Precigen Reports Third Quarter 2026 Results Highlighted by Strong Sequential PAPZIMEOS Revenue Growth and Positive Cash Flow Ahead of Guidance

Nov 04, 2026

- *PAPZIMEOS® net revenue rose 37% quarter-over-quarter to $72.9 million in the third quarter of 2026 bringing launch-to-date net product revenue to $151 million, underscoring sustained commercial momentum and expanding US adoption*
- *Achieved positive cash flow in the third quarter of 2026, a full quarter ahead of guidance, driven by robust PAPZIMEOS uptake*
- *Net income for the third quarter of $35.8 million*
- *Cash, cash equivalents, and investments totaled $51.0 million as of September 30, 2026*
- *Received FDA Platform Technology Designation for the AdenoVerse® platform, creating opportunities to expedite development of current and future therapies*
- *New long-term follow-up data presented at AAO-HNSF 2026 demonstrated ongoing durable complete responses after PAPZIMEOS treatment for up to five years*
- *Conference call scheduled for 4:30 PM ET today*

GERMANTOWN, Md., Nov. 4, 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 third quarter 2026 financial results and business updates.

"Precigen has established an exceptional position of strength, with commercial momentum and a proven strategy driving our next phase of growth," said Helen Sabzevari, PhD, President and CEO of Precigen. "PAPZIMEOS has transformed treatment for adults with RRP, with well over 500 patients initiating treatment and 300 of them having completed treatment demonstrating recognition as the first-line standard of care. Its compelling value proposition is supported by an unmatched 51% complete response rate, ongoing durable complete responses up to five years, a well-characterized safety profile, and straightforward administration without a specialized device. PAPZIMEOS also received full FDA approval without the need for a confirmatory trial. Strong commercial uptake has driven sequential revenue growth and positive cash flow ahead of guidance, putting us well on our way to realizing its blockbuster potential. We are actively advancing a comprehensive lifecycle strategy to unlock the full potential of PAPZIMEOS with ongoing redosing clinical trial, pediatric development, and geographic expansion activities. PAPZIMEOS has established a powerful foundation for our next chapter, and the FDA's Platform Technology Designation positions us to realize the broader potential of AdenoVerse to advance our portfolio."

"PAPZIMEOS net revenue grew 37% quarter-over-quarter to $72.9 million, demonstrating the strength of our commercial execution and growing demand for the first FDA-approved therapy for adults with RRP," said Phil Tennant, Chief Commercial Officer of Precigen. "As of today, well over 500 patients have begun PAPZIMEOS treatment and over 300 of them have completed treatment. Physicians are increasingly making PAPZIMEOS their treatment of choice, driven by its compelling efficacy, safety and long-term durability. We have established a commanding first-mover advantage, supported by broad payer coverage, a permanent J-code and a straightforward treatment experience, with subcutaneous administration that requires no specialized devices. With a substantial addressable patient population, we continue to build on this momentum as we deepen adoption, expand patient access and capitalize on PAPZIMEOS as the preferred first-line treatment for adults with RRP."

"PAPZIMEOS has fundamentally transformed how we treat adults with RRP, establishing a new first-line standard of care for a disease that, for more than a century, was managed primarily through repeated surgeries. The potential for durable freedom from surgery, combined with demonstrated clinical efficacy, a well-characterized safety profile, and straightforward subcutaneous administration, represents a remarkable advance for our patients," said Dr. Clark A. Rosen, Lewis Francis Morrison, MD Endowed Chair in Laryngology, Professor, Department of Otolaryngology – Head and Neck Cancer Center, Chief, Division of Laryngology, Co-Director, UCSF Voice and Swallowing Center, University of California, San Francisco. "We are moving beyond simply managing the recurrence of disease to a treatment approach that offers the possibility of sustained disease control."

KEY PLATFORM AND PROGRAM HIGHLIGHTS

AdenoVerse® Platform Technology Designation
In September 2026, Precigen announced that the US Food and Drug Administration (FDA) granted Platform Technology Designation to its AdenoVerse immunotherapeutic platform, building on the successful FDA approval of PAPZIMEOS, the first AdenoVerse-based therapy. The designation recognizes the platform's potential to be applied across multiple therapies and creates opportunities to expedite development of current and future AdenoVerse-based candidates by leveraging existing manufacturing and preclinical data, reducing duplicative development efforts, and enabling earlier and more frequent engagement with the FDA.

PAPZIMEOS®: First-line Standard of Care for the Treatment of Adults with RRP
PAPZIMEOS (zopapogene imadenovec-drba) is the first FDA-approved therapy for adults with recurrent respiratory papillomatosis (RRP). PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP.

- **Full approval with unmatched efficacy:** PAPZIMEOS received full FDA approval in August 2025, with a broad label and without the requirement for a post-approval confirmatory clinical trial to verify clinical benefit. In its pivotal clinical study, PAPZIMEOS demonstrated a 51% complete response rate (18 of 35 patients), defined as no surgeries during the 12 months following treatment completion. This primary efficacy result, reflected in its FDA-approved prescribing information, established a new clinical benchmark in RRP.
- **Established safety profile and straightforward administration:** In the pivotal clinical study, PAPZIMEOS demonstrated a well-characterized safety profile, with no dose-limiting toxicities or treatment-related adverse events greater than Grade 2 reported. PAPZIMEOS is administered subcutaneously without the need for an external specialized administration device, supporting adoption across a broad range of clinical settings.
- **Unmatched durability:** Updated long-term follow-up data presented at the 2026 American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Annual Meeting demonstrated sustained ongoing complete responses following PAPZIMEOS treatment for up to five years. Responses remain ongoing, and follow-up continues.
- **Preferred first-line treatment:** PAPZIMEOS has become the first-line standard of care treatment for adult RRP patients. An independent expert consensus paper sponsored by the Recurrent Respiratory Papillomatosis Foundation (RRPF) and authored by 16 leading RRP physicians recommends PAPZIMEOS as the preferred first-line treatment and it is widely recognized as the new standard of care.
- **Significant first-mover advantage:** As the first FDA-approved therapy for adults with RRP, PAPZIMEOS has established a significant first-mover advantage, supported by broad commercial access and growing adoption across major centers, a network of infusion centers and community practices.
- **Strong commercial adoption:** Within just over one year following FDA approval, well over 500 patients have initiated treatment with PAPZIMEOS, with well over 300 of them completing treatment. Rapid adoption across academic and community settings, including among patients with fewer than three surgeries in the preceding year, demonstrates strong physician uptake across the spectrum of RRP disease severity.
- **Broad payer coverage and streamlined reimbursement:** PAPZIMEOS has payer coverage across over 315 million US lives through private health plans, Medicare and Medicaid, representing nearly 100% of insured lives nationwide. The permanent J-code, J3404, effective April 1, 2026, provides a standardized reimbursement pathway, supporting efficient claims processing and facilitating broader institutional adoption.
- **Redosing study enrolling patients:** Enrollment in the Company's open-label study to evaluate redosing efficacy of zopapogene imadenovec in adults with RRP is ongoing (clinical trial identifier: NCT06538480). The goal of the study is to provide an opportunity for the partial responders to become complete responders.
- **MAA under review by the EMA:** The European Medicines Agency (EMA) has validated and is reviewing the Marketing Authorization Application (MAA) submitted in November 2025 for zopapogene imadenovec for the treatment of adults with RRP. PAPZIMEOS has been granted orphan drug designation from the European Commission.

PRGN-2009 AdenoVerse® Immunotherapy in HPV-associated Diseases
PRGN-2009 is an investigational AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-associated diseases.

- 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.
- A multicenter Phase 2 clinical trial of PRGN-2009 in combination with pembrolizumab in recurrent/metastatic cervical cancer is ongoing.
- The Company plans to present new Phase 2 clinical data from its PRGN-2009 program in newly diagnosed HPV-associated oropharyngeal cancer at a forthcoming R&D Day, together with a comprehensive update on PRGN-2009 and its broader AdenoVerse development strategy.

FINANCIAL RESULTS

"The third quarter marked another significant financial milestone for Precigen," said Harry Thomasian Jr., Chief Financial Officer of Precigen. "PAPZIMEOS net revenue grew 37% quarter-over-quarter to $72.9 million, driving net income of $35.8 million, or $0.08 per diluted share. We previously guided to positive cash flow by the end of the year, and we are pleased to have achieved it a full quarter ahead of that guidance, with net cash provided by operating activities of $11.9 million. These results reflect strong PAPZIMEOS uptake and our disciplined approach to spending. These results are particularly remarkable given that PAPZIMEOS launched just one year ago, and we expect continued revenue momentum as adoption grows while we maintain our focus on fiscal responsibility."

Third Quarter 2026 Financial Results Compared to Prior Year Period
Total revenues were $74.1 million for the three months ended September 30, 2026, an increase of $71.2 million compared to the three months ended September 30, 2025. The significant increase in total revenues was primarily due to the recording of commercial sales of PAPZIMEOS following its FDA approval in August 2025. Net product revenues from PAPZIMEOS for the three months ended September 30, 2026 were $72.9 million. No PAPZIMEOS sales were recorded for the three months ended September 30, 2025. The increase in total revenues was partially offset by a $1.8 million decrease in collaboration and licensing revenue.

Cost of product and services increased by $5.5 million, or greater than 500%, compared to the three months ended September 30, 2025, primarily due to costs related to the commercial sale of PAPZIMEOS following its FDA approval in August 2025. These costs include the cost of product sold as well as other production-related costs that do not meet the criteria for capitalization as inventory. Prior to regulatory approval, costs associated with the production of PAPZIMEOS were expensed as research and development in accordance with the Company's accounting policy.

R&D expenses decreased by $5.7 million, or 46.4%, compared to the three months ended September 30, 2025, primarily due to the change in the accounting treatment of PAPZIMEOS manufacturing costs. Prior to the FDA approval of PAPZIMEOS in August 2025, costs associated with the manufacturing of PAPZIMEOS were expensed as R&D. Following the FDA approval and the commencement of commercial sales, these production costs are no longer expensed as research and development but are capitalized as inventory on the balance sheet and recognized as cost of product and services as the product is sold. The decrease also reflects lower performance-based compensation expense compared to the prior year period.

SG&A expenses decreased by $1.6 million, or 6.8%, compared to the three months ended September 30, 2025, primarily driven by lower performance-based compensation expense in the current year period. This decrease was offset by higher compensation and benefit expense related primarily to the expansion of the Company's workforce as well as increases in marketing and freight expenses, both driven by the commercial launch of PAPZIMEOS.

Total other expense, net decreased by $109.2 million, or 97.6% compared to the three months ended September 30, 2025, primarily attributable to the absence of a $111.5 million charge related to the increase in the fair value of warrant liabilities that was recorded in the prior-year period. This decrease was offset by an increase of $2.1 million in interest expense related to long-term debt entered into in the third quarter of 2025.

During the third quarter of 2025, the Company recorded a one-time $179.0 million non-cash deemed dividend on preferred stock 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 then outstanding preferred shares were converted into common shares.

Net income was $35.8 million, or $0.10 per basic and $0.08 per diluted share for the three months ended September 30, 2026, compared to a net loss attributable to common shareholders of $325.3 million, or $1.06 per basic and diluted share, for the three months ended September 30, 2025.

First Nine Months 2026 Financial Results Compared to Prior Year Period
Total revenues were $152.4 million for the nine months ended September 30, 2026, an increase of $147.3 million compared to the nine months ended September 30, 2025. The significant increase in total revenues was primarily due to the recording of commercial sales of PAPZIMEOS following its FDA approval in August 2025. Revenues related to the sale of PAPZIMEOS for the nine months ended September 30, 2026 were $147.6 million. No PAPZIMEOS sales were recorded for the nine months ended September 30, 2025. Service revenue also increased $1.4 million, primarily due to higher revenue generated by the Company's Exemplar subsidiary.

Cost of product and services increased by $8.6 million, or greater than 250%, compared to the nine months ended September 30, 2025, primarily due to costs related to the commercial sale of PAPZIMEOS following its FDA approval in August 2025. These costs include the cost of product sold as well as other production-related costs that do not meet the criteria for capitalization as inventory. Prior to regulatory approval, costs associated with the production of PAPZIMEOS were expensed as research and development in accordance with the Company's accounting policy.

R&D expenses decreased by $14.8 million, or 43.1%, compared to the nine months ended September 30, 2025, primarily due to the change in the accounting treatment of PAPZIMEOS manufacturing costs. Prior to the FDA approval of PAPZIMEOS in August 2025, costs associated with the manufacturing of PAPZIMEOS were expensed as R&D, as regulatory approval and the probability of future economic benefit had not yet been established. Following the FDA approval and the commencement of commercial sales, these production costs are no longer expensed as research and development but are capitalized as inventory on the balance sheet and recognized as cost of product and services as the product is sold.

SG&A expenses increased by $13.2 million, or 25.1%, compared to the nine months ended September 30, 2025. This increase was primarily driven by commercial activities related to PAPZIMEOS following its FDA approval in August 2025. The higher expenses reflect increased costs to support commercialization, including third-party commercialization costs, freight expenses, expanded marketing and promotional activities to drive product awareness and adoption, and increased software subscription costs.

During the nine months ended September 30, 2025, the Company recorded a $3.9 million goodwill impairment charge related to the Company's Exemplar reporting unit with no comparable charge in the nine months ended September 30, 2026.

Total other expense, net decreased by $131.1 million, or 94.8%, compared to the nine months ended September 30, 2025, primarily attributable to the absence of a $139.5 million charge related to the increase in the fair value of warrant liabilities that was recorded in the prior-year period. The increase in warrant liabilities was mainly driven by a rise in the Company's common stock price and, to a lesser extent, by an increase in the liability for additional warrants that were expected at that point to be issued as paid-in-kind dividends on the Company's then outstanding Series A Preferred Stock. This decrease was offset by an increase of $8.0 million in interest expense related to long-term debt that was entered into in the third quarter of 2025.

During the nine months ended September 30, 2025, we recorded a one-time $179.0 million non-cash deemed dividend on preferred stock 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 GAAP. On September 15, 2025, all of the then outstanding preferred shares were converted into common shares.

Net income was $47.9 million, or $0.13 per basic and $0.12 per diluted share for the nine months ended September 30, 2026, compared to a net loss attributable to common shareholders of $406.1 million, or $1.36 per basic and diluted share, for the nine months ended September 30, 2025.

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.

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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 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 or maintain quarterly profitability and positive cash flow, 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, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 14,959	$ 30,234
Short-term investments	31,112	67,624
Receivables		
Trade, net	96,486	3,916
Other	133	446
Inventory	22,915	9,581
Prepaid expenses and other	6,157	3,434
Total current assets	171,762	115,235
Long-term investments	4,909	2,511
Property, plant and equipment, net	13,295	13,758
Intangible assets, net	2,227	3,182
Goodwill	15,232	15,232
Right-of-use assets	4,043	4,679
Other assets	634	908
Total assets	$ 212,102	$ 155,505
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 7,056	$ 11,985
Accrued compensation and benefits	7,855	10,199
Other accrued liabilities	14,568	10,993
Indemnification accruals	—	2,476
Deferred revenue	174	517
Current portion of lease liabilities	1,135	1,136
Total current liabilities	30,788	37,306
Long-term debt	94,256	93,174
Lease liabilities, net of current portion	3,216	3,980
Other long-term liabilities	48	134
Total liabilities	128,308	134,594
Shareholders' equity		
Additional paid-in capital	2,377,321	2,362,252
Accumulated deficit	(2,293,440)	(2,341,348)
Accumulated other comprehensive (loss) income	(87)	7
Total shareholders' equity	83,794	20,911
Total liabilities and shareholders' equity	$ 212,102	$ 155,505

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,	
	2026	2025	2026	2025
Revenues				
Product revenues, net	$ 72,959	$ 162	$ 148,049	$ 406
Service revenues	1,189	942	4,329	2,895
Collaboration and licensing revenues	—	1,818	—	1,818
Total revenues	74,148	2,922	152,378	5,119
Operating Expenses				
Cost of products and services	6,508	1,035	11,872	3,227
Research and development	6,631	12,377	19,551	34,343
Selling, general and administrative	22,359	23,991	65,657	52,483
Impairment of goodwill	—	—	—	3,907
Total operating expenses	35,498	37,403	97,080	93,960
Operating income (loss)	38,650	(34,481)	55,298	(88,841)
Other Income (Expense), Net				
Change in fair value of warrant liabilities	—	(111,502)	—	(139,523)
Interest expense	(2,996)	(902)	(8,857)	(903)
Interest income	323	534	1,372	2,148
Other income (expense), net	(11)	7	295	(17)
Total other expense, net	(2,684)	(111,863)	(7,190)	(138,295)
Income (loss) before income taxes	35,966	(146,344)	48,108	(227,136)
Income tax expense	(200)	—	(200)	(3)
Net income (loss)	$ 35,766	$ (146,344)	$ 47,908	$ (227,139)
Deemed dividends on preferred stock	—	(179,000)	—	(179,000)
Net income (loss) attributable to common shareholders	$ 35,766	$ (325,344)	$ 47,908	$ (406,139)
Net income (loss) per share				
Net income (loss) per share, basic	$ 0.10	$ (1.06)	$ 0.13	$ (1.36)
Net income (loss) per share, diluted	$ 0.08	$ (1.06)	$ 0.12	$ (1.36)
Weighted average shares outstanding, basic	358,249,260	307,170,490	356,492,444	299,210,344
Weighted average shares outstanding, diluted	421,162,494	307,170,490	415,432,302	299,210,344

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