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): August 8, 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 August 8, 2022, reporting its financial results for the quarter ended June 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 August 8, 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: August 8, 2022

Exhibit 99.1

Precigen Reports Second Quarter and First Half 2022 Financial Results

- *Enrollment complete in Phase 1 study of PRGN-3006 UltraCAR-T®® in acute myeloid leukemia (AML); enrollment ongoing in Phase 1b dose expansion study; Mayo Clinic in Rochester, Minnesota activated as first expansion site of Phase 1b multicenter expansion; technology transfer and site activation activities underway at multiple new sites –*
- *Enrollment complete in Phase 1 study of PRGN-3005 UltraCAR-T in advanced ovarian cancer; enrollment complete at Dose Level 3 with lymphodepletion in the IV arm; Phase 1b expansion study initiated at Dose Level 3 with lymphodepletion prior to IV infusion; technology transfer and site activation underway for Phase 1b multicenter expansion –*
- *Enrollment complete in Phase 1 study of PRGN-2012 AdenoVerse™ Immunotherapy in recurrent respiratory papillomatosis (RRP); Phase 2 study initiated and rapidly progressing –*
- *Enrollment complete in combination arm of Phase 1 study of PRGN-2009 AdenoVerse Immunotherapy in human papillomavirus (HPV)-associated cancers –*
- *Entered into agreement to sell wholly-owned subsidiary Trans Ova Genetics for $170 million in upfront cash and up to $10 million earn-out over two years; close expected in Q3 2022; Company intends to pay senior convertible notes when due in July 2023 –*
- *Cash, cash equivalents, short-term and long-term investments totaled $132.8 million as of June 30, 2022 –*

GERMANTOWN, MD, August 8, 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 second quarter and first half 2022 financial results.

“Precigen is laser focused on maximizing the value of our highest priority assets and prioritizing our capital allocation to enable us to reach critical inflection points in our clinical trials. We have been able to expedite our prioritized programs, rapidly progressing from Phase 1 dose escalations to 1b expansions and have already initiated Phase 2 studies for several programs,” said Helen Sabzevari, PhD, President and CEO of Precigen. “We continue to demonstrate the potential of these assets and their associated therapeutic platforms, and are actively pursuing rapid regulatory strategies for licensure to bring these potential investigational therapies to patients as quickly as possible. We expect additional data this year and early next for our prioritized programs, and are particularly excited for the Phase 1 data presentation for the PRGN-2012 AdenoVerse study in Q4 2022.”

“The transaction to sell Trans Ova Genetics, which is expected to close in Q3 2022, will provide Precigen with $170 million in cash up-front and up to a $10 million earn-out over the next two years. The proceeds from this sale will fortify our balance sheet and provide non-dilutive funds to pay our convertible notes, which we intend to do when due,” said Harry Thomasian Jr., CFO of Precigen. “We believe that our cash on hand and cost reduction initiatives, taking into account our plan for our convertible notes, give us enough runway to advance our clinical priorities into Q4 2023.”

Key Business Highlights

- **Agreement to Divest Non-Healthcare Subsidiary Trans Ova Genetics**
  - Precigen entered into an agreement to sell its wholly-owned subsidiary Trans Ova Genetics to URUS for $170 million in upfront cash and up to a $10 million earn-out based on the performance of Trans Ova Genetics in 2022 and 2023. The close, subject to customary closing conditions including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, is expected in Q3 2022.
  - Transaction will solidify the Company's balance sheet and provide the ability to pay off the outstanding convertible notes utilizing a non-dilutive funding source.

- **PRGN-3006 UltraCAR-T®® in AML**
  - The US Food and Drug Administration (FDA) Fast Track designation for PRGN-3006 UltraCAR-T, received in the first half of 2022, is important for patients with relapsed or refractory (r/r) AML, a serious condition with high unmet medical need, as it may facilitate development and expedite the review process for this promising investigational therapy.
  - Enrollment is ongoing in the Phase 1b expansion study of PRGN-3006 UltraCAR-T at Dose Level 3 with lymphodepletion (clinical trial identifier: NCT03927261).
  - The Phase 1b study of PRGN-3006 UltraCAR-T 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. Additionally, technology transfer was successfully completed and FDA clearance was received to initiate PRGN-3006 UltraCAR-T manufacturing and patient treatment at Mayo Clinic.
  - Multicenter expansion demonstrates proof of concept for the technology transfer and scale-up for decentralized manufacturing of UltraCAR-T using UltraPorator™ at multiple medical centers. Technology transfer and site activation activities are in progress at several major cancer centers across the US and additional expansion sites are anticipated to be activated in 2022 and 2023.
  - The Company received FDA clearance to incorporate repeat dosing in the Phase 1b expansion phase of the study and plans to initiate in 2022.
  - Additional data for the Phase 1/1b study is expected at a major scientific conference in Q4 2022.
- **PRGN-3005 UltraCAR-T®® in Ovarian Cancer**
  - Enrollment was completed in the dose escalation phase of both the intraperitoneal (IP) and intravenous (IV) arms of the Phase 1 study without lymphodepletion (clinical trial identifier: NCT03907527). The FDA cleared moving directly to Dose Level 3 after dosing one patient at Dose Level 1 in the IV arm, enabling rapid progression in the IV arm. Patient follow up is ongoing and the Company expects Phase 1 data to be presented in the first half of 2023.
  - FDA approval was received to incorporate lymphodepletion in the IV arm and enrollment (N=3) was completed at Dose Level 3 with lymphodepletion. Patient follow up is ongoing.
  - The Company initiated the Phase 1b expansion study of PRGN-3005 UltraCAR-T at Dose Level 3 with lymphodepletion prior to IV infusion.
  - The Company plans multicenter expansion of the Phase 1b study and site activation activities are in progress at major cancer centers in the US.
  - The Company received FDA clearance to incorporate repeat dosing in the Phase 1b expansion study and plans to initiate in 2022.
- **PRGN-3007 UltraCAR-T®® in Advanced ROR1^{+} Hematological and Solid Tumors**
  - PRGN-3007, based on the next generation UltraCAR-T, 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), is being readied for the clinic.
  - The Phase 1/1b umbrella study of PRGN-3007 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) is on track to initiate dosing in the second half of 2022.
- **PRGN-2012 AdenoVerse™ Immunotherapy in RRP**
  - Enrollment was completed in the Phase 1 study (N=15) and patient follow up is ongoing. The Company is planning an investigator-led Phase 1 data presentation to be held in Q4 2022.
  - The Company initiated a Phase 2 study of PRGN-2012 in adult patients with RRP (clinical trial identifier: NCT04724980). Enrollment is ongoing in the Phase 2 study with 11 patients enrolled to date.
  - 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 ongoing in the Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients with 17 patients enrolled to date.

Second Quarter and First Half 2022 Financial Highlights

- Net cash used in operating activities of $25.8 million during the six months ended June 30, 2022 compared to $24.2 million during the six months ended June 30, 2021;
- Cash, cash equivalents, short-term and long-term investments totaled $132.8 million as of June 30, 2022;
- Selling, general and administrative (SG&A) costs decreased for both the three and six months ended June 30, 2022 compared to the prior year periods; and
- As a result of the anticipated Trans Ova Genetics sale, the Trans Ova Genetics business is now classified as a discontinued operation, with its assets, liabilities and operations in prior periods reclassified to conform to the current presentation.

Second Quarter 2022 Financial Results Compared to Prior Year Period

- Total revenues decreased $0.9 million, or 24%, from the quarter ended June 30, 2021. Product and service revenues generated by Exemplar decreased $0.5 million and collaboration and license revenue decreased $0.3 million from the quarter ended June 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 decreased by $1.2 million, or 9%, from the quarter ended June 30, 2021. Contract research organization costs and lab supplies decreased $1.9 million due to timing differences, the completion of the Phase 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 $0.7 million primarily due to an increase in the hiring of employees to support the growth in the Company's development activities.
- SG&A expenses decreased $2.3 million, or 15%, from the quarter ended June 30, 2021. Salaries, benefits, and other personnel costs decreased $1.5 million primarily due to reduced stock compensation in 2022 and reduced head count. Professional fees decreased $0.4 million, primarily due to decreased legal fees associated with certain matters.
- Loss from continuing operations was $26.1 million, or $(0.13) per basic and diluted share, compared to loss from continuing operations of $30.9 million, or $(0.16) per basic and diluted share, in 2021.

First Half 2022 Financial Results Compared to Prior Year Period

- Total revenues increased $1.2 million, or 16%, from six months ended June 30, 2021. Product and service revenues generated by Exemplar increased $1.6 million, which was offset by a $0.3 million reduction in collaboration and license revenue from the six months ended June 30, 2021. Gross margin on 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 $0.4 million, or 2%, from the six months ended June 30, 2022. Salaries, benefits, and other personnel costs increased $1.2 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 of contract research organization costs and lab supplies of $0.9 million, primarily due to timing differences, the completion of the Phase 1b/2a clinical trial of AG019 in the fourth quarter of the prior year, and a continued prioritization of clinical product candidates with less expense incurred related preclinical research programs for the comparable period.

- SG&A expenses decreased $2.9 million, or 10%, from the six months ended June 30, 2021. Salaries, benefits, and other personnel costs decreased $3.5 million primarily due to reduced stock compensation in 2022 and reduced head count. This decrease was partially offset with an increase in legal and professional fees of $1.1 million, primarily due to increased consulting fees and legal fees associated with certain matters.
- Loss from continuing operations was $50.0 million, or $(0.25) per basic and diluted share, compared to loss from continuing operations of $57.8 million, or $(0.29) 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 consummation of the prospective sale of Trans Ova Genetics, the use of capital from that transaction, 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 sale of Trans Ova will not be consummated on the expected timeline or at all (whether due to a failure to receive, or delay in the receipt of, clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 or other third party consents required for the transaction or the failure to satisfy other conditions to the consummation of the transaction), 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)	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 43,844	$ 36,423
Short-term investments	71,453	72,240
Receivables		
Trade, net	1,307	1,341
Related parties, net	18	73
Other	546	566
Inventory	224	326
Prepaid expenses and other	2,654	5,471
Current assets held for sale	44,573	40,188
Total current assets	164,619	156,628
Long-term investments	11,877	48,562
Property, plant and equipment, net	7,726	8,599
Intangible assets, net	45,933	52,291
Goodwill	36,864	37,554
Right-of-use assets	8,944	9,990
Other assets	921	936
Noncurrent assets held for sale	44,340	45,296
Total assets	$ 321,224	$ 359,856
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 2,668	$ 3,112
Accrued compensation and benefits	4,864	7,856
Other accrued liabilities	9,666	7,817
Deferred revenue	164	1,490
Current portion of long-term debt	—	52
Current portion of lease liabilities	1,033	1,393
Related party payables	58	74
Current liabilities held for sale	11,448	12,851
Total current liabilities	29,901	34,645
Long-term debt, net of current portion	198,674	179,882
Deferred revenue, net of current portion	23,023	23,023
Lease liabilities, net of current portion	8,098	8,747
Deferred tax liabilities	2,260	2,539
Long-term liabilities held for sale	3,615	3,672
Total liabilities	265,571	252,508
Commitments and contingencies (Note 16)		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,993,979	2,022,701
Accumulated deficit	(1,933,770)	(1,915,556)
Accumulated other comprehensive (loss) income	(4,556)	203
Total shareholders' equity	55,653	107,348
Total liabilities and shareholders' equity	$ 321,224	$ 359,856

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

(Amounts in thousands, except share and per share data)	Three months ended June 30, 2022	Three months ended June 30, 2021	Six months ended June 30, 2022	Six months ended June 30, 2021
Revenues				
Collaboration and licensing revenues	$ —	$ 301	$ —	$ 367
Product revenues	621	694	1,113	1,306
Service revenues	2,213	2,679	7,146	5,303
Other revenues	77	141	165	274
Total revenues	2,911	3,815	8,424	7,250
Operating Expenses				
Cost of products	645	436	1,122	824
Cost of services	1,166	914	2,383	1,888
Research and development	11,954	13,184	23,755	23,321
Selling, general and administrative	12,670	14,954	26,359	29,220
Impairment of goodwill	—	—	482	—
Impairment of other noncurrent assets	638	543	638	543
Total operating expenses	27,073	30,031	54,739	55,796
Operating loss	(24,162)	(26,216)	(46,315)	(48,546)
Other Expense, Net				
Interest expense	(2,063)	(4,633)	(4,101)	(9,137)
Interest income	37	49	75	81
Other income (expense), net	40	(199)	238	(297)
Total other expense, net	(1,986)	(4,783)	(3,788)	(9,353)
Equity in net loss of affiliates	—	—	(1)	(3)
Loss from continuing operations before income taxes	(26,148)	(30,999)	(50,104)	(57,902)
Income tax benefit	89	60	147	112
Loss from continuing operations	$ (26,059)	$ (30,939)	$ (49,957)	$ (57,790)
Income from discontinued operations, net of income taxes	8,424	10,889	13,071	20,422
Net loss	$ (17,635)	$ (20,050)	$ (36,886)	$ (37,368)
Net Loss per Share				
Net loss from continuing operations per share, basic and diluted	$ (0.13)	$ (0.16)	$ (0.25)	$ (0.29)
Net income from discontinued operations per share, basic and diluted	0.04	0.06	0.07	0.10
Net loss per share, basic and diluted	$ (0.09)	$ (0.10)	$ (0.18)	$ (0.19)
Weighted average shares outstanding, basic and diluted	200,461,441	199,021,587	200,047,629	196,275,820