

**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): July 6, 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 1.02. Termination of a Material Definitive Agreement.

On July 6, 2020, Gilead Sciences (“Gilead”) notified Precision BioSciences, Inc. (the “Company”) of its termination of the Collaboration and License Agreement between Gilead and Precision (the “Collaboration and License Agreement”), dated September 10, 2018, as subsequently amended by Amendment No. 1 to the Collaboration and License Agreement (“Amendment No. 1”), dated March 10, 2020 (as amended, the “Agreement”). Pursuant to the termination notice, the Agreement will terminate effective September 4, 2020. Upon termination, the Company will regain full rights and all data it generated for the *in vivo* chronic hepatitis B virus program developed under the Agreement.

Pursuant to the terms of the Agreement, the Company and Gilead had agreed to develop genome editing tools using the application of the Company’s pioneering, proprietary ARCUS genome editing platform to target viral DNA associated with the hepatitis B virus. Gilead received an exclusive license to exploit the resulting synthetic nucleases and products that use them to treat the hepatitis B virus in humans, and the Company was entitled to receive up to approximately \$40 million in research funding over an initial three year term and milestone payments of up to an aggregate of \$445 million, consisting of up to \$105.0 million in development milestone payments and up to \$340.0 million in commercial milestone payments. The Company was also entitled to receive tiered royalties ranging from the high single digit percentages to the mid-teen percentages on worldwide net sales of the products developed through the term of the Agreement, subject to customary potential reductions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Collaboration and License Agreement filed as Exhibit 10.4 to the Company’s Registration Statement on Form S-1/A filed on March 13, 2019 and Amendment No. 1 filed as Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, each of which Collaboration and License Agreement and Amendment No. 1 is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

The Company has updated its corporate deck, which is available on in the “Investors & Media” portion of the Company’s website at <https://investor.precisionbiosciences.com>.

The information in Item 7.01 of this Current Report on Form 8-K 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

Exhibit No.	Description
99.1	Press Release of Precision BioSciences, Inc., dated July 6, 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.

Date: July 6, 2020

PRECISION BIOSCIENCES, INC.

By: /s/ Matthew Kane
Matthew Kane
President and Chief Executive Officer



Precision BioSciences Regains Rights to *In Vivo* Hepatitis B Virus Program

DURHAM, N.C., July 6, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company dedicated to improving life with its novel and proprietary ARCUS® genome editing platform, today announced that the Company will regain full rights and all data it generated for the *in vivo* chronic hepatitis B virus (HBV) program developed under its 2018 collaboration agreement with Gilead Sciences.

“This was a highly productive and well-aligned collaboration, and we deeply value the opportunity to advance our ARCUS genome editing technology and a potential cure for HBV alongside a global leader in infectious disease,” commented Derek Jantz, Ph.D., Chief Scientific Officer, Precision BioSciences. “Key learnings from this program and how to develop liver-directed gene editing therapeutic candidates are directly applicable to our *in vivo* pipeline. While we consider new partnership opportunities for HBV, we are focused on progressing our internal lead proprietary gene correction program for primary hyperoxaluria type 1 for which we expect to nominate a clinical candidate later this year.”

Under the terms of the collaboration agreement, Precision BioSciences was primarily responsible for the development, formulation, and preclinical evaluation of the investigational nucleases for HBV; Gilead funded the research and development and was responsible for the clinical development and commercialization of potential therapies. Upon the collaboration’s conclusion, effective September 4, 2020, Precision BioSciences will regain full clinical development and commercialization rights to the program.

The Company does not anticipate any changes to its cash runway. As of March 31, 2020, Precision had cash and cash equivalents of \$154.2 million, which is expected to sufficiently fund operations into the second half of 2021.

About Precision’s *In Vivo* Program for Chronic Hepatitis B Virus (HBV)

By directly targeting cccDNA and integrated HBV genomes, preclinical data have shown that ARCUS gene editing may be a promising approach for developing a potential HBV cure. Preclinical data presented earlier this year at the 2020 American Society of Genetic & Cell Therapy (ASGCT) Annual Meeting demonstrated that an optimized ARCUS nuclease effectively targeted and degraded cccDNA up to 75% with subsequent knockdown of surface antigen in HBV-infected primary human hepatocytes. Data from murine studies also showed that an ARCUS nuclease delivered by lipid nanoparticle (LNP) edited an HBV DNA target up to 70% after a single administration *in vivo*.

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.

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 timing of the nomination of a clinical candidate for the Company's internal lead proprietary gene correction program for primary hyperoxaluria type 1, the efficacy of ARCUS gene editing as a promising approach for developing a potential HBV cure and the Company's cash runway and ability to fund operations. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "may," "will," "would," "should," "could," "target," "project," "predict," "contemplate," "potential," 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; 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 dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; our or our collaborators' ability to identify, develop and 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 achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data 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 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 scientific and management personnel; market and economic conditions; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events effects of the outbreak of COVID-19, or any pandemic, epidemic or outbreak of an infectious disease; insurance expenses and exposure to uninsured liabilities; and other important factors discussed under the caption

“Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, 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 & Media page of our website 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 do not plan to publicly 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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