

**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): September 9, 2021

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 7.01. Regulation FD Disclosure.

On September 9, 2021, Precision BioSciences, Inc. (the “Company”) issued a press release to announce its first R&D event focused on *in vivo* gene editing and also announced its license and collaboration agreement with iECURE to develop ARCUS-based gene editing therapies. Copies of the press releases are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated in this Item 7.01 by reference.

As described in the accompanying press release, the Company will host a live webcast today, Thursday, September 9, 2021 at 8:00 a.m., Eastern Time, featuring presentations from Company management as well as featured guest speakers and will outline the Company’s development strategy to advance its *in vivo* gene editing portfolio. The agenda will include an overview of ARCUS, the Company’s proprietary platform for *in vivo* gene correction, new pre-clinical data, timelines for leading *in vivo* gene editing programs, and updates from academic and industry collaborators. Access to the live webcast and the accompanying presentation materials, including a copy of the Company’s corporate deck, will be available in the “Investors & Media” portion of the Company’s website at <https://investor.precisionbiosciences.com>.

The information in this Item 7.01 (including Exhibits 99.1 and 99.2) of this Form 8-K 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 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 8.01. Other Events.

On September 9, 2021, the Company provided an update regarding its clinical development strategy for its *in vivo* gene editing pipeline and also announced its license and collaboration agreement with iECURE to develop ARCUS-based gene editing therapies.

The Company expects that three of its preclinical programs will advance to investigational new drug (“IND”)/clinical trial application (“CTA”) in the next three years:

- As part of an agreement to expedite development, iECURE expects to advance the Company’s PBGENE-PCSK9 candidate for familial hypercholesterolemia (“FH”) through Phase 1 clinical studies with CTA filing expected as early as 2022.
- The Company has initiated IND-enabling activities and expects to submit an IND application for PBGENE-PH1 for primary hyperoxaluria type 1 (“PH1”) in 2023.
- The Company will pursue clinical development of its PBGENE-HBV candidate for chronic hepatitis B virus (“HBV”) and expects to submit an IND/CTA in 2024.

The Company has also announced that it has signed a license and collaboration agreement with iECURE, a mutation-agnostic *in vivo* gene editing company striving to cure devastating diseases with high unmet need, co-founded by James M. Wilson, M.D., Ph.D. Using the Company’s PCSK9-directed ARCUS nuclease, iECURE plans to advance the Company’s PBGENE-PCSK9 candidate into a Phase 1 study in FH and gains access to the Company’s PCSK9-directed ARCUS nuclease to develop four other pre-specified gene insertion therapies for genetic diseases, focusing initially on liver diseases. The Company will retain rights to PBGENE-PCSK9, including for FH and all products developed for genetic indications except those licensed to iECURE. In return for its license grant, the Company will receive an equity stake in iECURE and is eligible to receive milestone and royalty payments on sales of iECURE products developed with ARCUS.

Presentations from the Company’s *in vivo* Gene Editing R&D event will highlight the Company’s clinical development strategy and updates on the following wholly-owned and partnered preclinical programs using ARCUS-mediated editing:

Featured Preclinical Data

- **ARCUS for Gene Insertion into the PCSK9 locus:** Due to the unique type of cut made by ARCUS nucleases, we believe ARCUS may be better suited for gene insertion than CRISPR-based gene editing tools. In non-human primates (“NHPs”), ARCUS was observed to be more efficient than CRISPR at inserting a Factor IX transgene into the PCSK9 locus. The Factor IX transgene is responsible for making the coagulation Factor IX protein associated with hemophilia B bleeding disorder.
- **ARCUS for Chronic HBV (PBGENE-HBV):** Current standard-of-care treatments for HBV suppress viral replication, but often do not clear the virus, leaving covalently closed circular DNA (“cccDNA”) and integrated HBV genomes that enable viral persistence. The Company’s gene editing program for HBV applies ARCUS to knockout this persistent cccDNA and potentially further reduce viral persistence.

New preclinical data to be presented today, and data previously presented at the American Society of Gene & Cell Therapy Annual Meeting, show that ARCUS efficiently targeted and degraded HBV cccDNA in HBV-infected primary human hepatocytes and reduced expression of HBV S-antigen (“HBsAg”) by as much as 95%. Similar levels of HBsAg reduction were observed in a newly developed mouse model of HBV infection following administration of ARCUS mRNA using lipid nanoparticle (“LNP”) delivery. The Company will pursue clinical development of its PBGENE-HBV candidate using LNP delivery and expects to submit an IND in 2024.

- **ARCUS for Mitochondrial Genome Editing:** Mitochondrial diseases frequently are caused by pathogenic mutations in the mitochondrial genome that reduce the ability of mitochondria to convert food and oxygen into energy to sustain life and support organ function. Mitochondrial diseases affect approximately 1 in 5,000 individuals.

Recent preclinical studies used mitochondrial-targeted ARCUS (“mitoARCUS”) to selectively eliminate mutant mitochondrial genomes that cause disease in cell and animal models. In work conducted by the Company, a hybrid cell model with a mixture of wild-type (healthy) and mutant mitochondrial genomes, a single treatment with mitoARCUS mRNA converted the cells to >99% wild-type. Work led by Carlos T. Moraes, Ph.D., Esther Lichtenstein Professor in Neurology at the University of Miami Miller School of Medicine and in a mouse model of mitochondrial disease and published online in *Nature Communications* on May 28, 2021, found that mitoARCUS delivered by AAV effectively targeted and depleted mutant mitochondrial genomes in multiple tissues. No editing of potential nuclear off-target sites could be detected, and liver and skeletal muscle showed robust elimination of mutant mtDNA with concomitant restoration of markers of mitochondrial function.

- **ARCUS for FH (PBGENE-PCSK9):** The Company’s gene editing program for FH seeks to knockout expression of the PCSK9 gene. As published by Wang et al. in *Molecular Therapy* in June 2021, “Long-term Stable Reduction of Low-density Lipoprotein in Nonhuman Primates Following *In Vivo* Genome Editing,” PBGENE-PCSK9 is supported by extensive NHP data over a three-year period, which demonstrates a long-term, stable edit accompanied by up to an 82% reduction from baseline in PCSK9 levels and up to a 62% reduction in LDL levels.

Data will be presented on the clinical nuclease which is expected to be delivered by AAVrh79 in a Phase 1 clinical study to be conducted by iECURE.

- **ARCUS for PH1 (PBGENE-PH1):** The Company’s gene editing program for PH1 applies ARCUS to knockout the well-characterized HAO1 gene to prevent the production of a toxic metabolite called oxalate that causes extremely severe and potentially fatal kidney stone accumulation in patients. NHP data supporting this approach has shown, on average, a 98.0% reduction in HAO1 mRNA and a 97.9% reduction in the encoded protein after a single administration of an AAV vector encoding ARCUS. Compared to published results with siRNAs targeting HAO1, the Company’s approach appeared to provide an improved metabolic profile with the potential for long-term benefit from a single dose. The Company has initiated IND-enabling activities and expects to submit an IND application for this program in 2023 using LNP delivery.
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- **ARCUS for Duchenne Muscular Dystrophy (“DMD”) (PBGENE-DMD):** ARCUS genome editing has previously been shown to increase expression of a shortened version of dystrophin in cultured myoblasts from a DMD patient. The approach uses two ARCUS nucleases delivered by a single AAV to simultaneously cut and delete a large segment of the dystrophin gene that encodes exons 45 through 55 of dystrophin – a region of the gene that accounts for more than 50% of DMD-causing mutations.

In November 2020, the Company and Lilly announced an exclusive license agreement to utilize ARCUS genome editing for the research and development of up to six potential *in vivo* targets for genetic disorders. The collaboration initially included three gene targets, with the lead program targeting the dystrophin gene responsible for DMD (**PBGENE-DMD**). In addition, the Company will use ARCUS for one liver-directed target (**PBGENE-LLY2**) and one CNS-directed target (**PBGENE-LLY3**).

The Company’s balance of cash and cash equivalents is approximately \$167 million as of August 31, 2021. This estimate is unaudited and does not present all information necessary for an understanding of the Company’s financial condition as of August 31, 2021, and its results of operations for the period then ended. The Company continues to expect that existing cash and cash equivalents will be sufficient to fund planned operations into 2023.

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 Company’s expected cash balance, statements regarding the further development and potential of our ARCUS platform, the clinical development and timeline of PBGENE-PCSK9, PBGENE-PH1 and PBGENE-HBV, our agreement with iECURE and the potential clinical development and benefits thereunder, and our agreement with Lilly and the potential clinical development and benefits thereunder. 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 June 30, 2021, 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, the Company 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Precision BioSciences, Inc. regarding R&D Event, dated September 9, 2021.
99.2	Press release of Precision BioSciences, Inc. regarding iECURE License and Collaboration Agreement, dated September 9, 2021.
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.

Date: September 9, 2021

PRECISION BIOSCIENCES, INC.

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

Precision BioSciences Outlines Clinical Development Strategy for *In Vivo* Gene Editing Pipeline

- Accelerated Clinical Development Expected to Enable Three Investigational New Drug/Clinical Trial Applications Within Next Three Years, Including for Familial Hypercholesterolemia as early as 2022, Primary Hyperoxaluria Type 1 in 2023, and Chronic Hepatitis B in 2024
- Announced Licensing and Collaboration Agreement with iECURE to Advance PCSK9 Knockout Program for Familial Hypercholesterolemia Through Phase 1; iECURE Also Receives License to Develop Four ARCUS-Based Gene Insertion Programs
- Featured Preclinical Data Demonstrating Precision and Versatility of ARCUS Editing Platform, Including First Presentation of ARCUS-Mediated Gene Insertion in Non-Human Primates
- Gene Editing Event Broadcast at 8:00 am ET Includes Presentation by James M. Wilson, M.D., Ph.D., Professor in the Departments of Medicine and Pediatrics, Perelman School of Medicine, University of Pennsylvania and Chief Scientific Advisor of iECURE

DURHAM, N.C., September 9, 2021 -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, today provided strategic business updates on its *in vivo* gene editing pipeline during the Company's first gene editing R&D event.

"Gene editing promises to fundamentally reshape the treatment landscape across numerous therapeutic categories. Today's *in vivo* gene editing R&D event showcases the power of our ARCUS genome editing platform – including key demonstrations of capabilities, such as gene insertion and mitochondrial DNA gene editing – which offers distinct advantages in this emerging field," commented Matt Kane, CEO and co-founder of Precision BioSciences. "We are excited to announce a new collaboration with iECURE which we expect to help us expedite clinical validation of the ARCUS platform for both gene knockout and gene insertion."

"Today, we are excited to share additional data highlighting the precision and versatility of our ARCUS platform, which is designed to enable safe, specific and efficient gene editing. Since ARCUS can be delivered via AAV or LNP, it has potential utility in treating diseases in the liver as well as many genetic diseases that affect tissues beyond the liver. In addition, the unique enzymology of ARCUS enables it to make complex gene insertion and gene repair edits more efficiently than other editing platforms," said Derek Jantz, Ph.D., Chief Scientific Officer and co-founder of Precision. "We believe these unique attributes of ARCUS support its differentiation for *in vivo* use and its potential to treat a broader range of genetic diseases than other editing technologies. We are very excited about our near-term pipeline and expect ARCUS to deliver on its full promise as we take on more challenging programs."

Precision expects that three of its preclinical programs will advance to investigational new drug (IND)/clinical trial application (CTA) in the next three years:

- As part of an agreement to expedite development, iECURE expects to advance Precision's **PBGENE-PCSK9** candidate for familial hypercholesterolemia (FH) through Phase 1 clinical studies with CTA filing expected as early as 2022.
 - Precision has initiated IND-enabling activities and expects to submit an IND application for **PBGENE-PH1** for primary hyperoxaluria type 1 (PH1) in 2023.
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- Precision will pursue clinical development of its **PBGENE-HBV** candidate for chronic hepatitis B virus (HBV) and expects to submit an IND/CTA in 2024.

Announced today in a separate release, Precision BioSciences has signed a license and collaboration agreement with iECURE, a mutation-agnostic *in vivo* gene editing company striving to cure devastating diseases with high unmet need, co-founded by James M. Wilson, M.D., Ph.D. Using Precision's PCSK9-directed ARCUS nuclease, iECURE plans to advance Precision's PBGENE-PCSK9 candidate into a Phase 1 study in FH and gain access to Precision's PCSK9-directed ARCUS nuclease to develop four other pre-specified gene insertion therapies for genetic diseases, focusing initially on liver diseases. Precision will retain rights to PBGENE-PCSK9, including for FH and all products developed for genetic indications except those licensed to iECURE. In return for its license grant, Precision will receive an equity stake in iECURE and is eligible to receive milestone and royalty payments on sales of iECURE products developed with ARCUS.

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"Research conducted by the Gene Therapy Program has shown ARCUS is capable of precise edits that can be applied broadly across genetic diseases in a mutation-dependent manner," said Dr. James M. Wilson. "Additionally, as reported today, ARCUS has demonstrated highly efficient gene insertion with a PCSK9-directed nuclease that will be foundational to iECURE in addressing rare genetic diseases, as well as long-term durability reflecting its curative potential with a single administration. Taken together, these findings continue to support what we have learned over years of collaborating with Precision: that the unique properties of ARCUS are differentiated versus other tools in this field."

- **ARCUS for Chronic HBV (PBGENE-HBV):** Current standard-of-care treatments for HBV suppress viral replication, but often do not clear the virus, leaving covalently closed circular DNA (cccDNA) and integrated HBV genomes that enable viral persistence. Precision's gene editing program for HBV applies ARCUS to knockout this persistent cccDNA and potentially further reduce viral persistence.

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Precision will use ARCUS for one liver-directed target (**PBGENE-LLY2**) and one CNS-directed target (**PBGENE-LLY3**).

Dr. Jantz continued, “The versatility of our platform offers us the optionality to pursue numerous therapeutic applications through strategic partnerships, enabling us to capture more of the value of the ARCUS technology and accelerate key programs. For example, in addition to rapidly advancing PBGENE-PCSK9 to the clinic, iECURE will provide critical validation of ARCUS’ gene-insertion capabilities. Lilly will help us research ARCUS-mediated editing in muscle and CNS. Even as we aggressively invest in wholly-owned programs, we will continue to leverage collaborations that enable us to explore novel applications of ARCUS and reach patients quicker.”

The Company’s balance of cash and cash equivalents is approximately \$167 million as of August 31, 2021. The Company continues to expect that existing cash and cash equivalents will be sufficient to fund planned operations into 2023.

Call and Webcast Information

Precision’s gene editing R&D event is being held today, September 9, 2021, at 8:00 a.m. ET. The dial-in conference call numbers for domestic and international callers are (866) 970-2058 and (873) 415-0216, respectively. The conference ID number for the call is 6376435. Participants may also access the live webcast, including slides, available in the Investors and Media section under Events and Presentations. An archived replay of the webcast will be available on Precision’s website for one year following the presentation.

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 (knockout), 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 80 patents to date.

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 the further development and potential of our ARCUS platform, the clinical development and timeline of PBGENE-PCSK9, PBGENE-PH1 and PBGENEHBV, our agreement with iECURE and the potential clinical development and benefits thereunder, our agreement with Lilly and the potential clinical development and benefits thereunder, and our expected use of cash and cash equivalents. In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate,” “target,” “mission,”

“goal,” “may,” “will,” “would,” “should,” “could,” “target,” “potential,” “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 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 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 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 the outbreak of COVID-19, 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 Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, 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 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.

Investor Contact:

Alex Kelly
Chief Financial Officer
Alex.Kelly@precisionbiosciences.com

Media Contact:

Maurissa Messier
Senior Director, Corporate Communications
Maurissa.Messier@precisionbiosciences.com

Precision BioSciences and iECURE Announce License and Collaboration Agreement to Develop ARCUS-Based Gene Editing Therapies

iECURE to License Precision's PCSK9-Directed ARCUS Nuclease and Pursue Four Gene Insertion Programs Focused on Liver Diseases; Precision Retains Rights Across All Indications Except Those Licensed to iECURE

iECURE Expects to File a Clinical Trial Application as Early as 2022 for Precision's PBGENE-PCSK9 Candidate for Familial Hypercholesterolemia

Preclinical Data for ARCUS-Mediated Gene Insertion to be Presented Today by iECURE Chief Scientific Advisor, James M. Wilson, M.D., Ph.D. at Precision's Gene Editing R&D Event

Durham, NC and Philadelphia, PA, September 9, 2021 – Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical-stage biotechnology company developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, and iECURE, a mutation-agnostic *in vivo* gene editing company striving to cure devastating diseases with high unmet need, today announced a license and collaboration agreement under which iECURE plans to advance Precision's PBGENE-PCSK9 candidate into Phase 1 studies and gain access to Precision's PCSK9-directed ARCUS nuclease to develop additional gene editing therapies for genetic diseases, initially targeting liver diseases.

Under the terms of the agreement, iECURE plans to file a clinical trial application as early as 2022 to advance the PBGENE-PCSK9 clinical candidate through Phase 1 clinical studies for the treatment of familial hypercholesterolemia (FH). Precision will retain rights to PBGENE-PCSK9, including all products developed for genetic indications with increased risk of severe cardiovascular events such as FH. In return, Precision has granted iECURE a license to use its PCSK9-directed ARCUS nuclease to insert genes into the well-characterized PCSK9 locus to develop treatments for four other pre-specified rare genetic diseases. Precision will receive an equity stake in iECURE and is eligible to receive milestone and royalty payments on sales of iECURE products developed with ARCUS.

“We are excited to continue working with Jim Wilson under this new *in vivo* gene editing license and collaboration agreement with iECURE, as iECURE looks to rapidly advance our PBGENE-PCSK9 candidate, file for a clinical trial application in 2022, and use our PCSK9-directed ARCUS nuclease, and its knock-in capabilities, to pursue new treatments for rare genetic diseases,” said Derek Jantz, Ph.D., Chief Scientific Officer and Co-Founder of Precision BioSciences. “Through this collaboration we expect to gain important clinical validation for *in vivo* gene editing with ARCUS, while retaining rights to this PCSK9-directed nuclease, which we believe offers a safe harbor locus for DNA gene editing knock-in without deleterious effects when the PCSK9 gene is disrupted.”

“We founded iECURE with the aim of focusing on genetic diseases with significant unmet need that we could target in a mutation-agnostic manner. After evaluating different gene editing technologies and platforms, we believe gene editing with ARCUS, including use of the uniquely designed ARCUS nuclease as a gene insertion tool targeting the PCSK9 gene will help us rapidly advance several candidates to the clinic with the potential to deliver on the promise of highly efficient, specific, and safe gene insertion,” said Joe Truitt, Chief Executive Officer of iECURE. “We are excited to partner with Precision on this key pillar of our gene editing strategy, to advance this work for rare genetic diseases.”

James M. Wilson, M.D., Ph.D., Chief Scientific Advisor of iECURE and Professor in the Departments of Medicine and Pediatrics, Perelman School of Medicine, University of Pennsylvania, Director, Gene Therapy Program, will present new non-human primate data demonstrating ARCUS-mediated gene addition today, September 9, 2021 during the [Precision BioSciences gene editing R&D event](#). Dr. Wilson and his team have demonstrated in non-human primates that it is possible to use ARCUS to insert new genes stably into the PCSK9 locus, which could be used as a potential approach for treating multiple genetic diseases with a single therapeutic strategy.

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 (knockout), 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 80 patents to date.

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.

About iECURE

iECURE is an *in vivo* gene editing company striving to cure liver disorders with high unmet need. We are advancing our pipeline in close partnership with the world-class translational engine at the University of Pennsylvania's Gene Therapy Program. Using *in vivo* editing, our methods focus on inserting functioning genes into patients' genomes, which offers long-term, stable expression of those genes. With our team's proven track record, reversing the course of these devastating disorders is now hopefully within reach.

Financial disclosure: The University of Pennsylvania and Dr. James Wilson hold equity interests in iECURE, receive significant sponsored research support from the company, and will be entitled to receive licensing revenues from iECURE based on successful technology development and commercialization of the licensed technology.

Precision's 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 Company's agreement with iECURE to develop and commercialize gene editing therapies using the Company's PCSK9-directed ARCUS nuclease for cardiovascular and rare genetic diseases, the timing of clinical trials and results therefrom, any future milestones or royalty payments thereunder, the development and commercial potential of ARCUS-mediated gene addition and the potential value of iECURE equity. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate,"

“target,” “mission,” “goal,” “may,” “will,” “would,” “should,” “could,” “target,” “potential,” “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 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 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 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 the outbreak of COVID-19, 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 Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, 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 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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