Precision BioSciences Reports Third Quarter 2025 Financial Results and Provides Business Update

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- Late-breaking oral presentation at the Liver Meeting® 2025 to feature new data from multiple cohorts of the Phase 1 ELIMINATE-B trial of PBGENE-HBV in chronic hepatitis B

- Commenced dosing in Cohort 3 of the ELIMINATE-B trial with additional data readouts planned in early 2026

- Investigational new drug (IND) filing for PBGENE-DMD anticipated by end of 2025; Phase 1 initiation in Duchenne Muscular Dystrophy (DMD) patients anticipated in the first half of 2026 and initial data expected in the second half of 2026

- Presented PBGENE-DMD late-breaking poster at the 30th Annual International Congress of the World Muscle Society

- Expected cash runway into the second half of 2027 enables achievement of clinical milestones for PBGENE-HBV and PBGENE-DMD

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 3, 2025-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company utilizing its novel proprietary ARCUS® platform to develop *in vivo* gene editing therapies for high unmet need diseases, today announced financial results for the third quarter ended September 30, 2025, and provided a business update.

“Throughout the third quarter, we made strong progress across our gene editing pipeline and reported compelling Phase 1 safety and efficacy data for PBGENE-HBV at the International Coalition to Eliminate HBV Cure Symposium. We’re also eagerly awaiting a late-breaking oral presentation at AASLD on November 10th,” said Michael Amoroso, Chief Executive Officer of Precision BioSciences. “The PBGENE-HBV data presented so far this year has shown proof of durable activity and a safety profile that allows us to continue dose escalation in pursuit of achieving a complete cure for hepatitis B patients. With great excitement, in 2026 we anticipate starting the first-in-human clinical trial with our second program, PBGENE-DMD for DMD patients, following our targeted IND submission by the end of 2025. We are highly encouraged by the unique preclinical data showing the potential to restore a nearly full length dystrophin gene which is native to the human body with the goal of improving function over time.”

Wholly-Owned Portfolio:

PBGENE-HBV (Hepatitis B Viral Elimination Program):

On October 14th, Precision announced that it had been selected to deliver a late-breaking oral presentation at the upcoming Liver Meeting 2025 during the 75th American Association for the Study of Liver Diseases. The oral presentation will feature new data from the multiple cohorts of the ongoing Phase 1 ELIMINATE-B Trial.

On October 7th, Precision announced that the first clinical trial sites in the U.S. for the ELIMINATE-B trial had officially been activated. The site at Massachusetts General Hospital in Boston, Massachusetts, is now actively recruiting chronic hepatitis B patients along with multiple global clinical trial sites.

On September 12th, the Company presented data from the Phase 1 ELIMINATE-B trial of PBGENE-HBV at the 6th International Coalition to Eliminate HBV Cure Symposium in Berlin, Germany. To date, PBGENE-HBV has shown to be well-tolerated by patients in both Cohort 1 and Cohort 2, who received multiple doses of 0.2 mg/kg of PBGENE-HBV and 0.4 mg/kg, respectively. In addition, PBGENE-HBV has demonstrated a substantial HBsAg reduction in all patients across Cohort 1 with one patient in Cohort 1 achieving a durable HBsAg reduction of approximately 50% from baseline that was ongoing seven months following initial dose administration. Given the favorable safety profile of Cohorts 1 and 2, the Data Monitoring Committee recommended the Company to proceed with dosing Cohort 3 which occurred during the third quarter of 2025.

On September 8th, Precision announced the issuance of a U.S. Patent (No. 12,410,418) by the U.S. Patent and Trademark Office (USPTO) titled “Optimized engineered meganucleases having specificity for a recognition sequence in the Hepatitis B Virus genome.” The composition of matter claims in the patent encompass the PBGENE-HBV ARCUS nuclease which has an expiration date in March 2042. Patents in Europe and Hong Kong granted earlier this year included similar composition of matter claims.

PBGENE-DMD (Muscle Targeted Excision Program):

On October 10th, the Company presented a late-breaking poster presentation at the 30th Annual International Congress of the World Muscle Society meeting highlighting durable improvements in muscle function over time through increased dystrophin expression and dystrophin-positive cells for PBGENE-DMD. The data from a DMD mouse model demonstrated that dystrophin protein was detected in all muscles evaluated following the administration of PBGENE-DMD at doses up to $1x10^{14}$ vg/kg, with increased expression observed at nine months versus prior timepoints in the quadriceps, gastrocnemius, heart, and diaphragm, resulting in substantial and sustained functional muscle improvement. An increase in dystrophin-positive muscle cells were observed in all muscles. The maximum force output was significantly improved over untreated DMD mice at three, six and nine months post-treatment, highlighting strong durability of PBGENE-DMD outcomes.

Precision has completed final toxicology studies and is manufacturing clinical supplies, with an anticipated IND filing by the end of 2025. Pending IND clearance, Phase 1 initiation in DMD patients is anticipated in the first half of 2026 with initial data expected to follow in the second half of 2026.

Partnered *In Vivo* Gene Editing Programs:

iECURE-OTC (Gene Insertion Program)

Led by partner, iECURE, ECUR-506 is an ARCUS-mediated *in vivo* targeted gene insertion program currently in a first-in-human trial (OTC-HOPE) evaluating ECUR-506 as a potential treatment for neonatal onset ornithine transcarbamylase (OTC) deficiency.

Several recent medical conference presentations with updated ECUR-506 clinical data include:

The 6th International Symposium on Urea Cycle Disorders and the 15th International Congress of Inborn Errors of Metabolism, both held in early September in Kyoto, Japan. In October, presentations at medical conferences included the European Society of Gene & Cell Therapy Annual Congress held in Sevilla, Spain, and the American Society of Human Genetics Annual Meeting in Boston, Massachusetts.

These data presentations build upon previously reported clinical results demonstrating complete clinical response in the first participant at the lowest dose level ($1.3x10^{13}$ GC/kg) of ECUR-506, as defined by the study protocol. The OTC-HOPE study is ongoing in the U.K., the U.S., Australia, and Spain with data from the trial expected in the first half of 2026.

Non-Core *Ex Vivo* Programs:

Azer-Cel (azercabtagene zapreleucel allogeneic CAR T treatment for cancer)

Imugene Limited, Precision's clinical stage partner developing azer-cel for oncology indications, announced on September 17th, additional efficacy data from its Phase 1b clinical trial evaluating azer-cel in patients with relapsed/refractory diffuse large B-cell lymphoma. The updated data showcased an overall response rate of 81% in patients treated with azer-cel and IL-2 with seven complete responses and six partial responses including several patients remaining in durable remission beyond one year.

On October 28th, Imugene announced the first efficacy results from the CAR T-naïve indication cohort of its ongoing Phase 1b trial of azer-cel. Of the six evaluable CAR T-naïve patients, five (83%) achieved an overall response including three (50%) complete responses. The result of the sixth patient's follow-up scan is pending. A total of ten patients have been treated in this CAR T-naïve cohort thus far, with additional results to come upon patient follow-up. These initial results encompass several rare lymphoma subtypes, notably Waldenström Macroglobulinemia (WM), Marginal Zone Lymphoma (MZL) and Primary Central Nervous System Lymphoma (PCNSL).

Imugene is actively enrolling patients in the Phase 1b azer-cel trial at ten U.S. sites and five sites in Australia. Imugene has scheduled a Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss potential pivotal study design options for azer-cel. The decision to proceed to a meeting with the FDA to discuss a pivotal trial reflects the positive, durable clinical data that has been generated to date and adds to the growing clinical data set supporting the ARCUS platform. On October 31, 2025, Precision received an $8 million milestone payment in cash and stock from Imugene.

Corporate Updates:

Mark Sulkowski, M.D. Appointed Head Clinical Development Advisor

In August, Mark Sulkowski, Professor of Medicine at the Johns Hopkins University School of Medicine and renowned expert in hepatic and infectious diseases has expanded his advisory role with Precision. In the newly created role, Head Clinical Development Advisor, Dr. Sulkowski will work closely with Precision's leadership and cross-functional teams to support clinical strategy across the development lifecycle for the Company's on-going PBGENE-HBV Phase 1 clinical trial as well as initiation of later stage trials. His advisory role will focus on optimizing clinical trials, including translational integration, and aligning scientific rationale with regulatory objectives.

Quarter Ended September 30, 2025 Financial Results

In July 2025, the Company implemented operating efficiencies, including employment related and other expense reductions, to reduce annual operating expenses and extend its expected cash runway. In the third quarter of 2025, the Company realized reductions in early research and general & administrative expenses which reduced the Company's operating expenses compared to both the second quarter of 2025 and third quarter of 2024.

Cash, Cash Equivalents, and Restricted Cash: As of September 30, 2025, Precision had approximately $71.2 million in cash, cash equivalents and restricted cash. Based on its expected cash runway, Precision believes it is sufficiently capitalized to reach important milestones for PBGENE-HBV and PBGENE-DMD. The Company expects existing cash and cash equivalents, potential near-term cash from CAR T transactions, along with expected operating efficiencies, operational receipts, and availability of Precision's at-the-market (ATM) facility to extend Precision's cash runway into the second half of 2027.

Revenues: Total revenues for the quarter ended September 30, 2025, were less than $0.1 million as compared to $0.6 million for the quarter ended September 30, 2024. The decrease was primarily the result of less billable effort under the Novartis Agreement.

Research and Development Expenses: Research and development expenses were $13.4 million for the quarter ended September 30, 2025, as compared to $13.1 million for the quarter ended September 30, 2024. The increase was primarily the result of an increase in the PBGENE-DMD program partially offset by decreases in the PBGENE-HBV program as it transitioned to the clinic at the end of 2024 and the PBGENE-3243 program which has been paused.

General and Administrative Expenses: General and administrative expenses were $7.3 million for the quarter ended September 30, 2025, as compared to $8.8 million for the quarter ended September 30, 2024. The decrease was primarily the result of employee-related costs and other general and administrative expenses.

Net Loss: Net loss was $21.8 million, or ($1.84) per share (basic and diluted), for the quarter ended September 30, 2025. Net loss was $16.4 million or $(2.25) per share (basic and diluted) for the quarter ended September 30, 2024.

About PBGENE-HBV, A Viral Elimination Program

PBGENE-HBV is Precision's wholly owned *in vivo* gene editing program under investigation in a global first-in-human clinical trial, which is designed to be a potentially curative treatment for chronic Hepatitis B infection. PBGENE-HBV is the first and only potentially curative gene editing program to enter the clinic that is specifically designed to eliminate the root cause of chronic Hepatitis B, cccDNA, while inactivating integrated HBV DNA. The ELIMINATE-B trial is investigating PBGENE-HBV at multiple ascending dose levels with three dose administrations per dose level in patients with chronic Hepatitis B. PBGENE-HBV has been granted Breakthrough Therapy designation by the FDA.

About PBGENE-DMD, A Muscle-Targeted Excision Program

PBGENE-DMD is Precision's development program for the treatment of DMD. DMD is a genetic disease caused by mutations in the dystrophin gene that prevent production of the dystrophin protein and affects approximately 15,000 patients in the U.S. alone. There are currently no approved therapies that can drive durable and significant functional improvements over time. PBGENE-DMD is designed to improve function for more than 60% of patients afflicted with DMD by employing two complementary ARCUS nucleases delivered in a single AAV to excise exons 45-55 of the dystrophin gene. The aim of this approach is to restore a near-full length functional dystrophin protein within the body that more closely resembles normal dystrophin as opposed to synthetic, truncated dystrophin approaches with minimal functional benefit. PBGENE-DMD has received both Rare Pediatric Disease and Orphan Drug designations from the U.S. FDA.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage gene editing company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform that differs from other technologies in the way it cuts, its smaller size, and its simpler structure. Key capabilities and differentiating characteristics may enable ARCUS nucleases to drive more intended, defined therapeutic outcomes. Using ARCUS, the Company's pipeline is comprised of *in vivo* gene editing candidates designed to deliver lasting cures for the broadest range of genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit www.precisionbiosciences.com.

The ARCUS® platform is being used to develop *in vivo* gene editing therapies for sophisticated gene edits, including gene insertion (inserting DNA into gene to cause expression/add function), elimination (removing a genome e.g. viral DNA such as in the Company's PBGENE-HBV program), and excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV such as in the Company's DMD program).

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 key advantages of ARCUS and its key capabilities and differentiating characteristics; expectations about operational initiatives, strategies, further development, or timing of additional updates or data releases of PBGENE-HBV and PBGENE-DMD; the presentation in a late-breaking oral presentation at the Liver Meeting® 2025 of new data from the first two cohorts of the Phase 1 ELIMINATE-B trial of PBGENE-HBV in chronic hepatitis B, timing of dose administrations and subsequent cohorts in the ELIMINATE-B trial, including dosing in Cohort 3 of the ELIMINATE-B trial with additional data readouts planned in early 2026; the unique design of PBGENE-HBV to eliminate cccDNA and inactivate integrated HBV DNA with high specificity, potentially leading to complete cures; the suitability of PBGENE-HBV for the treatment of hepatitis and the targeting of the root cause of the disease; the expected timing of regulatory processes, including an investigational new drug (IND) filing for PBGENE-DMD anticipated by end of 2025; expected initiation of a Phase 1 clinical trial of PBGENE-DMD in DMD anticipated in 2026 and expectations concerning the receipt of initial clinical data for PBGENE-DMD in 2H 2026; the design of PBGENE-DMD to improve function over time and address more than 60% of patients with DMD; the potential for PBGENE-DMD to provide durable functional improvement with a one-time lower dose of AAV; the safety data and antiviral activity established after administrations of PBGENE-HBV; translation of results in preclinical studies of ARCUS nucleases to clinical studies in humans; the preclinical and clinical development and demonstrated, potential and expected safety, efficacy, durability, and benefit of PBGENE-HBV and PBGENE-DMD, as well as our other product candidates and those being developed by partners; expectations around enrollment completion for the OTC-HOPE clinical trial in late 2025 and data from the trial in the first half of 2026; our expected cash runway and the sufficiency of our cash runway extending into the second half of 2027 enabling achievement of clinical milestones for PBGENE-HBV and PBGENE-DMD. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "belief", "believe," "contemplate," "could," "design," "designed," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should," "strive," "suggest," "target," "will," "would," or the negative thereof and similar words and expressions.

Forward-looking statements are based on management's current expectations, beliefs, and assumptions and on information currently available to us. These statements are neither promises nor guarantees, and involve a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding to advance our programs; risks associated with our capital requirements, anticipated cash runway, requirements under our current debt instruments and effects of restrictions thereunder, including our ability to raise additional capital due to market conditions and/or our market capitalization; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the progression and success of our programs and product candidates in which we expend our resources; our limited ability or inability to assess the safety and efficacy of our product candidates; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies, including clinical trial and investigational new drug applications; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators' or other licensees' ability to identify, develop and commercialize product candidates; pending and potential product liability lawsuits and penalties against us or our collaborators or other licensees related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators' or other licensees' development of product candidates; our or our collaborators' or other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; delays or difficulties in our and our collaborators' and other licensees' ability to enroll patients; changes in interim "top-line" and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data protection, privacy and security regulations and our compliance therewith; our or our licensees' ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; our or our collaborators' or other licensees' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth

of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of any pandemic, epidemic, or outbreak of an infectious disease; the success of our existing collaboration and other license agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with and reliance on third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price; our ability to meet the requirements of and maintain listing of our common stock on Nasdaq or other public stock exchanges; and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, 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 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.

Precision Biosciences, Inc.
Statements of Operations
(In thousands, except share and per share amounts)

	For the Three Months Ended September 30,	
	2025	**2024**
Revenue	$ 13	$ 576
Operating expenses		
Research and development	13,352	13,084
General and administrative	7,328	8,767
Total operating expenses	20,680	21,851
Operating loss	(20,667)	(21,275)
Other (expense) income:		
Loss from equity method investment	(591)	(875)
(Loss) gain on changes in other fair value adjustments	(3)	571
(Loss) gain on change in fair value of warrant liability	(1,179)	3,647
Interest expense	(362)	(256)
Interest income	1,027	1,763
Gain on disposal of assets	3	0
Total other (expense) income	(1,105)	4,850
Loss from operations	$ (21,772)	$ (16,425)
Net loss	$ (21,772)	$ (16,425)
Net loss per share		
Basic	$ (1.84)	$ (2.25)

Diluted	$ (1.84)	$ (2.25)
Weighted-average shares of common stock outstanding		
Basic	11,818,145	7,287,173
Diluted	11,818,145	7,287,173

Precision Biosciences, Inc.
Balance Sheets Data
(In thousands, except share amounts)

	September 30, 2025	December 31, 2024
Cash, cash equivalents, and restricted cash	$ 71,212	$ 108,468
Working capital	36,709	80,009
Total assets	93,510	136,388
Total liabilities	76,876	79,995
Total stockholders' equity	$ 16,634	$ 56,393
Common stock outstanding	12,082,665	8,202,715

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