares of common stock outstanding- basic and diluted	61,031,775	56,625,024

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 116,222	\$ 143,663
Working capital	104,947	125,774
Total assets	181,351	211,498
Total stockholders' equity	\$ 69,659	\$ 91,168

**Investor Contact:**

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