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 15, 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 1.01 Entry into a Material Definitive Agreement.

On August 15, 2023, Precision BioSciences, Inc. (the "Company") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Imugene Limited, an Australian corporation ("Imugene Limited"), and its wholly owned subsidiary Imugene (USA) Inc. ("Imugene US"), a Nevada corporation (collectively, "Imugene"). Pursuant to and simultaneously with the execution of the Purchase Agreement, on August 15, 2023 (the "Closing Date"), Imugene US acquired the Company's manufacturing infrastructure used in the development and manufacture of azercabtagene zapreleucel ("azer-cel"), including the lease to the Company's manufacturing facility and certain contracts of the Company with respect to the Company's manufacturing facility, and related equipment, supplies, azer-cel clinical trial inventory and other assets related to the Company's CAR T cell therapy platform (the "Acquired Assets"). As part of the Purchase Agreement, Imugene is required to make an offer of employment to certain employees of the Company who are associated with the Company's CAR T cell therapy business.

In consideration for the Acquired Assets, Imugene US assumed certain liabilities of the Company, paid the Company $8 million in cash, and issued to the Company convertible notes in an aggregate principal amount of $13 million. The convertible notes are non-interest bearing and mature on the first anniversary of the closing date. On the maturity date, the notes generally must be redeemed with cash, converted into ordinary shares of Imugene Limited at a conversion price based on the 10-day volume weighted average price of Imugene Limited's ordinary shares prior to the date of conversion, or partially redeemed with cash and partially converted into shares.

The Purchase Agreement also includes customary representations and warranties, as well as indemnification rights for breaches of representations, warranties, and covenants, as well as certain other matters, subject to customary deductibles, caps, and other limitations.

In connection with the Purchase Agreement, on the Closing Date, the Company and Imugene US entered into a License Agreement (the "License Agreement"), pursuant to which the Company granted Imugene US certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize oncological applications of the Company's allogeneic CAR T therapy azer-cel and up to three additional research product candidates directed to targets that Imugene US may nominate prior to the fifth anniversary of the effective date of the License Agreement, pursuant to the terms of the License Agreement.

In addition, under the License Agreement, the Company is eligible to receive milestone payments of up to an aggregate of $206 million for azer-cel, inclusive of a payment of $8 million in cash and equity upon successful completion of the phase 1b dosing in the CAR T relapsed large B cell lymphoma ("LBCL") patient population. For azer-cel, Precision is eligible to receive double-digit royalties on net sales. For each additional research program selected by Imugene, the Company is eligible for up to $145 million in milestone payments and, if licensed products are approved and sold, tiered royalties ranging from the mid-single digit to low-double digit percentages on net sales of such licensed products. In addition, the Company is eligible to receive mid-single digit percentage-based fees for certain change of control transactions involving Imugene and for partnering transactions involving a licensed product. Imugene's obligation to pay royalties to the Company expires on a country-by-country and licensed product-by-licensed product basis, upon the latest to occur of certain events related to expiration of patents, regulatory exclusivity or a period of ten years following the first commercial sale of the respective licensed product.

Unless earlier terminated, the License Agreement will remain in effect on a licensed product-by-licensed product and country-by-country basis until the expiration of a defined royalty term for each licensed product and country. Precision may terminate the entire License Agreement due to a challenge to its patents brought by Imugene and a breach by Imugene in any material respect of the License Agreement, the Purchase Agreement or any related transaction documents. The Company may also terminate the License Agreement with respect to azer-cel if Imugene fails to initiate certain development activities with respect to azer-cel by a specified date, if Imugene fails to expend certain amounts on the development of azer-cel or if Imugene ceases active development of azer-cel for a specified period of time. Either party may terminate the License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the agreement or (ii) the other party's insolvency.

In connection with the Purchase Agreement and the License Agreement, the Company and Imugene have entered into other related agreements and documents, including a registration rights agreement, a transition services agreement, a sublease for laboratory space at the Company's headquarters and a parent company guaranty from Imugene Limited.

The above descriptions of the Purchase Agreement and the License Agreement do not purport to be complete and are qualified in their entirety by reference to the Purchase Agreement and the License Agreement, copies of which will be filed in an amendment to this Current Report on Form 8-K.

The representations, warranties and covenants contained in the Purchase Agreement and the License Agreement have been made solely for the benefit of the parties thereto and (i) may be intended not as statements of fact but rather as a way of allocating risk among the parties if those statements prove to be inaccurate and (ii) were made only as of the date of the Purchase Agreement and the License Agreement or such other dates as may be specified in the Purchase Agreement or the License Agreement and are subject to

more recent developments. Accordingly, any such representations and warranties should not be relied upon as characterizations of the actual state of facts or affairs on the date they were made or at any other time.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The information set forth in Item 1.01 above is incorporated by reference into this Item 2.01.

Item 7.01 Regulation FD Disclosure.

On August 15, 2023, the Company issued a press release announcing the transactions described in Item 1.01 above. 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) in this Current Report on Form 8-K is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 parties' expected actions under the Purchase Agreement and License Agreement, and the receipt of any milestone, royalty, or other payments. 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. These statements are neither promises nor guarantees, but involve number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to: our ability to become profitable; our ability to procure sufficient funding and requirements under our current debt instruments and effects of restrictions thereunder; risks associated with raising additional capital; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the success of our programs and product candidates in which we expend our resources; our limited ability or inability to assess the safety and efficacy of our product candidates; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; pending and potential product liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators' development of product candidates; our or our collaborators' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; our ability to obtain an adequate supply of T cells from qualified donors; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; changes in interim "top-line" and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data protection, privacy and security regulations and our compliance therewith; our ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of the COVID-19 pandemic and variants thereof, or any pandemic, epidemic, or outbreak of an infectious disease; the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with and reliance on third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price, and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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 August 15, 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 15, 2023

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

Precision BioSciences Completes Strategic Transaction with Imugene for Azer-Cel in Cancer

- *Precision Eligible to Receive up to $227 Million in Upfront Economics and Milestone Payments for Azer-Cel in Addition to Double-Digit Royalties on Sales*

- *Imugene to Assume Control of Precision's Cell Therapy Infrastructure in Pursuit of Biologics License Application for Azer-Cel in LBCL Patients who Relapse Following CAR T Treatment*

- *Upfront Cash and Reduced Operating Expenses Extend Precision's Expected Cash Runway through Q3 2025 as the Company Pivots to Focus on In Vivo Gene Editing*

DURHAM, N.C., August 15, 2023 -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *in vivo* gene editing therapies, today announced completion of a strategic transaction with Imugene Limited (ASX: IMU) for global rights to Azercabtagene Zapreleucel (azer-cel), Precision's lead allogeneic CAR T candidate, for cancer**.** Imugene will assume ongoing clinical execution for azer-cel in the large B-cell lymphoma (LBCL) population who have relapsed following autologous CAR T treatment. The license also includes an option to develop up to three other cancer research programs in the future.

"We are excited to reach this key inflection point for Precision BioSciences with the achievement of three milestones – first, the completion of a global deal with Imugene for azer-cel in cancer; second, the extension of our expected cash operating runway to greater than two years; and third, our pivot to focus exclusively on *in vivo* gene editing," said Michael Amoroso, Chief Executive Officer at Precision BioSciences. "We are very pleased to partner with Imugene as they plan to leverage azer-cel's clinical data package and recent regulatory feedback to continue its path toward a pivotal trial in LBCL and potentially help patients in dire need. Our commercial and scientific interests are closely aligned, and we believe Precision's allogeneic CAR T technology can complement the novel oncology approaches being pursued by Imugene, especially its OnCARlytics platform for solid tumors."

"After an extensive review of the allogeneic CAR T landscape, we are excited to progress what we believe is the most advanced allogeneic CAR T program – azer-cel, which has regulatory feedback and a broad data set. This is an important opportunity to develop a much-needed treatment for the growing number of lymphoma patients who have relapsed following CAR T treatment and is complementary to our pipeline, which is designed to unleash the immune system to fight cancer, including our OnCARlytics program," said Leslie Chong, Chief Executive Officer and Managing Director at Imugene Limited.

In exchange for global rights to azer-cel for cancer, as well as Precision BioSciences' CAR T infrastructure and its experienced cell therapy teams, Precision will receive upfront economics valued at $21 million (all figures in USD) consisting of cash and equity. In addition, Precision is eligible for an $8 million near-term payment in cash and equity upon successful completion of the phase 1b dosing in the CAR T relapsed LBCL patient population. For azer-cel, Precision is eligible to receive up to $198 million in additional milestone payments and double-digit royalties on net sales. For each additional research program selected by Imugene, Precision is eligible for up to $145 million in milestone payments and tiered royalties on net sales.

Precision's PBCAR19B stealth cell and its CAR T assets targeting multiple myeloma, as well as all rights to non-oncology indications for azer-cel, remain available for development through partnership only.

Corporate & Financial Update

As a result of this transaction, Precision expects to reduce its annual operating spend by approximately $20 million from the current base case and has right-sized the company to operate as a single platform company focused on *in vivo* gene editing. Upfront cash from this transaction, reduced CAR T operating expenses, and continued fiscal discipline are expected to extend Precision's cash runway through the third quarter of 2025.

"As we pivot our full attention and resources to leveraging the core features of ARCUS for differentiated *in vivo* gene editing programs, we are prepared to capitalize on the utility of ARCUS to produce a profound impact on diseases in the liver and beyond, including those that are best suited for gene insertion or excision of large defective gene sequences. We look forward to providing additional updates about our *in vivo* gene editing progress at our upcoming R&D event on September 12, 2023" added Mr. Amoroso.

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. 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 (including azer-cel) 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; the expected timing of regulatory processes; expectations about our operational initiatives and business strategy; expectations around partnership opportunities; our expected cash runway; expectations about achievement of key milestones and receipt of any milestone, royalty, or other payments; expected cash savings from the transaction with Imugene; expectations regarding our liquidity and capital resources; and the timing of our upcoming R&D event. 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 June 30, 2023, as any such factors may be updated from time to time in our other filings with the Securities and Exchange Commission ("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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