Precigen Reports First Quarter 2025 Financial Results and Business Updates

May 14, 2025

- *PRGN-2012 has the potential to be the first- and best-in-class treatment for RRP*
- *Company's BLA for PRGN-2012 for the treatment of adults with RRP is under priority review by the FDA with a PDUFA target action date set for August 27, 2025*
- *RRP is a rare, debilitating chronic disease with approximately 27,000 adult patients in the US and more than 125,000 patients outside of the US*
- *Company continues to rapidly advance commercial and manufacturing readiness campaign in anticipation of 2025 commercial launch*
- *Company and Recurrent Respiratory Papillomatosis Foundation to host the 2025 International RRP Awareness Day on June 11*
- *Cash, cash equivalents, and investments of $81.0 million as of March 31, 2025 are anticipated to fund operations into 2026, beyond the potential 2025 commercial launch of PRGN-2012*

GERMANTOWN, Md., May 14, 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 first quarter 2025 financial results and business updates.

"We are extremely pleased with the progress of our PRGN-2012 program and its immense potential for RRP patients. We remain laser-focused on advancing the program toward the rapidly approaching PDUFA target action date in August. If approved, PRGN-2012 has the potential to be the first and only FDA-approved therapeutic for the treatment of RRP," said Helen Sabzevari, PhD, President and CEO of Precigen. "We encourage anyone interested in learning more about RRP and hearing directly from RRP patients, caregivers, and the healthcare community supporting them to join Precigen and the Recurrent Respiratory Papillomatosis Foundation for the 2025 International RRP Awareness Day on June 11. Panelists will discuss the patient and caregiver experience with RRP, the significant burden of living with a rare and chronic disease such as RRP, and the challenges of repeated surgeries."

"We completed the first quarter with continued financial discipline while appropriately investing in activities related to the potential launch of PRGN-2012. We ended the quarter with cash, cash equivalents, and investments of $81 million, and we reiterate that our cash runway is expected to take us into 2026, without consideration of product-related revenue from the potential commercial launch of PRGN-2012 later this year," said Harry Thomasian Jr., CFO of Precigen.

Key Program and Company Highlights

2025 International RRP Awareness Day
The Company and the Recurrent Respiratory Papillomatosis Foundation (RRPF) will host the 2025 International RRP Awareness Day on June 11. RRP Awareness Day brings together patients with recurrent respiratory papillomatosis (RRP), their caregivers, and the healthcare community supporting them to encourage dialogue and build community among those affected by this rare, debilitating chronic disease. To stay up-to-date with RRP Awareness Day activities and to register for the June 11 webcast, please visit www.RRPAwareness.org.

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 adults with RRP. PRGN-2012 received Breakthrough Therapy Designation, Orphan Drug Designation, and an accelerated approval pathway from the US Food and Drug Administration (FDA), and Orphan Drug Designation from the European Commission.

- In February 2025, the FDA accepted the Company's biologics license application (BLA) for PRGN-2012, and granted priority review of 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 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 study 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 30 months, with some complete responders surgery-free for three years as of the March 20, 2025 data cutoff.
    - 86% (30 out of 35) of study patients 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 study 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 Derkay 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.
- The Company selected EVERSANA, a leading provider of commercialization services to the global life sciences industry, to support launch strategy and commercialization of PRGN-2012 in adults with RRP in the United States. The Company and EVERSANA are developing a targeted go-to-market strategy for PRGN-2012 in preparation for potential approval in August. As part of this strategy, the Company is deploying the first wave of field teams in support of launch readiness preparation.
- Based on an 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 United States. More than 125,000 patients are estimated outside of the United States.

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 AML.

Financial Highlights

- Cash, cash equivalents, and investments totaled $81.0 million as of March 31, 2025
- Cash burn for the quarter ended March 31, 2025 was $16.9 million

First Quarter 2025 Financial Results Compared to Prior Year Period
Total revenues increased $0.3 million, or 26%, compared to the three months ended March 31, 2024. This increase was primarily related to increased volume of products sold and services rendered at Exemplar.

Research and development expenses decreased by $3.8 million, or 27%, compared to the three months ended March 31, 2024. The decrease was primarily due to a $1.8 million decrease in costs associated with ActoBio, including depreciation, amortization, personnel, and other operating costs after the Company closed ActoBio's operations in late 2024. Additionally, there was a decrease of $1.2 million incurred at contract research organizations and an $0.8 million decrease due to a reduction in the number of Research and Development employees as a result of the Company's asset prioritization announced in the third quarter of 2024.

SG&A expenses increased by $2.2 million, or 22%, compared to the three months ended March 31, 2024. This increase was primarily associated with PRGN-2012 commercial readiness. This increase was partially offset by a reduction in insurance rates and license and patent fees compared to the three months ended March 31, 2024.

Total other income (expense), net, changed from income of $0.6 million in the three months ended March 31, 2024, to expense of $31.6 million in the three months ended March 31, 2025. This change was primarily driven by the recording of a $32.5 million increase in the fair value of warrant liabilities, which was influenced by an increase in the stock price of Precigen and to a lesser extent, an increase in the liability to account for the additional warrants that will be issued as part of the paid-in-kind dividends related to the Company's Series A Preferred Stock. This decrease was partially offset by a $0.3 million increase in interest income resulting from increased investment balances.

Net loss was $54.2 million, or $(0.18) per basic and diluted share, compared to net loss of $23.7 million, or $(0.10) per basic and diluted share, in the three months ended March 31, 2024. The non-cash change in the fair value of warrant liabilities of $32.5 million recorded in the three months ended March 31, 2025 reduced basic and diluted earnings per share in that period by $0.11.

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.

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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.

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†zopapogene 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)	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 6,058	$ 29,517
Short-term investments	74,184	68,393
Receivables		
Trade, net	751	926
Other	313	237
Prepaid expenses	3,295	3,341
Total current assets	84,601	102,414
Long-term investments	750	-
Property, plant and equipment, net	14,668	13,831
Intangible assets, net	4,136	4,455
Goodwill	19,139	19,139
Right-of-use assets	5,066	5,056
Other assets	427	371
Total assets	$ 128,787	$ 145,266
Liabilities, Mezzanine Equity and Shareholders' (Deficit) Equity		
Current liabilities		
Accounts payable	$ 3,107	$ 3,531
Accrued compensation and benefits	9,621	8,417
Other accrued liabilities	6,568	4,812
Indemnification Accruals	3,213	3,213
Deferred revenue	549	589
Current portion of lease liabilities	928	956
Total current liabilities	23,986	21,518
Deferred revenue, net of current portion	1,836	1,934
Lease liabilities, net of current portion	4,489	4,546
Warrant liabilities	83,018	50,537
Total liabilities	113,329	78,535
Mezzanine Equity		
Series A Preferred Stock	29,518	28,218

Shareholders' equity (deficit)		
Common stock	-	-
Additional paid-in capital	2,130,787	2,129,207
Accumulated deficit	(2,144,859)	(2,090,706)
Accumulated other comprehensive income	12	12
Total shareholders' (deficit) equity	(14,060)	38,513
Total liabilities, mezzanine equity and shareholders' (deficit) equity	$ 128,787	$ 145,266

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

	Three Months Ended March 31,	
(Amounts in thousands, except share and per share data)	**2025**	**2024**
Revenues		
Product revenues	$ 203	$ 138
Service revenues	1,115	919
Other revenues	23	8
Total revenues	1,341	1,065
Operating Expenses		
Cost of products and services	1,100	1,075
Research and development	10,478	14,249
Selling, general and administrative	12,359	10,151
Total operating expenses	23,937	25,475
Operating loss	(22,596)	(24,410)
Other Income (Expense), Net		
Change in fair value of warrant liabilities	(32,481)	-
Interest expense	(1)	(2)
Interest income	918	608
Other income, net	7	37
Total other (expense) income, net	(31,557)	643
Loss before income taxes	(54,153)	(23,767)
Income tax benefit	-	29
Net loss	$ (54,153)	$ (23,738)
Net Loss per share		
Net loss per share, basic and diluted	$ (0.18)	$ (0.10)
Weighted average shares outstanding, basic and diluted	293,879,653	249,220,335

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