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 11, 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 7.01 Regulation FD Disclosure.

On January 11, 2023, Precigen, Inc. (the "Company") issued a press release providing an overview of certain research and development and corporate updates that the Company presented at the 41st Annual J.P. Morgan Healthcare Conference on January 11, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

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 11, 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 11, 2023

Exhibit 99.1

Precigen Provides Pipeline and Corporate Updates at the 41st Annual J.P. Morgan Healthcare Conference

– Company achieved significant progress for its clinical pipeline in 2022 –
– Precigen to host R&D Day virtual event on January 24, 2023, at 4:30 PM ET to share safety and efficacy data from the Phase 1 dose escalation and expansion cohorts of PRGN-2012 AdenoVerse™ immunotherapy in recurrent respiratory papillomatosis (RRP) –

GERMANTOWN, MD, January 11, 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 presented pipeline and corporate updates at the 41st Annual J.P. Morgan Healthcare Conference. Helen Sabzevari, PhD, President and CEO of Precigen, presented a summary of 2022 achievements and set forth Precigen's goals for 2023.

"Precigen continued to make significant clinical progress for our UltraCAR-T and AdenoVerse programs in 2022 and we were able to meet or exceed substantially all of the clinical goals we outlined at the J.P. Morgan Healthcare Conference last year. For example, the PRGN-2012 study in RRP continues to accelerate at a rapid pace and we look forward to hosting an R&D update call on January 24th to share safety and efficacy data from the Phase 1 dose escalation and expansion cohorts," said Helen Sabzevari, PhD, President and CEO of Precigen. "In 2023, we will continue to advance our clinical programs with a focus on a rapid path to licensure for programs addressing high unmet patient need."

PRGN-2012 AdenoVerse™ Immunotherapy in RRP

- **Overview:** PRGN-2012 is an investigational off-the-shelf (OTS) AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for treatment of RRP. PRGN-2012 is currently under evaluation in a Phase 2 clinical trial (clinical trial identifier: NCT04724980). The clinical trial evaluates PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomas in adult patients with RRP. PRGN-2012 has been granted Orphan Drug Designation in patients with RRP by the US Food and Drug Administration (FDA).

- **Program Status:** Enrollment (N=15) was completed in the Phase 1 study. Precigen initiated dosing in the Phase 2 trial and is rapidly enrolling patients, with 20 patients enrolled to date. The Company will host a virtual R&D event on January 24, 2023 to showcase complete clinical trial data from the Phase 1 dose escalation and expansion cohorts of PRGN-2012 AdenoVerse Immunotherapy in RRP. The event will be led 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 Helen Sabzevari, PhD, President and CEO of Precigen. The Company plans to outline the regulatory strategy for PRGN-2012 in 2023 based on discussions with the FDA.

PRGN-2009 AdenoVerse™ Immunotherapy in HPV-associated Cancers

- **Overview:** PRGN-2009 is an 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 (clinical trial identifier: NCT04432597). The Phase 1 trial is evaluating safety and response of PRGN-2009 as a monotherapy (Arm A) and in combination with M7824 (Arm B) in previously treated patients with recurrent or metastatic HPV-associated cancers.

- **Program Status:** 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 and patient follow up is ongoing. The Company expects Phase 1 monotherapy and combination therapy safety and efficacy data to be presented in the first half of 2023. Enrollment is nearing completion in the Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients with 19 of 20 estimated patients enrolled as of the end of 2022. Interim clinical data presentation from the Phase 2 monotherapy arm is expected in the second half of 2023.

PRGN-3006 UltraCAR-T® in Acute Myeloid Leukemia (AML)

- **Overview:** PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a kill switch. PRGN-3006 UltraCAR-T is under evaluation in a Phase 1b clinical trial (clinical trial identifier: NCT03927261) for the treatment of patients with relapsed or refractory AML or higher-risk myelodysplastic syndromes (MDS). PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation in patients with AML and Fast Track Designation in patients with relapsed/refractory AML by the FDA.

- **Program Status:** Enrollment was completed in the Phase 1 dose escalation cohorts of the study. Precigen presented positive Phase 1 dose escalation data for autologous PRGN-3006 UltraCAR-T® manufactured overnight for next day infusion in relapsed or refractory AML patients at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. The Phase 1b dose expansion study of PRGN-3006 UltraCAR-T was expanded to Mayo Clinic in Rochester, Minnesota, enhancing the decentralized manufacturing model. The first patient was successfully dosed at the expansion site with PRGN-3006 UltraCAR-T. Site activation activities are in progress at several additional major cancer centers across the US as part of the multicenter expansion of the study. The Company received FDA clearance to incorporate repeat dosing in the Phase 1b expansion phase of the study, at the discretion of the treating physician. Phase 1b clinical trial data presentation is expected in 2024.

PRGN-3005 UltraCAR-T® in Ovarian Cancer

- **Overview:** PRGN-3005 UltraCAR-T is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, which is highly expressed on ovarian tumors with limited normal tissue expression, mbIL15, and a kill switch. PRGN-3005 UltraCAR-T is under evaluation in a Phase 1b clinical trial (clinical trial identifier: NCT03907527) for the treatment of patients with advanced, recurrent platinum-resistant ovarian cancer.

- **Program Status:** Enrollment was completed in the Phase 1 dose escalation cohorts of the intraperitoneal (IP) and intravenous (IV) arms without lymphodepletion as well as in the lymphodepletion cohort 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. The first patient received a repeat PRGN-3005 dose via IV infusion, following FDA clearance to incorporate repeat dosing in the study protocol. Enrollment is ongoing in the Phase 1b expansion study of PRGN-3005 UltraCAR-T at Dose Level 3 with lymphodepletion prior to IV infusion. Site activation activities are in progress at multiple major cancer centers in the US. Phase 1b clinical trial data presentation is expected in 2024.

PRGN-3007 Next Generation UltraCAR-T® with Intrinsic PD-1 Inhibition

- **Overview:** PRGN-3007, based on the next generation of the UltraCAR-T platform, is an investigational multigenic, autologous CAR-T cell therapy engineered to simultaneously express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression. ROR1 is aberrantly expressed in multiple 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 breast adenocarcinomas such as triple negative breast cancer (TNBC), pancreatic cancer, ovarian cancer, and lung adenocarcinoma. ROR1 is minimally expressed in healthy adult tissues.

- **Program Status:** Precigen presented an abstract titled, "A Phase1/1b Dose Escalation/Dose Expansion Study of PRGN-3007 UltraCAR-T Cells in Patients with Advanced Hematologic and Solid Tumor Malignancies," at ASH. Tech transfer was completed for initiation of the Phase 1 umbrella trial in ROR1^{+} hematological (CLL, MCL, ALL, DLBCL) and solid tumors (TNBC). The trial is currently open for enrollment and the Company expects to dose the first patient in the first quarter of 2023.

Precigen's J.P. Morgan presentation is available on the Company website in the Events & Presentations section.

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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. For more information about Precigen, visit www.precigen.com or follow us on Twitter @Precigen, LinkedIn or YouTube.

UltraCAR-T®

UltraCAR-T is a multigenic autologous CAR-T platform that utilizes Precigen's advanced non-viral Sleeping Beauty system to simultaneously express an antigen-specific CAR to specifically target tumor cells, mbIL15 for enhanced in vivo expansion and persistence, and a kill switch to conditionally eliminate CAR-T cells for a potentially improved safety profile. Precigen has advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. UltraCAR-T investigational therapies are manufactured via Precigen's overnight manufacturing process using the proprietary UltraPorator® electroporation system at the medical center and administered to patients only one day following gene transfer. The overnight UltraCAR-T manufacturing process does not use viral vectors and does not require ex vivo activation and expansion of T cells, potentially addressing major limitations of current T cell therapies.

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.

UltraPorator®

The UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk. The UltraPorator device is a high-throughput, semi-closed electroporation system for modifying T cells using Precigen's proprietary non-viral gene transfer technology. UltraPorator is being utilized for clinical manufacturing of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices.

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 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.

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