

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 14, 2024

PRECIGEN, INC.

(Exact name of registrant as specified in its charter)

Virginia
(State or other jurisdiction
of incorporation)

001-36042
(Commission
File Number)

26-0084895
(I.R.S. Employer
Identification No.)

20374 Seneca Meadows Parkway, Germantown, Maryland 20876
(Address of principal executive offices) (Zip Code)

(301) 556-9900
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|-----------------------------------|--------------------------|--|
| Common Stock, No Par Value | PGEN | Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

Attached as Exhibit 99.1 is a copy of a press release of Precigen, Inc., dated August 14, 2024, reporting its financial results for the quarter ended June 30, 2024.

This information, including the Exhibit attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|----------------------|--|
| 99.1 | Press release dated August 14, 2024 |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101) |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Precigen, Inc.

By: /s/ Donald P. Lehr
Donald P. Lehr
Chief Legal Officer

Dated: August 14, 2024



Precigen Reports Second Quarter and First Half 2024 Financial Results and Business Updates

- In June 2024, the Company announced groundbreaking pivotal study data for PRGN-2012 gene therapy at the 2024 ASCO annual meeting in which more than half of RRP patients achieved Complete Response –
- In July 2024, the Company appointed Phil Tennant as Chief Commercial Officer to spearhead potential PRGN-2012 commercial launch –
- In August 2024, the Company announced a strategic reprioritization of its pipeline to focus on advancement of its lead program, PRGN-2012 in RRP –
- PRGN-2012 rolling BLA submission, under an accelerated approval pathway, is anticipated in the second half of 2024; the Company has initiated enrollment in the confirmatory clinical trial of PRGN-2012 –
- In August 2024, the Company strengthened its cash position by raising approximately \$31.4 million via a public offering of common stock –

GERMANTOWN, MD, August 14, 2024 – 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 second quarter and first half 2024 financial results and business updates.

“We are all in on PRGN-2012 given the immense unmet need for RRP patients and our groundbreaking pivotal data supporting the potential of what we hope to be the first-ever FDA approved therapy to treat RRP,” said Helen Sabzevari, PhD, President and CEO of Precigen. “By strategically focusing our portfolio, streamlining resources and recent public offering, we have optimized the company to rapidly prepare for submission of a rolling biologics license application under an accelerated approval pathway. We are excited to have initiated enrollment in the confirmatory clinical trial and will continue to accelerate our commercial readiness campaign for a potential launch in 2025 under the leadership of our newly hired Chief Commercial Officer. Additionally, we plan to maximize portfolio value by focusing on strategic partnerships to further advance our highly promising UltraCAR-T programs.”

“Our recent reprioritization and public offering is expected to fund our operations into early 2025 allowing us to focus on advancement of PRGN-2012 while continuing to explore potential non-dilutive financing opportunities for future liquidity,” said Harry Thomasian Jr., CFO of Precigen.

Key Program Highlights

- **PRGN-2012 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 from the US Food and Drug Administration (FDA). PRGN-2012 also received Orphan Drug Designation from the FDA and Orphan Drug Designation from the European Commission.
 - o 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.”
 - Pivotal study met primary safety and efficacy endpoints.
 - 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 20 months as of the May 20, 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 was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
 - 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 Derkey and quality of life scores in complete responders.
 - o A rolling Biologics License Application (BLA) submission under an accelerated approval pathway is anticipated in the second half of 2024.
 - o The Company has initiated enrollment in the confirmatory clinical trial, in accordance with the guidance from the FDA, prior to submission of the BLA.
 - o The Company and the Recurrent Respiratory Papillomatosis Foundation held the inaugural RRP Awareness Day on June 11, 2024. The multi-stakeholder event raised awareness by bringing together individuals living with RRP, caregivers, clinicians, and government officials.



Strategic Prioritization: In August 2024, the Company announced a strategic prioritization of its clinical portfolio and associated streamlining of resources, including a reduction of over 20% of its workforce, to focus on potential commercialization of PRGN-2012.

o **PRGN-2009 AdenoVerse® Gene Therapy Clinical Trials**

- The Company plans to continue 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.
- PRGN-2009 cervical cancer clinical trial enrollment at non-NCI clinical sites will be paused.

o **UltraCAR-T® Clinical Programs**

- 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.
- The Company will pause the PRGN-3005 and PRGN-3007 clinical trials.
- The Company will minimize UltraCAR-T spend and focus on strategic partnerships to further advance UltraCAR-T programs.

o **Preclinical Programs**

- The Company will pause all preclinical programs.

o **ActoBio**

- The Company has initiated shutdown of its Belgium-based ActoBio subsidiary operations, including planned elimination of all ActoBio personnel.
- In conjunction with this shutdown, ActoBio's portfolio of intellectual property will be made available for prospective transactions.

Financial Highlights

Strategic prioritization resulted in non-cash impairment charges of \$32.9 million, net of tax, in the second quarter and severance charges of \$3.0 million, of which \$2.1 million was recorded in the second quarter and \$0.9 million is expected to be recorded in the third quarter.

The Company closed a public offering of its common stock in August 2024, resulting in net proceeds of approximately \$31.4 million.

Second Quarter 2024 Financial Results Compared to Prior Year Period

Research and development expenses increased \$3.8 million, or 32%, compared to the three months ended June 30, 2023. Salaries, benefits, and other personnel costs increased \$2.1 million primarily due to severance charges related to the shutdown of the Company's ActoBio subsidiary. Additionally, fees paid to contract research organizations related to the start of the PRGN-2012 confirmatory clinical trial and close out of the PRGN-2012 pivotal clinical trial activities and professional fees incurred related to our manufacturing facility readiness for anticipated BLA submission increased compared to the same period in 2023.

SG&A expenses increased by \$1.0 million, or 11%, compared to the three months ended June 30, 2023. This increase was primarily driven by severance costs incurred related to the suspension of ActoBio operations of \$0.4 million, increased costs associated with PRGN-2012 commercial readiness as well as increased professional fees incurred related to general corporate matters compared to the same period in 2023.

In conjunction with the suspension of ActoBio's operations, the Company recorded \$34.5 million of impairment charges related to goodwill and other noncurrent assets in the second quarter of 2024, as well as a related tax benefit of \$1.7 million.

Total revenues decreased \$1.1 million, or 59%, compared to the three months ended June 30, 2023. This decrease was related to reductions in product and service revenues at Exemplar.

Net loss was \$58.8 million, or \$(0.23) per basic and diluted share, compared to net loss of \$20.3 million, or \$(0.08) per basic and diluted share, in period ended June 30, 2023.



First Half 2024 Financial Results Compared to Prior Year Period

Research and development expenses increased \$5.9 million, or 25%, compared to the six months ended June 30, 2023. Salaries, benefits, and other personnel costs increased by \$3.3 million primarily due to \$2.1 million of severance charges related to the shutdown of the Company's ActoBio subsidiary and an increase in the hiring of employees related to the advancement of PRGN-2012 in 2023 at Precigen. Additionally, fees paid to contract research organizations related to the start of the PRGN-2012 confirmatory clinical trial and close out of the PRGN-2012 pivotal clinical trial activities and professional fees incurred related to our manufacturing facility readiness for anticipated BLA submission increased compared to the prior year period. These increases were offset by lower costs incurred at contract research organizations for other programs compared to the same period in 2023.

SG&A expenses decreased by \$0.5 million, or 2%, compared to the six months ended June 30, 2023. This decrease was primarily due to lower stock compensation and insurance expenses in 2024 compared to the same period in 2023. These decreases were offset by severance costs incurred in the second quarter of 2024 related to the suspension of ActoBio's operations, and increased costs related to PRGN-2012 commercial readiness compared to the same period in 2023.

In conjunction with the suspension of ActoBio's operations, the Company recorded \$34.5 million of impairment charges related to goodwill and other noncurrent assets in the second quarter of 2024, as well as a related tax benefit of \$1.7 million.

Total revenues decreased \$1.9 million, or 51%, compared to the six months ended June 30, 2023. This decrease was related to reductions in product and service revenues at Exemplar.

Net loss was \$82.5 million, or \$(0.33) per basic and diluted share, compared to net loss of \$43.1 million, or \$(0.18) per basic and diluted share, in period ended June 30, 2023.

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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 X @Precigen, 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.

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

| (Amounts in thousands) | June 30, 2024 | December 31, 2023 |
|---|---------------|-------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 9,345 | \$ 7,578 |
| Short-term investments | 10,191 | 55,277 |
| Receivables | | |
| Trade, net | 511 | 902 |
| Other | 505 | 673 |
| Prepaid expenses and other | 3,163 | 4,325 |
| Total current assets | 23,715 | 68,755 |
| Property, plant and equipment, net | 13,451 | 7,111 |
| Intangible assets, net | 5,091 | 40,701 |
| Goodwill | 24,918 | 26,612 |
| Right-of-use assets | 5,550 | 7,097 |
| Other assets | 435 | 767 |
| Total assets | \$ 73,160 | \$ 151,043 |
| Liabilities and Shareholders' Equity | | |
| Current liabilities | | |
| Accounts payable | \$ 4,846 | \$ 1,726 |
| Accrued compensation and benefits | 6,675 | 8,250 |
| Other accrued liabilities | 6,642 | 6,223 |
| Settlement and Indemnification Accrual | 3,213 | 5,075 |
| Deferred revenue | 378 | 509 |
| Current portion of lease liabilities | 1,269 | 1,202 |
| Total current liabilities | 23,023 | 22,985 |
| Deferred revenue, net of current portion | 1,818 | 1,818 |
| Lease liabilities, net of current portion | 5,072 | 5,895 |
| Deferred tax liabilities | 77 | 1,847 |
| Total liabilities | 29,990 | 32,545 |
| Shareholders' equity | | |
| Common stock | — | — |
| Additional paid-in capital | 2,093,080 | 2,084,916 |
| Accumulated deficit | (2,047,001) | (1,964,471) |
| Accumulated other comprehensive loss | (2,909) | (1,947) |
| Total shareholders' equity | 43,170 | 118,498 |
| Total liabilities and shareholders' equity | \$ 73,160 | \$ 151,043 |



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

| (Amounts in thousands, except share and per share data) | Three Months Ended | | Six Months Ended | |
|--|---------------------------|----------------------|-------------------------|---------------------|
| | June 30, 2024 | June 30, 2023 | June 30, 2024 | Jun 30, 2023 |
| Revenues | | | | |
| Product revenues | \$ 31 | \$ 324 | \$ 169 | \$ 648 |
| Service revenues | 673 | 1,438 | 1,592 | 2,965 |
| Other revenues | 13 | 5 | 21 | 5 |
| Total revenues | <u>717</u> | <u>1,767</u> | <u>1,782</u> | <u>3,618</u> |
| Operating Expenses | | | | |
| Cost of products and services | 1,014 | 1,697 | 2,089 | 3,224 |
| Research and development | 15,693 | 11,874 | 29,942 | 24,037 |
| Selling, general and administrative | 10,306 | 9,316 | 20,457 | 20,954 |
| Impairment of goodwill | 1,630 | — | 1,630 | — |
| Impairment of other noncurrent assets | 32,915 | — | 32,915 | — |
| Total operating expenses | <u>61,558</u> | <u>22,887</u> | <u>87,033</u> | <u>48,215</u> |
| Operating loss | <u>(60,841)</u> | <u>(21,120)</u> | <u>(85,251)</u> | <u>(44,597)</u> |
| Other Income (Expense), Net | | | | |
| Interest expense | (2) | (136) | (4) | (460) |
| Interest income | 319 | 828 | 927 | 1,460 |
| Other income, net | 43 | 44 | 80 | 424 |
| Total other income, net | <u>360</u> | <u>736</u> | <u>1,003</u> | <u>1,424</u> |
| Loss before income taxes | <u>(60,481)</u> | <u>(20,384)</u> | <u>(84,248)</u> | <u>(43,173)</u> |
| Income tax benefit | 1,689 | 65 | 1,718 | 120 |
| Net loss | <u>\$ (58,792)</u> | <u>\$ (20,319)</u> | <u>\$ (82,530)</u> | <u>\$ (43,053)</u> |
| Net Loss per share | | | | |
| Net loss per share, basic and diluted | <u>\$ (0.23)</u> | <u>\$ (0.08)</u> | <u>\$ (0.33)</u> | <u>\$ (0.18)</u> |
| Weighted average shares outstanding, basic and diluted | <u>252,366,533</u> | <u>248,003,322</u> | <u>250,803,790</u> | <u>240,307,403</u> |