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): April 11, 2024

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 Capital 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 1.02 Termination of a Material Definitive Agreement.

On April 11, 2024, Precision BioSciences, Inc. (the "Company") received written notice from Prevail Therapeutics Inc. ("Prevail"), a wholly-owned subsidiary of Eli Lilly and Company, of Prevail's termination of the Amended and Restated Development and License Agreement, dated June 30, 2023, between Prevail and the Company (the "Agreement"). Prevail's notice informed the Company that Prevail was exercising its right pursuant to Section 15.3.2 of the Agreement to terminate the Agreement in its entirety without cause upon 90 days' prior written notice to the Company. The termination will be effective on July 10, 2024.

Pursuant to the terms of the Agreement, Precision and Prevail agreed to collaborate and develop the Company's ARCUS nucleases for the research and development of potential in vivo therapies for three initial genetic disorder targets, including Duchenne muscular dystrophy ("DMD") in muscle, a liver directed target ("PBGENE-LLY2") and a central nervous system directed target ("PBGENE-LLY3" and together with DMD and PBGENE-LLY2, the "Programs"). Under the original agreement with Eli Lilly and Company signed November 19, 2020, Precision received $135 million in upfront investment consisting of $100 million upfront and $35 million from Lilly's purchase of 125,406 shares of the Company's common stock (on a post-reverse stock split basis). The Agreement was amended and restated in June 2023 with Prevail assuming and funding preclinical research and investigational new drug application-enabling activities, which had previously been conducted by the Company at its expense, as well as assuming responsibility for the manufacturing of initial clinical trial material for the first licensed product. Upon the achievement of various milestones, the Company would have been entitled to receive milestone payments of up to an aggregate of $390 million to $395 million per licensed product as well as nomination fees for additional targets and certain research funding. If licensed products resulting from the collaboration were approved and sold, Prevail would have also been required to pay tiered royalties ranging from the mid-single digit percentages to the low-teens percentages on world-wide net sales of the licensed products, subject to customary potential reductions. Prevail's exercise of its termination right is contemporaneous with achievement of defined preclinical activities on the collaboration for the Programs, at which time Prevail would have taken over all remaining development activities for the Programs.

In connection with the termination, the Company has exercised its reversion option (the "Reversion Option") under the Agreement to regain control over development of the Programs and plans to explore opportunities to further develop the Programs. As a result, Prevail is required upon Precision's request and to the extent permitted by law or terms of third party agreements, to assign and transfer to the Company all right, title and interest in and to all materials, preclinical and clinical data, safety data and all other supporting data in Prevail's control related to the terminated products for the continued development and commercialization of such products.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, a copy of which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 6, 2023, and is incorporated herein by reference.

Item 2.02 Results of Operations and Financial Condition.

Although it has not finalized its full financial results for the quarter ended March 31, 2024, the Company expects to report that it had approximately $137 million in cash and cash equivalents as of March 31, 2024. This estimate is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of March 31, 2024, and its results of operations for the quarter ended March 31, 2024. The review of the Company's financial statements for the quarter ended March 31, 2024 by the Company's independent registered public accounting firm is ongoing and could result in changes to the information set forth above.

Item 7.01 Regulation FD Disclosure.

On April 16, 2024, the Company issued a press release announcing the termination of the Agreement. A copy of the press release, which is attached to this Current Report on Form 8-K as Exhibit 99.1, is furnished pursuant to this Item 7.01.

The information under this Item 7.01 (including Exhibit 99.1 hereto) and Item 2.02 of this Current Report on Form 8-K is not deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section. Registration statements or other documents filed with the SEC shall not incorporate this information by reference, except as otherwise expressly stated in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the Company's plans in connection with

the termination of the Agreement, the Company's intention to exercise the Reversion Option, the future development of the Programs, including the possibility of new partners or collaborations for the Programs and the ability to generate future revenue from the Programs. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "designed to", "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 neither promises nor guarantees, and involve 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 factors, including, without limitation, our ability to procure sufficient funding or other partnership opportunities to advance the Programs or other programs on terms that are acceptable to us, or at all, the progression and 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 or our collaborators' or other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical trials; the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements; and the other risks referred to under the section "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as any such factors may be updated from time to time in our other filings 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 Current Report on Form 8-K 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Precision BioSciences, Inc. dated April 16, 2024.
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: April 16, 2024

By: /s/ John Alexander Kelly
John Alexander Kelly
Chief Financial Officer

Exhibit 99.1

Precision BioSciences Announces Return of Programs and Conclusion of Collaboration with Prevail Therapeutics

- *Productive collaboration advanced three programs and demonstrated proof of concept of ARCUS for gene excision and gene insertion*

- *Precision exercised option to regain control of programs and intends to bring collaboration programs back to develop independently or with new partners*

- *Precision's most important near-term clinical priorities in Hepatitis B (HBV) and Primary Mitochondrial Myopathy (PMM) and the expected cash runway into the second half of 2026 are not impacted*

DURHAM, N.C.—April 16, 2024-- Precision BioSciences, Inc. (Nasdaq: DTIL), an advanced gene editing company, today announced the anticipated return of three programs from Prevail Therapeutics Inc., a wholly owned subsidiary of Eli Lilly and Company. Precision exercised its option to regain rights for the programs following Prevail Therapeutics' decision to conclude the collaboration. Precision uses its novel proprietary ARCUS® platform to develop *in vivo* gene editing therapies for sophisticated gene edits, including gene elimination, insertion, and excision. The collaboration began in January 2021 and was amended in June 2023 to transfer certain preclinical research, manufacturing, and investigational new drug (IND)-enabling activities from Precision BioSciences to Prevail Therapeutics.

"We enjoyed a productive gene editing collaboration with Prevail Therapeutics and appreciate their contributions to the success of these programs. Together, we advanced three programs from concept toward clinical candidates, and Precision completed its workplan for these programs to the next stage gate, taking us to an important development decision point," said Michael Amoroso, President and Chief Executive Officer of Precision BioSciences. "Our decision to regain control of the programs brings exciting development opportunities to Precision's pipeline with a focus on benefiting people born with incurable genetic diseases."

"These *in vivo* gene editing programs are designed to take advantage of unique attributes of ARCUS, namely its cut, size, and simplicity. Our next steps will be to prepare for GLP toxicology studies followed by potential IND and clinical trial application (CTA) submissions," said Jeff Smith, PhD, Co-Founder and Chief Research Officer. "We are excited about the compelling *in vivo* proof-of-concept data generated for ARCUS gene excision of a "hot spot" region of the dystrophin gene in the DMD program. Additionally, *in vivo* data for the gene insertion program demonstrated up to 45% high efficiency gene insertion in non-dividing cells of non-human primates measured by total liver tissue. This is important and differentiating proof-of-concept data for ARCUS compared to CRISPR, base editors and prime editors, which have not demonstrated such high levels of gene insertion efficiency in dividing or non-dividing cells *in vivo,* potentially enabling broader therapeutic applicability for ARCUS."

As a result of the strong proof of concept data generated to date, Precision is exploring opportunities to develop the returned programs independently or in partnership with others. Importantly, the return of

these programs does not impact the Company's near-term clinical priorities in ornithine transcarbamylase (OTC) deficiency, HBV, and PMM or its expected cash runway to achieve these clinical data milestones.

"Turning to our fundamental story, Precision continues to make progress with our wholly owned programs for HBV and PMM as well as through partnerships with Novartis and iECURE. Most recently, iECURE has commenced regulatory and clinical activities in major markets around the world to use the ARCUS platform for gene insertion to address OTC deficiency using an ARCUS nuclease," added Mr. Amoroso.

Precision BioSciences remains focused on its most important near-term priorities and clinical data milestones with several opportunities to validate ARCUS for both wholly owned and the lead partnered program in 2024 and 2025.

- The OTC deficiency program partnered with iECURE is the most advanced ARCUS *in vivo* gene editing program with first-in-human clinical dosing expected to commence in 2024. IND and CTAs have been approved in the United States, United Kingdom, and Australia for the Phase 1/2 OTC-HOPE study.

- Following receipt of regulatory guidance in and outside of the United States, Precision's wholly owned PBGENE-HBV viral elimination program has commenced final IND and CTA enabling studies and is rapidly progressing toward the clinic with submissions planned in 2024.

- The PBGENE-PMM mutant mitochondrial DNA elimination program is on track for IND and/or CTA submission in 2025.

The cash received from our recent public offering, upfront and potential near-term cash from cell therapy transactions, along with existing cash and cash equivalents, expected operational receipts, continued fiscal and operating discipline, availability of our at-the-market facility, and available credit, are expected to provide Precision with a cash runway into the second half of 2026. The completion of the collaboration does not impact Precision's expected cash runway as no milestones from Prevail Therapeutics were assumed in our cash runway through 2026.

Company-Hosted Webcast and Conference Call Information
Precision will host a conference call and webcast on Tuesday, April 16, 2024, at 5:00pm EDT to discuss its *in vivo* gene editing business. The dial-in conference call number is (800) 715-9871 and the conference ID number for the call is 2110172. Participants may access the live webcast, and accompanying presentation materials, as well as the archived webcast on Precision's website in the Investors section under Events & Presentations: https://investor.precisionbiosciences.com/events-and-presentations.

About Precision BioSciences, Inc.
Precision BioSciences, Inc. is an advanced gene editing company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform that differs from other technologies in the way it cuts, its smaller size, and its simpler structure. Key capabilities and differentiating characteristics may enable ARCUS nucleases to drive more intended, defined therapeutic outcomes. Using ARCUS, the Company's pipeline is comprised of in vivo gene editing candidates designed to deliver lasting cures for

the broadest range of genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit www.precisionbiosciences.com.

The ARCUS® platform is being used to develop in vivo gene editing therapies for sophisticated gene edits, including gene insertion (inserting DNA into gene to cause expression/add function), elimination (removing a genome e.g. viral DNA or mutant mitochondrial DNA), and excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV).

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 safety, efficacy and benefit of our and our partners' product candidates and gene editing approaches including editing efficiency; the suitability of ARCUS nucleases for gene insertion, large gene excision and other gene editing approaches; the expected timing of regulatory processes, including filings and studies for PBGENE-HBV and PBGENE-PMM; expectations of further presentations and publications further differentiating ARCUS; expectations and updates around partnership and collaboration opportunities; our expected cash runway and available credit; the sufficiency of our cash runway and available credit extending through phase 1 clinical readouts for our HBV and PMM programs; expectations about achievement of key milestones and receipt of any milestone, royalty, or other payments; expectations regarding our liquidity and capital resources; expectations about our and our partners' operational initiatives and business strategy; and anticipated timing of clinical data. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "designed", "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should,", "strive", "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. These statements are neither promises nor guarantees, and involve 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 or other partnership opportunities to advance our programs on terms that are acceptable to us, or at all; risks associated with our capital requirements, anticipated cash runway, requirements under our current debt instruments and effects of restrictions thereunder, including our ability to raise additional capital due to market conditions and/or our market capitalization; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the progression and 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, including clinical trial and investigational new drug applications; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators' or other licensees' ability to identify, develop and commercialize product candidates; pending and potential product liability lawsuits and penalties against us or our collaborators or other licensees related to our technology and our product candidates; the U.S. and foreign regulatory

landscape applicable to our and our collaborators' or other licensees' development of product candidates; our or our collaborators' or other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical 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; delays or difficulties in our and our collaborators' and other licensees' 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 or our licensees' 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' or other licensees' 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; our ability to meet the requirements of and maintain listing of our common stock on Nasdaq or other public stock exchanges; 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, 2023, as any such factors may be updated from time to time in our other filings 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.

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