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 9, 2021

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 9, 2021, reporting its financial results for the three months ended June 30, 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 August 9, 2021
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 9, 2021

Exhibit 99.1

Precigen Reports Second Quarter and First Half 2021 Financial Results

- Company to provide comprehensive clinical pipeline and data updates at R&D call on November 4th -

GERMANTOWN, MD, August 9, 2021 – 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 2021 financial results.

"We have made significant progress in the first half of 2021 and are well on our way to meet or exceed the goals we set at the beginning of the year. We are excited about the advancement of our portfolio and look forward to providing further clinical updates and data readouts at a planned R&D call on November 4th as well as at medical congresses in the fourth quarter of the year," said Helen Sabzevari, PhD, President and CEO of Precigen. "We see 2021 as a pivotal year for the UltraCAR-T, ActoBiotics and AdenoVerse platforms with significant new clinical data on our most advanced therapeutic candidates from these core therapeutic platforms."

Business Highlights:

R&D Update Call

- Precigen will host an R&D call on November 4th that will be dedicated to reviewing progress made in advancing the Company's clinical pipeline, including the latest data for several of our key programs.

PRGN-3005 UltraCAR-T®

- PRGN-3005 UltraCAR-T is a first-in-class investigational therapy under evaluation in a Phase 1/1b clinical trial for the treatment of patients with advanced, recurrent platinum resistant ovarian cancer. Study subjects receive the PRGN-3005 infusion either via intraperitoneal (IP) (Arm A) or intravenous (IV) (Arm B) infusion.
- Preliminary Phase 1 data previously reported from the two lowest dose levels of the IP arm showed a favorable safety profile with no dose-limiting toxicities (DLTs), neurotoxicity or cytokine release syndromes (CRS); encouraging expansion and persistence without lymphodepletion; and clinical activity as evidenced by regression in total target tumor burden.
- The dose escalation phase of both the IP and IV arms of the trial is ongoing concurrently. Enrollment in dose level 4 of the IP arm and dose level 3 of the IV arm is ongoing.
- The Company anticipates the presentation of interim data from the Phase 1 trial in the fourth quarter of 2021.

PRGN-3006 UltraCAR-T®

- PRGN-3006 UltraCAR-T is a first-in-class investigational therapy under evaluation in a Phase 1/1b clinical trial for the treatment of patients with relapsed or refractory (r/r) acute myeloid leukemia (AML) or higher-risk myelodysplastic syndromes (MDS). Study subjects receive the PRGN-3006 infusion either without prior lymphodepletion (Cohort 1) or following lymphodepleting chemotherapy (Cohort 2). PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation in patients with AML by the US FDA.
- Preliminary Phase 1 data previously reported for the two lowest dose levels in Cohort 1 and the lowest dose level in Cohort 2 showed a favorable safety profile with no DLTs or neurotoxicity; encouraging expansion and persistence of PRGN-3006 UltraCAR-T in both cohorts; and clinical activity as evidenced by reduction in AML tumor blast levels. One of the patients treated with PRGN-3006 at the lowest dose level with lymphodepletion (Cohort 1), with approximately nine million UltraCAR-T cells, achieved complete remission with incomplete hematologic recovery (CRi) per European Leukemia Net (ELN) criteria and subsequently received allogeneic hematopoietic stem cell transplant (HSCT).
- The dose escalation phase of both the lymphodepletion and non-lymphodepletion cohorts of the Phase 1 trial is ongoing concurrently. Enrollment in dose level 4 of the non-lymphodepletion cohort and dose level 3 of the lymphodepletion cohort is ongoing.
- The Company anticipates the presentation of interim data from the Phase 1 trial in the fourth quarter of 2021.

PRGN-2009 AdenoVerse™ Immunotherapy

- PRGN-2009 is a first-in-class, off-the-shelf (OTS) investigational immunotherapy utilizing the AdenoVerse platform that has been designed to activate the immune system to recognize and target HPV-positive solid tumors. PRGN-2009 is currently under evaluation in a Phase 1/2 clinical trial as a monotherapy or in combination with bintrafusp alfa (M7824) in patients with HPV-associated cancers. The trial is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI).

- Preliminary Phase 1 data previously reported for the monotherapy arm of the Phase 1 trial showed that the treatment was well-tolerated with no DLTs. Furthermore, preliminary correlative analysis from the patients treated at the lowest dose in the monotherapy arm showed an increase in HPV-specific T-cell response in 100% (3 of 3) of patients and an increase in the magnitude of immune response with repeated PRGN-2009 administrations.

- As previously announced, enrollment in the Phase 1 monotherapy dose escalation arm is complete, with all patients (n=6) receiving multiple doses of PRGN-2009, as many as thirteen doses to date. Subsequently, the monotherapy arm of the Phase 2 trial, which evaluates PRGN-2009 as neoadjuvant therapy for newly diagnosed oropharyngeal or sinonasal squamous cell cancer patients as a first line treatment was initiated. Enrollment in the Phase 2 monotherapy arm is ongoing with four patients enrolled to date. Enrollment in the Phase 1 combination arm is also ongoing with six patients enrolled to date.

- A trial-in-progress update on the PRGN-2009 study was provided at the American Society of Clinical Oncology (ASCO) 2021 annual meeting as a poster presentation by Charalampos S. Floudas, MD, DMSc, MS, Assistant Research Physician, Genitourinary Malignancies Branch at the Center for Cancer Research at the NCI.

- The Company anticipates the presentation of interim Phase 1 data in the fourth quarter of 2021.

PRGN-2012 AdenoVerse™ Immunotherapy

- PRGN-2012 is a first-in-class, investigational OTS AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for treatment of recurrent respiratory papillomatosis (RRP). A Phase 1 clinical trial of PRGN-2012 in adult patients with RRP is ongoing. The Phase 1 trial is designed to follow 3+3 dose escalation of PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomas. Patients receive up to four injections of PRGN-2012. The study is designed to enroll 3 to 6 subjects at each dose level followed by an expansion cohort with 12 patients treated at the maximum tolerated dose. The trial is being conducted under a CRADA with the NCI. PRGN-2012 has been granted Orphan Drug Designation in patients with RRP by the US FDA.

- In January 2021, the Company announced US FDA clearance of the IND to initiate the PRGN-2012 Phase 1 trial.

- In March 2021, the first patient was dosed and, subsequently, enrollment was completed in the 3+3 dose escalation portion of the Phase 1 trial. Enrollment then was initiated and the first patient dosed in the expansion cohort of the Phase 1 study at the maximum study dose, exceeding the Company's goal this year.

AG019 ActoBiotics™

- AG019 ActoBiotics is a first-in-class, orally administered, investigational therapy designed to address the underlying cause of Type 1 diabetes (T1D) and is currently under evaluation in a Phase 1b/2a clinical trial for the treatment of early-onset T1D. The study is assessing safety and tolerability of AG019 administered as monotherapy or in combination with teplizumab.

- Enrollment and dosing is complete in the Phase 1b and Phase 2a portions of the study.

- Positive topline data from the AG019 Phase 1b/2a clinical trial were reported at the Federation of Clinical Immunology Societies (FOCIS) 2021 Virtual Annual Meeting by Kevan Herold, MD, CNH Long Professor of Immunobiology and of Medicine (Endocrinology) at the Yale School of Medicine, meeting the Company's goal to present AG019 Phase 1b/2a data this year. The primary endpoints of safety and tolerability for the Phase 1b AG019 monotherapy and the Phase 2a AG019 combination therapy were met. No serious adverse events (SAEs) were reported. AG019, as a monotherapy and in combination with teplizumab, showed stabilization or increase of C-peptide levels, a biomarker for T1D disease progression, and induced antigen-specific tolerance in conjunction with the reduction of disease-specific T cell responses. Results indicated the potential of the oral AG019 monotherapy to preserve insulin production in recent-onset T1D through its capacity to reduce autoreactive T cells and increase the frequency of memory Tregs to induce antigen-specific immune modulation.

- Additional data from the AG019 Phase 1b/2a clinical trial will be presented on October 1, 2021 at 12:00 PM CET as an oral presentation at the European Association for the Study of Diabetes (EASD) 57th Annual Meeting. The abstract entitled, "AG019 ActoBiotics as monotherapy or in association with teplizumab in recent-onset type 1 diabetes was safe and demonstrated encouraging metabolic and immunological effects" will be presented by Chantal Mathieu, MD, PhD, Professor of Medicine at the Katholieke Universiteit Leuven, Belgium.

- A clinical trial assessing the efficacy of prolonged treatment of oral AG019 is planned.

Second Quarter and First Half 2021 Financial Highlights

- Net cash used in operating activities of $24.2 million during the six months ended June 30, 2021 compared to $41.5 million during the six months ended June 30, 2020;

- Cash, cash equivalents, short-term and long-term investments totaled $200.4 million as of June 30, 2021; and

- Total revenues of $33.6 million and $58.1 million during the three and six months ended June 30, 2021, respectively, compared to $30.4 million and $60.3 million during the three and six months ended June 30, 2020, respectively.

Second Quarter 2021 Financial Results Compared to Prior Year Period

Research and development expenses increased $4.2 million, or 44%, over the quarter ended June 30, 2020. Contract research organization costs and lab supplies increased $3.8 million with the advancement of the Company's clinical and preclinical programs. Selling, general and administrative ("SG&A") expenses increased $2.1 million, or 12%. The majority of the SG&A increase was due to an increase in professional fees. Net loss from continuing operations was $20.1 million, or $(0.10) per basic share, of which $8.2 million was for non-cash charges in 2021 compared to net loss from continuing operations of $15.7 million, or $(0.10) per basic share, of which $8.7 million was for non-cash charges in 2020.

Total revenues increased $3.2 million, or 10%, over the quarter ended June 30, 2020. Collaboration and licensing revenues decreased $4.0 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 collaboration agreements. Product and service revenues generated by Trans Ova and Exemplar increased $7.2 million 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 and a change in pricing structure with certain customers, as well as increased services provided by Exemplar to new and existing customers. 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.

First Half 2021 Financial Results Compared to Prior Year Period

Research and development expenses increased $3.4 million, or 16%, over the six months ended June 30, 2020. Contract research organization costs and lab supplies increased $3.8 million with the advancement of the Company's clinical and preclinical programs. SG&A expenses were comparable period over period due to offsetting changes. Salaries, benefits, and other personnel costs decreased $1.6 million in 2021 primarily due to a reduced headcount as the Company scaled down its corporate functions to support a more streamlined organization and reduced stock compensation costs for previously granted awards that became fully vested in early 2021. These decreases were partially offset by an increase in professional fees. Net loss from continuing operations was $41.9 million, or $(0.21) per basic share, of which $17.9 million was for non-cash charges in 2021 compared to net loss from continuing operations of $36.6 million, or $(0.23) per basic share, of which $16.4 million was for non-cash charges in 2020.

Total revenues decreased $2.2 million, or 4%, from the six months ended June 30, 2020. Collaboration and licensing revenues decreased $14.7 million as the Company accelerated the recognition of previously deferred revenue in the prior period upon the mutual termination of one of its collaboration agreements in February 2020. Product and service revenues generated by Trans Ova and Exemplar increased $12.6 million 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 and a change in pricing structure with certain customers, as well as increased services provided by Exemplar to new and existing customers. 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 unique therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on Twitter @Precigen and LinkedIn.

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 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, and the promise of the Company's portfolio of therapies, and in particular its CAR-T therapies. 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) Precigen's strategy and overall approach to its health-focused business model; (iii) 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; (iv) the ability to successfully enter into optimal strategic relationships with its subsidiaries and operating companies that it may form in the future; (v) the ability to hold or generate significant operating capital, including through partnering, asset sales and operating cost reductions; (vi) actual or anticipated variations in operating results; (vii) actual or anticipated fluctuations in competitors' or collaborators' operating results or changes in their respective growth rates; (viii) cash position; (ix) market conditions in Precigen's industry; (x) the volatility of Precigen's stock price; (xi) the ability, and the ability of collaborators, to protect Precigen's intellectual property and other proprietary rights and technologies; (xii) 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; (xiii) outcomes of pending and future litigation; (xiv) the rate and degree of market acceptance of any products developed by Precigen, its subsidiaries, collaborations or joint ventures; (xv) the ability to retain and recruit key personnel; (xvi) expectations related to the use of proceeds from public offerings and other financing efforts; and (xvii) estimates regarding expenses, future revenue, capital requirements and needs for additional financing. 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)	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 36,412	$ 51,792
Short-term investments	78,694	48,325
Receivables		
Trade, net	26,016	16,487
Related parties, net	22	19
Notes	—	3,689
Other	633	232
Inventory	11,413	11,359
Prepaid expenses and other	3,484	7,192
Current assets held for sale or abandonment	11	9,853
Total current assets	156,685	148,948
Long-term investments	85,269	—
Property, plant and equipment, net	32,745	34,924
Intangible assets, net	59,942	65,396
Goodwill	54,273	54,363
Right-of-use assets	12,327	9,353
Other assets	1,332	1,603
Total assets	$ 402,573	$ 314,587
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,937	$ 4,598
Accrued compensation and benefits	7,766	8,097
Other accrued liabilities	10,473	9,549
Deferred revenue	3,276	2,800
Current portion of long-term debt	356	360
Current portion of lease liabilities	1,937	2,657
Related party payables	22	19
Current liabilities held for sale or abandonment	102	14,047
Total current liabilities	28,869	42,127
Long-term debt, net of current portion	176,922	171,522
Deferred revenue, net of current portion	23,023	23,023
Lease liabilities, net of current portion	11,821	7,744
Deferred tax liabilities	2,692	2,897
Other long-term liabilities	50	100
Total liabilities	243,377	247,413
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	2,017,413	1,886,567
Accumulated deficit	(1,860,758)	(1,823,390)
Accumulated other comprehensive income	2,541	3,997
Total shareholders' equity	159,196	67,174
Total liabilities and shareholders' equity	$ 402,573	$ 314,587

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

(Amounts in thousands, except share and per share data)	Three months ended June 30, 2021	Three months ended June 30, 2020	Six months ended June 30, 2021	Six months ended June 30, 2020
Revenues				
Collaboration and licensing revenues	$ 301	$ 4,315	$ 367	$ 15,036
Product revenues	8,335	8,540	14,716	13,501
Service revenues	24,803	17,381	42,734	31,327
Other revenues	141	188	274	398
Total revenues	33,580	30,424	58,091	60,262
Operating Expenses				
Cost of products	6,135	8,141	11,709	14,230
Cost of services	8,898	6,770	16,300	14,306
Research and development	13,681	9,474	24,202	20,801
Selling, general and administrative	19,997	17,869	38,699	39,355
Impairment of other noncurrent assets	543	—	543	—
Total operating expenses	49,254	42,254	91,453	88,692
Operating loss	(15,674)	(11,830)	(33,362)	(28,430)
Other Expense, Net				
Interest expense	(4,667)	(4,592)	(9,206)	(9,184)
Interest income	410	773	802	1,446
Other income (expense), net	(192)	71	(250)	135
Total other expense, net	(4,449)	(3,748)	(8,654)	(7,603)
Equity in net loss of affiliates	—	(251)	(3)	(602)
Loss from continuing operations before income taxes	(20,123)	(15,829)	(42,019)	(36,635)
Income tax benefit	60	120	112	80
Loss from continuing operations	$ (20,063)	$ (15,709)	$ (41,907)	$ (36,555)
Income (loss) from discontinued operations, net of income taxes	13	(27,645)	4,539	(62,797)
Net loss	$ (20,050)	$ (43,354)	$ (37,368)	$ (99,352)
Net Loss per Share				
Net loss from continuing operations per share, basic and diluted	$ (0.10)	$ (0.10)	$ (0.21)	$ (0.23)
Net income (loss) from discontinued operations per share, basic and diluted	—	(0.16)	0.02	(0.38)
Net loss per share, basic and diluted	$ (0.10)	$ (0.26)	$ (0.19)	$ (0.61)
Weighted average shares outstanding, basic and diluted	199,021,587	164,065,087	196,275,820	162,201,915