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, 2020

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, 2020, reporting its financial results for the three and nine months ended September 30, 2020.

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, 2020
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/ Rick L. Sterling
Rick L. Sterling
Chief Financial Officer

Dated: November 9, 2020

INTERNAL & CONFIDENTIAL

Precigen Reports Third Quarter 2020 and Year-to-Date Financial Results

– Company to provide comprehensive clinical pipeline and data updates in early December –

– Continues to advance healthcare portfolio and improve fiscal performance by executing operational efficiencies –

– Company to present PRGN-3006 UltraCAR-T at ASH annual meeting on December 7th –

GERMANTOWN, MD, November 9, 2020 – 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 and year-to-date financial results for 2020.

Business Highlights:

- **Clinical Pipeline and Data Update Conference Call:** In light of the substantive progress made in advancing its clinical pipeline, as well as anticipated data disclosures for several key programs, Precigen will host a conference call in early December dedicated to reviewing these important milestones. The Company plans to announce timing and details about the call in the coming weeks;
- **UltraPorator™:** Precigen announced that the US Food and Drug Administration (FDA) cleared UltraPorator as a manufacturing device for its UltraCAR-T manufacturing process. The Company announced that it has completed successful technology transfer of the UltraPorator system for the manufacturing of PRGN-3005 in ovarian cancer at the University of Washington/Fred Hutchinson Cancer Research Center and for PRGN-3006 in acute myeloid leukemia (AML) at the Moffitt Cancer Center. UltraPorator is a semi-closed, high-throughput system with a proprietary hardware and software solution designed to significantly reduce processing time and contamination risk, limitations inherent in existing electroporation devices that contribute to current hurdles for viable scale-up and commercialization of certain therapeutic programs;
- **PRGN-2009 AdenoVerse™ Immunotherapy:** Precigen announced that the first patient has been dosed in the Phase I/II trial for PRGN-2009, a first-in-class, off-the-shelf investigational immunotherapy utilizing the AdenoVerse™ platform and designed to activate the immune system to recognize and target HPV-positive solid tumors;
- **PRGN-3005 UltraCAR-T®:** Precigen completed dosing of patients in the dose level 3 of the intraperitoneal (IP) arm of the Phase 1 clinical trial of PRGN-3005 UltraCAR-T for the treatment of advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (clinical trial identifier: NCT03907527); and
- **PRGN-3006 UltraCAR-T®:** Precigen completed dosing of patients in the dose level 2 of the non-lymphodepletion arm and dose level 1 in the lymphodepletion arm of the Phase 1 trial of PRGN-3006 UltraCAR-T for treatment of patients with relapsed or refractory acute myeloid leukemia (AML) or higher-risk myelodysplastic syndromes (MDS) (clinical trial identifier: NCT03927261).

"The Precigen team has made impressive progress this quarter in driving value across our preclinical and clinical pipeline. In particular, we made several advances in our quest to meet unmet needs for patients, including dosing the first patient in our first-in-human study of PRGN-2009 AdenoVerse in HPV-positive solid tumors, and advancing our proprietary UltraPorator system towards clinical implementation," said Helen Sabzevari, PhD, President and CEO of Precigen. "In early December, we are excited to share a comprehensive update on our clinical pipeline progress towards meeting our 2020 goals laid out earlier this year as well as looking forward to the PRGN-3006 presentation by the trial's Principal Investigator Dr. Sallman at ASH."

Third Quarter 2020 Financial Highlights:

- Total revenues of $23.6 million in 2020 compared to $18.3 million in 2019;
- Net loss from continuing operations of $29.5 million, or $(0.18) per basic share, of which $10.1 million was for non-cash charges in 2020, compared to net loss from continuing operations of $49.1 million, or $(0.32) per basic share, of which $15.7 million was for non-cash charges in 2019; and
- Cash, cash equivalents, and short-term investments totaled $113.1 million as of September 30, 2020.

Year-to-Date 2020 Financial Highlights:

- Total revenues of $83.8 million in 2020 compared to $73.7 million in 2019;
- Net loss from continuing operations of $102.8 million, or $(0.63) per basic share, of which $50.6 million was for non-cash charges in 2020 compared to net loss from continuing operations attributable to Precigen of $132.7 million, or $(0.86) per basic share, of which $36.2 million was for non-cash charges in 2019.

Third Quarter 2020 Financial Results Compared to Prior Year Period

Total revenues increased $5.3 million, or 29%, over the quarter ended September 30, 2019. Collaboration and licensing revenues increased $2.9 million primarily due to the accelerated recognition of previously deferred revenue upon the mutual termination of one of the Company's collaboration agreements in July 2020. Product and service revenues generated by the Company's Trans Ova and Exemplar subsidiaries increased $2.4 million due to an increase in services performed for new and existing customers and the expansion of Trans Ova's commercial dairy business. Gross margin on products and services improved as a result of operational efficiencies gained through reductions in workforce and improved inventory management as well as a decrease in the cost of cows used in production.

Research and development expenses decreased $13.5 million, or 53%, from the quarter ended September 30, 2019. Salaries, benefits, and other personnel costs decreased $6.8 million and contract research organization costs and lab supplies decreased $5.1 million as Precigen suspended the operations of its

MBP Titan subsidiary in the second quarter and deprioritized certain internal programs at its ActoBio subsidiary in the fourth quarter of 2019. Selling, general and administrative (SG&A) expenses were comparable period over period.

Year-to-Date 2020 Financial Results Compared to Prior Year Period

Total revenues increased $10.1 million, or 14%, over the nine months ended September 30, 2019 primarily due to an increase in Precigen's collaboration and licensing revenues as the Company accelerated the recognition of previously deferred revenue upon the mutual termination of two of its collaboration agreements in 2020. Product and service revenues generated by Trans Ova and Exemplar increased $4.8 million due to an increase in services performed for new and existing customers and the expansion of Trans Ova's commercial dairy business. Gross margin on products and services improved as a result of operational efficiencies gained through reductions in workforce, improved inventory management, a reduction in third-party royalty rate obligations for certain licensed technologies and a decrease in the cost of cows used in production.

Research and development expenses decreased $35.6 million, or 44%, from the nine months ended September 30, 2019. Salaries, benefits, and other personnel costs decreased $13.7 million and contract research organization costs and lab supplies decreased $17.9 million as Precigen suspended the operations of its MBP Titan subsidiary in the second quarter and deprioritized certain internal programs at its ActoBio subsidiary in the fourth quarter of 2019. SG&A expenses decreased $8.4 million and include a net decrease in fees payable to certain third-party vendors and a reduction of 30% in corporate headcount to support a more streamlined organization. Other corporate expenses decreased $1.9 million as part of the streamlined organization and the impact of the COVID-19 pandemic on travel. These decreases were partially offset by increased share-based compensation expense attributable to equity grants made in in the first quarter of 2020 and one-time severance costs for terminated employees. The Company also recorded $23.0 million of impairment charges for the nine months ended September 30, 2020 primarily due to the write down of goodwill and intangible assets related to the MBP Titan subsidiary.

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 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 unique therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on LinkedIn.

Trademarks

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 Precigen's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of Precigen's business, including the timing, pace 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 therapies, and the Company's refocus to a healthcare-oriented business. Although management believes that the plans, objectives and results reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties, and actual future results may be materially different from the plans, objectives and expectations expressed. These risks and uncertainties include, but are not limited to, (i) the impact of the COVID-19 pandemic on our clinical trials, businesses, operating results, cash flows and/or financial condition, (ii) ongoing transition efforts following Precigen's recent divestment of several assets and businesses; (iii) Precigen's strategy and overall approach to its business model, its recent efforts to realign its business, and its ability to exercise more control and ownership over the development process and commercialization path; (iv) the ability to successfully enter new markets or develop additional products, including the expected timing and results of investigational studies and preclinical and clinical trials, including any delays or potential delays as a result of the COVID-19 pandemic, whether with its collaborators or independently; (v) the ability to successfully enter into optimal strategic relationships with its subsidiaries and operating companies that it may form in the future; (vi) the ability to hold or generate significant operating capital, including through partnering, asset sales and operating cost reductions; (vii) actual or anticipated variations in operating results; (viii) actual or anticipated fluctuations in competitors' or collaborators' operating results or changes in their respective growth rates; (ix) cash position; (x) market conditions in Precigen's industry; (xi) the volatility of Precigen's stock price; (xii) the ability, and the ability of collaborators, to protect Precigen's intellectual property and other proprietary rights and technologies; (xiii) the ability, and the ability of collaborators, to adapt to changes in laws or regulations and policies, including federal, state, and local government responses to the COVID-19 pandemic; (xiv) outcomes of pending and future litigation; (xv) the rate and degree of market acceptance of any products developed by Precigen, its subsidiaries, collaborations or joint ventures; (xvi) the ability to retain and recruit key personnel; (xvii) expectations related to the use of proceeds from public offerings and other financing efforts; (xviii) estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and (xix) the challenges inherent in leadership transitions. For further information on potential risks and uncertainties, and other important factors, any of which could cause Precigen's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Precigen'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, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 27,740	$ 65,793
Short-term investments	85,358	9,260
Receivables		
Trade, net	19,063	20,650
Related parties, net	12	600
Other	285	4,978
Inventory	10,348	16,097
Prepaid expenses and other	8,310	6,444
Current assets held for sale	—	110,821
Total current assets	151,116	234,643
Property, plant and equipment, net	44,685	60,969
Intangible assets, net	65,018	68,346
Goodwill	54,237	63,754
Investments in affiliates	337	1,461
Right-of-use assets	19,296	25,228
Other assets	1,497	1,362
Total assets	$ 336,186	$ 455,763
Current liabilities		
Accounts payable	$ 4,233	$ 5,917
Accrued compensation and benefits	7,567	14,091
Other accrued liabilities	9,355	12,049
Deferred revenue	4,144	5,697
Lines of credit	—	1,922
Current portion of long-term debt	421	31,670
Current portion of lease liabilities	4,584	4,182
Related party payables	357	51
Current liabilities held for sale	—	47,333
Total current liabilities	30,661	122,912
Long-term debt, net of current portion	193,801	186,321
Deferred revenue, net of current portion	30,015	48,136
Lease liabilities, net of current portion	20,323	23,849
Deferred tax liabilities	2,734	2,834
Other long-term liabilities	100	—
Total liabilities	277,634	384,052
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,838,919	1,752,048
Accumulated deficit	(1,781,729)	(1,652,869)
Accumulated other comprehensive income (loss)	1,362	(27,468)
Total shareholders' equity	58,552	71,711
Total liabilities and shareholders' equity	$ 336,186	$ 455,763

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

(Amounts in thousands, except share and per share data)	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Revenues				
Collaboration and licensing revenues	$ 5,223	$ 2,296	$ 20,259	$ 14,717
Product revenues	6,896	5,846	20,397	18,483
Service revenues	11,288	9,924	42,615	39,707
Other revenues	176	233	574	813
Total revenues	23,583	18,299	83,845	73,720
Operating Expenses				
Cost of products	7,296	7,906	21,526	24,130
Cost of services	5,891	6,550	20,197	21,860
Research and development	12,154	25,667	45,253	80,844
Selling, general and administrative	22,300	22,187	64,057	72,486
Impairment of goodwill	—	178	9,635	178
Impairment of other noncurrent assets	920	448	13,326	448
Total operating expenses	48,561	62,936	173,994	199,946
Operating loss	(24,978)	(44,637)	(90,149)	(126,226)
Other Expense, Net				
Unrealized and realized appreciation (depreciation) in fair value of equity securities and preferred stock, net	—	(3,139)	—	3,070
Interest expense	(4,646)	(4,466)	(13,830)	(13,124)
Interest and dividend income	579	883	2,025	3,268
Other income, net	10	2,781	145	671
Total other expense, net	(4,057)	(3,941)	(11,660)	(6,115)
Equity in net loss of affiliates	(523)	(479)	(1,125)	(1,943)
Loss from continuing operations before income taxes	(29,558)	(49,057)	(102,934)	(134,284)
Income tax benefit	50	3	130	25
Loss from continuing operations	$ (29,508)	$ (49,054)	$ (102,804)	$ (134,259)
Loss from discontinued operations, net of income taxes	—	(4,580)	(26,056)	(20,442)
Net loss	$ (29,508)	$ (53,634)	$ (128,860)	$ (154,701)
Net loss attributable to the noncontrolling interests	—	—	—	1,592
Net loss attributable to Precigen	$ (29,508)	$ (53,634)	$ (128,860)	$ (153,109)
Amounts Attributable to Precigen				
Net loss from continuing operations attributable to Precigen	$ (29,508)	$ (49,054)	$ (102,804)	$ (132,667)
Net loss from discontinued operations attributable to Precigen	—	(4,580)	(26,056)	(20,442)
Net loss attributable to Precigen	$ (29,508)	$ (53,634)	$ (128,860)	$ (153,109)
Net Loss per Share				
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.18)	$ (0.32)	$ (0.63)	$ (0.86)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	—	(0.03)	(0.16)	(0.14)
Net loss attributable to Precigen per share, basic and diluted	$ (0.18)	$ (0.35)	$ (0.79)	$ (1.00)
Weighted average shares outstanding, basic and diluted	165,527,024	154,596,257	163,318,375	153,770,785