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 1, 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 March 1, 2022, reporting its financial results for the quarter and year ended December 31, 2021.

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 1, 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: March 1, 2022

Exhibit 99.1

Precigen Reports Fourth Quarter and Full Year 2021 Financial Results

– 2021 clinical milestone objectives successfully accomplished –
– Positive clinical data presented across three platforms – UltraCAR-T®, AdenoVerse™, ActoBiotics™ – and five clinical programs –
– Public offering to strengthen balance sheet successfully closed while streamlining operations and reducing operating expenses –
– Concentration now on rapid paths to licensure for programs addressing high unmet patient needs –

GERMANTOWN, MD, March 1, 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 fourth quarter and full year 2021 financial results.

"In 2021, Precigen was able to demonstrate significant progress in our core therapeutic platforms with indicators of strong early efficacy and favorable safety profiles across each of our most clinically advanced assets," said Helen Sabzevari, PhD, President and CEO of Precigen. "As we advance assets with the most promising paths to licensure, we will continue to focus on strengthening our financial position by continuing to ensure operational efficiency while seeking strategic non-dilutive funding opportunities where appropriate."

Key Business Highlights

- **Public Offering:** In January, Precigen closed a public offering of 17,250,000 shares of common stock, which resulted in gross proceeds to Precigen of approximately $129.4 million before deducting the underwriting discount and other offering expenses payable by Precigen;
- **PRGN-3006 UltraCAR-T in Acute Myeloid Leukemia (AML)**: In 2021, enrollment in the dose escalation phase of the Phase 1/1b PRGN-3006 UltraCAR-T clinical trial for the treatment of patients with relapsed or refractory AML or higher-risk myelodysplastic syndromes (MDS) was completed for both the lymphodepletion and non-lymphodepletion cohorts. Interim data for patients treated in Dose Levels 1-3 of the non-lymphodepletion cohort and Dose Levels 1-2 of the lymphodepletion cohort were presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition in December 2021;
- **PRGN-3005 UltraCAR-T in Ovarian Cancer:** In 2021, enrollment in the dose escalation phase of the Phase 1/1b clinical trial for the treatment of patients with advanced, recurrent platinum-resistant ovarian cancer was completed for both the intraperitoneal (IP) and intravenous (IV) arms. Interim data for patients treated in Dose Levels 1-3 of the IP arm were presented at the Company's 2021 research and development (R&D) Virtual Event in November 2021;
- **PRGN-3007 Next Generation UltraCAR-T with Intrinsic PD-1 Inhibition:** In 2021, Precigen received investigational new drug (IND) application clearance from the US Food and Drug Administration (FDA) to initiate a Phase 1 study of PRGN-3007 UltraCAR-T in advanced receptor tyrosine kinase-like orphan receptor 1 positive (ROR1+) hematological tumors, including chronic lymphocytic leukemia (CLL), mantle cell leukemia (MCL), acute lymphoblastic leukemia (ALL) and diffuse large B-cell lymphoma (DLBCL) and solid tumors, including triple negative breast cancer (TNBC). An abstract highlighting PRGN-3007 preclinical data was presented as a poster presentation at the 63rd ASH Annual Meeting and Exposition in December 2021;
- **PRGN-2012 AdenoVerse Immunotherapy in Recurrent Respiratory Papillomatosis (RRP):** In 2021, Precigen received IND clearance from the FDA to initiate a Phase 1 study of PRGN-2012, an off-the-shelf (OTS) AdenoVerse immunotherapy, in patients with RRP and began dosing patients in the study. Precigen completed enrollment in the Phase 1 dose escalation and expansion cohorts. Interim data for the Phase 1 study were presented at the Company's 2021 R&D Virtual Event in November 2021;
- **PRGN-2009 AdenoVerse Immunotherapy in HPV-associated Cancers:** In 2021, Precigen completed enrollment in the PRGN-2009 Phase 1 monotherapy arm and enrollment is ongoing in the Phase 1 combination arm of the study. The Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients is also ongoing. In November 2021, interim data for patients in the Phase 1 monotherapy and combination arms were presented at the Company's 2021 R&D Virtual Event and Society for Immunotherapy of Cancer (SITC) 2021 Annual Meeting; and

- **AG019 ActoBiotics in Type 1 Diabetes (T1D):** In 2021, Precigen completed the Phase 1b/2a AG019 ActoBiotics clinical trial in T1D. Positive results from the trial were presented at the Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in June 2021 and European Association for the Study of Diabetes (EASD) 57th Annual Meeting in October 2021.

Fourth Quarter and Full Year 2021 Financial Highlights

- Net cash used in operating activities of $55.8 million in 2021 compared to $77.0 million in 2020;
- Net proceeds received from the issuance of common stock in January 2021 were $121.0 million;
- Cash, cash equivalents, and short-term and long-term investments totaled $163.7 million as of December 31, 2021;
- The Company anticipates that its cash, cash equivalents and short-term and long-term investments as of December 31, 2021 should enable the Company to fund operations well into 2023, assuming the Company's programs advance as currently contemplated; and
- The Company's non-core businesses continued to generate increased revenues and profitability.

Fourth Quarter 2021 Financial Results Compared to Prior Year Period

For the quarter ended December 31, 2021, R&D expenses increased $2.3 million, or 22%, from the quarter ended December 31, 2020. This was primarily the result of an increase in salaries, benefits, and other personnel costs of $1.4 million and an increase in contract research organization costs and lab supplies of $0.8 million due primarily to the advancement of the Company's clinical and preclinical programs. Selling, general and administrative (SG&A) expenses decreased $13.3 million, or 44%, due primarily to a noncash $11.4 million loss on a settlement agreement in the prior year as well as decreased salary, benefit and other personnel costs, including noncash share-based compensation expenses attributable to equity grants made in the first quarter of 2020. Net loss from continuing operations was $25.0 million, or $(0.13) per share for the quarter ended December 31, 2021, of which $5.0 million was for noncash charges, compared to net loss from continuing operations in the prior year's fourth quarter of $39.7 million, or $(0.22) per share, of which $19.7 million was for noncash charges in 2020.

Total revenues increased $4.9 million, or 25%, over the quarter ended December 31, 2020. This was primarily the result of product and service revenues generated by Trans Ova and Exemplar, which increased $5.8 million. This increase was due to higher customer demand for Trans Ova's products and services as a result of stronger beef and dairy industries in the current year and a change in pricing structure with certain customers, as well as increased services provided by Exemplar to new and existing customers. Collaboration and licensing revenues decreased $0.8 million primarily due to a decrease in the recognition of previously deferred revenue in the current period resulting from fewer services being performed pursuant to the Company's historical collaboration agreements.

Full Year 2021 Financial Results Compared to Prior Year Period

For the year ended December 31, 2021, R&D expenses increased $8.5 million, or 20%, over the prior year. This was the result of an increase in contract research organization costs and lab supplies of $6.7 million due primarily to the advancement of the Company's clinical and preclinical programs. SG&A expenses decreased $17.6 million, or 19%, from the prior year due primarily to certain costs incurred in 2020 that were not recurring in 2021 and a reduction in salary, benefit and other personnel costs. Costs incurred in 2020 that did not recur in 2021 included $13.9 million for certain legal settlements. Salaries, benefits, and other personnel costs decreased $4.9 million in 2021 primarily due (i) to reduced headcount as the Company scaled down its corporate functions to support a more streamlined organization and (ii) reduced stock compensation costs for previously granted awards that became fully vested in early 2021. Net loss from continuing operations for the year ended December 31, 2021 was $96.8 million, or $(0.49) per share, of which $29.4 million was for noncash charges compared to net loss from continuing operations of $103.8 million in the prior year, or $(0.62) per share, of which $45.9 million was for noncash charges in 2020.

Total revenues were comparable year-over-year, with increased revenues generated by Trans Ova and Exemplar being offset by a decrease in collaboration and licensing revenue as a result of the Company's changing business. The increase in Trans Ova and Exemplar revenues was $21.6 million. This increase was primarily due to higher customer demand for Trans Ova's products and services as a result of stronger beef and dairy industries in the current year, as well as increased services provided by Exemplar to new and existing customers combined with a change in pricing structure with certain customers for both Trans Ova and Exemplar. Collaboration and licensing revenues decreased $20.7 million as the Company accelerated

the recognition of previously deferred revenue in the prior period upon the mutual termination of two of its collaboration agreements in 2020. Gross margin on products and services improved as a result of the increased revenues, the change in pricing structure for certain customers, and operational efficiencies that have been gained through reductions in workforce and improved inventory management.

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, ActoBiotics, 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.

Investor Contact:
Steven Harasym
Vice President, Investor Relations
Tel: +1 (301) 556-9850
investors@precigen.com

Media Contacts:
Donelle M. Gregory
press@precigen.com
Glenn Silver
Lazar-FINN Partners
glenn.silver@finnpartners.com

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

(Amounts in thousands)	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 42,920	$ 51,792
Short-term investments	72,240	48,325
Receivables		
Trade, net	20,832	16,487
Related parties, net	73	19
Notes	—	3,689
Other	566	232
Inventory	13,261	11,359
Prepaid expenses and other	6,736	7,192
Current assets held for sale or abandonment	—	9,853
Total current assets	156,628	148,948
Long-term investments	48,562	—
Property, plant and equipment, net	34,315	34,924
Intangible assets, net	54,115	65,396
Goodwill	54,148	54,363
Right-of-use assets	10,900	9,353
Other assets	1,188	1,603
Total assets	$ 359,856	$ 314,587
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 5,405	$ 4,598
Accrued compensation and benefits	11,223	8,097
Other accrued liabilities	11,595	9,549
Deferred revenue	4,442	2,800
Current portion of long-term debt	402	360
Current portion of lease liabilities	1,551	2,657
Related party payables	27	19
Current liabilities held for sale or abandonment	—	14,047
Total current liabilities	34,645	42,127
Long-term debt, net of current portion	182,749	171,522
Deferred revenue, net of current portion	23,023	23,023
Lease liabilities, net of current portion	9,502	7,744
Deferred tax liabilities	2,539	2,897
Other long-term liabilities	50	100
Total liabilities	252,508	247,413
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	2,022,701	1,886,567
Accumulated deficit	(1,915,556)	(1,823,390)
Accumulated other comprehensive income	203	3,997
Total shareholders' equity	107,348	67,174
Total liabilities and shareholders' equity	$ 359,856	$ 314,587

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

(Amounts in thousands, except share and per share data)	Three months ended December 31, 2021	Three months ended December 31, 2020	Year ended December 31, 2021	Year ended December 31, 2020
Revenues				
Collaboration and licensing revenues	$ 117	$ 949	$ 506	$ 21,208
Product revenues	5,282	3,952	27,295	24,349
Service revenues	18,719	14,284	75,570	56,899
Other revenues	103	148	502	722
Total revenues	24,221	19,333	103,873	103,178
Operating Expenses				
Cost of products	5,663	7,024	24,864	28,550
Cost of services	9,263	6,766	33,521	26,963
Research and development	13,019	10,671	50,141	41,644
Selling, general and administrative	16,763	30,039	74,122	91,704
Impairment of other noncurrent assets	—	—	543	920
Total operating expenses	44,708	54,500	183,191	189,781
Operating loss	(20,487)	(35,167)	(79,318)	(86,603)
Other Expense, Net				
Interest expense	(4,886)	(4,570)	(18,891)	(18,400)
Interest and dividend income	312	426	1,617	2,451
Other income (expense), net	40	(310)	(330)	(165)
Total other expense, net	(4,534)	(4,454)	(17,604)	(16,114)
Equity in net loss of affiliates	—	(13)	(3)	(1,138)
Loss from continuing operations before income taxes	(25,021)	(39,634)	(96,925)	(103,855)
Income tax benefit (expense)	(13)	(48)	160	82
Loss from continuing operations	$ (25,034)	$ (39,682)	$ (96,765)	$ (103,773)
Income (loss) from discontinued operations, net of income tax benefit	—	(1,979)	4,599	(66,748)
Net loss	$ (25,034)	$ (41,661)	$ (92,166)	$ (170,521)
Net Loss per Share				
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.13)	$ (0.22)	$ (0.49)	$ (0.62)
Net income (loss) from discontinued operations attributable to Precigen per share, basic and diluted	—	(0.01)	0.02	(0.40)
Net loss attributable to Precigen per share, basic and diluted	$ (0.13)	$ (0.23)	$ (0.47)	$ (1.02)
Weighted average shares outstanding, basic and diluted	199,259,802	178,225,571	197,759,900	167,065,539