Precigen Reports Third Quarter 2024 Financial Results and Business Updates

Nov 14, 2024

– *Completed pre-BLA meeting with FDA with full alignment on content of BLA, including CMC module, and path for fourth quarter 2024 rolling BLA submission for PRGN-2012† in RRP under accelerated approval pathway* –

– *Commercial and manufacturing readiness campaign underway for PRGN-2012 in anticipation of a potential 2025 launch* –

– *Confirmatory clinical trial for PRGN-2012 in RRP was initiated in accordance with guidance from FDA to initiate prior to submission of the BLA; continuing enrollment* –

– *Preparing for end of Phase 1b meeting with FDA in early 2025 for PRGN-3006 in AML* –

– *Presented preclinical data at SITC 2024 for PRGN-3008, a next generation UltraCAR-T targeting CD19 showcasing potential to be best-in-class CD19-targeting CAR-T treatment in oncology and autoimmunity* –

GERMANTOWN, Md., Nov. 14, 2024 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today announced third quarter 2024 financial results and business updates.

"The strategic reprioritization of our portfolio announced last quarter has enabled us to focus our team and allocate resources to advance PRGN-2012 as rapidly as possible. We are excited about our imminent submission of a BLA for PRGN-2012 in RRP as we have finalized our pre-BLA meetings and are aligned with the FDA on the content for all modules and plan for submission in the fourth quarter. Our commercial and manufacturing readiness campaigns for PRGN-2012 are well underway to support a potential 2025 launch," said Helen Sabzevari, PhD, President and CEO of Precigen. "Although our primary focus is on PRGN-2012, we continue to demonstrate the many advantages of the UltraCAR-T platform over conventional CAR-Ts. Our recent data presentation at SITC for our next generation UltraCAR-T targeting CD19 reinforces the potential to be the best-in-class CD19-targeting medicine in oncology and autoimmune diseases, such as lupus nephritis. We are excited about the potential of this platform and the strategic partnership discussions that currently are underway."

"Following our reprioritization and public equity offering announced in August, we remain focused on fiscal management while appropriately investing in activities necessary for the potential launch of PRGN-2012. We are making good progress on a number of potential financing options, including strategic partnerships and other transactions. We will update our investors on this progress in the coming months," said Harry Thomasian Jr., CFO of Precigen.

Key Program Highlights

PRGN-2012 AdenoVerse® Gene Therapy in RRP

- PRGN-2012 is an investigational off-the-shelf AdenoVerse gene therapy designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11 for the treatment of recurrent respiratory papillomatosis (RRP). PRGN-2012 received Breakthrough Therapy Designation from the US Food and Drug Administration (FDA). PRGN-2012 also received Orphan Drug Designation from the FDA and Orphan Drug Designation from the European Commission.
- Results from the pivotal clinical study of PRGN-2012 for the treatment of RRP were presented at the 2024 American Society of Clinical Oncology (ASCO) annual meeting in a late-breaking oral presentation titled, "*PRGN-2012, a novel gorilla*

adenovirus-based immunotherapy, provides the first treatment that leads to complete and durable responses in recurrent respiratory papillomatosis patients."

- Pivotal study met primary safety and efficacy endpoints.
- 51% (18 out of 35) of patients achieved Complete Response, requiring no surgeries after treatment with PRGN-2012; Complete Responses have been durable beyond 12 months with median duration of follow up of 20 months as of the May 20, 2024 data cutoff.
- 86% of patients (30 out of 35) had a decrease in surgical interventions in the year after PRGN-2012 treatment compared to the year prior to treatment; RRP surgeries reduced from a median of 4 (range: 3-10) pre-treatment to 0 (range: 0-7) post-treatment.
- PRGN-2012 was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
- PRGN-2012 treatment induced HPV 6/11-specific T cell responses in RRP patients with a significantly greater expansion of peripheral HPV-specific T cells in responders compared with non-responders.
- PRGN-2012 significantly ($p < 0.0001$) improved Derkay and quality of life scores in complete responders.

- The Company has completed the pre-biologics license application (BLA) meeting with the FDA and is in full alignment on the content of the BLA, including the clinical and chemistry, manufacturing and controls (CMC) module, and the path for a fourth quarter 2024 rolling BLA submission under an accelerated approval pathway.
- The Company continues to rapidly advance its commercial and manufacturing readiness campaign in anticipation of a potential 2025 launch.
- Patient enrollment continues to advance in the confirmatory clinical trial of PRGN-2012 in accordance with the guidance from the FDA to initiate the study prior to submission of the BLA.

PRGN-2009 AdenoVerse® Gene Therapy in HPV-associated cancers

- PRGN-2009 Phase 2 clinical trials under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI) in recurrent/metastatic cervical cancer and in newly diagnosed HPV-associated oropharyngeal cancer are ongoing. As part of the strategic reprioritization announced earlier, the Company has paused enrollment in the cervical cancer Phase 2 clinical trial at non-NCI sites.

PRGN-3006 UltraCAR-T® in AML and MDS

- The Company has completed enrollment of the Phase 1b trial for PRGN-3006 in acute myeloid leukemia (AML), which received Fast Track designation from the FDA, and is preparing for an end of Phase 1b meeting with the FDA to discuss next steps.

PRGN-3008 UltraCAR-T® Targeting CD19 in Oncology and Autoimmune Diseases

- PRGN-3008 is an autologous CD19-directed UltraCAR-T, based on Precigen's next generation UltraCAR-T platform, which is engineered to express a CD19 chimeric antigen receptor (CAR), membrane-bound IL-15 (mbIL15) for enhanced persistence and maintenance of stem cell memory/naïve (Tscm) phenotype, an intrinsic PD-1 blockade without complex and expensive gene editing techniques to avoid exhaustion, and a safety/kill switch, all from a single non-viral transposon to ensure a homogenous cell product.
- Next generation UltraCAR-T aims to improve on conventional CAR-T through overnight manufacturing, incorporation of a safety/kill switch, built-in PD1 downregulation that avoids the need for checkpoint inhibitor combination, and the ability for repeat dosing. These advantages give Precigen's CD19 UltraCAR-T the potential to be the best-in-class treatment for B-cell malignancies and autoimmune indications for the proven CD19 target.
- Preclinical data for PRGN-3008 were presented at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting in a poster presentation titled, "*Non-viral engineered next generation CD19 UltraCAR-T with membrane bound IL-15 (mbIL15) and PD-1 blockade preserves stem cell memory/naïve phenotype and enhances anti-tumor efficacy*."
    - Preclinical data showed that in *in vivo* tumor models, a single administration of PRGN-3008 enhanced expansion and persistence, produced robust antitumor efficacy with complete tumor clearance, and demonstrated significantly longer survival compared to conventional CD19 CAR-T cells.
    - In a simulation of tumor relapse in the *in vivo* model, PRGN-3008 demonstrated persistence and long-term antitumor immunity extending overall survival without additional PRGN-3008 treatment.
- In a humanized mouse model of lupus nephritis, additional preclinical data for PRGN-3008 in an autoimmune setting presented at the 2024 Cell and Gene Meeting on the Mesa showed complete elimination of B-cells as well as a decrease in antibodies to double-stranded DNA (dsDNA), a specific marker of lupus.

Financial Highlights

- The Company closed a public offering of its common stock in August 2024, resulting in net proceeds of approximately $30.9 million (after deducting underwriting discounts, fees and other underwriting expenses).

- In August 2024, the Company began a strategic prioritization of its clinical portfolio and streamlining of its resources, including a reduction of over 20% of its workforce, to focus on potential commercialization of PRGN-2012.

Third Quarter 2024 Financial Results Compared to Prior Year Period

SG&A expenses increased by $0.6 million, or 7%, compared to the three months ended September 30, 2023. As a result of the Company's increased focus on PRGN-2012, commercial readiness costs increased in the current quarter versus the prior year period. In addition, the third quarter of 2024 included severance costs incurred related to the Precigen workforce reduction. These increases were partially offset by a reduction in insurance expenses due to decreasing rates and professional fees incurred related to general corporate matters compared to the same period in 2023.

Research and development expenses decreased by $0.2 million, or 2%, compared to the three months ended September 30, 2023. The decrease was primarily the result of the Company's portfolio reprioritization, which included a $2.0 million decrease in costs associated with ActoBio resulting from the shutdown of operations during the second quarter of 2024 as well as lower costs of $0.7 million incurred at contract research organizations for other programs compared to the same period in 2023. These decreases were offset by increased costs of approximately $2.5 million associated with PRGN-2012 in advance of the Company's planned BLA submission and the Company's ongoing confirmatory trial, as well as severance costs incurred related to the Precigen workforce reduction in the third quarter of 2024.

Other income (expense), net, decreased by $3.8 million compared to the three months ended September 30, 2023. This decrease was primarily due to the reclassification of cumulative translation losses of $2.9 million as a result of the final closing of the ActoBio facilities in the third quarter of 2024, as well as a reduction in interest income compared to the same period in 2023.

Total revenues decreased $0.4 million, or 31%, compared to the three months ended September 30, 2023. This decrease was related to reductions in product and service revenues at Exemplar.

Net loss was $24.0 million, or $(0.09) per basic and diluted share, compared to net loss of $19.8 million, or $(0.08) per basic and diluted share, in the three months ended September 30, 2023.

First Nine months 2024 Financial Results Compared to Prior Year Period

SG&A expenses increased by $0.1 million, or 1%, compared to the nine months ended September 30, 2023. As a result of the Company's increased focus on PRGN-2012, commercial readiness costs increased versus the prior year period. In addition, the second and third quarter of 2024 included higher severance costs associated with the suspension of ActoBio's operations and the 2024 Precigen workforce reduction. These increases were partially offset by a decrease in stock compensation and insurance expenses due to decreasing rates in 2024 compared to the same period in 2023.

Research and development expenses increased $5.7 million, or 16%, compared to the nine months ended September 30, 2023, primarily as a result of the Company's increased focus on PRGN-2012. There were $4.4 million of increased costs associated with PRGN-2012 in advance of the Company's planned BLA submission, including the start of the PRGN-2012 confirmatory clinical trial and close out of the PRGN-2012 pivotal clinical trial activities and professional fees incurred related to the Company's manufacturing facility. Additionally, personnel costs increased by $3.0 million due to an increase in the hiring of employees related to the advancement of PRGN-2012 in the third and fourth quarters of 2023 and severance charges incurred related to the Precigen workforce reduction in the third quarter of 2024. These increases were offset by lower costs incurred at contract research organizations for other programs compared to the prior year period as well as a reduction in total ActoBio operating expenses compared to the nine months ended September 30, 2023.

Other income (expense), net, decreased $4.3 million, or 166%, compared to the nine months ended September 30, 2023. This decrease was primarily due to the reclassification of cumulative translation losses of $2.9 million resulting from the final closing of the ActoBio facilities in the third quarter of 2024, as well as a reduction in net interest income compared to the same period in 2023.

In conjunction with the suspension of ActoBio's operations, the Company recorded $34.5 million of impairment charges related to goodwill and long-lived assets in the second quarter of 2024, as well as a related tax benefit of $1.7 million.

Total revenues decreased $2.3 million, or 45%, compared to the nine months ended September 30, 2023. This decrease was related to reductions in product and service revenues at Exemplar.

Net loss was $106.5 million, or $(0.41) per basic and diluted share, compared to net loss of $62.8 million, or $(0.26) per basic and diluted share, in the nine months ended September 30, 2023.

Precigen: Advancing Medicine with Precision®
Precigen (Nasdaq: PGEN) is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target the most urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. Our technologies enable us to find innovative solutions for affordable biotherapeutics in a controlled manner. Precigen operates as an innovation engine progressing a preclinical and clinical pipeline of well-differentiated therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on LinkedIn or YouTube.

Trademarks
Precigen, UltraCAR-T, UltraPorator, AdenoVerse, UltraVector and Advancing Medicine with Precision are trademarks of Precigen and/or its affiliates. Other names may be trademarks of their respective owners.

Cautionary Statement Regarding Forward-Looking Statements
Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon the Company's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of the Company's business, including the timing and progress of preclinical studies, clinical trials, discovery programs and related milestones, the promise of the Company's portfolio of therapies, and in particular its CAR-T and AdenoVerse therapies. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this press release. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly

qualified in their entirety by this cautionary statement. For further information on potential risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K and subsequent reports filed with the Securities and Exchange Commission.

Investor Contact:
Steven M. Harasym
Vice President, Investor Relations
Tel: +1 (301) 556-9850
investors@precigen.com

Media Contacts:
Donelle M. Gregory
press@precigen.com

Glenn Silver
Lazar-FINN Partners
glenn.silver@finnpartners.com

†zopapogene imadenovec is the international nonproprietary name (INN) for the investigational therapeutic known as PRGN-2012. Zopapogene imadenovec has not been approved by any health authority in any country for any indication.

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
(Unaudited)

(Amounts in thousands)	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 24,725	$ 7,578
Short-term investments	3,906	55,277
Receivables		
Trade, net	479	902
Other	250	673
Prepaid expenses and other	5,153	4,325
Total current assets	34,513	68,755
Property, plant and equipment, net	13,538	7,111
Intangible assets, net	4,773	40,701
Goodwill	24,918	26,612
Right-of-use assets	5,307	7,097
Other assets	425	767
Total assets	$ 83,474	$ 151,043
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,320	$ 1,726
Accrued compensation and benefits	6,612	8,250
Other accrued liabilities	5,676	6,223
Settlement and Indemnification Accrual	3,213	5,075
Deferred revenue	407	509
Current portion of lease liabilities	988	1,202
Total current liabilities	21,216	22,985
Deferred revenue, net of current portion	2,032	1,818
Lease liabilities, net of current portion	4,761	5,895
Deferred tax liabilities	89	1,847
Total liabilities	28,098	32,545
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,126,342	2,084,916
Accumulated deficit	(2,070,979)	(1,964,471)
Accumulated other comprehensive income (loss)	13	(1,947)
Total shareholders' equity	55,376	118,498
Total liabilities and shareholders' equity	$ 83,474	$ 151,043

Precigen, Inc. and Subsidiaries
Consolidated Statements of Operations
(Unaudited)

(Amounts in thousands, except share and per share data)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Revenues				
Product revenues	$ 66	$ 82	$ 235	$ 730
Service revenues	886	1,296	2,478	4,261
Other revenues	1	1	22	6
Total revenues	953	1,379	2,735	4,997
Operating Expenses				
Cost of products and services	1,009	1,537	3,098	4,761
Research and development	11,370	11,583	41,312	35,620
Selling, general and administrative	9,836	9,196	30,293	30,150
Impairment of goodwill	-	-	1,630	-
Impairment of other noncurrent assets	-	-	32,915	-
Total operating expenses	22,215	22,316	109,248	70,531
Operating loss	(21,262)	(20,937)	(106,513)	(65,534)
Other Expense, Net				
Interest expense	(2)	(1)	(6)	(461)
Interest income	283	856	1,210	2,316
Other income (expense), net	(2,985)	281	(2,905)	705
Total other income (expense), net	(2,704)	1,136	(1,701)	2,560
Loss before income taxes	(23,966)	(19,801)	(108,214)	(62,974)
Income tax benefit (expense)	(12)	6	1,706	126
Net loss	$ (23,978)	$ (19,795)	$ (106,508)	$ (62,848)
Net Loss per share				
Net loss per share, basic and diluted	$ (0.09)	$ (0.08)	$ (0.41)	$ (0.26)
Weighted average shares outstanding, basic and diluted	275,881,170	248,520,724	259,254,775	243,075,262

View original content to download multimedia:https://www.prnewswire.com/news-releases/precigen-reports-third-quarter-2024-financial-results-and-business-updates-302306364.html

SOURCE Precigen, Inc.