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): November 9, 2022

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 November 9, 2022, reporting its financial results for the quarter ended September 30, 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 November 9, 2022
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: November 9, 2022

Exhibit 99.1

Precigen Reports Third Quarter 2022 Financial Results and Progress of Clinical Programs

– Company will host virtual R&D event in early January 2023, timed to coincide with the 41st Annual JP Morgan Healthcare Conference, to showcase complete clinical trial data from Phase 1 dose escalation and expansion cohorts of PRGN-2012 AdenoVerse™ Immunotherapy in recurrent respiratory papillomatosis (RRP) –

– Company to present two abstracts at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in December: PRGN-3006 UltraCAR-T® Phase 1 safety and efficacy data in acute myeloid leukemia (AML) and PRGN-3007 UltraCAR-T Phase 1/1b trial-in-progress in ROR1-positive hematological and solid tumors –

– Retired $144.0 million of outstanding convertible notes due in July 2023 resulting in $5.4 million in savings via the discount realized and interest savings –

– Cash, cash equivalents, short-term investments and restricted cash totaled $153.8 million as of September 30, 2022 –

GERMANTOWN, MD, November 9, 2022 – 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 third quarter 2022 financial results and progress of clinical programs.

“Focusing and prioritizing our portfolio has led to rapid progression of our clinical programs. We are exceptionally pleased with the pace and results we are seeing from our portfolio, especially for the PRGN-2012 AdenoVerse Immunotherapy study in RRP, and are excited to showcase data at an investigator-led virtual R&D event in January. We expect the data will make a compelling case for the potential of PRGN-2012 to address the underserved RRP patient population and provide validation for the highly differentiated, first-in-class AdenoVerse therapeutic platform,” said Helen Sabzevari, PhD, President and CEO of Precigen. “We also have multiple data presentations at ASH in December, which will highlight continued safety and efficacy of the UltraCAR-T platform.”

“Precigen continues to exercise financial prudence and we believe our cash runway is sufficient to advance our clinical priorities into Q4 2023,” said Harry Thomasian Jr., CFO of Precigen. “Utilizing proceeds from the sale of Trans Ova, through today, we have been able to retire $144.0 million of the outstanding convertible notes due in July 2023. Retiring this debt, combined with our efforts to streamline and improve our operational efficiencies, further strengthens our financial position and significantly reduces our interest burden through the term of the notes.”

Key Program Highlights

- **PRGN-2012 AdenoVerse™ Immunotherapy in RRP**
  - Enrollment (N=15) was completed in the Phase 1 study and patient follow up is ongoing.
  - The Company will host a virtual R&D event in early January 2023, timed to coincide with the 41st Annual JP Morgan Healthcare Conference. The presentation will showcase complete clinical trial data from the Phase 1 dose escalation and expansion cohort of PRGN-2012 AdenoVerse Immunotherapy in RRP and will be led by Clint T. Allen, MD, Senior Investigator, Surgical Oncology Program, Center for Cancer Research, National Cancer Institute (NCI) and lead associate investigator for the PRGN-2012 clinical trial.
  - Enrollment is ongoing in the Phase 2 study of PRGN-2012 in adult patients with RRP (clinical trial identifier: NCT04724980) with 16 patients enrolled to date.
  - The US Food and Drug Administration (FDA) has granted orphan drug designation for PRGN-2012 for patients with RRP.
  - Discussions with the FDA are ongoing to evaluate various regulatory paths given the high unmet medical need for this patient population.

- **PRGN 2009 AdenoVerse™ Immunotherapy in HPV-associated Cancers**

  - Enrollment was completed in the Phase 1 monotherapy (N=6) and combination therapy (N=11) arms in patients with recurrent or metastatic HPV-associated cancers (clinical trial identifier: NCT04432597). Patient follow up is ongoing. The Company expects Phase 1 data to be presented in the first half of 2023.

  - Enrollment is nearing completion in the Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients with 19 of 20 estimated patients enrolled to date. Patient follow up is ongoing.

- **PRGN-3006 UltraCAR-T® in AML**

  - Enrollment was completed in the Phase 1 dose escalation cohorts of the Phase 1/1b study. An abstract for the clinical data of the PRGN-3006 Phase 1 study (Abstract# 4633) titled, "Phase 1/1b Safety Study of PRGN-3006 UltraCAR-T in Patients with Relapsed or Refractory CD33-Positive Acute Myeloid Leukemia and Higher Risk Myelodysplastic Syndromes," has been selected for poster presentation at ASH on December 12, 2022, from 6:00 to 8:00 PM CT.

  - The Phase 1b study of PRGN-3006 UltraCAR-T (clinical trial identifier: NCT03927261) has been expanded to Mayo Clinic in Rochester, Minnesota as the first of several new sites expected as part of the multicenter expansion of the study.

  - The first patient was successfully dosed at the expansion site with PRGN-3006 UltraCAR-T. Site activation activities are in progress at several additional major cancer centers across the US. In addition, the Company has received FDA clearance to incorporate repeat dosing in the Phase 1b expansion phase of the study.

  - The FDA has granted orphan drug designation and fast track designation for PRGN-3006 UltraCAR-T for patients with relapsed or refractory (r/r) AML.

- **PRGN-3005 UltraCAR-T® in Ovarian Cancer**

  - Enrollment was completed 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 (clinical trial identifier: NCT03907527). Patient follow up is ongoing and the Company expects Phase 1 data to be presented in the first half of 2023.

  - The first patient has received a repeat PRGN-3005 dose via IV infusion, following FDA clearance to incorporate repeat dosing in the study.

  - Enrollment is ongoing in the Phase 1b expansion study of PRGN-3005 UltraCAR-T at Dose Level 3 with lymphodepletion prior to IV infusion. Site activation activities are in progress at multiple major cancer centers in the US.

- **PRGN-3007 UltraCAR-T® in Advanced ROR1^{+} Hematological and Solid Tumors**

  - PRGN-3007 is based on the next generation UltraCAR-T and incorporates intrinsic PD-1 checkpoint inhibition in addition to the three effector genes (chimeric antigen receptor (CAR), membrane-bound interleukin 15 (mbIL15) and kill switch).

  - The Phase 1/1b umbrella study of PRGN-3007 in advanced receptor tyrosine kinase-like orphan receptor 1-positive (ROR1^{+}) hematological and solid tumors is on track to initiate dosing in the fourth quarter of 2022.

  - An abstract for the PRGN-3007 Phase 1 study (Abstract# 3334) titled, "A Phase1/1b Dose Escalation/Dose Expansion Study of PRGN-3007 UltraCAR-T Cells in Patients with Advanced Hematologic and Solid Tumor Malignancies," has been selected for trial-in-progress presentation at ASH on December 11, 2022, from 6:00 to 8:00 PM CT.

Third Quarter and First Nine Months 2022 Financial Highlights

- On August 18, 2022, the Company completed the previously announced sale of its wholly-owned subsidiary, Trans Ova Genetics.

- As of November 9, 2022, the Company has successfully retired $144.0 million of the original $200 million convertible notes due in July 2023 at a discount to par.

- Cash, cash equivalents, short-term investments and restricted cash totaled $153.8 million as of September 30, 2022.

- Net cash used in operating activities was $49.6 million during the nine months ended September 30, 2022 compared to $41.2 million during the nine months ended September 30, 2021.

- Selling, general and administrative (SG&A) expenses decreased for both the three and nine months ended September 30, 2022 compared to the prior year periods.

Third Quarter 2022 Financial Results Compared to Prior Year Period

Total revenues increased $13.4 million, or greater than 200%, from the quarter ended September 30, 2021. Collaboration and licensing revenues increased $14.5 million compared to the three months ended September 30, 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 $1.1 million from the quarter ended September 30, 2021. Gross margin on products and services declined as a result of the decreased revenues, and increased costs for supplies, drugs, and personnel costs.

Research and development expenses increased $0.2 million, or 2%, from the three months ended September 30, 2021. Contract research organization costs and lab supplies decreased $0.8 million due to timing differences, the completion of our 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 to preclinical research programs for the comparable period. This decrease was partially offset with an increase in salaries, benefits, and other personnel costs of $1.0 million primarily due to an increase in the hiring of employees to support the growth of our operations.

SG&A expenses decreased $0.8 million, or 8%, from the three months ended September 30, 2021. Salaries, benefits, and other personnel costs decreased $0.1 million primarily due to reduced head count. Professional fees decreased $0.6 million, primarily due to decreased legal and consulting fees associated with certain matters.

Loss from continuing operations was $7.6 million, or $(0.04) per basic and diluted share, compared to loss from continuing operations of $26.3 million, or $(0.13) per basic and diluted share, in 2021.

First Nine months 2022 Financial Results Compared to Prior Year Period

Total revenues increased $14.6 million, or 138%, from nine months ended September 30, 2021. Collaboration and licensing revenues increased $14.2 million from the nine months ended September 30, 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 increased $0.6 million from the nine months ended September 30, 2021, with that increase occurring earlier in 2022. Gross margin on product and services remained comparable to the prior year as increased revenues were offset by increased costs for supplies, drugs, and personnel costs.

Research and development expenses increased $0.6 million, or 2%, from the nine months ended September 30, 2021. Salaries, benefits, and other personnel costs increased $2.2 million due to an increase in the hiring of employees to support the growth in the Company's development activities. This increase was partially offset with a decrease in contract research organization costs and lab supplies of $1.6 million, primarily due to timing differences, the completion of our 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 $3.7 million, or 9%, from the nine months ended September 30, 2021. Salaries, benefits, and other personnel costs decreased $3.6 million primarily due to $2.6 million reduced stock compensation in 2022 and reduced head count.

Loss from continuing operations was $57.6 million, or $(0.29) per basic and diluted share, compared to loss from continuing operations of $84.1 million, or $(0.43) 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.

Trademarks

Precigen, UltraCAR-T, UltraPorator, AdenoVerse 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, 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)	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 9,067	$ 36,423
Restricted Cash	82,443	—
Short-term investments	62,260	72,240
Receivables		
Trade, net	1,175	1,341
Related parties, net	19	73
Other	1,260	566
Inventory	219	326
Prepaid expenses and other	6,363	5,471
Current assets held for sale	—	40,188
Total current assets	162,806	156,628
Long-term investments	—	48,562
Property, plant and equipment, net	7,611	8,599
Intangible assets, net	42,416	52,291
Goodwill	36,713	37,554
Right-of-use assets	8,828	9,990
Other assets	871	936
Noncurrent assets held for sale	—	45,296
Total assets	$ 259,245	$ 359,856
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,201	$ 3,112
Accrued compensation and benefits	5,792	7,856
Other accrued liabilities	11,685	7,817
Deferred revenue	76	1,490
Current portion of long-term debt	82,069	52
Current portion of lease liabilities	1,041	1,393
Related party payables	—	74
Current liabilities held for sale	—	12,851
Total current liabilities	104,864	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	7,939	8,747
Deferred tax liabilities	2,092	2,539
Long-term liabilities held for sale	—	3,672
Total liabilities	116,713	252,508
Commitments and contingencies (Note 16)		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,996,104	2,022,701
Accumulated deficit	(1,846,391)	(1,915,556)
Accumulated other comprehensive (loss) income	(7,181)	203
Total shareholders' equity	142,532	107,348
Total liabilities and shareholders' equity	$ 259,245	$ 359,856

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

(Amounts in thousands, except share and per share data)	Three months ended September 30, 2022	Three months ended September 30, 2021	Nine months ended September 30, 2022	Nine months ended September 30, 2021
Revenues				
Collaboration and licensing revenues	$ 14,561	$ 22	$ 14,561	$ 389
Product revenues	342	554	1,455	1,860
Service revenues	1,750	2,632	8,896	7,935
Other revenues	69	125	234	399
Total revenues	16,722	3,333	25,146	10,583
Operating Expenses				
Cost of products	463	482	1,585	1,306
Cost of services	1,114	970	3,497	2,858
Research and development	12,622	12,434	36,377	35,755
Selling, general and administrative	10,137	10,977	36,496	40,197
Impairment of goodwill	—	—	482	—
Impairment of other noncurrent assets	—	—	638	543
Total operating expenses	24,336	24,863	79,075	80,659
Operating loss	(7,614)	(21,530)	(53,929)	(70,076)
Other Expense, Net				
Interest expense	(2,036)	(4,765)	(6,137)	(13,902)
Interest income	56	48	131	129
Other income (expense), net	1,038	(133)	1,276	(430)
Total other expense, net	(942)	(4,850)	(4,730)	(14,203)
Equity in net income (loss) of affiliates	862	—	861	(3)
Loss from continuing operations before income taxes	(7,694)	(26,380)	(57,798)	(84,282)
Income tax benefit	50	61	197	173
Loss from continuing operations	$ (7,644)	$ (26,319)	$ (57,601)	$ (84,109)
Income (loss) from discontinued operations, net of income taxes	95,023	(3,445)	108,094	16,977
Net income (loss)	$ 87,379	$ (29,764)	$ 50,493	$ (67,132)
Net Income (Loss) per Share				
Net loss from continuing operations per share, basic and diluted	$ (0.04)	$ (0.13)	$ (0.29)	$ (0.43)
Net income (loss) from discontinued operations per share, basic and diluted	0.48	(0.02)	0.54	0.09
Net income (loss) per share, basic and diluted	$ 0.44	$ (0.15)	$ 0.25	$ (0.34)
Weighted average shares outstanding, basic and diluted	200,670,590	199,179,763	200,256,046	197,254,438