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 6, 2023

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 6, 2023, reporting its financial results for the quarter and year ended December 31, 2022.

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 6, 2023
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 6, 2023

Exhibit 99.1

Precigen Reports Fourth Quarter and Full Year 2022 Financial Results and Business Updates

- *Achieved significant clinical progress for UltraCAR-T® and AdenoVerse™ investigational therapeutics in 2022 –*
- *Presented positive clinical data for PRGN-2012 AdenoVerse immunotherapy in recurrent respiratory papillomatosis (RRP) showing favorable safety profile and significant reduction in surgeries with 50% of the patients in Complete Response following treatment with PRGN-2012 –*
- *Presented positive clinical data for PRGN-3006 UltraCAR-T in relapsed or refractory (r/r) acute myeloid leukemia (AML) showing a favorable safety profile, 27% objective response rate (ORR) and reduction in AML blasts in the majority of patients following treatment with PRGN-3006 –*
- *Significantly strengthened balance sheet via successful divesture of non-health subsidiary in the third quarter, retirement of the majority of the Company's $200 million outstanding convertible notes, and raising approximately $73 million (after deducting underwriting discounts, fees and other underwriting expenses) via a public offering of common stock –*
- *Cash, cash equivalents, short-term investments and restricted cash totaled $99.7 million as of December 31, 2022 –*

GERMANTOWN, MD, March 6, 2023 – 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 fourth quarter and full year 2022 financial results.

"2022 was a successful year with respect to clinical advancements for Precigen's UltraCAR-T and AdenoVerse programs. We showcased highly encouraging safety and efficacy results from Phase 1 dose escalation of PRGN-3006 UltraCAR-T in AML at ASH and Phase 1 dose escalation and expansion cohort data of our PRGN-2012 AdenoVerse immunotherapy in RRP at our Company's R&D Day," said Helen Sabzevari, PhD, President and CEO of Precigen. "These data set us up for a strong 2023 as we continue our focus on rapidly advancing clinical programs and pursuing the most promising regulatory paths to licensure."

"Through the actions that we have taken over the past year, we have significantly strengthened our financial position. These actions included the divesture of Trans Ova Genetics, from which the non-dilutive proceeds were used to early retire over 85% of our outstanding $200 million of convertible notes due in July, and our public offering of common stock in January 2023. We also continue to focus on cost containment," said Harry Thomasian Jr., CFO of Precigen. "Based on present expectations, these actions provide a healthy cash runway to advance our clinical priorities into late 2024."

Key Program Highlights

- **PRGN-2012 AdenoVerse™ Immunotherapy in RRP**
  - PRGN-2012 is an investigational off-the-shelf (OTS) AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for the treatment of RRP. The US Food and Drug Administration (FDA) granted orphan drug designation for PRGN-2012 for patients with RRP.
  - The Company completed a Phase 1 dose escalation and dose expansion trial of PRGN-2012 in adult patients with severe, aggressive RRP (≥3 surgeries in prior year).
  - The Company announced positive Phase 1 dose escalation and expansion cohort data (N=15) at the most recent R&D Day.
  - The Company initiated the Phase 2 study and enrollment is ongoing with 22 patients enrolled to date, bringing the total number of enrolled patients to 34 at Dose Level 2.
  - The Company plans to outline the regulatory strategy in RRP as FDA discussions advance.
- **PRGN 2009 AdenoVerse™ Immunotherapy in HPV-associated Cancers**
  - PRGN-2009 is an OTS investigational immunotherapy utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive (HPV+) solid tumors.
  - The Company completed enrollment in the Phase 1 monotherapy (N=6) and combination therapy (N=11) arms in patients with recurrent or metastatic HPV-associated cancers. A Phase 1 monotherapy and combination therapy safety and efficacy data presentation is expected in the first half of 2023.
  - Enrollment was completed in the Phase 2 monotherapy arm with 20 evaluable patients in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients. An interim clinical data presentation from the Phase 2 monotherapy arm is expected in the second half of 2023.

- **PRGN-3006 UltraCAR-T® in AML**
  - 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 kill switch. The FDA granted orphan drug designation and fast track designation for PRGN-3006 UltraCAR-T for patients with relapsed or refractory (r/r) AML.
  - The Company completed the Phase 1 dose escalation trial of PRGN-3006 in relapsed or r/r AML or higher-risk myelodysplastic syndromes (MDS).
  - The Company announced positive Phase 1 dose escalation data (N=10 non-lymphodepletion; N=16 with lymphodepletion) at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition.
  - The Company initiated a Phase 1b dose expansion trial of PRGN-3006 and expanded the trial to Mayo Clinic in Rochester, Minnesota, further validating the decentralized manufacturing model. The Company received FDA clearance to incorporate repeat dosing in the Phase 1b expansion trial. A Phase 1b clinical trial data presentation is expected in 2024.
- **PRGN-3005 UltraCAR-T® in Ovarian Cancer**
  - PRGN-3005 UltraCAR-T is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, mbIL15, and a kill switch.
  - The Company completed enrollment in the Phase 1 dose escalation cohorts of the intraperitoneal (IP) and intravenous (IV) arms without lymphodepletion as well as in the lymphodepletion cohort in the IV arm. A Phase 1 dose escalation data presentation is expected in the first half of 2023.
  - The Company initiated a Phase 1b dose expansion trial of PRGN-3005. The Company received FDA clearance to incorporate repeat dosing in the trial. A Phase 1b clinical trial data presentation is expected in 2024.
- **PRGN-3007 UltraCAR-T® in Advanced ROR1$^+$ Hematological and Solid Tumors**
  - PRGN-3007, based on the next generation of the 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 kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression.
  - Manufacturing technology transfer was completed for initiation of the Phase 1 umbrella trial in ROR1$^+$ hematological cancers (chronic lymphocytic leukemia (CLL), mantle cell leukemia (MCL), acute lymphoblastic leukemia (ALL), and diffuse large B-cell lymphoma (DLBCL)) and solid tumors (triple negative breast cancer (TNBC)). The Phase 1 trial is open for enrollment and the Company expects to dose the first patient in the first quarter of 2023.
  - The Company presented an abstract titled, "A Phase1/1b Dose Escalation/Dose Expansion Study of PRGN-3007 UltraCAR-T Cells in Patients with Advanced Hematologic and Solid Tumor Malignancies," at ASH.

Financial Highlights

- In January 2023, Precigen completed an underwritten public offering of approximately 44 million shares of common stock, including a partial exercise of the underwriters' option to purchase additional shares, at a price to the public of $1.75 per share, which resulted in net proceeds to Precigen of approximately $73 million (after deducting underwriting discounts, fees and other underwriting expenses).
- During the year ended December 31, 2022, Precigen completed the sale of its wholly owned subsidiary, Trans Ova Genetics, resulting in the receipt of $162.3 million in proceeds from the sale, net of certain transaction related expenses. The Company recorded a gain on sale of discontinued operations of $94.7 million.
- As of December 31, 2022, the Company had successfully retired, through open market purchases, $156.7 million of outstanding convertible notes due in July 2023 at a discount to par. Subsequent to year end, the Company retired an additional $15.4 million of outstanding convertible notes, bringing the total face value of retired notes to $172.1 million. The early retirement of these convertible notes has resulted in savings to the Company of $6.2 million due to the discounted amount paid for these bonds and reduced future interest costs.
- Cash, cash equivalents, short-term investments and restricted cash totaled $99.7 million as of December 31, 2022.
- Selling, general and administrative (SG&A) costs decreased for both the three and twelve months ended December 31, 2022 compared to the prior year periods.

Fourth Quarter 2022 Financial Results Compared to Prior Year Period

Total revenues decreased $1.9 million, or 52%, from the three months ended December 31, 2021. Product and service revenues generated by Exemplar decreased $1.8 million from the three months ended December 31, 2021. Gross margin on product and services decreased comparable to the prior year due to the reduction in revenues and increased costs for supplies, drugs, and personnel at Exemplar.

Research and development expenses decreased $1.4 million, or 11%, from the three months ended December 31, 2021. This decrease was primarily driven by a reduction in contract research organization costs of $0.9 million, primarily due to timing differences, the completion of the 1b/2a clinical trial of AG019 in the fourth quarter of the prior year, as well as a continued prioritization of clinical product candidates, with less expense incurred related preclinical research programs for the comparable period.

SG&A expenses decreased $0.3 million, or 2%, from the three months ended December 31, 2021. Salaries, benefits, and other personnel costs decreased $1.4 million primarily due to reduced headcount as the Company scaled down corporate functions to support the more streamlined organization, offset by other costs which were primarily due to timing and not individually significant.

Loss from continuing operations was $22.2 million, or $(0.11) per basic and diluted share, compared to loss from continuing operations of $26.7 million, or $(0.13) per basic and diluted share, in 2021.

Full Year 2022 Financial Results Compared to Prior Year Period
Total revenues increased $12.6 million, or 89%, from the twelve months ended December 31, 2021. Collaboration and licensing revenues increased $14.2 million from the twelve months ended December 31, 2021, primarily due to the recognition of revenue related to agreements for which revenue was previously deferred, as it became probable that additional performance under the agreements would not be required. Product and service revenues generated by Exemplar decreased $1.3 million from the twelve months ended December 30, 2021. Gross margin on product and services decreased comparable to the prior year due to the reduction in revenues and increased costs for supplies, drugs, and personnel costs.

Research and development expenses decreased $0.8 million, or 2%, over the twelve months ended December 31, 2021. Salaries, benefits, and other personnel costs increased $1.8 million due to an increase in the hiring of employees to support the growth in the Company's development activities as well as general salary increases. This increase was partially offset by a decrease in contract research organization costs and lab supplies of $2.4 million, primarily due to timing differences, the completion of the 1b/2a clinical trial of AG019 in the fourth quarter of the prior year, as well as a continued prioritization of clinical product candidates, with less expense incurred related preclinical research programs for the comparable period.

SG&A expenses decreased $4.0 million, or 8%, from the twelve months ended December 31, 2021. Salaries, benefits, and other personnel costs decreased $4.9 million primarily due to (i) a reduced headcount as the Company scaled down corporate functions to support the more streamlined organization and (ii) reduced stock compensation costs. This increase was partially offset by an increase of $0.9 million in legal and professional fees, primarily related to ongoing litigation.

Loss from continuing operations was $79.8 million, or $(0.40) per basic and diluted share, compared to loss from continuing operations of $110.8 million, or $(0.56) per basic and diluted share, in 2021.

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 Twitter @Precigen, LinkedIn or YouTube.

About 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 neutralizing antibodies and effector T cell immune responses as well as an ability to boost these antibody and T cell responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors combined with UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

About 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 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.

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 and its cash runway. 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, including the possibility that the timeline for the Company's clinical trials might be impacted by the COVID-19 pandemic, 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, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 4,858	$ 36,423
Restricted cash	43,339	—
Short-term investments	51,092	72,240
Receivables		
Trade, net	959	1,341
Related parties, net	19	73
Other	12,826	566
Inventory	287	326
Prepaid expenses and other	4,779	5,471
Current assets held for sale	—	40,188
Total current assets	118,159	156,628
Long-term investments	—	48,562
Property, plant and equipment, net	7,329	8,599
Intangible assets, net	44,455	52,291
Goodwill	36,923	37,554
Right-of-use assets	8,086	9,990
Other assets	1,025	936
Noncurrent assets held for sale	—	45,296
Total assets	$ 215,977	$ 359,856
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,068	$ 3,112
Accrued compensation and benefits	6,377	7,856
Other accrued liabilities	23,747	7,817
Deferred revenue	25	1,490
Current portion of long-term debt	43,219	52
Current portion of lease liabilities	1,209	1,393
Related party payables	—	74
Current liabilities held for sale	—	12,851
Total current liabilities	78,645	34,645
Long-term debt, net of current portion	—	179,882
Deferred revenue, net of current portion	1,818	23,023
Lease liabilities, net of current portion	6,992	8,747
Deferred tax liabilities	2,263	2,539
Long-term liabilities held for sale	—	3,672
Total liabilities	89,718	252,508
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,998,314	2,022,701
Accumulated deficit	(1,868,567)	(1,915,556)
Accumulated other comprehensive income	(3,488)	203
Total shareholders' equity	126,259	107,348
Total liabilities and shareholders' equity	$ 215,977	$ 359,856

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

(Amounts in thousands, except share and per share data)	December 31, 2022	December 31, 2021
Revenues		
Collaboration and licensing revenues	$ 14,661	$ 506
Product revenues	1,903	2,164
Service revenues	10,094	11,095
Other revenues	251	502
Total revenues	26,909	14,267
Operating Expenses		
Cost of products and services	6,339	5,745
Research and development	47,170	47,933
Selling, general and administrative	48,006	51,994
Impairment of goodwill	482	—
Impairment of other noncurrent assets	638	543
Total operating expenses	102,635	106,215
Operating loss	(75,726)	(91,948)
Other Expense, Net		
Interest expense	(6,774)	(18,755)
Interest and dividend income	133	171
Other income (expense), net	1,539	(432)
Total other expense, net	(5,102)	(19,016)
Equity in net income (loss) of affiliates	862	(3)
Loss from continuing operations before income taxes	(79,966)	(110,967)
Income tax benefit	189	160
Loss from continuing operations	(79,777)	(110,807)
Income (loss) from discontinued operations, net of income tax benefit	108,094	18,641
Net Income (loss)	$ 28,317	$ (92,166)
Net Income (loss) per Share		
Net loss from continuing operations per share, basic and diluted	$ (0.40)	$ (0.56)
Net income (loss) from discontinued operations per share, basic and diluted	0.54	0.09
Net Income (loss) per share, basic and diluted	$ 0.14	$ (0.47)
Weighted average shares outstanding, basic and diluted	200,360,821	197,759,900