Precision BioSciences Reports Fourth Quarter and Fiscal Year 2023 Financial Results and Provides Business Update

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- Initiated final IND/CTA enabling studies for lead in vivo gene editing program PBGENE-HBV; expect to submit IND and/or CTA in 2024

- Completed licensing agreements to monetize divested CAR T assets with Imugene, TG Therapeutics and Caribou Biosciences including nearly $50 million in upfront and potential near-term payments

- Completed $40 million in public offering extending our anticipated cash runway into the second half of 2026 which is expected to enable achievement of first-in-human Phase 1 clinical data for two wholly owned programs - Hepatitis B & Primary Mitochondrial Myopathy

DURHAM, N.C.--(BUSINESS WIRE)--Mar. 27, 2024-- Precision BioSciences, Inc. (Nasdaq: DTIL), an advanced gene editing company utilizing its novel proprietary ARCUS® platform to develop *in vivo* gene editing therapies for sophisticated gene edits, including gene elimination, insertion, and excision, today announced financial results for the fourth quarter and fiscal year ended December 31, 2023 and provided a business update.

"2023 was a transformative year for Precision BioSciences as we fully transitioned to our core capability as an *in vivo* gene editing company rapidly advancing development of our wholly owned *in vivo* programs led by PBGENE-HBV and quickly followed by PBGENE-PMM. As a part of this transition, we successfully monetized our prior CAR T investments and completed a $40 million public offering, strengthening our balance sheet beyond Phase 1 readouts for both wholly owned programs," said Michael Amoroso, President and Chief Executive Officer of Precision BioSciences. "We are well positioned to continue to execute against our objectives, having received regulatory feedback from the U.S. Food and Drug Administration (FDA) and key regulatory agencies outside the U.S. which provided clarity and alignment to guide our planned investigational new drug (IND) and/or clinical trial application (CTA) filings for PBGENE-HBV in 2024. In addition, our partner iECURE has advanced the first ARCUS-mediated gene editing program into the clinic, bolstering our confidence and establishing regulatory precedent for ARCUS *in vivo* gene editing programs with the potential to deliver a curative treatment for patients."

"As we look ahead, we continue to advance our focused strategy to differentiate ARCUS within the gene editing field and progress both our wholly owned and partnered gene editing programs. In our wholly owned pipeline, we plan to continue to advance PBGENE-HBV and PBGENE-PMM towards IND and/or CTA filings in 2024 and 2025, respectively, as well as commence a new gene insertion program of our own. More broadly, we anticipate presenting and publishing new data this year that further differentiates ARCUS as a potential best-in-class tool for high efficiency gene insertion via homology directed repair. We believe that these complementary objectives will continue to build momentum and establish Precision BioSciences as a leading *in vivo* gene editing company," added Mr. Amoroso.

Wholly Owned Portfolio

PBGENE-HBV (Viral Elimination Program): Precision is developing PBGENE-HBV for the treatment of patients with chronic hepatitis B. Currently, it is estimated that approximately 300 million people worldwide are afflicted with chronic Hepatitis B. In November 2023, Precision presented preclinical efficacy and safety data at the 2023 American Association for the Study of Liver Diseases Annual Meeting. The data demonstrated strong proof of concept efficacy and safety for the final clinical candidate including no detectable off-target editing at maximal on-target editing dose.

In February 2024, Precision announced that the company had received pre-IND regulatory feedback from the U.S. FDA in addition to regulatory feedback from agencies outside the U.S. providing clarity and alignment on PBGENE-HBV IND/CTA-enabling preclinical plans and clinical strategy. Precision expects to submit an IND and/or CTA for this program in 2024.

PBGENE-PMM (Mutant Mitochondrial DNA Elimination Program): PBGENE-PMM is a first of its kind potential treatment for m.3243-associated primary mitochondrial myopathy (PMM). Mitochondrial diseases are the most common hereditary metabolic disorder in the world, affecting 15,000 to 25,000 people in the U.S. alone. PMM currently lacks a curative treatment and impacts approximately 50% of patients with mitochondrial disease. In a 2023 publication in *Nature Metabolism*, Precision shared new pre-clinical data highlighting the high specificity of the mitoARCUS nucleases to edit and eliminate mutant mitochondrial DNA while allowing wild-type (normal) mitochondrial DNA to repopulate in the mitochondria, thus improving normal function. ARCUS nucleases are able to penetrate the mitochondrial membrane unlike CRISPR-Cas, base and prime editors because ARCUS is single component editor that does not require a guide RNA. Precision expects to submit an IND and/or CTA for this program in 2025.

Partnered Programs

iECURE-OTC (Gene Insertion Program): Led by iECURE, ECUR-506 is the first ARCUS-mediated gene editing program to advance into the clinic following approval from the Australian Therapeutic Goods Administration and the U.K. Medicines & Healthcare products Regulatory Agency (MHRA) for initiation of the OTC-HOPE study, in the first half of 2024. The OTC-HOPE study is a first-in-human Phase 1/2 trial evaluating ECUR-506 as a potential treatment for neonatal onset ornithine transcarbamylase (OTC) deficiency. Non-human primate (NHP) data presented by researchers from the University of Pennsylvania's Gene Therapy Program demonstrated sustained gene insertion of a therapeutic OTC transgene one-year post-dosing in newborn and infant NHP's with high efficiency.

PBGENE-NVS (Gene Insertion Program): Precision continues to advance its gene editing program with Novartis to develop a custom ARCUS

nuclease for patients with hemoglobinopathies, such as sickle cell disease and beta thalassemia. The collaborative intent is to insert, *in vivo*, a therapeutic transgene as a potential one-time transformative treatment administered directly to the patient to overcome disparities in patient access to treatment with other therapeutic technologies, including those that are targeting an *ex vivo* gene editing approach.

PBGENE-DMD (Gene Excision Program): Precision continues its *in vivo* gene editing collaboration with Prevail Therapeutics, a wholly owned subsidiary of Eli Lilly and Company (Lilly), in applying ARCUS nucleases to three initial targets, including Duchenne muscular dystrophy (DMD) in muscle, a central nervous system directed target, and a liver directed target. The goal of the PBGENE-DMD program is to utilize a pair of ARCUS nucleases, delivered by a single adeno-associated virus (AAV), that are designed to excise an approximately 500,000 base pair mutation "hot spot" region from the dystrophin gene to generate a variant of the dystrophin protein that is functionally competent. During the Company's September 2023 R&D Day, Precision highlighted preclinical data demonstrating the potential of ARCUS *in vivo* gene editing for large gene excisions and that the edited dystrophin variant was observed in multiple tissue types frequently involved in progression of DMD, including skeletal muscle, heart, and diaphragm, enabling significantly improved muscle function.

PBGENE-LLY2 (Gene Insertion Program): During the Precision 2023 Gene Editing R&D Day, Precision highlighted new data demonstrating that ARCUS is capable of high efficiency gene insertion in nondividing cells in adult nonhuman primates, the most challenging context for gene insertion. In the pre-clinical study involving coadministration of AAV and lipid nanoparticle, Precision scientists observed 40% to 45% overall gene insertion efficiency at 1- and 3-months. Precision scientists largely attribute this high efficiency to the unique ARCUS cut type which drives homology directed repair, even in nondividing cells.

Business Updates – Monetization of CAR T Investments:

Completed Licensing Deal with TG Therapeutics for Cell Therapy Azer-Cel in Autoimmune Diseases:
In January 2024, Precision announced the completion of a transaction with TG Therapeutics (Nasdaq: TGTX) for certain exclusive and non-exclusive license rights to develop Azercabtagene Zapreleucel (azer-cel) for autoimmune diseases and other indications outside of cancer. In exchange for these rights, Precision received upfront and potential near-term economics valued at $17.5 million. The upfront payment of $7.5 million consisted of cash and the purchase of 97,360 shares of Precision common stock by TG Therapeutics at a price of $23.10 per share, a 100% premium to the 30-day volume-weighted average price. Shares and per share amounts have been adjusted for Precision's reverse stock split effective February 14, 2024. In addition, Precision will receive $2.5 million in deferred consideration due within 12 months as an equity investment in Precision's common stock at a 100% premium to the then 30-day VWAP prior to purchase. Upon the achievement of certain near-term clinical milestones, Precision will receive an additional $7.5 million payment in cash and the purchase of Precision common stock by TG Therapeutics at a 100% premium to the then current 30-day VWAP. Precision is eligible to receive up to $288 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones, in addition to high-single-digit to low-double-digit royalties on net sales.

Completed Licensing Deal with Imugene Limited for Azer-Cel in Cancer:
The agreement with TG Therapeutics followed an agreement with Imugene Limited (ASX: IMU) in August 2023 for an exclusive license for azer-cel in cancer. In exchange for global rights to azer-cel for cancer Precision received upfront economics valued at $21 million consisting of cash and convertible notes. In addition, Precision is eligible for a potential $8 million near-term payment in cash and equity upon successful completion of the phase 1b dosing in the CAR T relapsed LBCL patient population. Precision is eligible to receive up to $198 million in additional milestone payments and double-digit royalties on net sales of azer-cel.

Completed Non-Exclusive Patent License Agreement with Caribou Biosciences:
In February 2024, Precision announced that it had granted Caribou Biosciences (Nasdaq: CRBU) a non-exclusive, worldwide license, with the right to sublicense, to one of Precision's foundational cell therapy patent families for use with CRISPR-based therapies in the field of human therapeutics. Under the terms of the agreement, Precision received an upfront payment and, upon commercialization by Caribou, will receive royalties on net sales of licensed products. In addition, for each occurrence of certain strategic transactions involving Caribou, Precision is entitled to receive a specific tiered milestone payment.

In total, these three transactions provide Precision BioSciences with nearly $50 million in upfront payments and potential near-term cash payments which, if realized, will be invested in the *in vivo* gene editing programs.

Business Updates – $40 Million Offering:

On March 1, 2024, Precision completed a $40 million public underwritten offering consisting of 2,500,000 shares of its common stock and accompanying warrants to purchase up to 2,500,000 shares of common stock at a combined offering price of $16.00 price per share, for total gross proceeds of $40 million, before deducting underwriting discounts and commissions. The financing included participation from leading life sciences investors, including Perceptive Advisors, Janus Henderson Investors, Aquilo Capital Management, LLC and LYFE Capital. The capital raised in the public offering is expected to extend the company's cash runway into the second half of 2026, fund development of our PBGENE-HBV and PBGENE-PMM *in vivo* gene editing programs through Phase 1 read out, and enable commencement of a new wholly owned gene insertion program.

Quarter Ended December 31, 2023 Financial Results:

Cash and Cash Equivalents: As of December 31, 2023, Precision had $116.7 million in cash and cash equivalents. The cash balance as of December 31, 2023 does not include the benefit of cash received from TG Therapeutics, Caribou or the $40 million capital raise since year-end. Upfront and potential near-term cash from CAR T transactions, cash received from the public offering, along with existing cash and cash equivalents, expected operational receipts, continued fiscal and operating discipline, availability of Precision's at-the-market (ATM) facility, and available credit are expected to extend Precision's cash runway into the second half of 2026.

Revenues: Total revenues for the quarter ended December 31, 2023 were $7.0 million, as compared to $10.6 million for the quarter ended December 31, 2022. The decrease of $3.6 million in revenue during the quarter ended December 31, 2023 was primarily the result of a decrease in revenue recognized from collaborations.

Research and Development Expenses: Research and development expenses were $13.4 million for the quarter ended December 31, 2023, as compared to $12.7 million for the quarter ended December 31, 2022. The increase of $0.7 million was primarily due to an increase in PBGENE-HBV and PBGENE-PMM program costs as the programs continue to advance toward the clinic.

General and Administrative Expenses: General and administrative expenses were $8.5 million for the quarter ended December 31, 2023, as compared to $10.0 million for the quarter ended December 31, 2022. The decrease of $1.5 million was primarily due to operational discipline, a decrease in the number of employees and a decrease in share-based compensation expense.

Other Income and Expense: Total other income was $1.5 million for the quarter ended December 31, 2023, as compared to total other expense of $7.3 million for the quarter ended December 31, 2022. The increase was primarily driven by an impairment related to the iECURE PCSK9 collaboration in the quarter ended December 31, 2022, and a gain in fair value of equity investment in iECURE in the quarter ended December 31, 2023, partially offset by a loss from equity method investments.

Continuing Operations: Loss from continuing operations was $13.4 million for the quarter ended December 31, 2023, as compared to $19.4 million for the quarter ended December 31, 2022.

Net Loss: Net loss was $16.3 million, or $(4.06) per share (basic and diluted), including a $2.9 million loss from discontinued operations for the quarter ended December 31, 2023. Net loss was $28.5 million, or $(7.70) per share (basic and diluted), including a $9.1 million loss from discontinued operations for the quarter ended December 31, 2022. Discontinued operations represent costs associated with the development of allogeneic CAR T immunotherapies.

Fiscal Year 2023 Financial Results:

Revenues: Total revenues for the year ended December 31, 2023 were $48.7 million, as compared to $25.1 million for the year ended December 31, 2022. The increase of $23.6 million in revenue during the year ended December 31, 2023 was primarily the result of an increase in revenue recognized under the Prevail and Novartis agreements.

Research and Development Expenses: Research and development expenses were $53.4 million for the year ended December 31, 2023, as compared to $46.1 million for the year ended December 31, 2022. The increase of $7.3 million was primarily due to an increase in PBGENE-HBV and PBGENE-PMM program costs as the programs continue to advance toward the clinic in addition to increases in outsourced research and development costs primarily related to consulting fees, employee-related costs, and facility-related costs.

General and Administrative Expenses: General and administrative expenses were $39.1 million for the year ended December 31, 2023, as compared to $41.3 million for the year ended December 31, 2022. The decrease of $2.2 million was a result of operational discipline, lower headcount, and decreases in share-based compensation expense.

Other Income and Expense: Total other income was $1.2 million for the year ended December 31, 2023, as compared to total other expense of $10.6 million for the year ended December 31, 2022. The increase was primarily driven by an impairment related to the iECURE PCSK9 collaboration in the year ended December 31, 2022, an increase in interest income, and an increase in the loss from equity method investments.

Continuing Operations: Loss from continuing operations was $42.5 million for the year ended December 31, 2023, as compared to $72.9 million for the year ended December 31, 2022.

Net Loss: Net loss was $61.3 million, or $(15.96) per share (basic and diluted), including a $18.8 million loss from discontinued operations for the year ended December 31, 2023. Net loss was $111.6 million, or $(38.10) per share (basic and diluted), including a $38.7 million loss from discontinued operations for the year ended December 31, 2022. Discontinued operations represent costs associated with the development of allogeneic CAR T immunotherapies.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is an advanced 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), excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV), and elimination (removing a genome e.g. viral DNA or mutant mitochondrial DNA).

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 clinical development and expected safety, efficacy and benefit of our product candidates (including azer-cel) and gene editing approaches including editing efficiency and differentiating aspects; the suitability of azer-cel for oncology indications and non-oncology indications including immunological diseases; the suitability of ARCUS nucleases for gene insertion, gene elimination, large gene deletion, and other gene editing approaches; the expected timing of regulatory processes (including filings and studies for PBGENE-HBV and PBGENE-PMM); expectations about our operational initiatives and business strategy; expectations of further presentations and publications further differentiating ARCUS; expectations and updates around partnership and collaboration opportunities; our expected cash runway and available credit; the sufficiency of our cash runway and available credit extending through clinical phase 1 readouts for our HBV and PPM programs; expectations about achievement of key milestones and receipt of any milestone, royalty, or other payments; expectations regarding our liquidity and capital resources; and anticipated timing of initial clinical data. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could,", "designed", "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "seek," "should," "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 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; 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 the COVID-19 pandemic and variants thereof, or any pandemic, epidemic, or outbreak of an infectious disease; 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; 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 Annual Report on Form 10-K for the quarterly period ended December 31, 2023, 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 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 December 31,	
	2023	**2022**
Revenue	$ 7,038	$ 10,598
Operating expenses		
Research and development	13,389	12,683
General and administrative	8,539	10,024
Total operating expenses	21,928	22,707
Operating loss	(14,890)	(12,109)
Other income (expense):		
Impairment charges	—	(10,844)
Loss on disposal of assets	(524)	(19)
Gain (loss) on changes in fair value	1,603	(510)
(Loss) gain from equity method investment	(871)	2,604

Interest expense	(579)	(486)
Interest income	1,827	1,937
Total other income (expense)	1,456	(7,318)
Loss from continuing operations	$ (13,434)	$ (19,427)
Loss from discontinued operations	(2,855)	(9,061)
Net Loss	$ (16,289)	$ (28,488)
Net loss per share attributable to common stockholders-basic and diluted	$ (4.06)	$ (7.70)
Weighted average shares of common stock outstanding-basic and diluted	4,010,467	3,698,456

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

	For the Years Ended December 31,	
	2023	**2022**
Revenue	$ 48,727	$ 25,098
Operating expenses		
Research and development	53,375	46,122
General and administrative	39,088	41,284
Total operating expenses	92,463	87,406
Operating loss	(43,736)	(62,308)
Other income (expense):		
Impairment charges	—	(10,844)
Loss on disposal of assets	(461)	(30)
Gain (loss) on changes in fair value	1,145	(510)
Loss from equity method investment	(4,931)	(1,579)
Interest expense	(2,230)	(1,111)
Interest income	7,686	3,473
Total other income (expense)	1,209	(10,601)
Loss from continuing operations	$ (42,527)	$ (72,909)

Loss from discontinued operations (including gain on disposal of $8,446 during the year ended December 31, 2023)	(18,792)	(38,728)
Net Loss	$ (61,319)	$ (111,637)
Net loss per share attributable to common stockholders-basic and diluted	$ (15.96)	$ (38.10)
Weighted average shares of common stock outstanding-basic and diluted	3,841,405	2,929,873

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

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 116,678	$ 189,576
Working capital	86,372	139,441
Total assets	159,781	238,169
Total liabilities	140,920	177,736
Total stockholders' equity	$ 18,861	$ 60,433
Common stock outstanding	4,164,038	3,698,674

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