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): January 24, 2023

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.

Precigen, Inc. (the "Company") hereby furnishes the following estimates with respect to its preliminary financial updates as of December 31, 2022:

- Cash, cash equivalents, short-term and long-term investments totaled approximately $56.0 million as of December 31, 2022;
- Restricted cash of approximately $43.7 million as of December 31, 2022, of which approximately $43.4 million was restricted for certain permitted purposes, including the resolution of the Company's outstanding 3.50% convertible senior notes due 2023; and
- The face value of the Company's outstanding 3.50% convertible senior notes due 2023 as of December 31, 2022 was approximately $43.4 million and convertible into approximately 2,542,000 shares of the Company's common stock.

The information set forth above is preliminary and unaudited and reflects preliminary financial information as of and for the year ended December 31, 2022. In preparing this information, the Company's actual results for the year ended December 31, 2022 have not yet been finalized by management or reviewed or audited by the Company's independent registered public accounting firm. The foregoing results are also not a comprehensive statement of financial results as of and for the year ended December 31, 2022. Subsequent information or events may lead to material differences between the foregoing preliminary financial information and those reported in the Company's subsequent SEC filings. Accordingly, investors should not place undue reliance on this preliminary financial information.

Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 is a copy of a press release of the Company, dated January 24, 2023, providing an overview of certain research and development updates that the Company intends to present during a conference call.

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 99.1	Press Release issued by Precigen, Inc., dated January 24, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: January 24, 2023

Exhibit 99.1

Precigen Announces Positive Phase 1 Dose Escalation and Expansion Cohort Data for Investigational Off-the-Shelf PRGN-2012 AdenoVerse™ Immunotherapy in Patients with Recurrent Respiratory Papillomatosis

– Repeated administrations of PRGN-2012 were well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2 –

– Clinical data show strong response in RRP patients with 50% of patients in Complete Response, requiring no post-treatment surgeries, following PRGN-2012 treatment at Dose Level 2; All complete responders remain surgery-free post-treatment with a minimum 12-months of follow up –

– PRGN-2012 treatment at Dose Level 2 significantly reduced the need for surgeries in severe, aggressive RRP patients; Median number of RRP surgeries in 12-month period reduced from 6.5 pre-treatment to 0.5 post-treatment –

– Phase 2 study is enrolling patients with a total of 32 patients enrolled at Dose Level 2 to date –

– Company to outline regulatory strategy in RRP as US Food and Drug Administration (FDA) discussions advance –

– Precigen to host R&D Day virtual event today at 4:30 PM ET –

Germantown, MD, January 24, 2023 – Precigen, Inc. (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today announces positive Phase 1 dose escalation and expansion cohort data as of the January 12, 2023 cutoff for the investigational, potential first-in-class PRGN-2012 off-the-shelf (OTS) AdenoVerse™ immunotherapy in patients with recurrent respiratory papillomatosis (RRP).

The company will host an R&D Day virtual event today at 4:30 PM ET to showcase the data and will feature presentations by Clint T. Allen, MD, Senior Investigator, Surgical Oncology Program, Center for Cancer Research, National Cancer Institute (NCI) and lead associate investigator for the PRGN-2012 clinical trial, and Precigen's President and CEO, Helen Sabzevari, PhD. Participants may register and access the live webcast through Precigen's investor relations website in the Events & Presentations section.

"As a patient and an advocate on behalf of the RRP community, the potential for a therapeutic alternative to surgical intervention would be nothing short of life changing," said Kim McClellan, President, Recurrent Respiratory Papillomatosis Foundation (RRPF). "There has never been a therapeutic option for the RRP patient community and we are incredibly hopeful that this will change in the near future. Our community faces ongoing risks from hospitalizations and repeat surgeries, coupled with daily quality-of-life challenges, such as obstructed breathing, difficulties swallowing, and impaired speech, and our community bears a tremendous financial burden from the significant lifetime costs to patients and their families affiliated with this disease."

"RRP is a rare disease with no cure. The current standard-of-care is repeated surgery to treat symptoms, which exposes patients to surgical risks, emotional distress and poses a significant economic burden to families and the healthcare system overall. We are thrilled to present these Phase 1 results today as PRGN-2012 has the potential to improve the lives of patients with severe, aggressive RRP through reduced surgeries," said Helen Sabzevari, PhD, President and CEO of Precigen. "Any treatment that reduces the burden of surgeries in RRP is considered meaningful and in the PRGN-2012 Phase 1 study, 50% of patients had a Complete Response, requiring no surgeries as of the data cutoff more than 12 months following treatment."

About RRP

RRP is a rare, difficult-to-treat and sometimes fatal neoplastic disease of the upper and lower respiratory tracts that is caused by infection with HPV 6 or HPV 11.[1-4] RRP is classified based on age of onset as juvenile or adult. There is no approved therapeutic treatment for RRP and the current standard-of-care is repeated endoscopic debulking with ablation or excision of papillomatous lesions.[3,4] Surgeries are not curative and recurrence of papilloma after surgical removal is very common and repeated procedures are required to debulk and monitor the disease, which exposes patients to anesthetic and surgical risks, and emotional distress. Patients with aggressive RRP can undergo hundreds of lifetime surgeries to control their disease.[5] RRP morbidity and

mortality results from the effects of papilloma mass on the vocal cords, trachea, and lungs, which may cause voice changes, stridor, airway occlusion, loss of lung volume, and/or post-obstructive pneumonia.[6] Although rare, RRP has potential for malignant transformation in three to seven percent of adult patients.[7]

About PRGN-2012 AdenoVerse™ Immunotherapy

PRGN-2012 is an innovative therapeutic vaccine with optimized antigen design that uses Precigen's gorilla adenovector technology, part of Precigen's proprietary AdenoVerse platform, to elicit immune responses directed against cells infected with HPV 6 or HPV 11. Gorilla adenovectors have numerous advantages, including the ability for repeat administration, the inability to replicate *in vivo,* which may improve safety, and the ability to deliver large payload capacity. In preclinical models, PRGN-2012 has demonstrated strong and specific immune response against HPV 6 and HPV 11. PRGN-2012 has been granted Orphan Drug Designation in patients with RRP by the FDA.

About the Phase 1 Clinical Trial

The Phase 1 clinical trial (clinical trial identifier: NCT04724980) evaluated safety and efficacy of PRGN-2012 as an immunotherapy following standard-of-care RRP surgery. Trial design included initiation of a 3+3 dose escalation cohort followed by a dose expansion cohort to enroll additional patients at the recommended Phase 2 dose (RP2D). Adult patients with severe, aggressive RRP, defined as greater than or equal to three surgeries in the prior 12 months, were enrolled to the clinical trial. A total of 15 patients were enrolled in the Phase 1 dose escalation and expansion cohorts at Dose Level 1: 1 x 10^{11} viral particles (vp)/dose (N=3) or Dose Level 2: 5 x 10^{11} vp/dose (N=12) with patients receiving four PRGN-2012 administrations (on days 1,15, 43 and 85) via subcutaneous injection.

Patient Characteristics

Baseline patient characteristics of the 15 adult patients included a median age of 51 years (range: 30-73). Ten patients were male and 5 were female. Patients had an average of 6.2 surgeries (range: 3-10) in the last 12 months before enrolling in the trial. Patients were diagnosed with RRP for an average of 15 years prior to enrollment.

Safety Summary

Repeated administrations of PRGN-2012 were well-tolerated with no dose-limiting toxicities and no treatment-related adverse events (TRAEs) greater than Grade 2 (TABLE 1). All patients received four administrations of PRGN-2012 at the intended dose levels. TRAEs were all mild and reduced in frequency over the treatment interval. The most common TRAE was injection site reaction, which occurred in all of the patients. Most other TRAEs occurring in more than one subject were similar to seasonal vaccines and the most common were fatigue, fever, and chills (TABLE 2). The lack of a significant neutralizing antibody response to gorilla adenovector over time with subsequent additional vaccinations highlights the ability to deliver repeated administrations of PRGN-2012, a differentiating feature of the AdenoVerse platform.

TABLE 1: Treatment-related Adverse Events

Total Patients (N=15)

	Dose Level 1 1 x 10^{11} vp (N=3)		**Dose Level 2 5 x 10^{11} vp (N=12)**		**All Subjects (N=15)**	
	Subjects (N, %)	**Events (N)**	**Subjects (N, %)**	**Events (N)**	**Subjects (N, %)**	**Events (N)**
Grade 1	3 (100%)	7	12 (100%)	105	15 (100%)	112
Grade 2	0 (0%)	0	2 (16.7%)	4	2 (13.3%)	4
Grades 3 -5	0 (0%)	0	0 (0%)	0	0 (0%)	0

TABLE 2: Treatment-related Adverse Events by Grade
Total Patients (N=15)

	Grade 1		Grade 2	
	Subjects (N, %)	**Events (N)**	**Subjects (N, %)**	**Events (N)**
Chills	10/15 (66.7%)	14	0 (0%)	0
Diarrhea	1/15 (6.7%)	1	0 (0%)	0
Shortness of breath (Dyspnea)	1/15 (6.7%)	1	0 (0%)	0
Excessive sweating (Hyperhidrosis)	2/15 (13.3%)	2	0 (0%)	0
Fatigue	9/15 (60.0%)	20	2/15 (13.3%)	2
Fever	9/15 (60.0%)	17	0 (0%)	0
Injection site reaction	15/15 (100%)	46	0 (0%)	0
Muscle aches (Myalgia)	2/15 (13.3%)	2	2/15 (13.3%)	2
Nausea	4/15 (26.7%)	6	0 (0%)	0
Skin itching (Pruritus)	1/15 (6.7%)	1	0 (0%)	0
Vomiting	2/15 (13.3%)	2	0 (0%)	0

Clinical Efficacy Summary

Clinical data show PRGN-2012 treatment significantly reduced the need for surgeries for severe, aggressive RRP patients treated at Dose Level 2. At Dose Level 2, 50% (6 out of 12) patients had a Complete Response, which is defined as no surgeries needed during the 12-month period following PRGN-2012 treatment completion (TABLE 3). All complete responders remained surgery-free as of the cutoff date post PRGN-2012 treatment.Patients in Dose Level 2 had a 58% (7 out of 12) Overall Response Rate, defined as greater than or equal to 50% reduction in the surgeries in 12-months post PRGN-2012 treatment completion compared to 12-months pre-treatment. 83% (10 out of 12) of patients treated at Dose Level 2 had reduced surgeries post PRGN-2012 treatment. The number of RRP surgeries in the patients (N=12) in Dose Level 2 reduced from a median of 6.5 surgeries (range: 3-10) in the 12-months pre-treatment to 0.5 surgeries (range: 0-6) in 12-months post PRGN-2012 treatment completion.

Further, PRGN-2012 treatment showed significant improvement in anatomical Derkay scores, a tool used for research purposes to quantify RRP severity based on involvement of laryngeal structures, and voice quality, evaluated using the validated Vocal Handicap Index-10 (VHI-10), at 24-weeks post PRGN-2012 treatment completion compared to baseline.

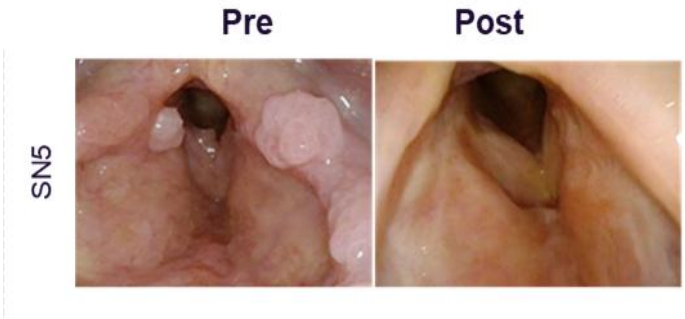
Phase 1 data show that PRGN-2012 treatment resulted in an increase in HPV 6/11-specific T-cell response in the peripheral blood of RRP patients. Furthermore, the T-cells infiltrating papillomas from patients who had an objective response and a biopsy sample available showed an increase in HPV 6/11-specifc T-cells in papillomas after PRGN-2012 treatment.

TABLE 3: Clinical Efficacy Summary
Total Patients (N=15)

	Dose Level 1 (N=3)	Dose Level 2 (N=12)
Complete Response (CR) No surgeries needed during 12-months post-treatment	**0% (0/3)**	**50% (6/12)**
Overall Response Rate (ORR) ≥ 50% reduction in surgeries during 12-months post-treatment compared to 12-months pre-treatment	**33% (1/3)**	**58% (7/12)**
Decrease in Rate of Surgery 12-months post-treatment compared to 12-months pre-treatment	**100% (3/3)**	**83% (10/12)**

Case Studies
Case studies will be presented for three of the six complete responders. For each case study, papilloma growth, as measured by the Derkay score, decreased to zero following completion of PRGN-2012 treatment. An example case study included subject #5, a 40 year old male who required eight surgeries in the 12-months prior to treatment to control papilloma growth. This patient has been in Complete Response after completing PRGN-2012 treatment, and has been surgery-free up to 18-months as of the cutoff date (FIGURE 1). Consistent with the disease response, the patient's Derkay score and VHI-10 index showed significant reduction at 24-weeks post treatment compared to baseline indicating improvement in disease severity and vocal function, respectively. The patient showed improvement in HPV-specific immune response in peripheral blood and papilloma post PRGN-2012 treatment.

FIGURE 1: Patient Papilloma Growth at Baseline (Pre-Treatment) and 24-weeks Post-Treatment with PRGN-2012



Phase 2 Study
Precigen initiated dosing in the Phase 2 trial at Dose Level 2 and is rapidly enrolling patients, with 20 patients enrolled to date in the Phase 2 trial, bringing the total number of enrolled patients to 32 at Dose Level 2. The Phase 2 clinical trial evaluates PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomas in adult patients with RRP.

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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.

About AdenoVerse Immunotherapy
Precigen's AdenoVerse immunotherapy platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse immunotherapies have been shown to generate high-level and durable antigen-specific neutralizing antibodies and effector T cell immune responses as well as an ability to boost these antibody and T cell responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors combined with UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

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.

References

[1] Mounts, P *et al.* (1982). "Viral etiology of juvenile- and adult-onset squamous papilloma of the larynx." *Proc Natl Acad Sci* U S A 79(17): 5425-5429.

[2] Smith, E *et al.* (1993). "Human papillomavirus infection in papillomas and nondiseased respiratory sites of patients with recurrent respiratory papillomatosis using the polymerase chain reaction." *Arch Otolaryngol Head Neck Surg* 119(5): 554-557.

[3] Derkay, CS *et al.* (2008). "Recurrent respiratory papillomatosis: a review." *Laryngoscope* 118(7): 1236-1247.

[4] Derkay, CS *et al.* (2019). "Update on Recurrent Respiratory Papillomatosis." *Otolaryngol Clin North Am* 52(4): 669-679.

[5] Allen, CT *et al.* (2019). “Safety and clinical activity of PD-L1 blockade in patients with aggressive recurrent respiratory papillomatosis.” J. Immunotherapy Cancer 7, 119.

[6]Seedat, RY (2020). "Juvenile-Onset Recurrent Respiratory Papillomatosis Diagnosis and Management - A Developing Country Review." *Pediatric Health Med Ther* 11: 39-46.

[7] Katsenos S, *et al.* (2011). “Recurrent respiratory papillomatosis: a rare chronic disease, difficult to treat, with potential to lung cancer transformation: apropos of two cases and a brief literature review.” Case Rep Oncol. 2011 Mar 23;4(1):162-71.

Investor Contact:
Steven M. Harasym
Vice President, Investor Relations
Tel: +1 (301) 556-9850
investors@precigen.com

Media Contacts:
Donelle M. Gregory
press@precigen.com

Glenn Silver
Lazar-FINN Partners
glenn.silver@finnpartners.com