Precision BioSciences Sets Strategic Priorities for 2026 Focused on Continued Advancement of Clinical-Stage Programs PBGENE-HBV for Chronic Hepatitis B and PBGENE-DMD for Duchenne Muscular Dystrophy

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Phase 1/2a ELIMINATE-B trial for PBGENE-HBV ongoing across multiple dosing cohorts; Data updates expected at medical conferences in 2026

PBGENE-DMD expecting IND clearance in Q1 2026 for Phase 1/2 FUNCTION-DMD study with initial data from multiple patients expected in 2026

Unaudited cash, cash equivalents, and restricted cash of approximately $137 million as of December 31, 2025, anticipated to fund PBGENE-HBV and PBGENE-DMD data milestones through 2028

DURHAM, N.C.--(BUSINESS WIRE)--Jan. 12, 2026-- 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 provided a business update and announced strategic priorities for 2026, highlighting recent progress for its two lead programs, upcoming clinical milestones, and a strong financial position supporting execution through key value-inflection points.

“We continue to make steady, disciplined progress across our clinical-stage programs,” said Michael Amoroso, Chief Executive Officer of Precision BioSciences. “With multiple dosing cohorts underway in our global Phase 1/2a ELIMINATE-B trial, our first-in-class gene editing approach for DMD entering the clinic in early 2026, and cash runway through 2028, we expect continued operational excellence this year with clear clinical and regulatory milestones for these potentially transformative therapies.”

PBGENE-HBV -Dose Finding Phase 1/2a ELIMINATE-B Trial in Chronic Hepatitis B

PBGENE-HBV is uniquely designed to potentially achieve a complete cure of hepatitis B by eliminating cccDNA, preventing the chance of viral relapse, and inactivating integrated HBV DNA. The data reported at AASLD in November 2025 as of the October 31st cutoff date showed clear positive evidence of dose-dependent effects and antiviral activity in all patients. The data also included paired biopsies providing the first molecular evidence of successful viral DNA gene editing in patients with hepatitis B.

The safety data showed PBGENE-HBV to have no dose-limiting toxicities at doses up to 0.8 mg/kg (Cohort 3) following the first administration. Adverse events across 22 total administered doses in 9 patients in the first 3 dose cohorts (0.2 mg/kg, 0.4 mg/kg, and 0.8 mg/kg) were predictable, manageable, and transient, including hypotension in the higher dose cohorts. Transaminase elevations were transient without elevations in bilirubin and resolved without intervention, and platelet fluctuations were transient and asymptomatic.

Given the safety profile after multiple repeat doses and durability of response with PBGENE-HBV, Precision has administered additional doses in Cohort 3 and in parallel commenced dosing two additional cohorts as previously planned to investigate a shorter dosing interval. Cohort 4 is being dosed at 0.4 mg/kg every 4 weeks and Cohort 5 at 0.65 mg/kg every 4 weeks to evaluate the potential for an optimized therapeutic index. To date, 12 participants have completed at least one dose administration of PBGENE-HBV across Cohorts 1 through 5.

Additional biopsy data is expected in the first half of 2026 building upon the first clinical evidence of viral gene editing for PBGENE-HBV which was shared at AASLD. In addition, Precision expects to complete dosing Cohorts 3, 4, and 5 and choose the optimal dosing regimen to achieve the goal of stopping nucleos(t)ide analog treatment and begin Part 2 expansion of the trial.

“We continue to advance PBGENE-HBV through Part 1 of the ELIMINATE-B dose-finding study and are encouraged by the activity we are seeing at all dose levels,” said Cindy Atwell, Chief Development and Business Officer. “As part of our dose optimization efforts, we are evaluating different levers for PBGENE-HBV across escalating doses, frequency of doses, and number of administrations in order to maximize the therapeutic index of PBGENE-HBV and start the expansion phase. We look forward to sharing further details at hepatitis-focused medical conferences in 2026.”

PBGENE-DMD - Phase 1/2 FUNCTION-DMD Trial in Duchenne Muscular Dystrophy (DMD) Patients

PBGENE-DMD, a novel first-in-class gene editing therapy, utilizes a gene excision approach, which is clearly differentiated from existing microdystrophin and exon skipping treatments. PBGENE-DMD is designed to potentially provide durable functional muscle improvement for DMD patients with mutations in exons 45-55 impacting up to 60% of boys with DMD. A single AAV encodes two ARCUS proteins designed to permanently edit a patient’s DNA within the dystrophin gene, resulting in a naturally-expressed, near full-length, functional dystrophin protein. Supported by robust preclinical evidence, PBGENE-DMD is designed to drive functional improvement over time by targeting muscle satellite cells.

Following clearance of the investigational new drug (IND) application, the FUNCTION-DMD Phase 1/2 clinical trial is expected to dose the first patient in late-Q1 or early-Q2 2026. The study will employ an appropriate immune modulation regimen and safety monitoring program to treat ambulatory patients with mutations in exons 45-55 at world class specialized DMD clinical sites. Initial data from multiple patients is expected by year end 2026, with early efficacy assessed by the percentage of near full-length dystrophin protein expression from muscle biopsies. Following supportive data from at least 10 DMD patients, the company would meet with the FDA to align on a regulatory path forward.

Partnered Programs

ECUR-506, being developed by iECURE, uses Precision BioSciences' ARCUS nuclease and is being evaluated as a potentially curative treatment for neonatal onset OTC deficiency in the ongoing OTC-HOPE study. Recently, iECURE reached alignment with the U.S Food and Drug Administration (FDA) on the primary and key secondary efficacy endpoints, comparators and study size for the ongoing OTC-HOPE study which could support a Biologics License Application. In addition, ECUR-506 was granted FDA Regenerative Medicine Advanced Therapy (RMAT) designation for neonatal onset OTC deficiency. iECURE's receipt of these regulatory milestones is supported by encouraging clinical data from the ongoing OTC-HOPE clinical study, including a complete clinical response observed in the first infant treated with ECUR-506. iECURE expects to release data from the ongoing clinical trial in the first half of 2026.

Azer-Cel, a novel allogeneic CAR T treatment originally created by Precision, is being developed by Imugene for diffuse large B-cell lymphoma. Imugene's recent FDA discussions have reached clear alignment across key elements required to advance azer-cel into a pivotal study including dosing regimen, patient population, endpoints, and manufacturing readiness.

Precision received an $8 million milestone payment in the fourth quarter of 2025 as a result of Imugene's progress with Azer-Cel.

Azer-Cel is also being developed by TG Therapeutics. Enrollment for patients with progressive multiple sclerosis is ongoing in a Phase 1 clinical trial evaluating azer-cel for the treatment of autoimmune diseases. Precision is eligible for additional milestone payments from TG Therapeutics, including a $7.5M near term clinical milestone.

Financial Position

Although it has not finalized its full financial results for the year ended December 31, 2025, Precision expects to report it had approximately $137 million in cash, cash equivalents, and restricted cash. Existing cash and cash equivalents, potential near-term consideration to be received from licensees, continued fiscal and operating discipline, and availability of its ATM facility are expected to provide sufficient cash runway through 2028.

About the ELIMINATE-B Trial:

The Phase 1/2a ELIMINATE-B study is currently enrolling HBeAg-negative chronic hepatitis B patients at world-class sites in Hong Kong, New Zealand, United States and Moldova. The goal of the study is to define the optimal dose and number of dose administrations for safely eliminating cccDNA and inactivating integrated HBV DNA. With regulatory approval already granted, Precision expects to expand the study to clinical trial sites in the U.K. and continue accelerating recruitment and evaluation of a genetically diverse patient population in the Phase 1/2a study.

About FUNCTION-DMD Trial:

The Phase 1/2 FUNCTION-DMD study is expected to enroll ambulatory DMD patients with mutations in exons 45-55 impacting up to 60% of boys with DMD. Pending IND clearance, the clinical trial is anticipated to begin dosing patients at world class sites starting in late Q1/early-Q2 with initial clinical data from multiple patients expected later in 2026.

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, expectations about operational initiatives, strategies, further development including dose expansion, and timing of additional updates or data releases of PBGENE-HBV, PBGENE-DMD, and the OTC-HOPE trial; translation of results in preclinical studies of ARCUS nucleases to clinical studies in humans; the design of PBGENE-HBV to potentially achieve a complete cure of hepatitis B by eliminating cccDNA and inactivating integrated HBV DNA at the source of hepatitis B, preventing the chance of viral relapse; the potential tolerability and hepatic safety for repeat administrations of PBGENE-HBV to drive antiviral responses; the expectation of biopsy data in the first half of 2026 and to complete dosing Cohorts 3, 4, and 5 and choose the optimal dosing regimen to achieve the goal of stopping nucleos(t)ide analog treatment and begin Part 2 expansion of the ELIMINATE-B trial; expected regulatory processes, including an investigational new drug (IND) clearance for PBGENE-DMD; expected dosing of the first patient in the Phase 1 clinical trial of PBGENE-DMD in late Q1 or early Q2 of 2026; expectations of initial data for multiple patients in the PBGENE-DMD program by year end 2026; expected communication with the FDA and alignment on regulatory path forward following supportive data from at least 10 DMD patients; the expected cash, cash equivalents, and restricted cash balance as of December 31, 2025; and the expected cash runway and the sufficiency of the cash runway to fund of data milestones for PBGENE-HBV and PBGENE-DMD through 2028. 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, 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; 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; our ability to advance product candidates into, and successfully design, implement and complete, clinical trials; changes in interim “top-line” and initial data that we announce or publish; our current and future relationships with and reliance on third parties including suppliers and manufacturers; and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2025, June 30, 2025, and September 30, 2025 as any such factors may be updated from time to time in our other filings with the U.S. Securities and Exchange Commission (SEC), which are accessible on the SEC’s website at www.sec.gov and the Investors page of our website under SEC Filings at investor.precisionbiosciences.com.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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