Precigen Reports Third Quarter 2025 Financial Results and Business Updates

Nov 13, 2025

- *PAPZIMEOS (zopapogene imadenovec-drba) received full approval by the FDA in August*
- *PAPZIMEOS launched with a broad label in the US as the first and only FDA-approved treatment for adults with RRP*
- *PAPZIMEOS is now available and shipping to prescribers in the US for the treatment of adults with RRP*
- *To date, over 100 patients have been registered in the PAPZIMEOS Patient Hub*
- *The Company has made significant progress with private health insurance coverage, with more than 100 million lives covered to date; PAPZIMEOS is now available through Medicare and Medicaid*
- *Rapid commercial launch execution underway with full deployment of the sales team in September and over 90% of target institutions engaged*
- *In October, the Company announced long-term follow-up results from the PAPZIMEOS pivotal clinical trial highlighting ongoing durable (median 36 months) complete responses without any additional treatment interventions*
- *In November, the Company submitted a Marketing Authorization Application to the European Medicines Agency for zopapogene imadenovec for the treatment of adults with RRP*
- *Cash, cash equivalents, and investments totaled $123.6 million as of September 30, 2025, which is expected to fund the Company's operations to cash flow break-even*

GERMANTOWN, Md., Nov. 13, 2025 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), a biopharmaceutical company specializing in the advancement of innovative precision medicines to improve the lives of patients, today announced third quarter 2025 financial results and business updates.

"FDA approval of PAPZIMEOS in August marked the beginning of a new era for adults living with RRP," said Helen Sabzevari, PhD, President and CEO of Precigen. "PAPZIMEOS is the first and only treatment for adults with RRP, with an excellent safety profile and unmatched efficacy based on the groundbreaking pivotal study that supported full FDA approval, granted ahead of the PDUFA action date. PAPZIMEOS is already available to prescribers, and demand from both physicians and patients has been exceptional. For the first time, adults with RRP have access to an emerging standard of care—the first therapy capable of breaking the relentless cycle of surgeries by targeting the root cause of the disease."

"We are very encouraged by the strong early interest in PAPZIMEOS and the rapid pace of activation since approval in August and the deployment of our sales force in September," said Phil Tennant, Chief Commercial Officer of Precigen. "Patient identification has been outstanding, with prescribers and institutions actively working to bring PAPZIMEOS to their patients. To date, over 100 patients have already been registered in the PAPZIMEOS Patient Hub. In addition, a significantly larger number of patients have been identified through institutional patient hubs as potential candidates for treatment with PAPZIMEOS. Our team has swiftly mobilized the market: engaging over 90% of target institutions, advancing payer and formulary access, and driving broad educational and promotional outreach. These efforts have laid a firm foundation for PAPZIMEOS as the new standard of care for adults with RRP."

"PAPZIMEOS represents a monumental shift in how we care for adults with RRP," said Dr. Simon R. Best, MD, Associate Professor of Otolaryngology-Head and Neck Surgery, Johns Hopkins University School of Medicine. "For the first time, we can offer adult patients a safe and effective treatment that addresses the underlying disease rather than repeatedly managing symptoms through endless surgeries. The durable patient outcomes from the pivotal trial are nothing short of remarkable, and it's clear PAPZIMEOS is poised to become the new standard of care for this debilitating condition."

KEY PROGRAM AND COMPANY HIGHLIGHTS

PAPZIMEOS™ (zopapogene imadenovec-drba) AdenoVerse® Immunotherapy for Adults with RRP

- **PAPZIMEOS full approval:** In August 2025, the US Food and Drug Administration (FDA) granted full approval of PAPZIMEOS with a broad label and no requirement for a confirmatory trial for the treatment of adults with recurrent respiratory papillomatosis (RRP). Approval was supported by the groundbreaking results from the Phase 1/2 pivotal study—the only study in RRP ever conducted with a prospectively defined statistical primary endpoint.
- **PAPZIMEOS now available:** Following FDA approval in August 2025, PAPZIMEOS is now commercially available and commercial product is shipping to prescribers in the US for the treatment of adults with RRP.
- **Early adoption momentum:** Rapid commercial launch execution is underway with over 90% of target institutions engaged since full deployment of the sales team in September. To date, over 100 patients have been registered in the PAPZIMEOS Patient Hub.
- **Positive payer coverage:** Private health insurance coverage is progressing rapidly with more than 100 million lives covered to date; PAPZIMEOS is also now available through Medicare and Medicaid.
- **Long-term durability data published:** The Company announced long-term follow-up results highlighting ongoing durable complete responses after treatment with PAPZIMEOS at the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) 2025 Annual Meeting and the Society for Immunotherapy of Cancer (SITC) annual meeting 2025. As of the September 19, 2025 data cutoff:
  - 15 out of 18 complete responders (83%) demonstrated continued complete response without any additional treatment interventions with a median follow-up of 36 months (range 27 to 37). Median duration of complete response has yet to be reached.
  - Reduction in surgeries compared to the year prior to treatment with PAPZIMEOS was observed in 86% of patients in Year 1, 91% in Year 2, and 95% in Year 3.
  - No new safety events observed during long-term follow-up.
- **Healthcare resource utilization data published:** The Company announced new data at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Europe 2025 showing that, above and beyond the impact of surgery, healthcare resource utilization is substantially higher in adults with RRP with significantly higher emergency and healthcare visits, opioid use, and mental health service needs, reflecting the substantial burden on the healthcare system.
- **Quality of life data published:** The Company announced new data at ISPOR Europe 2025 showing results from a survey of adult RRP patients highlighting the substantial impact of RRP on the patient journey and quality of life. RRP patients reported a substantial physical and mental health burden that impacts overall well-being, results in job losses and productivity declines, and lowers overall quality of life.
- **Geographic expansion:** The Company submitted a Marketing Authorization Application (MAA) for zopapogene imadenovec for the treatment of adults with RRP to the European Medicines Agency (EMA) in November 2025.

PRGN-2009 AdenoVerse® Immunotherapy in HPV-associated Cancers
PRGN-2009 is an investigational off-the-shelf 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.
- The Phase 2 randomized, open-label study of PRGN-2009 in combination with pembrolizumab in patients with HPV-associated recurrent/metastatic cervical cancer is ongoing with two additional clinical sites active in addition to NCI.

FINANCIAL HIGHLIGHTS

- Cash, cash equivalents, and investments totaled $123.6 million as of September 30, 2025 which is expected to fund the Company's operations to cash flow break-even.
- In September 2025, the Company entered into a credit facility that provides up to $125 million of non-dilutive financing and received the first tranche of $100 million.

"In the third quarter of 2025, we significantly increased investment in commercialization efforts to support the successful launch of PAPZIMEOS," said Harry Thomasian Jr., Chief Financial Officer of Precigen. "With the launch now underway, we are confident that we are well-equipped to maximize the impact of the historic PAPZIMEOS launch, drive ongoing commercialization of PAPZIMEOS, and support sustainable growth. Importantly, based upon our present forecast, we expect our current cash position to fund operations through cash flow break-even, representing a strong financial foundation as we continue to execute on our commercial and strategic objectives."

Third Quarter 2025 Financial Results Compared to Prior Year Period
Total revenues increased by $2.0 million compared to the three months ended September 30, 2024. This increase was primarily driven by the increase in collaboration and licensing revenue 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 increased by $1.0 million, or 9%, compared to the three months ended September 30, 2024. The increase was primarily driven by increased manufacturing expenses and lab supplies related to commercial manufacturing of PAPZIMEOS prior to its FDA approval,

professional fees incurred in connection with regulatory filing procedures as well as employee-related costs. These increases were partially offset by the capitalization of inventory-related costs subsequent to the FDA's approval of PAPZIMEOS.

Selling, General and Administrative (SG&A) expenses increased by $14.2 million, or 144%, compared to the three months ended September 30, 2024. This increase was primarily due to a $9.0 million increase in costs incurred related to PAPZIMEOS commercial readiness, including sales and marketing efforts as well as professional and consulting fees. Other employee-related costs increased approximately $4.0 million, and professional and legal fees increased by $1.0 million.

Total other expense, net, increased by $109.2 million compared to the three months ended September 30, 2024. This change was primarily due to a non-cash $111.5 million increase in the fair value of warrant liabilities related to the convertible preferred transaction from 2024.

The Company recorded a one-time $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 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 $325.3 million, or $(1.06) per basic and diluted share for the three months ended September 30, 2025, compared to a net loss of $24 million, or $(0.09) per basic and diluted share, for the three months ended September 30, 2024. The increase in net loss was significantly impacted by non-cash items including the increase in the fair value of the warrant liabilities and the deemed dividend on preferred shares (combined impact of $0.95 per share for the three months ended September 30, 2025).

About RRP
RRP is a rare, debilitating, and potentially life-threatening disease of the upper and lower respiratory tract caused by chronic HPV 6 or HPV 11 infection. RRP can lead to severe voice disturbance, compromised airways, and recurrent post-obstructive pneumonia. Although rare, RRP has the potential for transformation to malignant cancer and can be fatal. Management of RRP has primarily consisted of repeated surgeries, which do not address the underlying cause of the disease and can be associated with significant morbidity as well as significant patient and health system burden. As the number of lifetime surgeries increases, the risk for irreversible iatrogenic laryngeal injury increases with each surgery, and patients may undergo hundreds of these surgeries over their lifetimes. RRP can impact patients' work and social lives, financial stability, and mental health. Patients with RRP can experience substantial impacts to daily living with decreased quality of life and high health care utilization. Based on an internal analysis of claims data and electronic health records, there are approximately 27,000 adult RRP patients in the US.

About PAPZIMEOS (zopapogene imadenovec-drba), for subcutaneous injection only
PAPZIMEOS is the first and only FDA-approved therapy for the treatment of adults with RRP and the first and only approved therapy to address the root cause of RRP. PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of human papillomavirus (HPV) types 6 and 11 proteins. PAPZIMEOS is designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP. Discovered and designed in Precigen's labs using Precigen's proprietary AdenoVerse therapeutic platform, PAPZIMEOS represents a new therapeutic paradigm for RRP.

Indication and Important Safety Information

What is PAPZIMEOS?
PAPZIMEOS is a type of immunotherapy used to treat a condition called recurrent respiratory papillomatosis (RRP) in adults.

What is the most important information I should know about PAPZIMEOS?
Some people may have a reaction to the shot. Signs and symptoms may include redness, pain, swelling, itching, or warmth where the shot was given. After your first treatment, your healthcare provider will watch you for at least 30 minutes to make sure you're feeling okay.

Please contact your doctor immediately if you develop an infection, the reaction to your shot worsens, or you experience any of the below symptoms, which may indicate a systemic allergic reaction:

- Difficulty breathing
- Widespread rash
- Facial swelling

Thrombotic events (blood clots that block your blood vessels) may occur after your PAPZIMEOS shot. Please notify your doctor immediately if you have the following symptoms:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches
- Blurred vision

What should I know before taking PAPZIMEOS?
Before taking PAPZIMEOS, tell your healthcare provider about all of your medical conditions, including:

- If you are pregnant or plan to become pregnant because it is not known if PAPZIMEOS will harm the unborn baby.
- If you are breastfeeding or plan to breastfeed. It is unknown if PAPZIMEOS is present in breast milk, or how it affects the breastfeeding child or milk production. Talk to your healthcare provider about the best way to feed your baby during treatment with PAPZIMEOS.

What are the most common side effects of PAPZIMEOS?
The most common side effects include:

- Pain, redness, or swelling where the shot was given
- Feeling tired
- Chills
- Fever
- Muscle aches
- Nausea (feeling sick)
- Headache
- Increased heart rate
- Diarrhea
- Vomiting
- Sweating a lot

These are not all of the possible side effects of PAPZIMEOS. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Precigen, Inc. at 1-855-PGE-NRRP (1-855-743-6777).

Please see full Prescribing Information **.**

Precigen: Advancing Medicine with Precision®
Precigen (Nasdaq: PGEN) is a 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.

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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, 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, 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.

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

(Amounts in thousands)	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 14,322	$ 29,517
Short-term investments	106,813	68,393
Receivables		
Trade, net	580	926
Other	520	237
Inventory	3,059	-

Prepaid expenses	4,303	3,341
Total current assets	129,597	102,414
Long-term investments	2,508	-
Property, plant and equipment, net	14,813	13,831
Intangible assets, net	3,500	4,455
Goodwill	15,232	19,139
Right-of-use assets	4,861	5,056
Other assets	753	371
Total assets	$ 171,264	$ 145,266
Liabilities, Mezzanine Equity and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 6,262	$ 3,531
Accrued compensation and benefits	10,167	8,417
Other accrued liabilities	10,824	4,812
Indemnification accruals	3,213	3,213
Deferred revenue	480	589
Current portion of lease liabilities	1,123	956
Total current liabilities	32,069	21,518
Long-term debt	92,890	-
Deferred revenue, net of current portion	95	1,934
Lease liabilities, net of current portion	4,179	4,546
Warrant liabilities	-	50,537
Other long-term liabilities	163	-
Total liabilities	129,396	78,535
Mezzanine equity	-	28,218
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,359,689	2,129,207
Accumulated deficit	(2,317,845)	(2,090,706)
Accumulated other comprehensive income	24	12
Total shareholders' equity	41,868	38,513
Total liabilities, mezzanine equity and shareholders' equity	$ 171,264	$ 145,266

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

(Amounts in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Collaboration and licensing revenue	$ 1,818	$ -	$ 1,818	$ -
Product revenues	162	66	406	235
Service revenues	942	886	2,838	2,478
Other revenues	-	1	57	22
Total revenues	2,922	953	5,119	2,735
Operating Expenses				
Cost of products and services	1,035	1,009	3,227	3,098
Research and development	12,377	11,370	34,343	41,312
Selling, general and administrative	23,991	9,836	52,483	30,293
Impairment of goodwill	-	-	3,907	1,630
Impairment of other noncurrent assets	-	-	-	32,915
Total operating expenses	37,403	22,215	93,960	109,248
Operating loss	(34,481)	(21,262)	(88,841)	(106,513)
Other Income (Expense), Net				
Change in fair value of warrant liabilities	(111,502)	-	(139,523)	-
Interest expense	(902)	(2)	(903)	(6)
Interest income	534	283	2,148	1,210
Other (expense) income, net	7	(2,985)	(17)	(2,905)
Total other expenses, net	(111,863)	(2,704)	(138,295)	(1,701)

Loss before income taxes	(146,344)	(23,966)	(227,136)	(108,214)
Income tax (expense) benefit	-	(12)	(3)	1,706
Net loss	$ (146,344)	$ (23,978)	$ (227,139)	$ (106,508)
Deemed dividends on preferred stock	(179,000)	-	(179,000)	-
Net loss attributable to common shareholders	$ (325,344)	$ (23,978)	$ (406,139)	$ (106,508)
Net Loss per share attributable to common shareholders				
Net loss per share attributable to common shareholders, basic and diluted	$ (1.06)	$ (0.09)	$ (1.36)	$ (0.41)
Weighted average shares outstanding, basic and diluted	307,170,490	275,881,170	299,210,344	259,254,775

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