

**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): November 19, 2020

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.

Item 1.01. Entry into a Material Definitive Agreement.

Development and License Agreement

On November 19, 2020, Precision BioSciences, Inc. (the “Company”), entered into a development and license agreement (the “Development and License Agreement”) with Eli Lilly and Company (“Lilly”) to collaborate to discover and develop *in vivo* gene editing products incorporating the Company’s ARCUS nucleases. Lilly has initially nominated Duchenne muscular dystrophy and two gene targets for other genetic disorders, and has the right to nominate up to three additional gene targets for genetic disorders over the first four years of the Development and License Agreement (the “Nomination Period”). Lilly may extend the Nomination Period for an additional two years from the date on which such initial Nomination Period ends, upon Lilly’s election and payment of an extension fee. Under the terms of the Development and License Agreement, Lilly will receive an exclusive license to research, develop, manufacture and commercialize the resulting licensed products to diagnose, prevent and treat any and all diseases by *in vivo* gene editing directed against the applicable gene target. The Development and License Agreement provides that the Company will be responsible for conducting certain pre-clinical research and IND-enabling activities with respect to the gene targets nominated by Lilly to be subject to the collaboration, including manufacture of initial clinical trial material for the first licensed product. Lilly will be responsible for, and must use commercially reasonable efforts with respect to, conducting clinical development and commercialization activities for licensed products resulting from the collaboration, and may engage the Company for additional clinical and/or initial commercial manufacture of licensed products.

Upon closing of the transactions under the Development and License Agreement (the “Effective Date”), the Company will receive an upfront cash payment of \$100 million, and Lilly will make an equity investment of \$35 million in shares of the Company’s common stock pursuant to a stock purchase agreement between the Company and Lilly as described below (the “Stock Purchase Agreement”). The cash payment and equity investment are projected to extend the Company’s cash runway into 2023. The Company will also be eligible to receive milestone payments of up to an aggregate of \$420 million per licensed product as well as nomination fees for additional targets and certain research funding. If licensed products resulting from the collaboration are approved and sold, the Company will also be entitled to receive tiered royalties ranging from the mid-single digit percentages to the low-teens percentages on worldwide net sales of the licensed products, subject to customary potential reductions. Lilly’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 first commercial sale of the licensed product.

The Company has the right to elect to co-fund the clinical development of one licensed product, which may be selected from among the third or any subsequent licensed products to reach IND filing. If the Company elects to co-fund such licensed product, the Company would reimburse Lilly for a portion of the clinical development expenses for such product and, in exchange, each royalty tier with respect to net sales of such licensed product would be increased by a low single digit percentage. During the term of the Development and License Agreement, the Company may not (and may not license or collaborate with any third party to) research, develop, or commercialize any *in vivo* gene editing product directed against any gene targets that have been nominated and are subject to the Development and License Agreement.

Unless earlier terminated, the Development and 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. Lilly has the right to terminate the Development and License Agreement for convenience by providing advance notice to the Company. Either party may terminate the Development and 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) due to a challenge to its patents brought by the other party.

The transactions contemplated in the Development and License Agreement and the Stock Purchase Agreement (as further described below) are subject to customary closing conditions, including the expiration or termination of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Stock Purchase Agreement

Concurrently with the execution of the Development and License Agreement, on November 19, 2020, the Company and Lilly entered into the Stock Purchase Agreement pursuant to which the Company agreed to issue and sell Lilly 3,762,190 shares of the Company's common stock (the "Shares") in a private placement transaction for an aggregate purchase price of \$35 million, or approximately \$9.30 per share. The price per share of the Company's common stock under the Stock Purchase Agreement represents a 25% premium over the volume-weighted-average-price (VWAP) of the Company's common stock over the 30 trading days preceding the execution date of the Stock Purchase Agreement.

Pursuant to the Stock Purchase Agreement, subject to certain exceptions, Lilly may not sell the Shares without the Company's approval for a period of nine months following the Effective Date. In addition, for a period of one year following the Effective Date, Lilly and its affiliates may not (i) effect or otherwise participate in, directly or indirectly, any acquisition of any securities or material assets of the Company, any tender or exchange offer, merger or other business combination or change of control involving the Company, any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company, or any solicitation of proxies or consents to vote any securities of the Company or (ii) act with any other person, or publicly disclose any intention, to do any of the foregoing. The Stock Purchase Agreement also contains customary representations, warranties, and covenants of each of the Company and Lilly.

The foregoing descriptions of the Development and License Agreement and the Stock Purchase Agreement are not complete and are qualified in their entirety by reference to the Development and License Agreement and the Stock Purchase Agreement, each of which will be filed as exhibits to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2020.

Item 3.02. Unregistered Sales of Equity Securities.

The description of the Stock Purchase Agreement and the issuance and sale of the Shares thereunder set forth in Item 1.01 above is incorporated by reference into this Item 3.02. The Shares are being offered and sold to Lilly in a private placement that is exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act").

Item 7.01. Regulation FD Disclosure.

On November 20, 2020, the Company and Lilly issued a joint press release announcing their research collaboration and exclusive license agreement to utilize the Company's proprietary ARCUS® genome editing platform for the research and development of potential therapies for genetic disorders such as Duchenne muscular dystrophy (DMD). A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

As described in the accompanying press release, the Company will be hosting a conference call at 8:30 a.m., Eastern Time, on November 20, 2020 to discuss the collaboration with Lilly. Access to the live webcast and the accompanying presentation materials will be available in the "Investors & Media" portion of the Company's website at <https://investor.precisionbiosciences.com>.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and 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 in any filing of the Company under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements regarding the expected benefits of the collaboration, that the collaboration will yield commercially successful products, the expected milestone and royalty

payments and the projected cash runway. Forward-looking statements may be identified by words such as “anticipates,” “believe,” “continue,” “expect,” “intend,” “may,” “plan to,” “potential,” “projects,” “will,” and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including, without limitation, the risks referred to under the section “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as such factors may be updated from time to time in the Company’s other filings with the Securities and Exchange Commission (“SEC”), which filings are accessible on the SEC’s website at www.sec.gov and the Investors & Media page of the Company’s website at <https://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 | Joint Press Release of Precision BioSciences, Inc. and Eli Lilly and Company, dated November 20, 2020 |

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: November 20, 2020

By: /s/ Matthew Kane

Matthew Kane

President and Chief Executive Officer



November 20, 2020

For Release: Immediately
Refer to: Mark Taylor; mark.taylor@lilly.com; (317) 276-5795 (Lilly Media)
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**Lilly and Precision BioSciences Announce Genome Editing Research Collaboration
and License Agreement**

***Research collaboration using ARCUS genome editing technology will initially include three gene targets, with right to select three additional gene targets; lead program focused on Duchenne Muscular Dystrophy
Precision will receive \$100 million cash upfront and an equity investment by Lilly of \$35 million; Precision also eligible to receive potential milestones up to \$420 million per product, as well as tiered royalties on sales of licensed products***

Precision to host conference call today at 8:30 a.m. ET

INDIANAPOLIS, IN and DURHAM, NC — Eli Lilly and Company (NYSE: LLY) and Precision BioSciences, Inc. (Nasdaq: DTIL) today announced a research collaboration and exclusive license agreement to utilize Precision's proprietary ARCUS® genome editing platform for the research and development of potential *in vivo* therapies for genetic disorders, with an initial focus on Duchenne muscular dystrophy (DMD) and two other undisclosed gene targets.

Genome editing technologies enable precise editing of the DNA of a living organism, opening up the possibility of correcting genetic problems at their source. ARCUS is a unique, proprietary, and versatile genome editing platform with attributes including specificity, ability to make a variety of efficient edits (knock-in, knock-out, and repair), and small size, thereby enabling a range of therapeutic editing. The platform is derived from a natural genome-editing enzyme called I-CreI, a homing endonuclease that can be optimized to control for potency and specificity.

Under the terms of the agreement, Precision will receive an upfront cash payment of \$100 million, as well as an equity investment by Lilly of \$35 million in Precision's common stock. Precision is also

eligible to receive up to \$420 million in potential development and commercialization milestones per product, as well as tiered royalties ranging from the mid-single digits to low-teens on product sales should Lilly successfully commercialize a therapy from the collaboration. Precision will lead pre-clinical research and IND-enabling activities, with Lilly then assuming responsibility for clinical development and commercialization. Lilly will have the right to select up to three additional gene targets for this collaboration. Precision can co-fund clinical development of one product in exchange for an increased royalty rate on co-funded product sales.

“Gene-edited therapies are emerging as a promising approach to help patients afflicted with genetic conditions,” said Ruth Gimeno, Ph.D., vice president of diabetes and metabolic research at Lilly. “We look forward to working closely with Precision’s scientific team and leveraging their platform to develop and deliver breakthrough medicines for untreated genetic disorders.”

“This collaboration with Precision BioSciences represents another milestone in the realization of our vision to create medicines with transformational potential, using new therapeutic modalities such as gene editing to tackle targets and indications which were previously undruggable,” added Andrew Adams, Ph.D., vice president of new therapeutic modalities at Lilly.

“We look forward to working with Lilly to leverage our deep understanding of *in vivo* gene editing and experience with ARCUS to develop new therapies, including a potentially transformative treatment for Duchenne muscular dystrophy,” said Derek Jantz, chief scientific officer and co-founder of Precision BioSciences. “Collaborating with Lilly, a global healthcare leader with strong clinical and commercial experience in difficult-to-treat diseases, will help us accelerate our work aimed to solve genetic diseases with unique editing challenges.”

This transaction is subject to clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act and other customary closing conditions. This transaction will be reflected in Lilly’s reported results and financial guidance according to Generally Accepted Accounting Principles (GAAP). There will be no change to Lilly’s 2020 non-GAAP earnings per share guidance as a result of this transaction.

Precision BioSciences Conference Call and Webcast Information

Precision’s management team will host a conference call and webcast at 8:30 a.m. ET today, Friday, November 20, 2020 to discuss the collaboration. The dial-in conference call numbers for domestic and international callers are (866) 996-7202 and (270) 215-9609, respectively. The conference ID

number for the call is 3135225. Participants may access the live webcast on Precision's website <https://investor.precisionbiosciences.com/events-and-presentations> in the Investors and Media section under Events and Presentations. An archived replay of the webcast will be available on Precision's website.

About ARCUS

ARCUS® is a proprietary genome editing technology discovered and developed by scientists at Precision BioSciences. It uses sequence-specific DNA-cutting enzymes, or nucleases, that are designed to either insert (knock-in), remove (knock-out), or repair DNA of living cells and organisms. ARCUS is based on a naturally occurring genome editing enzyme, I-CreI that evolved in the algae *Chlamydomonas reinhardtii* to make highly specific cuts in cellular DNA. Precision's platform and products are protected by a comprehensive portfolio including more than 65 patents to date.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com. C-LLY

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 specific 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 "off-the-shelf" CAR T immunotherapy clinical candidates and several *in vivo* gene correction therapy candidates to cure genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences please visit www.precisionbiosciences.com.

Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the benefits of a collaboration between Lilly and Precision BioSciences, and reflects Lilly's current beliefs. However, as with any such undertaking,

there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that Lilly will realize the expected benefits of the collaboration, or that the collaboration will yield commercially successful products. For a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see Lilly's most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

Precision Forward-Looking Statements

Statements in this press release regarding Precision's future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the expected benefits of the collaboration, that the collaboration will yield commercially successful products and the expected milestone and royalty payments. Forward-looking statements may be identified by words such as "anticipates," "believe," "continue," "expect," "intend," "may," "plan to," "potential," "will," and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including without limitation, the risks referred to under the section "Risk Factors" in Precision's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as such factors may be updated from time to time in Precision's other filings with the SEC, which filings are accessible on the SEC's website at www.sec.gov and the Investors & Media page of Precision's website at <https://investor.precisionbiosciences.com>. All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, Precision has 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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