Precision BioSciences Reports Third Quarter 2022 Financial Results and Provides Business Update

November 8, 2022 at 7:00 AM EST

- Allogeneic CAR T Program Updates Planned for Late Q4 2022 or Early Q1 2023

- Abstract Showcasing Functional Attributes of Azer-cel (PBCAR1091) Accepted for Presentation at the 64th American Society of Hematology (ASH) Annual Meeting

- Preclinical Research on In Vivo Gene Editing Programs Presented at the European Society of Gene & Cell Therapy (ESGCT) 29th Congress

- Strong Cash Position Provides More than Two Years of Expected Runway

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 8, 2022-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *ex vivo* allogeneic CAR T and *in vivo* gene editing therapies, today announced financial results for the third quarter ended September 30, 2022 and provided a business update.

"Over the last year, Precision has made considerable progress against our corporate and development objectives. We executed a disciplined portfolio strategy to focus on human therapeutics, advanced our lead clinical stage CAR T programs, leveraged platform partnerships, and made data-informed decisions designed to maximize patient impact and extend our expected cash runway to the end of 2024," said Michael Amoroso, Chief Executive Officer of Precision BioSciences. "We have refined the scope of our CAR T portfolio, focusing on PBCAR0191, known as azer-cel, in the growing CAR T-relapsed population, which has shown high complete response rates, long-term responses, and peak CAR T expansion on par with autologous CAR T in durable responders. We are also exploring the potential of our immune-evading stealth cell technology with PBCAR19B in earlier line DLBCL patients with the goal of displacing autologous CAR T treatment options. Looking ahead, our team is focused on executing and advancing our clinical stage CD19 targeted CAR T programs and providing a clinical update in late Q4 2022 or early Q1 2023, depending on patient accrual and follow-up."

Mr. Amoroso continued, "We also advanced multiple in vivo gene editing programs, independently and with partners, highlighted by our research collaboration with Novartis in June and recent preclinical data shared at ESGCT. As a result of ARCUS' versatility, recent high efficiency *in vivo* gene insertion data, and scientific progress with wholly-owned and partnered programs, we have commenced a portfolio review of our *in vivo* gene editing programs. We are exploring ways to expedite key programs, advance new indications, and maximize ARCUS' core features which have the potential to enable high efficiency gene insertion and complex edits aimed at restoring genomic function and treating the underlying root cause of specific genetic diseases. Our aim is to focus on programs in which ARCUS is most differentiated and where we see potential for a clear and rapid path to market, while providing a potentially curative therapeutic solution to patients with the highest unmet need. We look forward to providing meaningful progress updates along the way."

Recent Developments and Upcoming Milestones:

***Ex Vivo* Allogeneic CAR T Portfolio:**

PBCAR0191: PBCAR0191, azercabtagene zapreleucel (azer-cel), is Precision's lead investigational anti-CD19 allogeneic CAR T candidate in a Phase 1/2a clinical trial of adult subjects with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL). An abstract on the cell dose and functional attributes of azer-cel that may be associated with positive safety and efficacy results for CAR T therapy in R/R B-cell lymphoma was accepted for poster presentation at the 64th ASH Annual Meeting taking place December 10-13, 2022. The poster presentation will highlight the first analysis of an allogeneic CD19 CAR T product composition to demonstrate that strategies intended to maximize stem central memory T-cell fraction ($CCR7^+$) while limiting $CD4^+$ $CCR7^+$ differentiated fraction may improve safety and efficacy of CAR T therapy.

Precision continues dosing subjects with optimized azer-cel CAR T cells in the CAR T relapsed population in which it has shown high and durable complete response rates, while further reducing the dose of lymphodepletion to standard levels in pursuit of best therapeutic index for this patient population.

PBCAR19B: PBCAR19B is Precision's second generation, anti-CD19 targeting allogeneic CAR T candidate designed to evade immune rejection by host T cell and natural killer (NK) cells with a single-gene edit to knock-down beta-2 microglobulin and insert an HLA-E transgene. Precision continues to recruit patients at Dose Level 2 (flat dose of 540 million cells) with the intent to complete the Phase 1 dose escalation.

Precision expects to provide an update in late Q4 2022 or early Q1 2023, depending on patient accrual and follow-up, on its two distinct CD19 targeted products, including azer-cel which is aiming to achieve a potential first-in-class allogeneic CAR T therapy in the CAR T relapsed population, and PBCAR19B which is seeking to displace autologous CAR T in the second/third line DLBCL population.

PBCAR269A + GSI: PBCAR269A is Precision's investigational allogeneic CAR T cell candidate targeting B-cell maturation antigen (BCMA) for R/R multiple myeloma in combination with nirogacestat, a gamma secretase inhibitor (GSI) developed by SpringWorks Therapeutics, Inc. The combination therapy and increased dose of PBCAR269A resulted in improved cell expansion, which correlated with increased clinical activity when compared to dose-matched PBCAR269A monotherapy treatment. However, in light of the competitive landscape of BCMA targeted therapies in multiple myeloma, Precision has made the strategic decision not to continue the PBCAR269A clinical program. All subjects enrolled in the study and evaluated for

treatment with PBCAR269A and nirogacestat had acceptable tolerability results. While no clinical spending is planned, Precision researchers will evaluate further modifications to the BCMA construct aimed at enabling an allogeneic approach similar to that of autologous CAR T in multiple myeloma. Precision thanks the patients and clinicians for their participation in the PBCAR269A clinical program.

***In Vivo* Gene Editing Portfolio:**

Precision believes that *in vivo* applications are particularly well suited to ARCUS because they require extremely low levels of off-target editing and efficient delivery. As a gene editing tool, ARCUS can be differentiated by unique attributes which are designed for precise, specific and versatile gene editing. By nature of its origin from a homing endonuclease, ARCUS can be particularly applicable to gene insertion and complex edits designed for gene repair aimed at restoring function, as well as more simple gene knock outs. ARCUS is also unique in its relatively small size which allows delivery to a wider range of cells and tissues using viral and non-viral gene delivery methods.

Novartis *In Vivo* Gene Editing Collaboration Precision is advancing its gene editing research and development collaboration and license agreement with Novartis to develop a single, custom ARCUS nuclease designed to insert a therapeutic transgene, *in vivo*, at a “safe harbor” location in the genome. This has the potential to be a one-time transformative treatment option for diseases including certain hemoglobinopathies such as sickle cell disease and beta thalassemia. In conjunction with the close of the agreement, Novartis made a $25 million equity investment in Precision in the second quarter of 2022 and Precision received $50 million in cash in the third quarter of 2022.

Lilly *In Vivo* Gene Editing Collaboration: Precision continues its *in vivo* gene editing collaboration with Lilly and is applying ARCUS nucleases for three initial targets, including Duchenne muscular dystrophy in muscle, a *central nervous system* directed target and a liver directed target.

PBGENE-HBV: Precision’s gene editing program for chronic Hepatitis B applies ARCUS to knock out persistent covalently closed circular DNA (cccDNA) and inactivate integrated hepatitis B genomes, potentially achieving durable HBV S-antigen (HBsAg) loss and reducing viral persistence. Preclinical data from this program were presented during ESGCT in October 2022. Data presented demonstrated that ARCUS efficiently targeted and degraded hepatitis B virus (HBV) cccDNA by 85% and reduced expression of HBsAg by 77% in HBV-infected primary human hepatocytes (PHH). Importantly, the optimized specificity of the ARCUS nuclease completely prevented detectable chromosomal translocations in the PHH model.

PBGENE-PH1: Precision has initiated IND-enabling activities for its PBGENE-PH1 candidate designed to knock out the HAO1 gene as a potential one-time treatment for primary hyperoxaluria type 1 (PH1).

PBGENE-PCSK9: In 2021, Precision initiated a collaboration with iECURE, pursuant to which iECURE is expected to advance Precision’s PBGENE-PCSK9 candidate through preclinical activities as well as a Phase 1 study in familial hypercholesterolemia. As of this date, IND enabling activities for PBGENE-PCSK9 have not been completed. Precision is in discussions with iECURE and will provide an update on the program when more information is available.

Other ARCUS Research:

International Conference on Ureagenesis Defects and Allied Conditions 2022[1]: Preclinical data were presented by researchers from the University of Pennsylvania’s Gene Therapy Program in collaboration with iECURE, Precision’s partner, highlighting an ARCUS-based gene insertion approach for the treatment of ornithine transcarbamylase (OTC) deficiency. Non-human primate (NHP) data demonstrated stable insertion of the therapeutic gene one year post-dosing in newborn and infant NHPs In the follow up data, 12-month biopsies continued to demonstrate construct stability, with transduction efficiency up to 28.2% as measured by in-situ hybridization (ISH). These data further demonstrate the preclinical feasibility of using an ARCUS-mediated gene insertion approach.

ESGCT 29th Congress: Additional abstracts on ARCUS *in vivo* gene editing were presented in addition to Precision’s HBV program, including one poster presentation each on Precision’s Apolipoprotein C3 and mitochondrial DNA preclinical research.

- APOC3 poster presentation: ARCUS gene editing of Apolipoprotein C3 results in substantial reduction in serum triglycerides *in vivo*
- Mito DNA poster presentation: Specific elimination of m.3243A>G mutant mitochondrial DNA using mitoARCUS in cultured cells and a novel xenograft mouse model

Quarter Ended September 30, 2022 Financial Results:

Cash and Cash Equivalents: As of September 30, 2022, Precision had approximately $212.1 million in cash and cash equivalents. The Company expects that existing cash and cash equivalents, expected operational receipts, and available credit will be sufficient to fund its operating expenses and capital expenditure requirements to the end of 2024.

Revenues: Total revenues for the quarter ended September 30, 2022 were $7.4 million, as compared to $24.0 million for the same period in 2021. The decrease of $16.6 million in revenue during the quarter ended September 30, 2022 was primarily the result of the absence of $17.9 million in revenue recognized under the iECURE Agreement in August 2021 subsequent to the full satisfaction of the performance obligation. These decreases in revenue were partially offset by an increase of $3.6 million in revenue recognized under the Novartis Agreement.

Research and Development Expenses: Research and development expenses were $20.0 million for the quarter ended September 30, 2022, as compared to $25.9 million for the same period in 2021. The decrease of $5.9 million was primarily due to a decrease of $3.6 million in external development costs associated with our allogeneic CAR T product candidates, a decrease of $0.9 million in employee-related and other operational costs driven by the separation of Elo in 2021, and a decrease of $1.4 million in clinical manufacturing organization and research costs related to our preclinical studies.

General and Administrative Expenses: General and administrative expenses were $10.3 million for the quarter ended September 30, 2022, as compared to $9.6 million for the same period in 2021. The increase of $0.7 million was primarily due to increased share-based compensation expense.

Other Income and Expense: Total other expense was $1.0 million for the quarter ended September 30, 2022, as compared to total other income of $0.3 million for the same period in 2021.

Net Loss: Net loss was $23.9 million, or $(0.22) per share (basic and diluted), for the quarter ended September 30, 2022, as compared to net loss of $11.3 million, or $(0.19) per share (basic and diluted), for the same period in 2021. Weighted average shares of common stock outstanding were approximately 110.8 million for the quarter ended September 30, 2022, as compared to approximately 59.7 million for the quarter ended September 30, 2021. The increase in weighted average shares of common stock outstanding was primarily due to a $50 million underwritten offering of common stock and Novartis' $25 million equity investment in the nine months ended September 30, 2022.

Corporate:

Executive Leadership: In September 2022, Cindy Atwell, formerly Senior Vice President of Business Development and Alliance Management, was promoted to Chief Business Officer and continues to oversee the Business Development and Alliance functions with added responsibility for Project and Portfolio Management. Jeff Smith, Ph.D., co-founder and formerly Chief Technology Officer, was promoted to Chief Research Officer and assumed responsibility for the management and direction of the Company's research programs, reporting directly to the CEO. Derek Jantz, Ph.D., co-founder and Chief Scientific Officer is focusing his time partnering with Michael Amoroso in formulating company strategy and managing relationships with external stakeholders, including current and potential collaboration partners.

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 precise 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 *ex vivo* "off-the-shelf" CAR T immunotherapy clinical candidates and several *in vivo* gene editing candidates designed 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 clinical development and expected efficacy and benefit of our product candidates and programs, the expected timing of updates regarding programs in our allogeneic CAR T and *in vivo* portfolio and ARCUS research, planned development activities with our collaboration partners, expectations about our operational initiatives, our business strategy and portfolio review and expectations regarding our liquidity and capital resources. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "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. 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 studies and clinical trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and 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 COVID-19 pandemic and variants thereof, 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, 2022, as any such factors may be updated from time to time in our other filings with the SEC, including, but not limited to, our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, to be filed 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.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(unaudited)

	For the Three Months Ended September 30,	
	2022	**2021**
Revenue	$ 7,363	$ 24,036
Operating expenses		
Research and development	19,959	25,940
General and administrative	10,334	9,638
Total operating expenses	30,293	35,578
Operating loss	(22,930)	(11,542)
Other (expense) income:		
Change in fair value of equity investment	—	274
Loss from equity method investment	(1,783)	—
Interest expense	(405)	(55)
Interest income	1,172	44
Total other (expense) income, net	(1,016)	263
Net loss	$ (23,946)	$ (11,279)
Net loss per share - basic and diluted	$ (0.22)	$ (0.19)
Weighted average shares of common stock outstanding - basic and diluted	110,849,196	59,657,677

	For the Nine Months Ended September 30,	
	2022	**2021**
Revenue	$ 14,500	$ 109,190

Operating expenses		
Research and development	62,867	88,768
General and administrative	31,510	29,074
Total operating expenses	94,377	117,842
Operating loss	(79,877)	(8,652)
Other (expense) income:		
Change in fair value of equity investment	—	274
Loss from equity method investment	(4,183)	—
Interest expense	(625)	(79)
Interest income	1,536	145
Total other (expense) income, net	(3,272)	340
Net loss	$ (83,149)	$ (8,312)
Net loss per share - basic and diluted	$ (1.04)	$ (0.14)
Weighted average shares of common stock outstanding - basic and diluted	80,127,701	58,018,550

Precision BioSciences, Inc.

Condensed Consolidated Balance Sheets Data

(In thousands, except share amounts)

(Unaudited)

	September 30, 2022	**December 31, 2021**
Cash and cash equivalents	$ 212,051	$ 143,663
Working capital	164,217	125,774
Total assets	271,733	211,498
Total liabilities	187,353	120,330

Total stockholders' equity	$ 84,380	$ 91,168
Common stock outstanding	110,934,747	60,902,105

[1] University of Pennsylvania’s Gene Therapy Program presentation sponsored by iECURE. iECURE has a license to use of ARCUS for gene insertion for OTC.

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