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): May 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 May 9, 2022, reporting its financial results for the quarter ended March 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 May 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: May 9, 2022

Precigen Reports First Quarter 2022 Financial Results and Business Updates

– Fast Track designation received for PRGN-3006 UltraCAR-T®, an important milestone for patients with relapsed or refractory acute myeloid leukemia, a rapidly progressing disease with limited treatment options –

– Phase 1b expansion arm initiated for PRGN-3006 UltraCAR-T® at Dose Level 3 with lymphodepletion –

– Dosing initiated in patients at Dose Level 3 via intravenous infusion with lymphodepletion in the PRGN-3005 UltraCAR-T® Phase 1 study –

– Phase 2 study initiated for PRGN-2012 AdenoVerse™ Immunotherapy as an adjuvant treatment in patients with recurrent respiratory papillomatosis –

– Cash, cash equivalents, short-term and long-term investments totaled $142.1 million as of March 31, 2022 –

– Company to host a pipeline update call in the coming months –

GERMANTOWN, MD, May 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 first quarter 2022 financial results and business updates.

“Precigen's portfolio has been prioritized based on the positive preliminary data we have seen for key programs and we are exploring potential rapid paths to licensure with the FDA for programs with compelling data in diseases that have a high unmet medical need. The FDA Fast Track designation recently received for PRGN-3006 UltraCAR-T will help facilitate development and expedite the review process and is an important milestone for patients with relapsed or refractory acute myeloid leukemia,” said Helen Sabzevari, PhD, President and CEO of Precigen. “As a result of these advancements, we look forward to hosting a call to provide pipeline updates in the coming months.”

“We remain focused on enhancing our financial position, expanding our financial flexibility, and extending our cash runway to help Precigen achieve our near-term objectives,” said Harry Thomasian Jr., CFO of Precigen. “As the year progresses, we intend to expound on these initiatives.”

Key Business Highlights

- **PRGN-3006 UltraCAR-T® in Acute Myeloid Leukemia (AML)**
  - In April 2022, Precigen announced that the US Food and Drug Administration (FDA) granted Fast Track designation for PRGN-3006 UltraCAR-T in patients with relapsed or refractory (r/r) AML. Fast Track designation facilitates development and expedites the review process for drugs that address serious conditions and high unmet medical needs, such as r/r AML.
  - Enrollment and dosing were completed in the dose escalation phase of the Phase 1 PRGN-3006 UltraCAR-T clinical trial for both the lymphodepletion and non-lymphodepletion cohorts.
  - The Phase 1b expansion arm was initiated and the first patient was dosed at Dose Level 3 with lymphodepletion. The Company plans to incorporate repeat dosing in 2022.
- **PRGN-3005 UltraCAR-T® in Ovarian Cancer**
  - Enrollment and dosing was completed in the dose escalation phase of both the intraperitoneal (IP) and intravenous (IV) arms of the Phase 1 clinical trial.
  - Dosing was initiated in patients at Dose Level 3 with lymphodepletion prior to IV administration of PRGN-3005 UltraCAR-T.
  - The Company plans to initiate a Phase 1b expansion arm and incorporate repeat dosing in 2022.
- **Next Generation UltraCAR-T® Platform**
  - An abstract titled, *Incorporation of intrinsic checkpoint blockade enhances functionality of multigenic autologous UltraCAR-T®–cells manufactured using non-viral gene delivery and rapid manufacturing process*, was presented as a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022. The poster highlighted preclinical data showcasing the advancement of the UltraCAR-T platform to simultaneously express CAR, membrane bound IL-

15 (mbIL15), a kill switch, and address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic downregulation of one or more checkpoint inhibitor genes.

- **PRGN-2012 AdenoVerse™ Immunotherapy in Recurrent Respiratory Papillomatosis (RRP)**
  - Enrollment was completed in the dose escalation and expansion cohorts of the Phase 1 study.
  - The first patient was dosed in the Phase 2 study of PRGN-2012 in adult patients with RRP (clinical trial identifier: NCT04724980).
  - The Company plans to seek FDA guidance on a rapid regulatory strategy for licensure given the high unmet medical need for this patient population.
- **PRGN 2009 AdenoVerse™ Immunotherapy in Human Papillomavirus (HPV)-associated Cancers**
  - Enrollment in the Phase 1 monotherapy arm was completed in patients with recurrent or metastatic HPV-associated cancers (clinical trial identifier: NCT04432597).
  - Enrollment is ongoing in the Phase 1 combination arm in patients with recurrent or metastatic HPV-associated cancers. The Company expects to complete enrollment in the Phase 1 combination arm in the second quarter of 2022.
  - Enrollment is ongoing in the Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients.

First Quarter 2022 Financial Highlights

- Net cash used in operating activities of $18.7 million in 2022 compared to $16.4 million in 2021. This increase was primarily due to the acceleration of the Company's pipeline programs;
- Cash, cash equivalents, short-term and long-term investments totaled $142.1 million as of March 31, 2022; and
- Total revenues of $32.0 million in 2022 compared to $24.5 million in 2021.

First Quarter 2022 Financial Results Compared to Prior Year Period

Total revenues increased $7.5 million, or 31%, from the quarter ended March 31, 2021. Product and service revenues generated by Trans Ova and Exemplar increased $7.6 million primarily due to higher customer demand for animals and services as a result of stronger beef and dairy industries in the current year as well as an increase in services performed at Exemplar, offset by a $0.1 million reduction in collaboration and license revenue from the quarter ended March 31, 2021.

Gross margin on products and services improved as a result of the increased revenues, a change in pricing structure for certain customers, and operational efficiencies that have been gained through improved inventory management offset by increased costs for supplies, drugs, and personnel costs.

Research and development expenses increased $2.2 million, or 21%, from the quarter ended March 31, 2021. Contract research organization costs and lab supplies increased $1.6 million with the advancement of the Company's clinical and preclinical programs.

Selling, general and administrative (SG&A) expenses increased $0.9 million, or 5%, over the three months ended March 31, 2021. Professional fees increased $1.6 million, primarily due to increased legal fees associated with certain litigation matters. This increase was partially offset with a decrease in salaries, benefits, and other personnel costs of $1.3 million primarily due to reduced stock compensation in 2022 and reduced head count.

Loss from continuing operations was $19.3 million, or $(0.10) per basic share, compared to loss from continuing operations of $21.8 million, or $(0.11) per basic 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, 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)	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 40,321	$ 42,920
Short-term investments	71,821	72,240
Receivables		
Trade, net	24,308	20,832
Related parties, net	15	73
Other	543	566
Inventory	12,730	13,261
Prepaid expenses and other	5,199	6,736
Total current assets	154,937	156,628
Long-term investments	29,914	48,562
Property, plant and equipment, net	33,583	34,315
Intangible assets, net	51,427	54,115
Goodwill	53,613	54,148
Right-of-use assets	10,963	10,900
Other assets	1,131	1,188
Total assets	$ 335,568	$ 359,856
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,415	$ 5,405
Accrued compensation and benefits	6,052	11,223
Other accrued liabilities	10,494	11,595
Deferred revenue	2,669	4,442
Current portion of long-term debt	355	402
Current portion of lease liabilities	1,590	1,551
Related party payables	26	27
Total current liabilities	25,601	34,645
Long-term debt, net of current portion	201,112	182,749
Deferred revenue, net of current portion	23,023	23,023
Lease liabilities, net of current portion	9,508	9,502
Deferred tax liabilities	2,438	2,539
Other long-term liabilities	50	50
Total liabilities	261,732	252,508
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,991,670	2,022,701
Accumulated deficit	(1,916,135)	(1,915,556)
Accumulated other comprehensive (loss) income	(1,699)	203
Total shareholders' equity	73,836	107,348
Total liabilities and shareholders' equity	$ 335,568	$ 359,856

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

(Amounts in thousands, except share and per share data)	Three months ended March 31, 2022	2021
Revenues		
Collaboration and licensing revenues	$ —	$ 66
Product revenues	8,724	6,381
Service revenues	23,209	17,931
Other revenues	88	133
Total revenues	32,021	24,511
Operating Expenses		
Cost of products	7,510	5,574
Cost of services	9,589	7,402
Research and development	12,760	10,521
Selling, general and administrative	19,576	18,702
Impairment of goodwill	482	—
Total operating expenses	49,917	42,199
Operating loss	(17,896)	(17,688)
Other Expense, Net		
Interest expense	(2,069)	(4,539)
Interest income	434	392
Other income (expense), net	223	(58)
Total other expense, net	(1,412)	(4,205)
Equity in net loss of affiliates	(1)	(3)
Loss from continuing operations before income taxes	(19,309)	(21,896)
Income tax benefit	58	52
Loss from continuing operations	$ (19,251)	$ (21,844)
Income (loss) from discontinued operations, net of income taxes	—	4,526
Net loss	$ (19,251)	$ (17,318)
Net Loss per Share		
Net loss from continuing operations per share, basic and diluted	$ (0.10)	$ (0.11)
Net income (loss) from discontinued operations per share, basic and diluted	—	0.02
Net loss per share, basic and diluted	$ (0.10)	$ (0.09)
Weighted average shares outstanding, basic and diluted	199,629,218	193,499,546