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 10, 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 May 10, 2021, reporting its financial results for the three months ended March 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

Exhibit No.	**Description**
99.1	Press release dated May 10, 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: May 10, 2021

Exhibit 99.1

Precigen Reports First Quarter 2021 Financial Results

– Company on track to achieve stated 2021 milestones –

– Initiated Phase 2 clinical trial of PRGN-2009 AdenoVerse™ immunotherapy –

– Initiated Phase 1 clinical trial of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis (RRP) –

– Upcoming presentation at FOCIS Virtual Annual Meeting to provide clinical progress for AG019 ActoBiotics™ in Type 1 diabetes (T1D) –

GERMANTOWN, MD, May 10, 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 first quarter 2021 financial results.

"In the first quarter of 2021, our portfolio, including our most advanced clinical programs, has progressed consistent with guidance," said Helen Sabzevari, PhD, President and CEO of Precigen. "Our UltraCAR-T trials for PRGN-3005 in ovarian cancer and PRGN-3006 in acute myeloid leukemia as well as the PRGN-2009 trial in HPV-associated cancers continue to progress according to plan. We were pleased to initiate the first-in-human Phase 1 study of PRGN-2012, Precigen's first off-the-shelf AdenoVerse immunotherapy targeting infectious disease to enter the clinic, and receive orphan drug designation from the US FDA in patients with RRP. We look forward to upcoming presentations of new clinical data for AG019 at FOCIS and the current trial status for PRGN-2009 at ASCO and we anticipate multiple data readouts from our portfolio in the coming months, meeting our stated milestones."

Business Highlights:

PRGN-3005 UltraCAR-T®

- **Overview:** PRGN-3005 UltraCAR-T is a first-in-class investigational therapy under evaluation in a Phase 1/1b clinical trial for the treatment of advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer. Study subjects receive the PRGN-3005 infusion either via intraperitoneal (IP) (Arm A) or intravenous (IV) (Arm B) infusion (clinical trial identifier: NCT03907527). The study is being conducted in collaboration with the University of Washington and Fred Hutchinson Cancer Research Center. Preliminary Phase 1 data reported from the lowest two 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.

- **Enrollment Status:** Dose escalation in both IP and IV arms of the Phase 1 trial is ongoing concurrently. Enrollment was completed in dose level 3 of the IP arm and dosing was initiated in dose level 4 of the IP arm. Escalation to higher doses is made possible as a result of the implementation of the UltraPorator™ system for on-site rapid manufacturing. The first patient was dosed in the IV arm after the US Food and Drug Administration (US FDA) cleared dosing of patients in the dose escalation phase of the IV arm concurrently with the IP arm. The US FDA has cleared enrollment of patients in dose level 3 in the IV arm without the need to follow 3+3 dose escalation through dose levels 1 and 2.

- **Upcoming Milestones**: The Company anticipates the presentation of interim data from the IP arm of the Phase 1 dose escalation trial as well as the initiation of the expansion phase of the IP arm in the second half of 2021.

PRGN-3006 UltraCAR-T®

- **Overview:** PRGN-3006 UltraCAR-T is a first-in-class investigational therapy currently 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) (clinical trial identifier: NCT03927261). The study is being conducted in collaboration with the H. Lee Moffitt Cancer Center & Research Institute. PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation in patients with AML by the US FDA. Preliminary Phase 1 data 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.

- **Enrollment Status:** The dose escalation phase of both the lymphodepletion and non-lymphodepletion cohorts of the Phase 1 trial is ongoing concurrently. Enrollment was completed in dose level 3 of the non-lymphodepletion cohort and dose level 2 of the lymphodepletion cohort.

- **Upcoming Milestones:** The Company anticipates the presentation of interim Phase 1 data as well as the initiation of the dose expansion phase in the second half of 2021.

AG019 ActoBiotics™

- **Overview:** 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 (clinical trial identifier: NCT03751007; EudraCT 2017-002871-24). Interim data from both the Phase 1b monotherapy and Phase 2a combination arms showed a favorable safety profile with no dose-related adverse events or serious adverse events; an encouraging trend in insulin C-peptide levels, a biomarker for T1D disease progression; an increase in preproinsulin (PPI)-specific Type 1 regulatory (Tr1) cells; and a decrease in PPI specific $CD8^+$ T cells.

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

- **Clinical Data Presentation at FOCIS 2021:** Interim data from the AG019 Phase 1b/2a clinical trial will be presented on June 10, 2021 at 2:05 PM PT as an oral presentation at the Federation of Clinical Immunology Societies (FOCIS) 2021 Virtual Annual Meeting. The abstract entitled, "*Lactococcus lactis* producing Proinsulin and IL-10 therapy increases Antigen Specific Regulatory T-cells in Monotherapy and in Combination with an anti-CD3 Monoclonal Antibody (Teplizumab) in newly diagnosed T1D patients" will be presented by Kevan Herold, MD, CNH Long Professor of Immunobiology and of Medicine (Endocrinology) at the Yale School of Medicine.

PRGN-2009 AdenoVerse™ Immunotherapy

- **Overview:** PRGN-2009 is a first-in-class, off-the-shelf (OTS) investigational immunotherapy utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive (HPV+) 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 (clinical trial identifier: NCT04432597). The study is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI). Preliminary Phase 1 data from the monotherapy arm of the Phase 1 trial showed that all patients (n=6) received multiple PRGN-2009 administrations and repeated administration of PRGN-2009 treatment was well-tolerated with no DLTs. Preliminary correlative analysis from patients treated with PRGN-2009 monotherapy at dose level 1 (n=3) demonstrated an increase in HPV 16 and/or HPV 18-specific T-cell response post PRGN-2009 administration in 100% (3 of 3) of patients and an increase in the magnitude and breadth of immune response was seen with repeated administrations of PRGN-2009.

- **Enrollment Status:** The Phase 1 monotherapy arm has completed enrollment. Subsequently, the Phase 2 trial in patients with newly diagnosed stage II/III p16-positive oropharyngeal cancer or patients with newly diagnosed operable stage II/III/IVA/IVB HPV+ sinonasal squamous cell cancer was initiated. The first patient in the Phase 2 trial was dosed.

- **Preclinical Data Publication:** Preclinical data for PRGN-2009 was published in the *Journal of Clinical Investigation* entitled, "Characterization of recombinant gorilla adenovirus HPV therapeutic vaccine PRGN-2009," which provides the first evaluation of PRGN-2009 and shows promising preclinical antitumor efficacy and induction of HPV-specific T cells, along with the rationale for its evaluation in clinical trials.

- **Trial-in-Progress Presentation at ASCO 2021:** A trial-in-progress update on the PRGN-2009 study will be provided at the American Society of Clinical Oncology (ASCO) 2021 annual meeting. The abstract entitled, “First-in-human Phase 1/2 trial of PRGN-2009 vaccine as monotherapy or with bintrafusp alfa in patients with recurrent/metastatic (R/M) human papillomavirus (HPV)-associated cancers (HPVC) and as neoadjuvant/induction therapy in locoregionally advanced (LA) HPV oropharyngeal (OP) and sinonasal (SN) squamous cell cancer (SCC)” will be presented 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.

- **Upcoming Milestones:** The Company anticipates the presentation of interim Phase 1 data in the second half of 2021.

PRGN-2012 AdenoVerse™ Immunotherapy

- **Overview:** 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 AdenoVerse immunotherapy in adult patients with RRP is ongoing (clinical trial identifier: NCT04724980). In preclinical studies, PRGN-2012 showed robust HPV 6 and HPV 11-specific T-cell responses in RRP patient samples *in vitro*.

- **Orphan Drug Designation:** In March 2021, the Company received US FDA Orphan Drug Designation for PRGN-2012 AdenoVerse immunotherapy in patients with RRP.

- **Enrollment Status:** In March 2021, the first patient was dosed in the Phase 1 study.

First Quarter 2021 Financial Highlights

- Net cash used in operating activities of $16.4 million in 2021 compared to $27.7 million in 2020;

- Cash, cash equivalents, short-term and long-term investments totaled $209.3 million as of March 31, 2021; and

- Total revenues of $24.5 million in 2021 compared to $29.8 million in 2020.

First Quarter 2021 Financial Results Compared to Prior Year Period

Research and development expenses decreased $0.8 million, or 7%, from the quarter ended March 31, 2020. Salaries, benefits, and other personnel costs decreased $0.7 million in 2021 as the Company scaled down certain research and development functions in the first quarter of 2020 as a result of certain programs being previously deprioritized. Selling, general and administrative expenses decreased $2.8 million, or 13%. Salaries, benefits, and other personnel costs decreased $1.0 million in 2021 primarily due to a reduced headcount as the Company scaled down its corporate functions to support its more streamlined organization and reduced stock compensation costs for previously granted awards that became fully vested in early 2021. Professional fees decreased $1.0 million primarily due to a decrease in legal fees associated with certain litigation matters that were settled in the second half of 2020. Net loss from continuing operations was $21.8 million, or $(0.11) per basic share, of which $9.7 million was for non-cash charges in 2021 compared to net loss from continuing operations of $20.8 million, or $(0.13) per basic share, of which $7.7 million was for non-cash charges in 2020.

Total revenues decreased $5.3 million, or 18%, from the quarter ended March 31, 2020. Collaboration and licensing revenues decreased $10.7 million primarily due to the recognition of previously deferred revenue upon the mutual termination of one of its collaboration agreements in February 2020. Product and service revenues generated by Trans Ova and Exemplar increased $5.4 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, 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, a 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, UltraPorator, 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)	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 27,355	$ 51,792
Short-term investments	78,331	48,325
Receivables		
Trade, net	20,790	16,487
Related parties, net	12	19
Notes	—	3,689
Other	555	232
Inventory	10,637	11,359
Prepaid expenses and other	6,430	7,192
Current assets held for sale or abandonment	8	9,853
Total current assets	144,118	148,948
Long-term investments	103,610	—
Property, plant and equipment, net	33,716	34,924
Intangible assets, net	61,230	65,396
Goodwill	54,238	54,363
Right-of-use assets	8,639	9,353
Other assets	1,433	1,603
Total assets	$ 406,984	$ 314,587
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,295	$ 4,598
Accrued compensation and benefits	6,425	8,097
Other accrued liabilities	7,437	9,549
Deferred revenue	3,845	2,800
Current portion of long-term debt	359	360
Current portion of lease liabilities	2,658	2,657
Related party payables	52	19
Current liabilities held for sale or abandonment	172	14,047
Total current liabilities	25,243	42,127
Long-term debt, net of current portion	174,158	171,522
Deferred revenue, net of current portion	23,023	23,023
Lease liabilities, net of current portion	6,943	7,744
Deferred tax liabilities	2,722	2,897
Other long-term liabilities	100	100
Total liabilities	232,189	247,413
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	2,013,757	1,886,567
Accumulated deficit	(1,840,708)	(1,823,390)
Accumulated other comprehensive income	1,746	3,997
Total shareholders' equity	174,795	67,174
Total liabilities and shareholders' equity	$ 406,984	$ 314,587

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

(Amounts in thousands, except share and per share data)	Three months ended March 31, 2021	2020
Revenues		
Collaboration and licensing revenues	$ 66	$ 10,721
Product revenues	6,381	4,961
Service revenues	17,931	13,946
Other revenues	133	210
Total revenues	24,511	29,838
Operating Expenses		
Cost of products	5,574	6,089
Cost of services	7,402	7,536
Research and development	10,521	11,327
Selling, general and administrative	18,702	21,486
Total operating expenses	42,199	46,438
Operating loss	(17,688)	(16,600)
Other Expense, Net		
Interest expense	(4,539)	(4,592)
Interest income	392	673
Other income (expense), net	(58)	64
Total other expense, net	(4,205)	(3,855)
Equity in net loss of affiliates	(3)	(351)
Loss from continuing operations before income taxes	(21,896)	(20,806)
Income tax benefit (expense)	52	(40)
Loss from continuing operations	$ (21,844)	$ (20,846)
Income (loss) from discontinued operations, net of income taxes	4,526	(35,152)
Net loss	$ (17,318)	$ (55,998)
Net Loss per Share		
Net loss from continuing operations per share, basic and diluted	$ (0.11)	$ (0.13)
Net income (loss) from discontinued operations per share, basic and diluted	0.02	(0.22)
Net loss per share, basic and diluted	$ (0.09)	$ (0.35)
Weighted average shares outstanding, basic and diluted	193,499,546	160,338,743