



Precigen Reports Full Year 2024 Financial Results and Business Updates

Mar 19, 2025

- FDA granted priority review to Company's BLA for PRGN-2012 for the treatment of adults with recurrent respiratory papillomatosis and set PDUFA target action date for August 27, 2025
- Results from pivotal clinical study of PRGN-2012 were published in *The Lancet Respiratory Medicine*
- PRGN-2012 treatment demonstrated durable complete responses with median duration of response of two years, with some complete responders surgery-free beyond three years as of August 28, 2024 data cutoff
- Company continues to rapidly advance commercial and manufacturing readiness campaign in anticipation of 2025 commercial launch
- Company ended 2024 with \$97.9 million in cash, cash equivalents, and investments, extending its cash runway into 2026, beyond potential 2025 commercial launch of PRGN-2012

GERMANTOWN, Md., March 19, 2025 /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 full year 2024 financial results and business updates.

"Last year, we achieved several milestones on our path to potentially bring our innovative PRGN-2012 therapy to RRP patients, including presentation of groundbreaking pivotal data and BLA submission to the FDA. Through prioritizing our portfolio and financing activities, we strengthened our financial position, enabling ongoing commercial and manufacturing readiness efforts for PRGN-2012 in anticipation of a potential 2025 launch. Our commercial organization has been working to scale up quickly, right-sizing the organization to rapidly capitalize on the immense demand from patients and treating physicians for a new treatment paradigm that may finally address the underlying cause of the disease," said Helen Sabzevari, PhD, President and CEO of Precigen. "Already this year, our BLA for PRGN-2012 received priority review from the FDA with an August 2025 PDUFA action date, bringing us a step closer to launching the first and only FDA-approved treatment to the approximately 27,000 adult RRP patients in the US. FDA approval for PRGN-2012 would fundamentally change Precigen, enabling the transition from clinical to commercial stage with the real and imminent potential to begin realizing product sales this year and providing financial tailwinds to enable potential expansion of PRGN-2012 to new indications and geographical markets."

"As a result of the preferred stock offering and sale of intellectual property and related royalty rights for a non-core asset, we extended our cash runway into 2026, beyond the potential commercial launch of PRGN-2012 this year. We are preparing for the transition to a commercial stage company and the potential to add product-related revenue," said Harry Thomasian Jr., CFO of Precigen.

Key Program Highlights

PRGN-2012 (nonproprietary name: zopapogene imadenovec[†]) 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](#), [Orphan Drug Designation](#), and [an accelerated approval pathway](#) from the FDA, and [Orphan Drug Designation](#) from the European Commission.

- In February 2025, the US Food and Drug Administration (FDA) accepted the company's biologics license application (BLA) for PRGN-2012, and [granted priority review to the BLA](#) with a Prescription Drug User Fee Act (PDUFA) target action date set for August 27, 2025. The FDA has indicated that they are not currently planning to hold an advisory committee meeting to discuss the BLA.
- [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](#)" and published in [The Lancet Respiratory Medicine](#).
 - Pivotal study successfully met its primary safety and pre-specified primary efficacy endpoints.
 - PRGN-2012 was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
 - 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 24 months, with some complete responders surgery-free beyond three years as of the August 28, 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 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 anatomical Derkey scores and VHI-10 scores in complete responders.
- 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.
- The Company continues to rapidly advance its commercial and manufacturing readiness campaign in anticipation of a potential launch in 2025.
- Based on recently updated internal analysis derived from review of claims data, the market opportunity for PRGN-2012 in RRP is estimated to be approximately 27,000 adult patients in the US and more than 125,000 patients outside of the US.

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

PRGN-2009 is an investigational off-the-shelf AdenoVerse gene therapy designed to activate the immune system to recognize and target 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.

PRGN-3006 UltraCAR-T[®] in AML and MDS

PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a safety/kill switch. PRGN-3006 has been granted [Orphan Drug Designation](#) in patients with acute myeloid leukemia (AML) and [Fast Track Designation](#) in patients with relapsed/refractory (r/r) AML by the FDA.

- 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.

Financial Highlights

- In December 2024, the Company raised \$87.5 million, of which \$79.0 million was from a private placement offering of convertible preferred stock, and an additional \$8.5 million was from the sale of certain intellectual property and royalty rights related to a non-core asset.
- By year's end 2024, cash, cash equivalents, and investments totaled \$97.9 million.

Full Year 2024 Financial Results Compared to Prior Year Period

Total revenues decreased \$2.3 million, or 37%, and cost of products and services decreased \$1.8 million or 30% compared to the year ended December 31, 2023. These decreases were primarily related to reductions in product and service volumes at Exemplar.

Research and development expenses increased \$4.5 million, or 9%, compared to the year ended December 31, 2023. This increase was primarily the result of \$3.1 million of increased costs associated with the initiation of the PRGN-2012 confirmatory clinical trial, increased drug manufacturing material costs related to PRGN-2012 for potential commercial use, and professional fees incurred in conjunction with the Company's completed BLA submission and commercial readiness planning as well as the design and implementation of our manufacturing facility. Additionally, employee-related expenses rose by \$3.0 million primarily due to severance charges incurred as a result of the Precigen workforce reduction in 2024 and the suspension of ActoBio's operations. These increases were partially offset by a \$1.9 million reduction in depreciation and amortization expense as a result of the impairment of noncurrent assets related to the suspension of ActoBio's operations during the second quarter of 2024 as well as a reduction in clinical study expenses associated with programs that were deprioritized during the third quarter of 2024.

SG&A expenses increased \$0.9 million, or 2%, compared to the year ended December 31, 2023. As a result of the Company's increased focus on PRGN-2012, commercial readiness costs increased in 2024 compared to the prior year. In addition, the second and third quarters of 2024 included higher severance costs associated with the suspension of ActoBio's operations and the Precigen workforce reduction. These increases were partially offset by a decrease in stock compensation and insurance rates in 2024 compared to the same period in 2023.

The Company recorded a \$5.8 million impairment charge in the fourth quarter of 2024 related to its Exemplar subsidiary as a result of the Company's annual goodwill impairment test. Also, in conjunction with the suspension of ActoBio's operations, the Company recorded \$34.5 million of impairment charges related to goodwill (\$1.6 million) and other noncurrent assets (\$32.9 million) in the second quarter of 2024.

Total other income, net, increased \$3.6 million, or 106% compared to the year ended December 31, 2023. This increase was primarily derived from an \$8.5 million gain on the sale of intellectual property rights and royalty rights related to a non-core asset in December 2024 as well as a \$0.5 million reduction in interest expense due to the final retirement of the Company Convertible Notes in the second quarter of 2023. This increase was partially offset by a reclassification of cumulative translation losses of \$2.9 million, which resulted from the final closing of the ActoBio facilities in the third quarter of 2024, as well as a reduction of \$1.8 million in interest income compared to the same period in 2023.

Net loss was \$126.2 million, or \$(0.47) per basic and diluted share, compared to net loss of \$95.9 million, or \$(0.39) per basic and diluted share, in year ended December 31, 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
Tel: +1 (301) 556-9850
investors@precigen.com

Media Contact:

Donelle M. Gregory
press@precigen.com

ƒzopapogene imadenovec is the nonproprietary name 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)	December 31, 2024		December 31, 2023	
Assets				
Current assets				
Cash and cash equivalents	\$	29,517	\$	7,578
Short-term investments		68,393		55,277
Receivables				
Trade, net		926		902
Other		237		673
Prepaid expenses and other		3,341		4,325
Total current assets		102,414		68,755
Property, plant and equipment, net		13,831		7,111
Intangible assets, net		4,455		40,701
Goodwill		19,139		26,612
Right-of-use assets		5,056		7,097
Other assets		371		767
Total assets	\$	145,266	\$	151,043
Liabilities, Mezzanine Equity and Shareholders' Equity				
Current liabilities				
Accounts payable	\$	3,531	\$	1,726
Accrued compensation and benefits		8,417		8,250
Other accrued liabilities		4,812		6,223
Indemnification Accrual		3,213		5,075
Deferred revenue		589		509
Current portion of lease liabilities		956		1,202
Total current liabilities		21,518		22,985
Deferred revenue, net of current portion		1,934		1,818
Lease liabilities, net of current portion		4,546		5,895
Deferred tax liabilities		-		1,847
Warrant liabilities		50,537		-

Total liabilities	78,535	32,545
Mezzanine Equity		
Series A Preferred Stock	28,218	-
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,129,207	2,084,916
Accumulated deficit	(2,090,706)	(1,964,471)
Accumulated other comprehensive income (loss)	12	(1,947)
Total shareholders' equity	38,513	118,498
Total liabilities, mezzanine equity and shareholders' equity	\$ 145,266	\$ 151,043

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

(Amounts in thousands, except share and per share data)	Year ended	
	December 31, 2024	December 31, 2023
Revenues		
Collaboration and licensing revenues	\$ -	\$ 75
Product revenues	422	840
Service revenues	3,470	5,301
Other revenues	33	9
Total revenues	3,925	6,225
Operating Expenses		
Cost of products and services	4,267	6,119
Research and development	53,070	48,614
Selling, general and administrative	41,293	40,415
Impairment of goodwill	7,409	10,390
Impairment of other noncurrent assets	32,915	445
Total operating expenses	138,954	105,983
Operating loss	(135,029)	(99,758)
Other Income (Expense), Net		
Interest expense	(6)	(468)
Interest income	1,418	3,237
Other income, net	5,589	627
Total other income, net	7,001	3,396
Loss before income taxes	(128,028)	(96,362)
Income tax benefit	1,793	458
Net loss	\$ (126,235)	\$ (95,904)
Net Loss per share		
Net loss per share, basic and diluted	\$ (0.47)	\$ (0.39)
Weighted average shares outstanding, basic and diluted	267,727,426	244,536,221

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