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): March 19, 2024

PRECIGEN, INC.
(Exact name of registrant as specified in its charter)

Virginia	001-36042	26-0084895
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 March 19, 2024, reporting its financial results for the quarter and year ended December 31, 2023.

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 March 19, 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: March 19, 2024

Exhibit 99.1

Precigen Reports Full Year 2023 Financial Results and Business Updates

– *Significant progress made in the development of the PRGN-2012 AdenoVerse immunotherapy for the treatment of RRP; Precigen plans to submit a BLA under an accelerated approval pathway in the second half of 2024;ramping up commercial readiness activities for a potential launch in 2025 –*

– *Precigen's PRGN-2012 received the first Breakthrough Therapy Designation and accelerated approval pathway from the FDA for the treatment of RRP –*

– *Precigen received IND clearance for a randomized Phase 2 study of PRGN-2009 AdenoVerse immunotherapy in combination with pembrolizumab in HPV-associated recurrent/metastatic cervical cancer; study now active and recruiting patients –*

– *Interim data from the ongoing Phase 1b study of PRGN-3006 UltraCAR-T in relapsed/refractory AML anticipated in the second half of 2024 –*

– *Preliminary data from the Phase 1 study of PRGN-3007 next generation UltraCAR-T in ROR1+ advanced cancers anticipated in the second half of 2024 –*

– *Cash, cash equivalents, short-term and long-term investments totaled $62.9 million as of December 31, 2023 –*

– *Continued focus on cost containment resulted in a reduction in SG&A costs of 16% for the twelve months ended December 31, 2023, compared to the prior year period –*

GERMANTOWN, MD, March 19, 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 full year 2023 financial results and business updates.

"2024 is poised to be a transformative year for Precigen, as we are on track to present pivotal Phase 2 data in the second quarter and submit a BLA for PRGN-2012 in the second half, a milestone bolstered by the Breakthrough Therapy Designation and accelerated approval pathway granted by the FDA," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are preparing our manufacturing facility and commercial operations in anticipation of the launch of PRGN-2012 in 2025. We are also looking forward to exciting updates from our UltraCAR-T programs, which offer a novel approach compared to traditional CAR-T therapies and have garnered significant interest from potential partners due to the safety, preliminary efficacy, and manufacturing advantages."

"With multiple value inflection points anticipated in 2024, we remain steadfastly committed to a strategy of sound financial management," said Harry Thomasian Jr., CFO of Precigen. "We are evaluating various financing opportunities to strengthen our balance sheet as we prepare our lead asset PRGN-2012 for potential commercial launch in 2025."

Key Program Highlights

AdenoVerse™ Immunotherapies

- **PRGN-2012 in RRP:** PRGN-2012 is an investigational off-the-shelf AdenoVerse immunotherapy 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 has received Breakthrough Therapy Designation and Orphan Drug Designation from the US Food and Drug Administration (FDA) and Orphan Drug Designation from the European Commission.
  - PRGN-2012 is currently under investigation in a Phase 1/2 pivotal single-arm study in adult patients with RRP (clinical trial identifier: NCT04724980).
  - PRGN-2012 demonstrated strong efficacy and a favorable safety profile in the Phase 1 portion of the study with 50% of patients (N=12) in durable and ongoing Complete Response more than two years after PRGN-2012 treatment. Results of the Phase 1 portion of the Phase 1/2 study were published in the peer-reviewed journal, *Science Translational Medicine*, a leading publication from the American Association for the Advancement of Science (AAAS).
  - Enrollment and dosing in the Phase 2 portion of the study is complete and a Phase 2 data presentation is anticipated in the second quarter of 2024.
  - The Company has received agreement from the FDA that PRGN-2012 is eligible for consideration of a rolling Biologics License Application (BLA) review. A planned BLA submission under an accelerated approval pathway is anticipated in the second half of 2024.
  - Commercial readiness preparations are underway for a potential launch in 2025.

- **PRGN-2009 in OPSCC and Cervical Cancer:** PRGN-2009 is an investigational off-the-shelf AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-associated cancers.
    - The Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) is enrolling patients (clinical trial identifier: NCT05996523).
    - The Phase 2 randomized, open-label study of PRGN-2009 in combination with pembrolizumab in patients with HPV-associated recurrent/metastatic cervical cancer is active and recruiting patients (clinical trial identifier: NCT06157151).

UltraCAR-T® Cell Therapies

- **PRGN-3006 in AML/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.
    - PRGN-3006 is currently under investigation in a Phase 1b dose expansion clinical trial (clinical trial identifier: NCT03927261) for the treatment of patients with r/r AML or higher-risk myelodysplastic syndromes (MDS).
    - The first-in-human Phase 1 dose escalation study data show that PRGN-3006 was well-tolerated with no dose-limiting toxicities (DLTs) and a 27% objective response rate (ORR) in heavily pre-treated r/r AML patients infused following lymphodepletion.
    - An interim Phase 1b dose expansion data presentation is anticipated in the second half of 2024.
- **PRGN-3005 in Ovarian Cancer:** PRGN-3005 is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, mbIL15, and a safety/kill switch.
    - The Phase 1b dose expansion portion of the Phase 1/1b study is ongoing (clinical trial identifier: NCT03907527).
- **PRGN-3007 in Advanced ROR1+ Hematological and Solid Tumors:** PRGN-3007, based on the next generation UltraCAR-T platform, is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a safety/kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression.
    - The Phase 1 dose escalation portion of the Phase 1/1b study is ongoing (clinical trial identifier: NCT05694364).
    - A preliminary Phase 1 dose escalation data presentation is anticipated by the end of 2024.

Financial Highlights

- Cash, cash equivalents, short-term and long-term investments totaled $62.9 million as of December 31, 2023.
- Selling, general, and administrative (SG&A) costs decreased versus the prior year, 16% for the twelve months ended December 31, 2023.

Full Year 2023 Financial Results Compared to Prior Year Period

Research and development expenses increased $1.4 million, or 3.1%, compared to year ended December 31, 2022. Salaries, benefits, and other personnel costs increased $2.8 million due to an increase in the hiring of employees to support the growth in the Company's development activities, and to a lesser extent, increases in salaries of our continuing employees. These increases were offset by less expenses incurred related to preclinical research programs for the comparable period.

SG&A expenses decreased $7.6 million, or 15.8%, compared to the year ended December 31, 2022. This decrease was primarily driven by a reduction in professional fees of $6.5 million, due to decreased legal fees associated with certain litigation matters, and $0.7 million decreased insurance-related premiums.

Total revenues decreased $20.7 million, or 76.9%, compared to the year ended December 31, 2022. Collaboration and licensing revenues decreased $14.6 million, or 99.5%, compared to the year ended December 31, 2022, primarily due to the prior year period non-cash recognition of revenue related to historical collaboration agreements for which revenue was previously deferred. Product and services revenues decreased $5.9 million, or 48.8%, compared to the year ended December 31, 2022. This decrease is related to reductions in services performed at Exemplar as well as the recognition of revenue in the first quarter of 2022 related to agreements for which revenue was previously deferred that did not occur in 2023.

Total other income, net, increased $8.5 million, compared to the year ended December 31, 2022. This was primarily due to $6.3 million in reduced interest expense associated with the Convertible Notes as they were fully retired in the second quarter of 2023, and $3.1 million increased interest income due to higher interest rates on investments. This increase was partially offset

by a $0.9 million decrease in gain recorded on the early retirement of a portion of our Convertible Notes compared to the year ended December 31, 2022.

The Company recorded a $10.4 million impairment charge in the fourth quarter of 2023 related to its Exemplar subsidiary as a result of the Company's annual goodwill impairment test.

Loss from continuing operations was $95.9 million, or $(0.39) per basic and diluted share, compared to loss from continuing operations of $79.8 million, or $(0.40) per basic and diluted share, in year ended December 31, 2022.

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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.

UltraCAR-T®

UltraCAR-T is a multigenic autologous CAR-T platform that utilizes Precigen's advanced non-viral *Sleeping Beauty* system to simultaneously express an antigen-specific CAR to specifically target tumor cells, mbIL15 for enhanced *in vivo* expansion and persistence, and a kill switch to conditionally eliminate CAR-T cells for a potentially improved safety profile. Precigen has advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. UltraCAR-T investigational therapies are manufactured via Precigen's overnight manufacturing process using the proprietary UltraPorator® electroporation system at the patient's medical center and administered to patients only one day following gene transfer. The overnight UltraCAR-T manufacturing process does not use viral vectors and does not require *ex vivo* activation and expansion of T cells, potentially addressing major limitations of current T cell therapies.

UltraCAR-T® Clinical Program

Precigen's UltraCAR-T platform is currently under clinical investigation for hematological and solid tumors, including a Phase 1/1b study of PRGN-3005 UltraCAR-T in patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (NCT03907527), a Phase 1/1b study of PRGN-3006 UltraCAR-T in patients with relapsed or refractory acute myeloid leukemia (AML) or higher risk myelodysplastic syndrome (MDS) (NCT03927261) and a Phase 1/1b study of PRGN-3007 UltraCAR-T incorporating PD-1 checkpoint inhibition in patients with ROR1-positive ($ROR1^+$) chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL) and triple negative breast cancer (TNBC) (NCT05694364). PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation and Fast Track Designation in patients with AML by the US Food and Drug Administration (FDA).

UltraCAR-T® Library Approach

Precigen's UltraCAR-T library approach is designed to transform the personalized cell therapy landscape for cancer patients. Precigen's goal is to develop and validate a library of non-viral plasmids to target tumor-associated antigens. Enabled by design and manufacturing advantages of UltraCAR-T, coupled with the capabilities of the UltraPorator® system, Precigen is working to empower medical centers to deliver personalized, autologous UltraCAR-T treatment with overnight manufacturing to any cancer patient. Based on the patient's cancer indication and biomarker profile, one or more non-viral plasmids would be selected from the library to build a personalized UltraCAR-T treatment. After initial treatment, this approach has the potential to allow for redosing of UltraCAR-T targeting the same or new tumor-associated antigen(s) based on the treatment response and the changes in antigen expression of the patient's tumor. Precigen believes that the combination of the advanced UltraVector® DNA construction platform and the ease of overnight manufacturing gives this library approach a proprietary advantage over traditional T-cell therapies.

UltraPorator®

The UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk. The UltraPorator device is a high-throughput, semi-closed electroporation system for modifying T cells using Precigen's proprietary non-viral gene transfer technology. UltraPorator is being utilized for clinical manufacturing of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices.

AdenoVerse™ Immunotherapy

Precigen's AdenoVerse immunotherapy platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse immunotherapies have been shown to generate high-level and durable antigen-specific T-cell immune responses as well as an ability to boost these responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors leveraging UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

AdenoVerse™ Immunotherapy Clinical Program

Precigen's AdenoVerse immunotherapy platform is currently under clinical investigation in a Phase 1/2 study of PRGN-2009 AdenoVerse immunotherapy alone or in combination with an anti-PDL1/TGF-Beta Trap in patients with HPV-associated cancers (NCT04432597), a Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) (NCT05996523), a Phase 2 study of PRGN-2009 AdenoVerse immunotherapy in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer (NCT06157151), and a Phase 1/2 study of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis (RRP) (NCT04724980). PRGN-2012 has been granted Orphan Drug Designation and Breakthrough Therapy Designation in patients with RRP by the FDA and Orphan Drug Designation by the European Commission.

Trademarks

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)	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 7,578	$ 4,858
Restricted cash	-	43,339
Short-term investments	55,277	51,092
Receivables		
Trade, net	902	978
Other	673	12,826
Prepaid expenses and other	4,325	5,066
Total current assets	68,755	118,159
Property, plant and equipment, net	7,111	7,329
Intangible assets, net	40,701	44,455
Goodwill	26,612	36,923
Right-of-use assets	7,097	8,086
Other assets	767	1,025
Total assets	$ 151,043	$ 215,977
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 1,726	$ 4,068
Accrued compensation and benefits	8,250	6,377
Other accrued liabilities	6,223	4,997
Settlement and Indemnification Accrual	5,075	18,750
Deferred revenue	509	25
Current portion of long-term debt	-	43,219
Current portion of lease liabilities	1,202	1,209
Total current liabilities	22,985	78,645
Deferred revenue, net of current portion	1,818	1,818
Lease liabilities, net of current portion	5,895	6,992
Deferred tax liabilities	1,847	2,263
Total liabilities	32,545	89,718
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,084,916	1,998,314
Accumulated deficit	(1,964,471)	(1,868,567)
Accumulated other comprehensive loss	(1,947)	(3,488)
Total shareholders' equity	118,498	126,259
Total liabilities and shareholders' equity	$ 151,043	$ 215,977

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

(Amounts in thousands, except share and per share data)	Year ended December 31, 2023	December 31, 2022
Revenues		
Collaboration and licensing revenues	$ 75	$ 14,661
Product revenues	840	1,903
Service revenues	5,301	10,094
Other revenues	9	251
Total revenues	6,225	26,909
Operating Expenses		
Cost of products and services	6,119	6,339
Research and development	48,614	47,170
Selling, general and administrative	40,415	48,006
Impairment of goodwill	10,390	482
Impairment of other noncurrent assets	445	638
Total operating expenses	105,983	102,635
Operating loss	(99,758)	(75,726)
Other Expense, Net		
Interest expense	(468)	(6,774)
Interest income	3,237	133
Other income, net	627	1,539
Total other income (expense), net	3,396	(5,102)
Equity in net loss of affiliates	-	862
Loss from continuing operations before income taxes	(96,362)	(79,966)
Income tax benefit	458	189
Loss from continuing operations	$ (95,904)	$ (79,777)
Income from discontinued operations, net of income taxes	-	108,094
Net loss	$ (95,904)	$ 28,317
Net Loss per share		
Net loss from continuing operations per share, basic and diluted	$ (0.39)	$ (0.40)
Net income from discontinued operations per share, basic and diluted	-	0.54
Net loss per share, basic and diluted	$ (0.39)	$ 0.14
Weighted average shares outstanding, basic and diluted	244,536,221	200,360,821