Precigen Reports Full Year 2025 Financial Results and Business Updates

Mar 25, 2026

- *Precigen transitioned to a commercial stage company with the US approval of PAPZIMEOS™ (zopapogene imadenovec-drba), the first-and-only FDA-approved treatment for adults with RRP, in August 2025*
- *PAPZIMEOS generated $3.4 million in net product revenue in the fourth quarter of 2025, reflecting the first partial quarter of US commercial sales as payer policies came into effect; the US launch continues to build strong momentum, with a significant increase in demand in the first quarter of 2026*
- *The Centers for Medicare and Medicaid Services has assigned a permanent J-code, J3404, to PAPZIMEOS, effective April 1, 2026, streamlining the claims process and facilitating broader patient access*
- *Marketing Authorization Application for PAPZIMEOS for the treatment of adults with RRP validated by the European Medicines Agency and is under review*
- *Open-label redosing study initiated to evaluate retreatment efficacy of zopapogene imadenovec in adults with RRP*
- *Expert consensus paper sponsored and published by the Recurrent Respiratory Papillomatosis Foundation and authored by 16 leading physicians in the field of RRP recommended PAPZIMEOS as the new standard of care first-line treatment for adults with RRP in the US*
- *Cash, cash equivalents, and investments totaled $100.4 million as of December 31, 2025, which is expected to fund the Company's operations to cash flow break-even*
- *Conference call scheduled for 4:30 PM ET today to discuss full year 2025 financial results and provide further substantive updates on commercial progress for the first quarter of 2026*

GERMANTOWN, Md., March 25, 2026 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to improve the lives of patients, today announced full year 2025 financial results and business updates.

"With the FDA approval and launch of PAPZIMEOS, 2025 marked a transformational year for Precigen as we transitioned from a clinical-stage to a commercial-stage company and recognized our first commercial product revenues toward the end of the year," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are seeing strong alignment within the physician community around PAPZIMEOS as the first-line standard of care for adults with RRP, supported by its profile as the only approved therapy for RRP, the compelling safety and efficacy data, and the encouraging durability of response observed to date. This is an exciting time for Precigen, and we look forward to sharing further updates during our call regarding the significant momentum we're seeing in the first quarter."

"Commercialization of PAPZIMEOS continues to move rapidly, with growing physician adoption and patient uptake since approval in August. Since deploying our full field organization, we have engaged all target medical institutions and are seeing prescriptions and active treatment across the United States in both major medical centers and community practices. Patient hub enrollment has surpassed 300 patients, reflecting strong demand, while payer coverage now extends to approximately 215 million lives across private insurers, as well as Medicare and Medicaid. The recently published Recurrent Respiratory Papillomatosis Foundation-sponsored expert consensus paper recommending PAPZIMEOS as the first-line standard of care for adults with RRP further reinforces the momentum we are seeing as we continue to see expanded patient access." said Phil Tennant, Chief Commercial Officer of Precigen.

KEY PROGRAM HIGHLIGHTS

PAPZIMEOS: Establishing a New Standard of Care for the Treatment of Adults with RRP

- **PAPZIMEOS full approval with broad label:** In August 2025, the FDA granted full approval of PAPZIMEOS with a broad label for the treatment of adults with RRP.
- **PAPZIMEOS prescribing, treatment, and distribution:** Since full deployment of the PAPZIMEOS field team in September 2025, 100% of target medical institutions have been engaged. PAPZIMEOS is now being prescribed nationwide across both major medical centers and community practices, with patients spanning a range of disease severities actively receiving treatment.
- **Strong patient and physician demand:** To date, PAPZIMEOS patient hub enrollment has surpassed 300 registered patients, reflecting substantial patient and physician demand. In addition to these registered patients, a significant number of patients have been identified outside of the PAPZIMEOS hub through the Company's field engagement efforts.
- **Positive payer coverage:** Patient access continues to expand, with private health plan coverage now estimated at approximately 215 million US lives, including the significant majority of leading insurers. PAPZIMEOS is also covered under Medicare and Medicaid. Collectively, coverage now extends to approximately 90% of insured lives in the US.
- **J-code assigned:** The Centers for Medicare and Medicaid Services has assigned a permanent J-code, J3404, to PAPZIMEOS, effective April 1, 2026. J-codes are standardized reimbursement codes that allow healthcare providers to bill government and commercial insurers for physician-administered therapies. Assignment of a permanent J-code streamlines claims processing and will likely facilitate broader patient access.
- **PAPZIMEOS recommended as new standard of care first-line treatment:** In January 2026, an expert consensus paper sponsored and published by the Recurrent Respiratory Papillomatosis Foundation and authored by 16 leading physicians in the field of RRP recommended PAPZIMEOS as the new standard of care first-line treatment for adults with RRP in the US.
- **Compelling long-term clinical and real-world evidence published:** At AAO-HNSF 2025, SITC 2025, and EUROGIN 2026, the Company presented long-term durable complete responses with PAPZIMEOS, and at ISPOR Europe 2025, the Company published data demonstrating the substantial healthcare resource utilization and patient-reported quality-of-life burden of RRP, underscoring the disease's significant clinical, economic, and human impact.
- **Redosing study initiated:** The Company initiated an open-label study to evaluate safety, vector shedding, and retreatment efficacy of zopapogene imadenovec in adults with RRP (clinical trial identifier: NCT06538480).
- **MAA under review by the EMA:** Following submission in November 2025, the Marketing Authorization Application for PAPZIMEOS for the treatment of adults with RRP was validated by the European Medicines Agency and is under review. PAPZIMEOS was granted orphan drug designation by the European Commission.

PRGN-2009 AdenoVerse® Immunotherapy in HPV-associated cancers
PRGN-2009 is an investigational AdenoVerse immunotherapy 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 newly diagnosed HPV-associated oropharyngeal cancer are ongoing.
- PRGN-2009 Phase 2 clinical trial in combination with pembrolizumab in recurrent/metastatic cervical cancer is ongoing.

FINANCIAL RESULTS

"2025 was a game-changing year for Precigen with the FDA approval of PAPZIMEOS. We began preparing for the commercial launch of PAPZIMEOS well before the FDA's approval and significantly increased our investment in commercialization efforts as 2025 progressed to support the successful launch of PAPZIMEOS," said Harry Thomasian Jr., Chief Financial Officer of Precigen. "Our first sale of PAPZIMEOS was recorded in the fourth quarter of 2025 and we are encouraged by continued revenue momentum we're seeing as we begin the new year. Based upon our present forecast, we expect our current cash position and anticipated cash to be received from PAPZIMEOS sales will fund operations through cash flow break-even by the end of 2026, representing a strong financial foundation as we continue to execute on our commercial and strategic objectives."

Full Year 2025 Financial Results Compared to Prior Year Period
Total revenues increased by $5.8 million compared to the year ended December 31, 2024. This increase was primarily driven by the commencement of PAPZIMEOS product revenue, which totaled $3.4 million in 2025, reflecting the first partial quarter of US commercial sales following the Company's commercial launch, as well as higher collaboration and licensing revenue of $1.8 million as a result of the recognition of the remaining deferred revenue associated with the termination of an exclusive channel collaboration agreement.

Research and development expenses decreased by $11.7 million, or 22.1%, compared to the year ended December 31, 2024. The decrease was primarily driven by a $5.4 million reduction in costs associated with ActoBio after the Company closed its operations in 2024. External services also declined by approximately $4.0 million, due to reduced activity for contract research organizations as a result of the strategic prioritization of the Company's pipeline announced in the third quarter of 2024. In addition, the Company, upon FDA approval of PAPZIMEOS, began classifying manufacturing-related costs to inventory, which ultimately will be recorded as cost of products and services when the related inventory is sold. Manufacturing costs related to PAPZIMEOS were recorded as research and development expenses prior to the FDA approval of PAPZIMEOS.

Selling, General and Administrative (SG&A) expenses increased by $28.8 million, or 69.8%, compared to the year ended December 31, 2024. This increase was primarily due to a $27.3 million increase in costs incurred related to PAPZIMEOS commercial readiness, including sales force expansion, marketing and advertising, as well as professional and other fees associated with the commercial launch of PAPZIMEOS.

In connection with the suspension of ActoBio's operations in 2024, the Company recorded $34.5 million of impairment charges related to goodwill and long-lived assets in the second quarter of 2024. Additionally, in the second quarter of 2025, the Company recorded $3.9 million of impairment charges related to the Exemplar reporting unit, compared to $5.8 million of impairment charges related to the Exemplar reporting unit in the prior year period.

Total other income (expense), net, decreased from income, net of $7.0 million in 2024 to expense, net of $140.1 million in 2025. This decrease was primarily driven by a $139.5 million increase in the fair value of warrant liabilities prior to their reclassification into permanent equity in the third quarter of 2025. Substantially all of the increase in the fair value of warrant liabilities was as a result of an increase in the Company's common stock price at the valuation date compared to December 31, 2024.

The Company recorded a $179.0 million non-cash deemed dividend on preferred stock in the third quarter of 2025 as a reduction to additional paid-in capital (and an increase in net loss attributable to common shareholders when computing net loss per share) in accordance with US Generally Accepted Accounting Principles (GAAP). On September 15, 2025, all of the outstanding Preferred Shares were converted into common shares.

Net loss attributable to common shareholders was $429.6 million, or $1.37 per basic and diluted share for the year ended December 31, 2025, compared to a net loss of $126.2 million, or $0.47 per basic and diluted share, for the year ended December 31, 2024. The increase in net loss was primarily driven by non-cash items, including the increase in the fair value of the warrant liabilities and the deemed dividend on preferred shares noted above (combined impact of $318.5 million or $1.02 per share).

Precigen: Advancing Medicine with Precision®
Precigen (Nasdaq: PGEN) is a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to address difficult-to-treat diseases with high unmet patient need. Precigen is dedicated to advancing scientific breakthroughs from proof-of-concept through commercialization. With a strong commitment to innovation, Precigen is developing a robust pipeline of differentiated therapies across its core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. For more information about Precigen, visit www.precigen.com or follow us on LinkedIn or YouTube.

Trademarks
Precigen, PAPZIMEOS, AdenoVerse, 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
This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what the Company expects. Examples of forward-looking statements include, among others, information relating to the Company's business and business plans, the success of efforts to commercialize PAPZIMEOS™ (zopapogene imadenovec-drba) for the treatment of recurrent respiratory papillomatosis (RRP) in adults including the revenue that the Company expects to realize from such efforts, the Company's ability to successfully obtain foreign regulatory approvals for PAPZIMEOS, expectations about the safety and efficacy of PAPZIMEOS, the ability of PAPZIMEOS to treat RRP, the Company's future financial and operational results including the Company's ability to reach cash flow break-even, and the Company's ability to commence clinical studies or complete ongoing clinical studies for the Company's clinical and pre-clinical stage candidates. 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 (202) 365-2563
investors@precigen.com

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

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

(Amounts in thousands)	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 30,234	$ 29,517
Short-term investments	67,624	68,393
Receivables		
Trade, net	3,916	926
Other	446	237
Inventory	9,581	—
Prepaid expenses and other	3,434	3,341
Total current assets	115,235	102,414
Long-term investments	2,511	—

Property, plant and equipment, net	13,758	13,831
Intangible assets, net	3,182	4,455
Goodwill	15,232	19,139
Right-of-use assets	4,679	5,056
Other assets	908	371
Total assets	$ 155,505	$ 145,266
Liabilities, Mezzanine Equity and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 11,985	$ 3,531
Accrued compensation and benefits	10,199	8,417
Other accrued liabilities	10,993	4,812
Indemnification accrual	2,476	3,213
Deferred revenue	517	589
Current portion of lease liabilities	1,136	956
Total current liabilities	37,306	21,518
Long-term debt	93,174	—
Deferred revenue, net of current portion	—	1,934
Lease liabilities, net of current portion	3,980	4,546
Other long-term liabilities	134	—
Warrant liabilities	-	50,537
Total liabilities	134,594	78,535
Mezzanine equity	-	28,218
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,362,252	2,129,207
Accumulated deficit	(2,341,348)	(2,090,706)
Accumulated other comprehensive income	7	12
Total shareholders' equity	20,911	38,513
Total liabilities, mezzanine equity and shareholders' equity	$ 155,505	$ 145,266

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

(Amounts in thousands, except share and per share data)	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenues		
Collaboration and licensing revenue	$ 1,818	$ -
Product revenues, net	3,975	422
Service revenues	3,891	3,503
Total revenues	9,684	3,925
Operating Expenses		
Cost of products and services	4,823	4,267
Research and development	41,333	53,070
Selling, general and administrative	70,128	41,293
Impairment of goodwill	3,907	7,409
Impairment of other noncurrent assets	-	32,915
Total operating expenses	120,191	138,954
Operating loss	(110,507)	(135,029)
Other Income (Expense), Net		
Change in fair value of warrant liabilities	(139,523)	-
Interest expense	(3,867)	(6)
Interest income	3,215	1,418
Other income, net	43	5,589
Total other (expense) income, net	(140,132)	7,001
Loss before income taxes	(250,639)	(128,028)
Income tax (expense) benefit	(3)	1,793
Net loss	$ (250,642)	$ (126,235)
Deemed dividends on preferred stock	(179,000)	-

Net loss attributable to common shareholders	$ (429,642)	$ (126,235)
Net Loss per share attributable to common shareholders		
Net loss per share attributable to common shareholders, basic and diluted	$ (1.37)	$ (0.47)
Weighted average shares outstanding, basic and diluted	312,980,562	267,727,426

View original content to download multimedia:https://www.prnewswire.com/news-releases/precigen-reports-full-year-2025-financial-results-and-business-updates-302725242.html

SOURCE Precigen, Inc.