UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number:

001-36042

PRECIGEN, INC.

(Exact name of registrant as specified in its charter)

Virginia	**26-0084895**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
20374 Seneca Meadows Parkway Germantown, Maryland	**20876**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (301) 556-9900

Securities registered pursuant to Section 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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. Yes ☐ No ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates based upon the closing price of such shares on the Nasdaq Global Select Market on such date was approximately $219.4 million.

As of February 15, 2026, 353,928,672 shares of common stock, no par value per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the registrant's Definitive Proxy Statement for its 2026 Annual Meeting of Shareholders are incorporated by reference in Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

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Precigen®, AdenoVerse®, UltraCAR-T®, RheoSwitch®, UltraVector®, RTS®, UltraPorator®, ActoBiotics®, Advancing Medicine With Precision®, RRP Awareness Day ®, Giving Voice to Inspire Change ®, and RheoSwitch Therapeutic System® are our and/or our affiliates' registered trademarks in the United States and GenVec™, Papzimeos™, Recurrent Respiratory Papillomatosis Awareness Giving Voice to Inspire Change™, RRP Awareness & Design™, and RRP Awareness Day Giving Voice to Inspire Change™ are our and/or our affiliates' common law trademarks in the United States. This Annual Report on Form 10-K, or Annual Report, and the information incorporated herein by reference contain references to trademarks, service marks, and trade names owned by us or other companies. Solely for convenience, trademarks, service marks, and trade names referred to in this Annual Report and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks, and trade names. We do not intend our use or display of other companies' trade names, service marks, or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names, and service

marks appearing in this Annual Report are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report to "Precigen", "Company", "we", "us", and "our" refer to Precigen, Inc.

Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report, including statements regarding our strategy; future events, including their outcome or timing; future operations; future financial position; future revenue; projected costs; prospects; plans; objectives of management; and expected market growth, are forward-looking statements. The words "aim", "anticipate", "assume", "believe", "continue", "could", "due", "estimate", "expect", "intend", "may", "objective", "plan", "positioned", "potential", "predict", "project", "seek", "should", "target", "will", "would", and the negatives of these terms or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements may relate to, among other things: (i) our commercialization plans in the United States, the European Union ("EU"), and elsewhere for our first commercial product, Papzimeos (zopapogene imadenovec-drba, PRGN-2012); (ii) our strategy and overall approach to our business model; (iii) our ability to successfully enter new markets or develop additional product candidates, including the expected timing and results of investigational studies, preclinical and clinical trials, and regulatory approvals; (iv) our or the ability of third-parties to consistently manufacture our product and product candidates on a timely basis (v) actual or anticipated variations in our operating results; (vi) our cash position; (vii) market conditions in our industry; (viii) our expectations regarding the size of the patient populations amenable to treatment with our product and product candidates; (ix) the volatility of our stock price; (x) the ability to protect our intellectual property and other proprietary rights and technologies; (xi) outcomes of pending and future litigation; (xii) the rate and degree of market acceptance of products developed by us, and competition from existing technologies and products or new technologies and products that may emerge; (xiii) our ability to retain and recruit key personnel; (xiv) expectations related to the use of proceeds from public offerings and other financing efforts; (xv) estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; and (xvi) our expectations regarding pre-launch inventory, including the exception of future revenue to be generated from such inventory and timing of selling such inventory and (xvii) expectations regarding our gross margins from sales of Papzimeos.

Forward-looking statements are based on our beliefs, assumptions, and expectations of our future performance, and may also concern our expectations relating to our subsidiaries and other affiliates. We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report, particularly in "Summary of Risk Factors" set forth below and Item 1A, "Risk Factors," that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, JVs, or investments that we may make.

You should read this Annual Report, the documents that we reference in this Annual Report, the audited consolidated financial statements and related notes thereto included in this Annual Report, the other reports we have filed with the Securities and Exchange Commission, or SEC, and the documents that we have filed as exhibits to our filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Market and Industry Data

This Annual Report contains industry and market data that are based on general and industry publications, surveys and studies commissioned or conducted by third parties, some of which may not be publicly available, and our own internal estimates and research. Third-party publications, surveys and studies generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. These data involve a number of assumptions and limitations and contain projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

Summary of Risk Factors

We are subject to a variety of risks and uncertainties, including risks that could have a material adverse effect on our business, financial condition, results of operations, and cash flows. The following summary of the principal factors that make an investment in our securities speculative or risky should not be relied upon as an exhaustive summary of the material risks facing us. You should read the following summary together with the more detailed description of the risks that we deem material described under "Risk Factors" in Item 1A of this Annual Report and the other information contained in this Annual Report before investing in our securities.

Risks Related to Our Financial Position and Capital Needs

- We are substantially dependent on the commercial success of Papzimeos.
- We have a history of net losses, and we may not achieve or maintain profitability.
- We expect our future capital requirements will be substantial and will depend on many factors.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.
- Failure of the U.S. federal government to manage its fiscal matters or to raise or further suspend the debt ceiling may expose us to increased financial and operational risk.

Risks Related to the Discovery and Development of Our Product Candidates

- We are heavily dependent on the successful commercialization of Papzimeos in the U.S. and other jurisdictions, where we may obtain regulatory approval, and our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and ultimately commercialize them.
- The market opportunities for our product and product candidates may be smaller than we estimate.
- The regulatory approval processes of the United States Food and Drug Administration, or FDA, and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable, and we may be unable to obtain FDA approval of our product candidates. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business, and our results of operations.
- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.
- As an organization, we have limited experience designing and implementing clinical trials and failure to adequately design a trial, conduct a trial in accordance with regulatory requirements, or enroll patients in clinical trials, could result in adverse effects, including but not limited to increased or unexpected costs and delayed timelines.
- Cell and gene therapies are novel, complex, and difficult to manufacture.
- Interim and preliminary results from our clinical trials that we announce or publish from time to time may change, which could result in material changes in the final data.
- We have chosen to prioritize certain of our product candidates and, as a result, may expend our limited resources on product candidates that do not yield a successful product, or fail to capitalize on opportunities that may be more profitable.

Risks Related to the Commercialization of Our Product and Product Candidates and Other Legal Compliance Matters

- Our product and product candidates may fail to achieve the degree of market acceptance necessary for commercial success.

- Delays in obtaining regulatory approval of manufacturing processes and facilities or disruptions in manufacturing processes may delay or disrupt our commercialization efforts.

- Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply Papzimeos for commercial and future clinical uses would adversely affect our ability to commercialize Papzimeos and our business and business prospects could be severely harmed.

- We rely on third parties for certain aspects of the manufacture of our product, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or potential future commercialization efforts.

- Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

- We have limited experience as a commercial company and the sales, marketing, and distribution of Papzimeos or any future approved products may be unsuccessful or less successful than anticipated.

- The successful commercialization of product and our product candidates will depend in part on the extent to which third-party payers provide coverage and adequate reimbursement levels.

- Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to governmental enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity.

Risks Related to Our Business Operations and Strategy

- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

- We may be sued for product liability.

- Our insurance policies are expensive and protect only from some business risks, which leaves us exposed to significant uninsured liabilities.

- Competitors and potential competitors may develop products and technologies that make ours obsolete or garner greater market share than ours.

- If we lose key personnel, including key management personnel, or are unable to attract and retain additional personnel, it could delay our product development programs, harm our research and development efforts, and we may be unable to continue to commercialize our product candidates.

- If we experience a significant breach of data security or disruption in our information systems, our business could be adversely affected.

Risks Related to Our Intellectual Property

- Our ability to compete may decline if we do not adequately protect our proprietary technologies or intellectual property rights.

- Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violation could require us to spend significant time and money and could prevent us from commercializing our technologies or impact our stock price.

- Enforcing our intellectual property rights may be difficult and unpredictable.

Risks Related to Our Common Stock

- We have failed in the past and may fail in the future to meet all applicable continued listing requirements of the

Nasdaq Global Select Market, which could result in a delisting of our common stock.

- Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline.

- Our stock price is volatile, and purchasers of our common stock could incur substantial losses.

- As of February 15, 2026, Randal J. Kirk controlled approximately 34 percent of our common stock and may be able to control or significantly influence shareholder votes and other corporate actions.

- Sales of a substantial number of shares of our common stock in the public market could occur at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

PART I

Item 1. Business

Overview

We are a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to improve the lives of patients. We are leveraging our proprietary technology platforms to develop product candidates designed to target urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases.

We believe that our array of technology platforms uniquely positions us among other biotechnology companies to advance precision medicine. Precision medicine is the practice of therapeutic product development that takes into account specific genetic variations within populations impacted by a disease to design targeted therapies to improve outcomes for a disease or patient population. Our proprietary and complementary technology platforms provide a strong foundation to realize the core promise of precision medicine by supporting our efforts to construct powerful gene programs to drive efficacy, deliver these programs through viral, non-viral, and microbe-based approaches to drive lower costs, and control gene expression to drive safety. Our therapeutic platforms, including AdenoVerse immunotherapy, and UltraCAR-T, are designed to allow us to precisely control the level and physiological location of gene expression and modify biological molecules to control the function and output of living cells to treat underlying disease conditions. We have developed a proprietary electroporation device, UltraPorator, designed to further streamline and ensure the rapid and cost-effective manufacturing of UltraCAR-T therapies.

In August 2025, the FDA granted full approval to our product, Papzimeos (zopapogene imadenovec-drba, PRGN-2012), for the treatment of adults with recurrent respiratory papillomatosis (RRP). RRP is a rare, debilitating, and potentially life-threatening disease caused by chronic human papillomavirus (HPV) 6 or HPV 11 infection, which results in recurrent benign tumors in the respiratory tract. Papzimeos is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of HPV types 6 and 11 proteins. Papzimeos is designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP.

Our clinical pipeline includes PRGN-2009, which is based on our AdenoVerse immunotherapy platform; and PRGN-3005, PRGN-3006 and PRGN-3007, which are built on our UltraCAR-T platform. We have completed enrollment in the Phase 1b clinical trial of PRGN-3006. As part of the strategic prioritization of our pipeline we announced in August 2024 that we have paused enrollment in the PRGN-3005 and PRGN-3007 clinical trials. In addition, we announced a plan to continue PRGN-2009 Phase 2 clinical trials under a cooperative research and development agreement ("CRADA") with the National Cancer Institute ("NCI") in recurrent/metastatic cervical cancer and in newly diagnosed HPV-associated oropharyngeal cancer.

We exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid "go" and "no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials.

To guide our decision-making and operations, we have adopted the following tenets, which form the core of our operating ideology:

- ***Financial Discipline***. Responsibly allocate capital in an effort to ensure maximum value creation.
- ***Active Portfolio Management***. Continuously evaluate our portfolio and strictly adhere to data-driven "go" and "no go" decisions to advance programs with the highest probability of success.
- ***Rapid Execution***. Advance priority programs quickly to value inflection points.
- ***Strategic Partnerships***. Seek strategic partnerships to maximize value generation.

Our Strategy

Our strategy is to use our discovery and clinical development infrastructure to continue advancement of our clinical programs with the goal of improving outcomes for patients with significant unmet medical needs. The key elements of our strategy include:

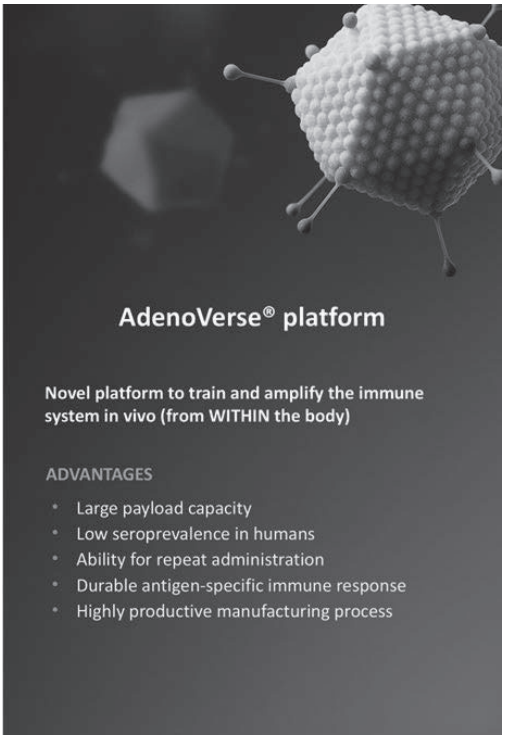
- ***Advancing our lead clinical stage programs and seeking opportunities to maximize their value.*** We are actively

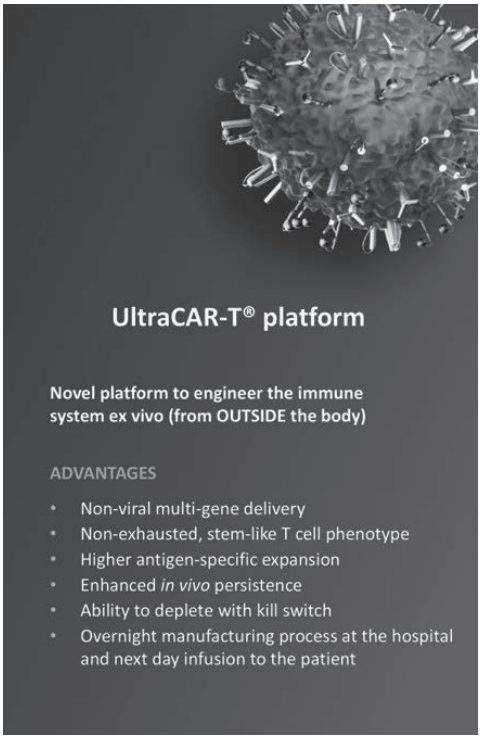
advancing our lead programs that we believe have significant potential value. We intend to efficiently pursue these programs toward clinical proof-of-concept and commercialization, whether independently or with collaborators.

- ***Strategically pursuing our preclinical programs.*** We are strategically focusing on selecting preclinical programs to create long-term value. We exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid "go" and "no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials.

- ***Leveraging our technology and therapeutic platforms across indications.*** Through the application of our suite of proprietary and complementary synthetic biology technologies, we believe we can create optimized biological processes and overcome the limitations of traditional techniques, leading to precision medicines that are manufactured more efficiently and cost-effectively with superior performance. We continually assess the application of these technologies across therapeutic areas to determine where we can develop and provide unique solutions to challenges facing existing therapies.

We have strategically focused our efforts on developing an innovative pipeline of therapies based on our transformative AdenoVerse immunotherapy and UltraCAR-T therapeutic platforms. A core focus of our research and development programs has been an effort to address the drawbacks associated with conventional cell and gene therapy manufacturing approaches. To this end, we are developing therapeutic candidates that reduce manufacturing risk by eliminating the need for centralized cell therapy manufacturing and have invested in internal manufacturing capabilities to reduce manufacturing risk for our pipeline assets.





Our Clinical Pipeline

Product	Target	Indication	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVED
ADENOVERSE								
PAPZIMEOS™	HPV 6/11	RRP						
PRGN-2009 (+pembrolizumab)	HPV 16/18	OPSCC/Head & Neck Cancer						
PRGN-2009 (+pembrolizumab)	HPV 16/18	R/M Cervical Cancer						

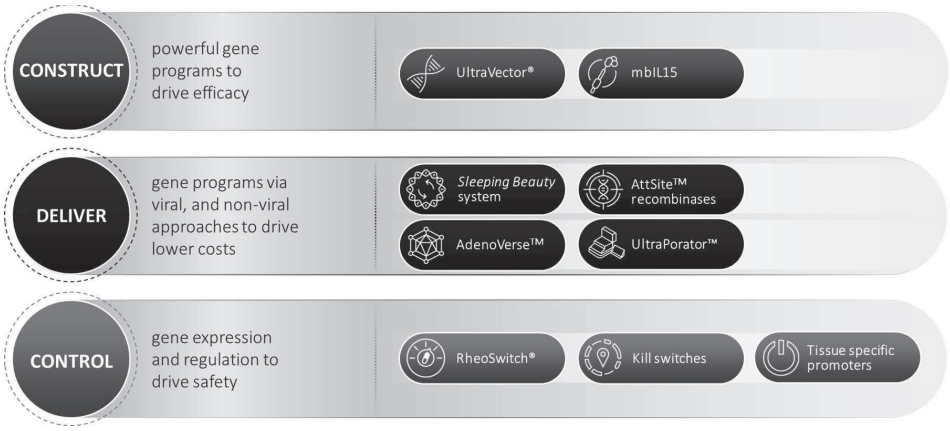
ACRONYMS: RRP=recurrent respiratory papillomatosis; OPSCC=oropharyngeal squamous cell carcinoma; R/M=recurrent/metastatic

Product	Target	Indication	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVED
ULTRACAR-T								
PRGN-3005	Unshed MUC16	Ovarian Cancer						
PRGN-3006	CD33	R/R AML, MDS						
PRGN-3007	ROR1	ROR1+ Hematological & Solid Tumors						

ACRONYMS: R/R=relapsed or refractory; AML=acute myeloid leukemia; MDS=myelodysplastic syndrome; ROR=receptor tyrosine kinase-like orphan receptor; HPV=human papillomavirus; MUC=mucin

Our Technology Platforms

We leverage a diverse portfolio of proprietary technology platforms to accelerate research and development efforts to deliver the promise of precision medicine. Precigen's innovative technology platforms enable us to *construct* powerful, multigenic programs that we believe will drive efficacy, *deliver* multigenic constructs using viral and non-viral approaches that we believe will drive lower costs, and *control* expression of genes and performance of therapeutics *in vivo* for precise targeting of complex malignancies. The following discussion describes the technology platforms that we use for our approach to precision medicine.



We believe that the development of innovative biological products requires a deep understanding of the complexity of cellular processes and the construction of improved gene programs developed in conditions reflective of the natural environment. We accomplish the design of optimized gene programs for our therapeutic approaches via our UltraVector platform that incorporates advanced DNA construction technologies and computational models to design and assemble genetic components into complex gene expression programs. UltraVector-enabled matrices facilitate rapid identification of components that yield desired gene expression. Our library of characterized genetic components and associated functional characterization data enables construction of gene programs for optimized expression of multiple effector genes. Expression of our membrane-bound interleukin-15, or mbIL15, gene improves functional characteristics of certain immune cells, including T-cells, by enhancing their potential for expansion and persistence.

We deliver gene programs via viral, non-viral, and microbe-based approaches, including *Sleeping Beauty*, AttSite recombinases, and gorilla adenoviral vectors, from our AdenoVerse library. *Sleeping Beauty* is a non-viral transposon/transposase system licensed from the University of Texas MD Anderson Cancer Center that stably reprograms immune cells by inserting specific DNA sequences into their genome. The *Sleeping Beauty* system has been shown to promote random integration in the genome without insertion bias, which contrasts with the predilection of other viral and non-viral methods such as lentiviral vectors and the PiggyBac transposon system for integration at transcriptionally active sites. We believe that our non-viral system may confer benefits including a reduction of the risk of genotoxicity. Precigen has made significant improvements to the *Sleeping Beauty* system by optimizing gene elements, genetic payload capacity, and efficiency of delivery, which provides a system tailored to our multigenic UltraCAR-T platform. Our AttSite recombinases, which break and rejoin DNA at specific sequences in unidirectional, irreversible fashion to direct integration of a transgene into the host cell genome, allow for stable, site-specific gene integration. The UltraPorator system includes proprietary hardware and software solutions and potentially represents major advancements over current electroporation devices by significantly reducing the processing time and contamination risk. UltraPorator is designed for rapid and cost-effective manufacturing of UltraCAR-T therapies and has the potential to enable rapid manufacturing of a range of gene and cell therapies beyond UltraCAR-T.

Genetically engineered adenoviruses (a common group of viruses) called adenovectors that are designed to insert genes into cells are an important part of our technology platforms. Our AdenoVerse technology platform is composed of a library of engineered adenovector serotypes that yield greater tissue specificity and target selection as compared to known human Ad5 adenovectors. This includes our gorilla adenovectors, which provide a potential competitive advantage with their large payload capacity, ability for repeat administrations and generation of robust antigen-specific immune responses.

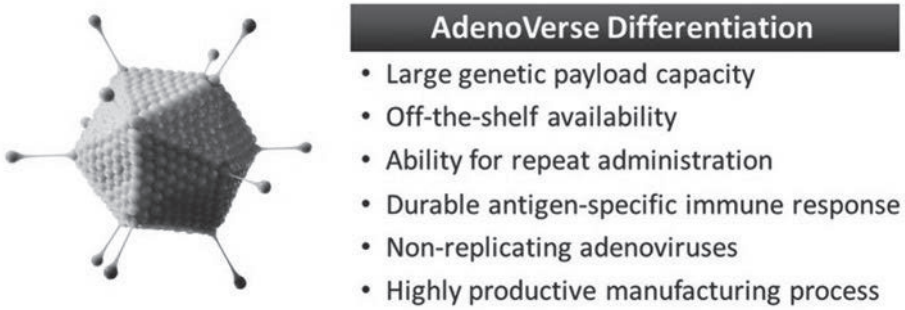
The final component of our approach to precision medicine is our ability to control gene expression and regulation using the RheoSwitch, kill switches, and tissue-specific promoters. The RheoSwitch Therapeutic System, our inducible gene switch system, provides quantitative dose-proportionate regulation of the amount and timing of target protein expression in response to an orally available activator ligand. We have developed kill switches, which allow us to selectively eliminate cell therapies *in vivo* after their administration, to improve their safety profile. We are developing tissue-specific promoters to only induce gene expression locally in cells or tissues of therapeutic interest.

We have leveraged our proprietary and complementary technology platforms discussed above and our expertise in immunology to develop key therapeutic platforms, including UltraCAR-T and AdenoVerse, to address multiple pathways of complex disorders with significant unmet medical needs and to realize our core promise of precision medicine.

Our Therapeutic Platforms

AdenoVerse

Our AdenoVerse platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens. We have established proprietary manufacturing cell lines and production methodologies from our AdenoVerse platform, which we believe are scalable for commercial supply. We believe that our proprietary gorilla adenovectors, part of the AdenoVerse technology, have superior performance characteristics as compared to current competition, including standard human adenovirus serotype 5, or Ad5, rare human adenovirus types and other non-human primate adenovirus types.



The key advantages of AdenoVerse platform include:

Large genetic payload capacity

Our gorilla adenovectors have a larger genetic payload capacity than other viral vectors that currently dominate the gene therapy field, allowing us to engineer multigenic therapeutic candidates to treat complex diseases. Currently, we are able to engineer up to a 12kb genetic payload using our gorilla adenovectors, providing us with an advantage to express multiple genes in a controlled manner.

Repeat administration

Unlike most competing approaches, our gorilla adenovectors are suitable for repeat administration, which can lead to boosted antibody and T-cell responses. This suitability for repeat administration stems from the very low to non-existent seroprevalence of and limited immunity to gorilla adenoviruses in the human population. For example, our gorilla adenovector variant GC46 has been shown to have a seroprevalence of less than 6 percent in the United States, with low seropositive titers. In comparison, the seroprevalence of Ad5 in the United States is estimated to be 58 percent, with most of seropositive individuals having high titers. This high Ad5 seroprevalence limits the effectiveness of Ad5-based adenovectors in clinical studies. The rare and weak pre-existing immunity against gorilla adenovectors may therefore provide an advantage in clinical applications as compared to existing competition.

Replication incompetence

Our gorilla adenovectors are engineered and manufactured using a process that ensures the production of replication incompetent adenoviral therapeutic candidates with no cytopathic or cytotoxic effect in normal human cells. This has been achieved by engineering deletions of two regions essential for replication of the adenoviral genome. The use of a proprietary complementing cell line provides the necessary genetic elements for manufacture of AdenoVerse immunotherapy candidates. We believe our AdenoVerse immunotherapy candidates have reduced regulatory and commercialization risk due to their design, which renders them incapable of replicating and therefore less susceptible to manufacturing failures. Furthermore, our gorilla adenovector manufacturing process has yielded therapeutic candidates at a very high titer and has reduced the complexity of manufacturing.

Durable antigen-specific immune response

Gorilla adenovectors have been shown in preclinical studies 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.

cGMP Manufacturing Facility

We have built internal cGMP manufacturing capabilities for our AdenoVerse-based therapeutics in Germantown, Maryland, with the aim to reduce the risks associated with technology transfer and timing when outsourcing to contract manufacturing organizations. We are able to execute drug substance manufacturing at this facility in an expedited manner at reduced cost compared to contract manufacturing organizations. We expanded our drug substance cGMP manufacturing capabilities at this facility to support the commercial launch of Papzimeos. We will continue to evaluate internal and external strategies to support cGMP manufacturing needs of our AdenoVerse-based therapeutics.

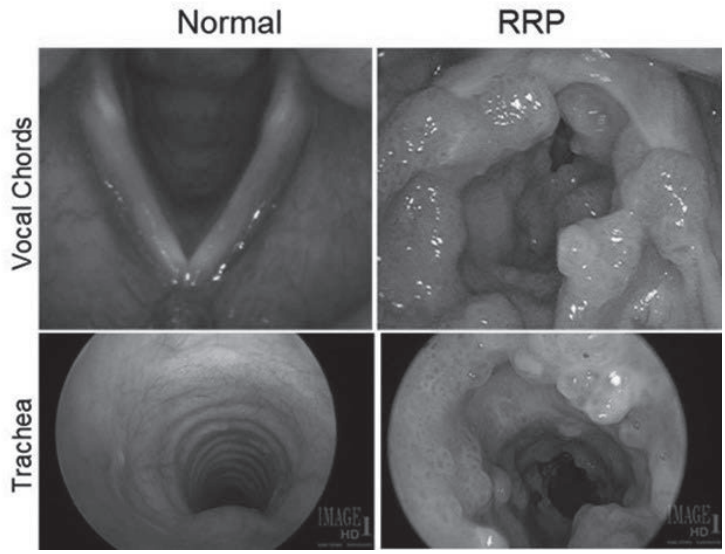
Precigen's most advanced programs based on the AdenoVerse immunotherapy platform include: (i) Papzimeos, a non-replicating adenoviral vector-based immunotherapy designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP; and (ii) PRGN-2009, an investigational off-the-shelf AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-associated cancers, which is in Phase 2 clinical trials for patients with HPV-associated cancers.

Papzimeos (zopapogene imadenovec-drba, PRGN-2012) - Our FDA Approved Commercial Product

Papzimeos (zopapogene imadenovec-drba, PRGN-2012) is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of HPV types 6 and 11 proteins—the root cause of RRP.

RRP is a rare, debilitating, and potentially life-threatening disease of the upper and lower respiratory tract caused by chronic HPV 6 or HPV 11 infection. RRP can lead to severe voice disturbance, compromised airways, and recurrent post-obstructive pneumonia. Although rare, RRP has the potential for transformation to malignant cancer and can be fatal. Management of RRP has primarily consisted of repeated surgeries, which do not address the underlying cause of the disease and can be associated with significant morbidity as well as significant patient and health system burden. As the number of lifetime surgeries increases,

the risk for irreversible iatrogenic laryngeal injury increases with each surgery, and patients may undergo hundreds of these surgeries over their lifetimes. RRP can impact patients' work and social lives, financial stability, and mental health. Patients with RRP can experience substantial impacts to daily living with decreased quality of life and high health care utilization.



In August 2025, FDA granted full approval to Papzimeos for the treatment of adults with RRP. The Papzimeos approval marks a historic milestone for the RRP patient community as the first and only FDA-approved therapy for the treatment of adults with RRP. We completed submission of the rolling Biologics License Application (BLA) in December 2024 under an accelerated approval pathway; however, the FDA has granted Papzimeos full approval. As a result of Papzimeos receiving full FDA approval, a confirmatory clinical trial is no longer required.

The Papzimeos FDA approval was supported by data from the open-label, single-arm, pivotal study in adult patients with RRP:

- The pivotal study successfully met its primary safety and pre-specified primary efficacy endpoints.
- 51% (18 out of 35) of study patients achieved Complete Response, requiring no surgeries in the 12 months after treatment with Papzimeos. These Complete Responses remained durable for over 12 months. Of the 18 patients with a Complete Response in the ongoing study, 15 patients have demonstrated continued Complete Response at median follow-up duration of 36 months.
- Papzimeos was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
- Papzimeos induced HPV 6/11-specific T cell responses in RRP study patients with a significantly greater expansion of peripheral HPV-specific T cells in responders compared with non-responders.

The Pivotal Phase 1/2 clinical trial (clinical trial identifier: NCT04724980) evaluated safety and efficacy of Papzimeos. The study design included an initial 3+3 dose escalation cohort to identify the recommended Phase 2 dose ("RP2D"). Adult RRP patients who had three or more surgeries in the prior 12 months were eligible for the study. The study enrolled a total of 38 patients who were treated with subcutaneous injections of Papzimeos over a 12-week period. Of the 38 patients, 3 patients were treated with Papzimeos at a dose of 1×10^{11} particle units ("PU") per injection. Thirty-five patients were treated at a dose of 5×10^{11} PU per injection and were included in the efficacy evaluation.

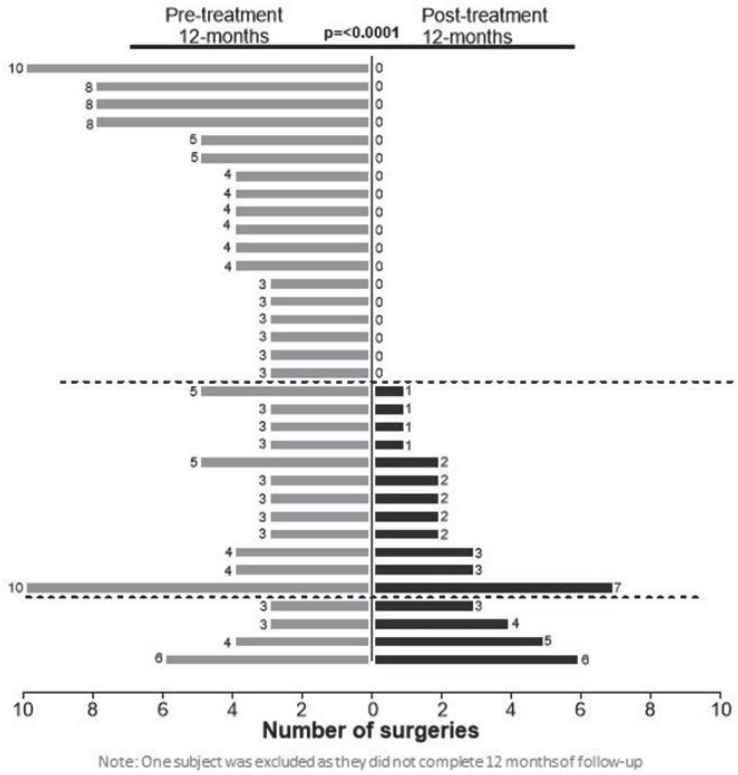
Primary endpoints included safety and Complete Response rate defined as the percentage of patients who require no RRP surgeries in the 12-month period after PRGN-2012 treatment completion.

The demographic characteristics of the population were as follows: the median age was 50 years (range 20 to 88 years), 15 patients (39%) were female, 33 patients (87%) were White, 1 patient (3%) was Asian, 1 patient (3%) was African American, 1 patient (3%) was of “other” race, 2 patients (5%) were of unknown race, and 32 patients (84%) were non-Hispanic or Latino.

The mean (Standard Deviation) BMI was 28 (6) kg/m^2. The median number of baseline surgical procedures performed in the 12 months prior to treatment was 4 (range 3 to 10).

Papzimeos treatment was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events ("TRAEs") greater than Grade 2. All patients received four administrations of Papzimeos at the intended dose levels. TRAEs were mostly mild with no treatment-related serious adverse events reported. The most common adverse reactions (incidence ≥5%) included injection site reaction, fatigue, chills, pyrexia, myalgia, nausea, headache, tachycardia, diarrhea, vomiting and hyperhidrosis.

At a dose of 5×10^{11} PU per injection, 18 out of 35 patients achieved a complete response at 12 months resulting in a complete response rate of 51% [95% confidence interval ("CI") 34 to 69%].



Note: One subject was excluded as they did not complete 12 months of follow-up

Complete responses after Papzimeos treatment have been durable. Of the 18 patients with a complete response in the ongoing study, 15 demonstrated continued complete response with median duration of follow-up at 36 months (range: 27 to 37) as of September 19, 2025 data cutoff date. Median durability of response has yet to be reached.

Papzimeos treatment induced HPV 6/11-specific T cell responses in RRP patients with a significantly greater expansion of peripheral HPV-specific T cells observed in responders compared with non-responders. In 28 patients evaluated at completion of treatment, the induction of HPV 6- and HPV 11-specific T cell responses was higher in RRP patients demonstrating a clinical response to treatment, i.e. reduction in or elimination of the requirement for surgical debulking during the 12 months following completion of treatment, with mean fold-change from baseline of 164.9 versus 5.1 ($p<0.018$). This difference persisted at 12 weeks post-treatment, with mean fold-change of 61.5 in responders versus 11.5 in non-responders.

Following the FDA-approval, we launched Papzimeos in the United States as the first and only FDA approved treatment for adults with RRP. We estimate that there are approximately 27,000 adults patients in the United States living with RRP.

Commercial readiness efforts had been underway prior to the FDA approval of Papzimeos. We had selected Eversana, a leading provider of commercialization services to the global life sciences industry, to support launch strategy and commercialization of Papzimeos in the United States. In the United States, prior to FDA approval and Papzimeos launch, our Medical Science Liaisons had been interacting with health care professionals (“HCPs”) for appropriate scientific exchange related to RRP. Additionally, a team of National Account Directors and Key Account Directors organized many Pre-Approval Information Exchange (PIE) meetings with payers and population health decision makers at large hospital systems, in order to help prepare

for ultimate market entry. We have established Papzimeos Support, a comprehensive patient support program to offer personalized services, including insurance navigation, financial assistance, and ongoing access support. Our field sales team was onboarded and fully deployed immediately following FDA approval, and continues to engage with large Integrated Delivery Networks (IDNs) as well as community physicians treating RRP patients.

Our market access team has successfully secured private health plan coverage with approximately ~215 million lives covered to date, including the majority of leading insurers. Papzimeos is also covered under Medicare and Medicaid. Papzimeos early demand is consistent with internal expectations, with patients being treated nationwide within IDN and community settings.

Papzimeos had been granted Breakthrough Therapy Designation and Orphan Drug designation for the treatment of RRP by the FDA. In addition, zopapogene imadenovec-drba has received Orphan Drug Designation for the Treatment of RRP from the European Commission as well. We submitted a Marketing Authorization Application ("MAA") for zopapogene imadenovec-drba for the treatment of adults with RRP to the European Medicines Agency ("EMA") in November 2025. The MAA has been validated by the EMA and is currently under review.

PRGN-2009

PRGN-2009, an investigational non-replicating adenoviral vector-based immunotherapy, based on our AdenoVerse platform, is designed to activate the immune system to recognize and target HPV+ solid tumors. PRGN-2009 leverages our UltraVector and AdenoVerse platforms to optimize HPV type 16, or HPV16, and HPV type 18, or HPV18, antigen design for delivery via a proprietary gorilla adenovector with a large genetic payload capacity and the ability for repeat administrations. Guided by our bioinformatics analysis and *in silico* protein engineering, PRGN-2009 encodes for a novel, multi-epitope antigen design to target HPV16 and HPV18 infected cells and potentially differentiates from the competition. PRGN-2009 has been engineered using our AdenoVerse platform to be replication deficient *in vivo*.

HPV infections account for 5 percent of all cancers globally, and 690,000 new cancer cases are attributable to HPV infections per year. HPV-related cancers include cervical, oropharyngeal, anal, penile, vaginal, and vulvar. Approximately 39,000 HPV-associated cancers are estimated to occur in the United States each year. HPV is considered responsible for more than 90% of anal and cervical cancers, approximately 75% of vaginal cancers, 70% vulvar cancers, more than 60% of penile cancers, and approximately 70% of cancers of the oropharynx. We have completed a Phase 1 clinical trial of PRGN-2009 as a monotherapy or in combination with bintrafusp alfa, or M7824, an investigational bifunctional fusion protein, for patients with HPV-associated cancers in collaboration with the National Cancer Institute, or NCI, pursuant to a cooperative research and development arrangement, or CRADA.

PRGN-2009 is being evaluated in two Phase 2 clinical trials for patients with newly-diagnosed HPV-associated oropharyngeal cancer cancers in collaboration with NCI pursuant to a CRADA.

The first Phase 2 clinical trial is designed to evaluate PRGN-2009 in combination with anti-PD1 antibody, pembrolizumab, in adult patients with newly-diagnosed HPV-associated oropharyngeal cancer. The primary objective of the study is to determine if there is an increase in CD3+ tumor infiltrating T cells post treatment compared with pre-treatment. Secondary objectives include safety and overall survival. The second Phase 2 clinical trial is designed to evaluate PRGN-2009 in combination with neoadjuvant chemotherapy in adult patients with newly-diagnosed HPV-associated oropharyngeal cancer. The primary objective of the study is to determine the rate of pathological complete response rates in patients receiving neoadjuvant chemotherapy alone or in combination with PRGN-2009. Secondary objectives include safety and recurrence free survival.

PRGN-2009 is also being evaluated in a randomized, open-label Phase 2 clinical trial of in combination with pembrolizumab to treat patients with recurrent or metastatic, or R/M, cervical cancer. Patients in the Phase 2 trial will be randomized 1:1 to the combination of PRGN-2009 and pembrolizumab (cohort 1) or pembrolizumab monotherapy (cohort 2). Patients randomized to the PRGN-2009 plus pembrolizumab cohort will receive PRGN-2009 via subcutaneous (SC) injection (5×10^{11} PU every 3 weeks for three administrations followed by administration each 6 weeks thereafter). Patients in the PRGN-2009 plus pembrolizumab cohort and pembrolizumab monotherapy cohort will receive pembrolizumab via intravenous (IV) infusion (400 mg every 6 weeks). Patients randomized to the pembrolizumab monotherapy cohort will be offered the option to crossover to the PRGN-2009 plus pembrolizumab cohort if certain conditions are met.

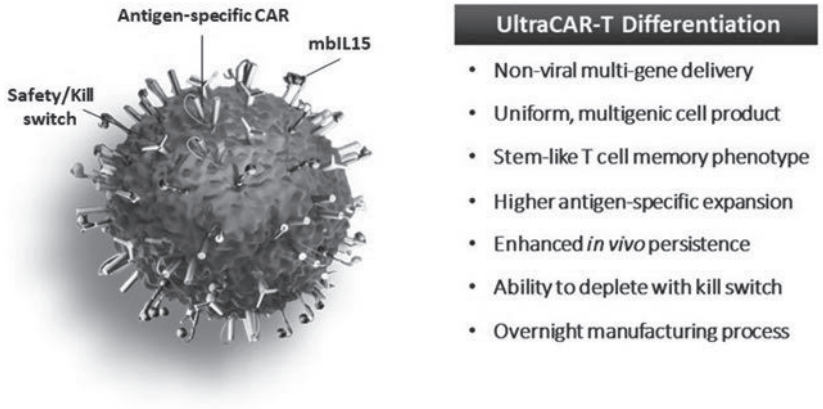
The primary objective of the Phase 2 trial in R/M cervical cancer is to assess the objective response rate (ORR) per RECIST v1.1 following treatment with PRGN-2009 in combination with pembrolizumab or pembrolizumab monotherapy. Secondary objectives include the evaluation of safety and tolerability, progression-free survival (PFS), overall survival (OS), best overall

responses (BOR), Disease Control Rate (DCR), time to response and duration of response. The Phase 2 trial in R/M cervical cancer is enrolling patients with two additional clinical sites active in addition to NCI.

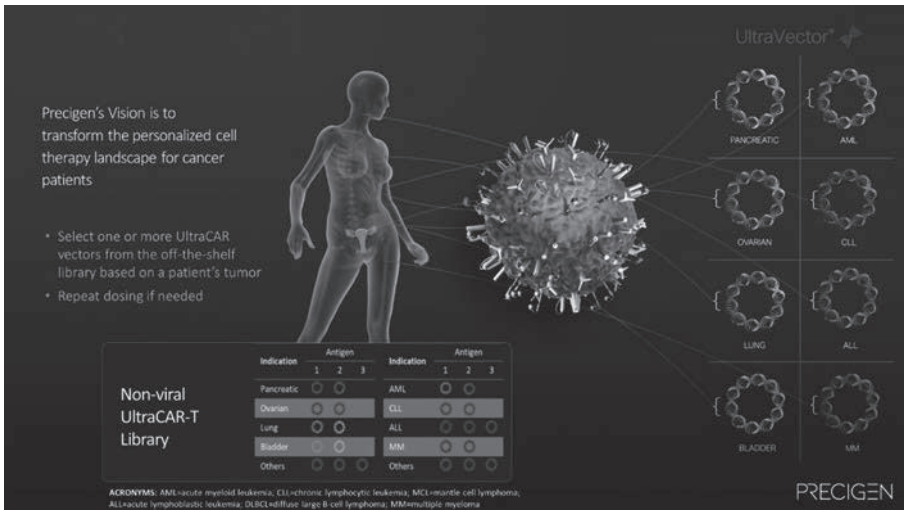
UltraCAR-T

Recent technological advances have revolutionized the field of immunotherapy for the treatment of cancer. Of the many immunotherapy approaches, chimeric antigen receptor T, or CAR-T, cell therapies in particular have shown remarkable responses in cancer patients with hematological malignancies. These therapies rely on the genetic modification of T-cells to express chimeric antigen receptors and enable these modified T-cells to bind to specific antigens on the patient's tumor cells and kill the tumor cells. Concerns remain, however, regarding complex and lengthy manufacturing processes and the safety profile of CAR-T cell therapies. Furthermore, current autologous and allogeneic CAR-T cell therapies face challenges in the treatment of solid tumors due to rapid exhaustion and limited *in vivo* persistence of CAR-T cells. Current approaches to CAR-T manufacturing require extensive *ex vivo* expansion following viral vector transduction to achieve clinically relevant cell numbers. We believe such an *ex vivo* expansion process can result in the exhaustion of CAR-T cells prior to their administration, limiting their potential for persistence in patients after administration. Furthermore, the lengthy and complex manufacturing of current CAR-T approaches results in high manufacturing costs and long delays in providing the CAR-T treatment to cancer patients. Time is of the essence for advanced cancer patients and even modest delays in treatment can adversely affect outcomes.

Our UltraCAR-T platform differentiates from the competition, and we believe it has the potential to address the shortcomings of current technologies and disrupt the CAR-T treatment landscape by increasing patient access through shortening manufacturing time from weeks to days, decreasing manufacturing-related costs, and improving outcomes. We advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. The next generation of UltraCAR-T utilizes a single multicistronic transposon DNA and our overnight, decentralized manufacturing process of UltraCAR-T.



We have introduced our vision for a new UltraCAR-T library approach, which is intended to transform the personalized cell therapy landscape for cancer patients. Our goal is to develop and validate a library of non-viral plasmids to target tumor-associated antigens. Enabled by what we believe to be design and manufacturing advantages of UltraCAR-T, coupled with the capabilities of the UltraPorator system, we are working to empower cancer centers to deliver personalized, autologous UltraCAR-T treatment with overnight manufacturing to any cancer patient. If our goal is realized, one or more non-viral plasmids could be selected based on the patient's cancer indication and biomarker profile from the library to build a personalized UltraCAR-T treatment. After initial treatment, this approach has the potential to allow for redosing of UltraCAR-T targeting the same or new tumor-associated antigens based on the treatment response and the changes in antigen expression of the patient's tumor.



The key advantages of UltraCAR-T versus the traditional CAR-T approaches include:

Advanced non-viral multigenic delivery system

We have optimized and advanced the *Sleeping Beauty* system using our UltraVector DNA construction platform to produce multigenic UltraCAR-T cells. As a result of this optimization, our UltraCAR-T cells are precision-engineered to produce a homogeneous cell product that simultaneously co-expresses antigen-specific CAR, kill switch, and mbIL15 genes in any genetically modified UltraCAR-T cell. We recently introduced the next generation UltraCAR-T platform that addresses the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic downregulation of one or more checkpoint inhibitor, or CPI, genes. This design achieves intrinsic CPI blockade without gene editing and is aimed at avoiding systemic toxicity and the high cost of combining CPI antibodies. The next generation UltraCAR-T cells simultaneously express CAR, mbIL15, and a kill switch, and incorporate intrinsic CPI blockade using a single multicistronic non-viral transposon. This design differentiates our UltraCAR-T platform from the approaches used by our competitors and, we believe, reduces the developmental risk as compared to those approaches because product homogeneity is a critical consideration for later stages of clinical development and subsequent commercialization. We utilize our protein engineering and immunology expertise to optimize antigen binding, hinge, and signaling domains of each CAR based on the target antigen expression profile and cancer indication. We have also included our proprietary kill switch technology in our UltraCAR-T cells to improve the safety profile.

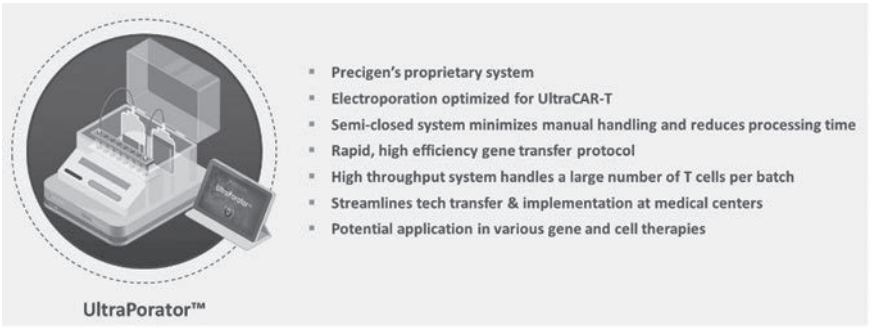
Enhanced persistence and elimination of ex vivo expansion step due to expression of mbIL15

A key driver of improved UltraCAR-T cell performance is mbIL15. The expression of mbIL15 has been shown to enhance *in vivo* expansion of UltraCAR-T cells in the presence of tumor antigens and prevent T-cell exhaustion to maintain a less differentiated, stem-cell like memory phenotype leading to longer persistence of UltraCAR-T cells. This yields an enduring anti-tumor response that has been shown to outlast conventional CAR-T cells in preclinical studies, which we believe is essential to successfully targeting solid tumors. This design allows us to eliminate the need for *ex vivo* expansion prior to administration, a requirement that is a major limitation of current CAR-T treatments.

Scalable, rapid, decentralized manufacturing process

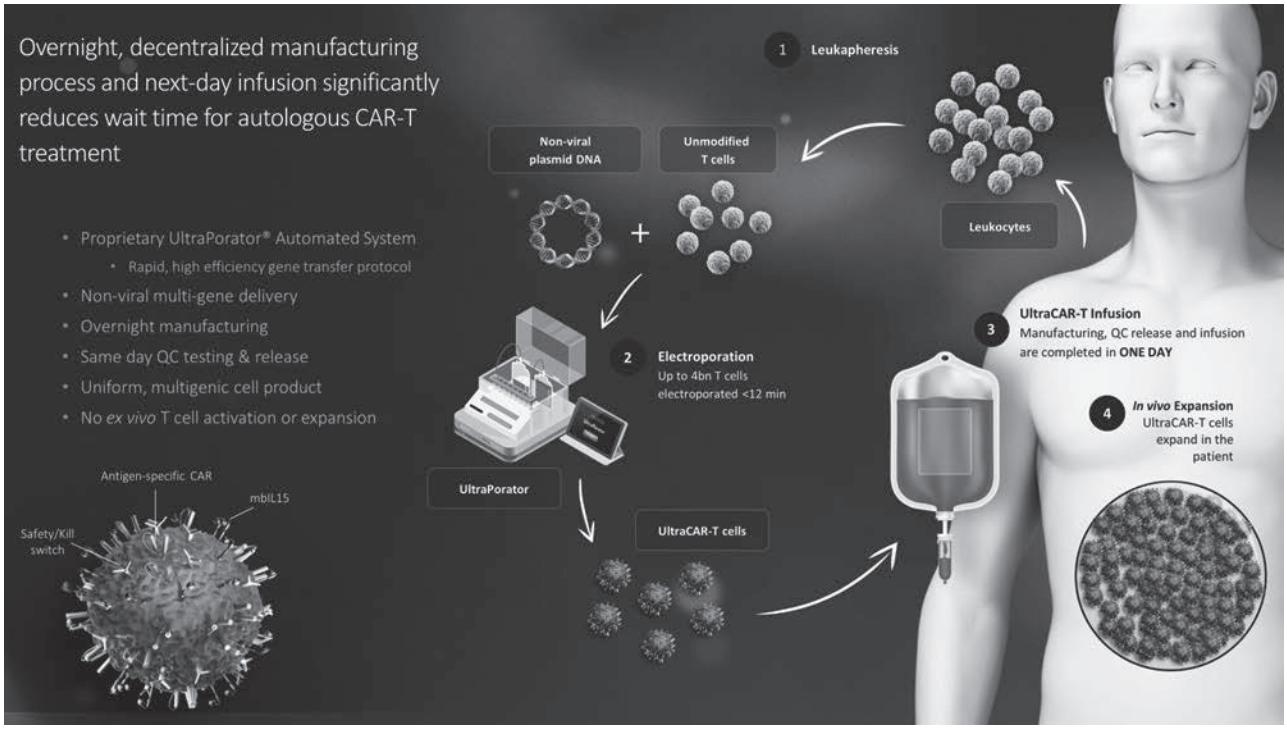
Another key differentiator of the UltraCAR-T therapeutic platform is our rapid and decentralized proprietary manufacturing process, which allows us to manufacture UltraCAR-T cells overnight at a medical center's current good manufacturing practices, or cGMP, facility and reinfuse the patient the following day after gene transfer. This process improves upon current approaches to CAR-T manufacturing, which require extensive *ex vivo* expansion following viral vector transduction that we believe can result in the exhaustion of CAR-T cells prior to their administration, limiting their potential for persistence in patients. The decentralized nature of the manufacturing process allows us to scale beyond the confines of a dedicated facility. We believe we are the first company to validate non-viral, rapid, decentralized manufacturing of CAR-T cells in the clinic by infusing patients one day after gene transfer at two different sites in our ongoing clinical trials. We believe UltraCAR-T is the only autologous CAR-T platform with manufacturing, quality control release and infusion back to the patient, occurring in one day.

We have developed a proprietary electroporation device, UltraPorator, designed to further streamline and ensure the rapid and cost-effective manufacturing of UltraCAR-T therapies. The UltraPorator system, intended to be a viable scale-up and commercialization solution for decentralized UltraCAR-T manufacturing, includes proprietary hardware and software solutions and potentially represents major advancements over current electroporation devices by significantly reducing processing time and contamination risk. The FDA has cleared UltraPorator as a manufacturing device for clinical trials of our UltraCAR-T investigational therapies.



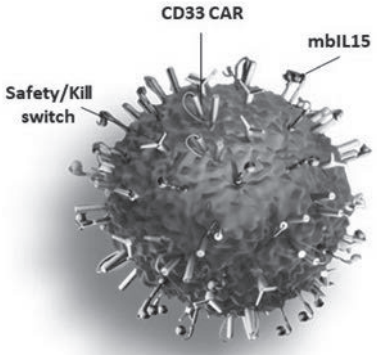
We believe our UltraCAR-T manufacturing process will provide a significant potential competitive advantage in the timeline and cost required to manufacture and deliver CAR-T therapies to patients as compared to current treatment approaches that require large, centralized facilities to support manufacturing of a relatively small number of treatments. We believe development of rapid and successful overnight manufacturing of UltraCAR-T therapies at medical centers signifies a paradigm shift in CAR-T therapy by eliminating manufacturing and timing risks associated with conventional CAR-T therapies, and our intent is for it to take place directly in numerous treatment centers, which can improve the accessibility of our therapies for patients.

Precigen's most advanced program based on the UltraCAR-T platform is PRGN-3006, which has completed enrollment in a Phase 1b clinical trial for patients with relapsed or refractory acute myeloid leukemia, or AML.



PRGN-3006

PRGN-3006 is an investigational autologous CAR-T therapy that utilizes our UltraCAR-T platform to express a CAR to target CD33, mbIL15 and a kill switch for better precision and control.



PRGN-3006 UltraCAR-T

CD33, also known as Siglec-3, is a single pass transmembrane glycoprotein and a member of the sialic acid-binding immunoglobulin-like lectin super-family. CD33 is an attractive target for immunotherapy because it is over-expressed on AML blasts and leukemic stem cells, or LSCs, but is not expressed on normal blood stem cells, also known as hematopoietic stem cells. Approximately 85-90 percent of AML patients express CD33 on their tumor cells. In addition to broad expression on AML blasts, CD33 is expressed on LSCs underlying AML. LSCs are thought to be more resistant to chemotherapy treatment and to be capable of reinitiating the disease resulting in high relapse rates for AML. In healthy subjects, CD33 is primarily expressed on normal myeloid precursors, colony-forming cells, monocytes, and maturing granulocytes. Because CD33 is not expressed outside the hematopoietic system or on normal hematopoietic stem cells, it is an attractive target for treatment of AML.

AML is among the most common types of leukemia in adults with approximately 22,000 AML patients diagnosed in the United States annually. AML is a heterogeneous disease with 50-70 percent relapse rates and rapid progression. The prognosis for patients with AML is poor, with an average five-year survival rate of approximately 25 percent overall, and less than a 5 percent five-year survival rate for patients older than 65. More than 10,000 cases of higher-risk MDS are diagnosed annually in the United States. Due to the aggressive nature of AML progression, rapid availability of treatment is of even greater importance in this patient population, and our non-viral UltraCAR-T manufacturing process would represent a significant potential advantage over current approaches that require long lead times for manufacturing.

PRGN-3006 is in a Phase 1/1b clinical trial designed to enroll in two phases, an initial dose escalation phase (Phase 1) followed by a dose expansion phase (Phase 1b). We have completed Phase 1 dose escalation portion and completed enrollment in Phase 1b portion of the trial. The Phase 1 portion of this study is a dual-arm, non-randomized, dose-escalation clinical trial where PRGN-3006 is delivered via intravenous infusion. The patient population included patients with relapsed or refractory AML, or r/r AML, higher-risk MDS, and CMML. In the Phase 1 3+3 dose escalation portion, patients are treated in one of the two arms: patients in Cohort 1, or No Lymphodepletion arm, receive UltraCAR-T cell infusion without prior lymphodepletion, and patients in Cohort 2, or Lymphodepletion arm, receive lymphodepleting chemotherapy prior to UltraCAR-T infusion. The primary objective included assessment of safety of PRGN-3006 and determination of the MTD.

The Phase 1 study enrolled a total of 26 patients (N=10 non-lymphodepletion; N=16 with lymphodepletion) and included 21 patients with r/r AML, 2 patients with chronic myelomonocytic leukemia (CMML), and 3 patients with MDS. The median age was 60.5 years (range: 32-77). Patients were heavily pre-treated with a median of 3.5 prior regimens (range: 1-9) and 58% of patients (N=15) had prior allogeneic hematopoietic stem cell transplantation (allo-HSCT). Patients treated in the non-lymphodepletion cohort and lymphodepletion cohort received a single administration of 1.8 to 50 x 106 and 4.4 to 83 x 106 UltraCAR-T cells via IV infusion, respectively.

In both the non-lymphodepletion (Cohort 1) and the lymphodepletion (Cohort 2) cohorts, PRGN-3006 was well-tolerated with no dose-limiting toxicities (DLTs) reported. The majority of treatment emergent adverse events (TEAEs) were either Grade 1 or 2. There was only one transient Grade 3 CRS reported in each cohort with the Cohort 2 event subsequently downgraded to Grade 1 by the investigator. Incidence of immune effector cell-associated neurotoxicity syndrome (ICANS) was rare with one Grade 1 event and one Grade 2 event in Cohort 1 and Cohort 2, respectively.

Excellent dose-dependent expansion and persistence of PRGN-3006 in peripheral blood and bone marrow was observed following a single infusion in both the non-lymphodepletion and lymphodepletion cohorts highlighting the ability of UltraCAR-

T cells to engraft and survive even in the absence of lymphodepletion. Higher peak expansion (> 10 fold) in peripheral blood was observed in the lymphodepletion cohort compared to non-lymphodepletion cohort at the same dose level.

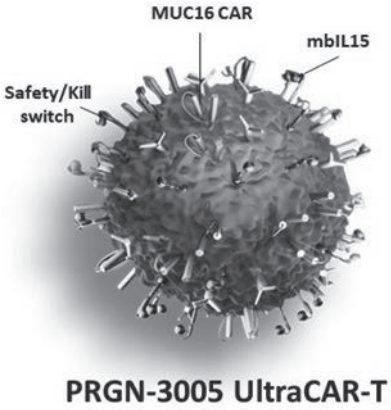
In the lymphodepletion cohort (Cohort 2), an objective response rate (ORR) of 27% (3 out of 11) was reported for heavily pre-treated r/r AML patients with poor prognosis (median prior treatments: 4; range: 1-9). A disease control rate (DCR) of 45% (5 out of 11) was reported at day 28 for r/r AML patients and 100% of MDS patients, respectively. Additionally, of the 15 evaluable patients in the lymphodepletion cohort (Cohort 2), 60% (9 out of 15) heavily pre-treated patients had a reduction in bone marrow blasts following a single PRGN-3006 infusion, with 4 patients experiencing a substantial decrease to ≤5%.

Analysis of peripheral blood samples post PRGN-3006 infusion showed gene expression changes consistent with improvement in the immune compartment function for anti-tumor effect in responders. There was an increase in cytotoxicity, costimulatory signaling, and lymphoid compartment and decreased apoptosis pathway scores in the lymphodepletion cohort on Days 14 and 28 post PRGN-3006 treatment compared to baseline. Based on the results of correlative studies of the patient samples from the Phase 1/1b study, we have identified clinical biomarkers that correlate to objective responses after PRGN-3006 treatment in r/r AML patients. This advancement may further enable patient stratification and positively impact efficacy.

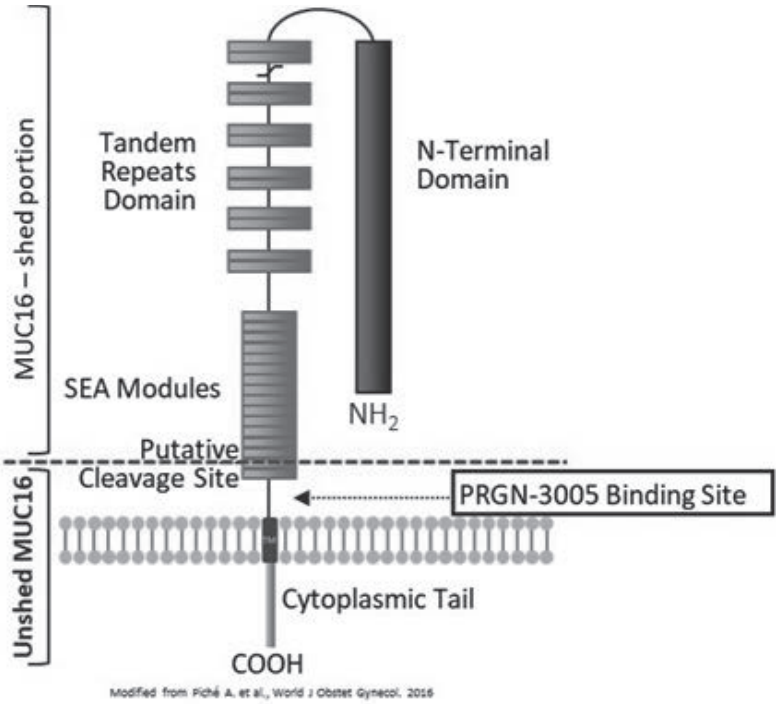
We have completed enrollment in the Phase 1b dose expansion study. We are preparing for an end of Phase 1b meeting with the FDA to discuss the results and next steps. We plan to focus on strategic partnership opportunities to advance PRGN-3006 UltraCAR-T program in AML. PRGN-3006 has been granted Orphan Drug designation in patients with AML and Fast Track Designation in patients with r/r AML by the FDA.

PRGN-3005

PRGN-3005 is an investigational autologous CAR-T therapy that utilizes our UltraCAR-T platform to simultaneously express a CAR targeting the unshed portion of the Mucin 16 antigen, or MUC16, mbIL15, and kill switch genes.



MUC16 is an extremely large, type I transmembrane cell surface glycoprotein that plays a key role in the pathogenesis of ovarian cancer by promoting an increase in cell proliferation, metastasis, resistance to chemotherapy and immune system evasion by cancer cells. MUC16 is overexpressed on more than 80 percent of ovarian tumors but has limited expression in healthy tissues, making it an attractive CAR-T target for ovarian cancer. Other cancers with known overexpression of MUC16 include pancreatic, breast, endometrial, lung, and bladder cancers. MUC16 undergoes proteolytic cleavage in the extracellular domain resulting in shedding of a large portion of extracellular domain, termed CA125, from the cell surface and leaving only a short, unshed extracellular domain tethered to the cell surface. Therapies that target the region of MUC16 that is shed from the cell surface may have limited effectiveness due to their binding to CA125 in circulation which is not associated with tumor cells. In order to eliminate binding to circulating CA125, we have designed our MUC16 CAR using an antigen binding domain that specifically binds the unshed portion of MUC16 and optimized its affinity to preferentially target PRGN-3005 to tumor cells.



Advanced ovarian cancer is often fatal, with Stage IV survival rates as low as 20 percent, and has limited treatment options. Patients with ovarian cancer represent a large population, with approximately 325,000 patients diagnosed worldwide annually, including approximately 21,000 in the United States alone.

PRGN-3005 is in a 1/1b clinical trial designed to enroll in two phases, an initial dose escalation phase (Phase 1) followed by a dose expansion phase (Phase 1b). We have completed the Phase 1 dose escalation portion of the PRGN-3005 Phase 1/1b study. The Phase 1 portion of the study is a dual-arm, non-randomized, open-label clinical trial in patients with advanced, recurrent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer. Patients in the Phase 1 dose escalation trial received either intraperitoneal, or IP (Arm 1), or intravenous, or IV (Arm 2), administration of PRGN-3005 without prior lymphodepletion. After receiving FDA clearance, we incorporated a cohort with lymphodepletion at Dose Level 3 of the IV arm in the Phase 1 study. The primary objectives of the Phase 1 trial included assessment of safety and maximum tolerated dose, or MTD, of PRGN-3005.

The Phase 1 study enrolled a total of 27 patients (N=12 IP; N=6 IV; and N=9 IV with lymphodepletion). Patients were heavily pretreated with a median of greater than or equal to 8 prior lines of therapy across all arms. Patients had significantly advanced stage disease with a high baseline tumor burden with most patients having distant metastases, including liver, spleen, bladder and lung.

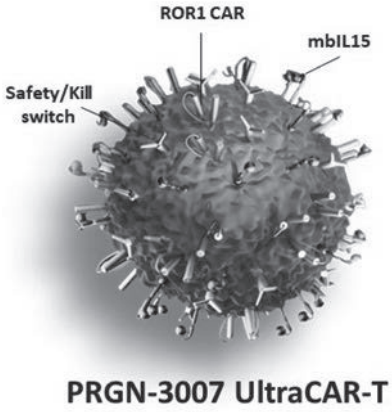
PRGN-3005 treatment was well-tolerated with low incidence of treatment related adverse events (TRAEs), no dose limiting toxicities (DLTs), and no neurotoxicity. The most common side effects for the IV and IP arms without lymphodepletion were abdominal pain, fever and decreased absolute lymphocyte count (ALC). Serious Adverse Events included five incidences of Cytokine Release Syndrome (CRS), with no incidence of CRS greater than Grade 2. One patient with CRS required specific intervention which was resolved following standard CRS management after 24 hours. There was no use of tocilizumab or dexamethasone or kill switch.

PRGN-3005 administered via either IP or IV infusion resulted in a dose-dependent expansion and encouraging persistence in peripheral blood. Best responses in patients treated without lymphodepletion were stable disease with complete responses observed in certain individual target lesions. Incorporating lymphodepletion prior to IV infusion led to an encouraging anti-tumor activity with a decrease in tumor burden in 67% (6/9) of patients and stable or partial response in 90% of the individual target lesions in these patients.

Subsequently, we initiated the Phase 1b dose expansion study of PRGN-3005 UltraCAR-T at Dose Level 3 with lymphodepletion prior to IV infusion. As part of the strategic prioritization of our pipeline announced in August 2024, we have paused enrollment in the Phase 1b clinical trial of PRGN-3005.

PRGN-3007

PRGN-3007 is an investigational autologous CAR-T therapy that utilizes the next generation UltraCAR-T platform to express a CAR to target ROR1, mbIL15, kill switch, and a novel mechanism for the intrinsic blockade of the programmed death 1, or PD-1, gene expression.



ROR1 is a type I orphan-receptor that is expressed during embryogenesis and by certain hematological and solid tumors but is undetectable on normal adult tissues. ROR1 in malignancies is aberrantly expressed in B-cell malignancies such as B-cell acute lymphoblastic leukemia, or B-ALL, diffuse large cell B-cell lymphoma, or DLBCL, chronic lymphocytic leukemia, or CLL, and mantle cell lymphoma, or MCL. Furthermore, upregulated expression has been detected in various solid tumors, including ovarian cancer, breast adenocarcinomas encompassing triple negative breast cancer, or TNBC, pancreatic cancer, Ewing's sarcoma and lung adenocarcinoma. The increased expression of ROR1 in hematological and solid tumor malignancies has been associated with tumor proliferation, metastasis and poor clinical outcomes.

The PD-1/programmed death ligand 1, or PD-L1, pathway plays a vital role in how tumor cells evade immune response. While the blockade of the PD-1/PD-L1 pathway has demonstrated considerable benefit for treating various cancers, the use of systemic CPI can lead to side effects associated with autoimmune response. The innovative design of PRGN-3007, where the blockade of PD-1 expression is intrinsic and localized to UltraCAR-T cells, is aimed at avoiding systemic toxicity and the high cost of CPI by eliminating the need for combination treatment.

The Phase 1/1b clinical trial is designed as an open-label study designed to evaluate the safety and efficacy of PRGN-3007 in patients with advanced ROR1^{+} hematological (Arm 1) and solid (Arm 2) tumors. The target patient population for Arm 1 includes relapsed or refractory CLL, relapsed or refractory MCL, relapsed or refractory B-ALL, and relapsed or refractory DLBCL. The target patient population for Arm 2 includes locally advanced unresectable or metastatic histologically confirmed TNBC. The study will enroll in two parts: an initial 3+3 dose escalation in each arm followed by a dose expansion at the maximum tolerated dose. As part of the strategic prioritization of our pipeline announced in August 2024, we have paused enrollment in the Phase 1 clinical trial of PRGN-3007.

Preclinical Programs

We have a robust pipeline of preclinical programs in order to drive long-term value creation. Our pipeline includes product candidates based on UltraCAR-T and "off-the-shelf" AdenoVerse immunotherapy therapeutic platforms. We expect to continue development of a number of potential product candidates in our preclinical pipeline and, consistent with our commitment to actively manage our portfolio programs, we exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid "go" and "no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials.

Precigen ActoBio (ActoBio)

ActoBio developed a proprietary class of microbe-based biopharmaceuticals designed to enable expression and local delivery of disease-modifying therapeutics. We refer to these microbe-based biopharmaceuticals as ActoBiotics. In 2024, the Company completed the shutdown of ActoBio's operations. ActoBio’s lead asset, AG019, is a disease modifying antigen-specific, investigational immunotherapy for the prevention, delay, or reversal of type 1 diabetes mellitus, or T1D. We have completed a Phase 1b/2a clinical trial of AG019 in patients with early-onset T1D. In connection with the shutdown of ActioBio's operations, ActoBio's portfolio of intellectual property is now available for prospective transactions.

Precigen Exemplar

Exemplar is committed to enabling the study of life-threatening human diseases through the development of MiniSwine Yucatan miniature pig research models and services. Historically, researchers have lacked animal models that faithfully represent human diseases. As a result, a sizeable barrier has blocked progress in the discovery of human disease mechanisms; novel diagnostics, procedures, devices, prevention strategies and therapeutics; and the ability to predict in humans the efficacy of those next-generation procedures, devices, and therapeutics. Exemplar's MiniSwine models are genetically engineered to exhibit a wide variety of human disease states, which provides a more accurate platform to test the efficacy of new medications and devices.

As of December 31, 2025, Exemplar had 20 employees. Exemplar's primary domestic production facilities are located in Sioux County and Johnson County, Iowa, and include approximately 57,711 square feet of production, lab, and office facilities.

Competition: Healthcare Business

While we believe that our novel approach to developing innovative precision medicines utilizing our AdenoVerse and UltraCAR-T platforms to target the most urgent and intractable challenges in immuno-oncology, autoimmune disorders, and infectious diseases provides us with competitive advantages, our industry is highly competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical, and human resource capabilities than we do, and certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. In addition, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of the resources available to our competitors, our competitors may be able to develop competing and/or superior technologies and processes, and compete more aggressively and sustain that competition over a longer period of time than we can.

Product candidates that we successfully develop and commercialize will compete with a range of therapies that are currently approved and any new therapies that may become available in the future. Our ability to compete successfully will depend on our ability to develop proprietary technologies that can be used to produce products that reach the market in a timely manner and are technologically superior to and/or are less expensive than other products on the market. The availability of reimbursement from government and other third-party payers will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products, as well as the availability of intellectual property protection.

AdenoVerse Immunotherapy

While we believe that our FDA-approved product Papzimeos for the treatment of RRP, is based on a novel design of antigen targeting HPV6 and HPV11 and use of our gorilla adenovector, we face competition in the treatment of RRP. We believe our main competitor in the field is INOVIO Pharmaceuticals. INOVIO is developing their investigational DNA vaccine INO-3107, which is delivered via use of an electroporation device and targets HPV6 and HPV11 antigens. The BLA for INO-3107 is currently under review by the FDA. In addition we believe that academic investigator initiated clinical trials to evaluate bevacizumab and pembrolizumab for RRP are in progress.

For our PRGN-2009 candidate in HPV-associated cancers, we believe that INOVIO Pharmaceuticals, BioNTech SE, PDS Biotechnology, NeoTrail Therapeutics, Nykode Therapeutics, and ViciniVax B.V. are developing immunotherapies that are in clinical testing. INOVIO's lead investigational candidate VGX-3100 is a plasmid DNA based vaccine, delivered via an electroporation device, is designed to increase T cell immune responses against the E6 and E7 antigens of HPV16 and HPV18. VGX-3100 is in clinical trials for anal dysplasia. INOVIO is also developing INO-3112, a DNA medicine candidate targeting HPV 16/18 and delivered via an electroporation device, combined with a DNA plasmid for IL-12 in combination with an anti-PD1 monoclonal antibody for locoregionally advanced, high-risk, HPV16/18 positive oropharyngeal squamous cell carcinoma. We believe BioNTech is developing BNT113, an investigational HPV16 E6/7 mRNA vaccine. We believe BNT113 in combination with an anti-PD1 monoclonal antibody is in a clinical trial for HPV16+PD1+ Head and Neck squamous cell carcinoma. We believe PDS Biotechnology is developing Versamune® HPV (previously PDS0101), an investigational HPV16 peptide vaccine for various HPV-associated cancers. We believe Versamune HPV is in clinical trials as monotherapy and combination therapy for recurrent/metastatic HPV16+ head and neck cancer, pre-metastatic HPV-associated oropharyngeal cancer, and HPV+ anal, cervical, head and neck, penile, vaginal, vulvar cancers. We believe NeoTrail Therapeutics is developing Eseba-vec (HB-200), acquired from Hookipa Pharma, based on two single-vector compounds with arenaviral backbones based on lymphocytic choriomeningitis virus and pichinde virus expressing the same transgene encoding an HPV16 E7E6 fusion protein, which is in a clinical trial for HPV16+ head and neck cancers. Cellid is developing BVAC-C, which is

based on CeliVax technology that uses patient-derived B cells and monocytes transfected with E6/E7 recombination gene of HPV16 and HPV18 and loaded with an adjuvant for HPV-associated cancers. Nykode Therapeutics is developing abi-suva (VB10.16), a DNA-based therapeutic vaccine targeting malignancies caused by HPV16, which is being evaluated in a clinical trial for HPV16-positive Head and Neck Squamous Cell Carcinoma. ViciniVax B.V. is developing Vvax001, a T-cell–priming immunotherapy based on a self-amplifying RNA (saRNA) replicon delivered by a replication-incompetent Semliki Forest virus (SFV) vector encoding fusion HPV16 E6 and E7 protein is in a clinical trial.

In addition to our direct competitors developing vaccines for treatment of HPV-associated cancers, various development-stage companies are involved in different vaccine and immunotherapy technologies, including Bavarian Nordic. We also face competition from non-vaccine based approaches being developed by companies such as Kite, Iovance, Bristol-Myers Squibb, and Merck.

UltraCAR-T

Our lead product candidates include PRGN-3005, PRGN-3006, and PRGN-3007, each of which are built on our UltraCAR-T platform. While we are employing a novel approach, there are a number of competitors pursuing CAR-T cell therapies for the treatment of cancer. We believe that, among others, Regeneron Pharmaceuticals, and Anixa Biosciences are developing CAR-T based treatments for ovarian cancer and US WorldMeds is developing TCR-T based treatment for ovarian cancer. We believe that Essen Biotech, Senti Bio and Allogene Therapeutics are using cell therapy technologies to develop product candidates for the treatment of AML.

Regeneron Pharmaceuticals is developing 27T51(BBT-4015), which we believe is under development in Phase 1 clinical trial for the treatment of epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. 27T51 is based on autologous T cells modified with a lentiviral vector to express a CAR targeting cells expressing MUC16. Anixa Biosciences is developing an autologous CAR-T treatment targeting follicle stimulating hormone receptor (FSHR) for ovarian cancer, which we believe is in a clinical trial. Arsenal Biosciences is developing AB-1015 CAR-T, which we believe is in a clinical trial for platinum resistant ovarian cancer. US WorldMeds is developing uza-cel (ADP-A2M4CD8) TCR T-cell therapy that co-expresses CD8α co-receptor alongside the engineered TCR targeting MAGE-A4 which we believe is in a Phase 1clinical trial. For the treatment of AML using cell therapies, we believe that Kite, 2seventy bio and Nkarta have product candidates in the most advanced clinical trials. We believe Arcellx is developing ACLX-002, CAR-T targeting CD123 based on ARC-SparX platform. We believe Allogene Therapeutics' allogeneic CAR-T therapy ALLO-316, targeting CD70 is manufactured using healthy donor T-cells that are engineered using lentiviral transduction to express CAR followed by gene editing to eliminate expression of TCR, is in preclinical development for CD70+ heme malignancies. Senti Bio is developing SENTI-202 an off-the-shelf logic-gated selective CD33 or FLT3 targeted CAR-NK cell therapy, which we believe is in early phase clinical trial for AML. Essen Biotech is developing a CAR-T therapy that targets CD33 or CD123 or both, which we believe is in a Phase 1/2 clinical trial for AML.

In addition to our direct competitors that are using CAR-T therapies specifically for the treatment of ovarian cancer and AML, the CAR-T technology space has significant other competition including from multiple companies and their collaborators, such as Novartis, Kite and Gilead, Bristol-Myers Squibb, Janssen and Legend Biotech, US WorldMeds, Autolus Therapeutics, Roche and Poseida Therapeutics, and Gracell and AstraZeneca. Various companies including AstraZeneca and EsoBiotec, Eli Lilly and Orna Therapeutics and Interius BioTherapeutics are evaluating *in vivo* CAR-T cell therapies. We also face competition from non-cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Merck, Abbvie, and Roche.

See "Precigen's Therapeutic Platforms" for a discussion of the features that we believe differentiate our UltraCAR-T treatments from our competitors.

Exemplar

Precigen Exemplar provides porcine research models and services that aid scientists in the understanding of human disease mechanisms and development of new therapeutics. We use precise genome modification to recapitulate numerous human diseases in our Yucatan MiniSwine platform, which are utilized by our industry and academic clientele for the development of new small molecules, gene, and cell therapies. We believe that the primary competitors of Exemplar are smaller privately owned entities.

Intellectual Property

We apply a multilayered approach for protecting intellectual property relating to the inventions we have developed internally, as well as those we have acquired from third parties, such as by assignment or by in-license. As we advance technologies, we evaluate and determine under the circumstances what type or types of intellectual property is appropriate for the technology, including patents, trademarks, know-how and trade secret protections. We seek patent protection in the United States and in other countries for our inventions, and we develop and protect our know-how and trade secrets relating to our platform technologies, as well as to our pipeline products including those of our subsidiaries and collaborators.

For instance, we pursue protection to switch technologies, gene delivery technologies, and genetic componentry related to our pipeline products. In addition, we seek patents covering specific collaborator's products.

We focus our intellectual property on aspects of our platforms and technologies that provide for the design and creation of cells, vectors and components for our pipeline and the pipelines of our collaborators, as well as technologies directed to improve delivery and expression of our pipeline products.

Our success depends, in part, upon our ability to obtain patents and maintain adequate protection for our intellectual property relating to our technologies and product pipeline. We have adopted a strategy of seeking patent protection in the United States and in other jurisdictions globally as we deem appropriate under the circumstances, with respect to certain of the technologies used in or relating to our technologies and product pipeline. For instance, where we believe appropriate, we have counterpart patents and patent applications in other jurisdictions, such as Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, Oman, Qatar, Saudi Arabia, Singapore, South Africa, Taiwan, and United Arab Emirates. In the future, we may file in these or additional jurisdictions as deemed appropriate for the protection of our technologies.

As of December 31, 2025, we owned or in-licensed patents in the United States and have pending United States patent applications relating to various aspects of our platforms and technologies, and we have pursued counterpart patents and patent applications in other jurisdictions around the world, as we have deemed appropriate. We continue to actively develop our portfolio through the filing of new patent applications, provisional and continuations or divisionals relating to our advancing technologies, methods and products as we and our collaborators deem appropriate.

We work to maintain protection for our key technologies including: our various switch technologies, with a last to expire patent currently in 2032; our portfolio around various gene delivery technologies and their use, with a last to expire patent in 2046; and our portfolio around various genetic componentry such as specialized vectors containing these genetic componentry and their use, with a last to expire patent in 2044. Although we have no certainty that these patents will not be subject to challenge in the future, as of this filing, there are currently no material contested proceedings and/or third-party claims with respect to any of these patent portfolios.

Additionally, we complement our intellectual property portfolio with exclusive and non-exclusive patent licenses and options for licenses to third-party technologies.

We further solidify our intellectual property protection through a combination of trade secrets, know-how, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information related to each platform and collaborator program. We regularly assess and review the risks and benefits of protecting our developments through various aspects of intellectual property available to us.

Because we rely on trade secrets, know-how, and continuing technological advances to protect various aspects of our technology, we require our employees, consultants and scientific collaborators to execute confidentiality and invention assignment agreements with us to maintain the confidentiality of our trade secrets and proprietary information. Our confidentiality agreements generally provide that the employee, consultant or scientific collaborator will not disclose our confidential information to third parties. These agreements also provide that inventions conceived by the employee, consultant or scientific collaborator in the course of working for us will be our exclusive property. Additionally, our employees agree to

take certain steps to facilitate our assertion of ownership over such intellectual property. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technologies, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have.

Regulatory Environment

With our diverse portfolio of proprietary technologies and novel therapeutic candidates, we are subject to significant and diverse regulations governing, among other things, research, operations and product approval. Regulatory compliance is critical to our ability to operate, our management of potential liabilities, and ultimately, our freedom to sell our products. Moreover, the products we are pursuing or are produced by us are subject to extensive regulation. Moreover, to the extent we utilize, now and in the future, third party service providers or license our programs to collaborators, we will need to rely on such third parties' compliance with laws and regulations applicable to the products or services they provide. We may not be able to independently monitor whether such third parties comply with applicable laws and regulations. Please see the risk factor entitled "We may rely on third parties, including through collaborations, to develop and commercialize some of our product candidates. Markets in which our collaborators develop product candidates using our technologies are subject to extensive regulation, and we will rely on our collaborators to comply with all applicable laws and regulations."

Environmental regulations affecting our business

We are subject to various federal, state and local environmental laws, rules and regulations, including those relating to the discharge of materials into the air, water and ground; the generation, storage, handling, use, transportation and disposal of hazardous materials; and the health and safety of employees with respect to laboratory activities required for the development of products and technologies. These laws and regulations require us to obtain environmental permits and comply with numerous environmental restrictions. These laws and regulations also may require expensive pollution control equipment or operational changes to limit actual or potential impacts to the environment.

Our laboratory activities inherently involve the use of potentially hazardous materials, which are subject to health, safety and environmental regulations. We design our infrastructure, procedures, and equipment to meet our obligations under these regulations. We perform recurring internal and third-party audits and provide employees ongoing training and support, as required. All of our employees must comply with safety instructions and procedures, which are codified in our employment policies. Federal and state laws and regulations impose requirements on the production, importation, use, and disposal of chemicals and genetically-modified material which impact us. Our processes may contain genetically engineered organisms which, when used in industrial processes, are considered new chemicals under the Toxic Substances Control Act program of the United States Environmental Protection Agency, or EPA. These laws and regulations would require us to obtain and comply with the EPA's Microbial Commercial Activity Notice process to operate. In the European Union, we may be subject to a chemical regulatory program known as REACH (Registration, Evaluation, Authorization and Restriction of Chemical Substances). Under REACH, companies are required to register their products with the European Commission, and the registration process could result in significant costs or delay the manufacture or sale of products in the European Union.

Healthcare regulations affecting our business

Human therapeutics regulation

Governmental authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, sale, marketing, import and export of therapeutic products such as those being developed by us. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes, regulations, and requirements imposed by regulatory agencies, require the expenditure of substantial time and financial resources.

In the United States, pharmaceuticals and biological products must receive approval from the FDA before being marketed. The FDA approves drug products other than biological products through its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The FDA licenses biological products, or biologics, through its authority under the Public Health Service Act, or PHSA, and implementing regulations. The development processes for obtaining FDA approval for a non-biological drug product under the FDCA and for biologic licensure under the PHSA are generally similar but have product-related differences reflected in regulations and in FDA guidance documents.

United States pharmaceutical development process

The process required by the FDA before a pharmaceutical product candidate may be marketed generally involves the following:

- completion of preclinical laboratory tests and *in vivo* studies in accordance with applicable regulatory requirements, which may include the FDA's current Good Laboratory Practice regulations and the Animal Welfare Act;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence;
- performance of adequate and well-controlled human clinical trials according to the FDA's Good Clinical Practices, or GCP, regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product candidate for each intended use;
- preparation and submission to the FDA of an application for marketing approval that includes substantial evidence of safety, purity and potency for a biologic, or of safety and efficacy for a non-biologic drug, including from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with cGMP and that the methods and controls are adequate to assure the product candidate's identity, safety, strength, quality, potency and purity;
- potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the application; and
- FDA review and approval of the application.

Preclinical testing

Before testing any product candidate in humans in the United States, a company must develop preclinical data, generally including laboratory evaluation of the product candidate's chemistry and formulation, as well as toxicological and pharmacological studies in animal species to assess safety and quality. Certain types of animal studies must be conducted in compliance with the FDA's Good Laboratory Practice regulations and the Animal Welfare Act, which is enforced by the Department of Agriculture.

IND application

A person or entity sponsoring clinical trials in the United States to evaluate a product candidate's safety and effectiveness must submit to the FDA, prior to commencing such trials, an IND application, which contains preclinical testing results and other data and information that allow the FDA to evaluate whether there is an adequate basis for testing the drug in humans. If the FDA does not object to the IND application within 30 days of submission, the clinical testing proposed in the IND may begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may put clinical trials on "clinical hold," suspending or, in some cases, ending them because of safety concerns or for other reasons.

Human clinical trials under an IND

Clinical trials involve administering the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials must be conducted and monitored in accordance with the FDA's regulations, such as GCP requirements. Each clinical trial must also be conducted under a protocol that details, among other things, the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency. Further, each clinical trial must be reviewed and approved by an Institutional Review Board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers, among other things, whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The sponsor of a clinical trial, the investigators, and IRBs each must comply with requirements and restrictions that govern, among other things, obtaining informed consent from each study subject, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting adverse events. Clinical trials involving recombinant or synthetic nucleic acid molecules, such as DNA, conducted at institutions that receive any funding from the National Institutes of Health also must be reviewed by

an institutional biosafety committee, an institutional committee that reviews and oversees basic and clinical research that utilizes recombinant DNA at that institution.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as *clinicaltrials.gov*.

Human clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The product candidate is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain early understanding of its effectiveness. For some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease.

- *Phase 2*. The product candidate is administered and evaluated in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminary efficacy evidence for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. The product candidate is administered to an expanded patient population with the target disease or disorder, often at geographically dispersed clinical trial sites, in adequate and well-controlled clinical trials to generate sufficient data to evaluate the safety and efficacy of the non-biologic drug, or the safety, purity, and potency of the biologic. These clinical trials are intended to establish the overall risk/benefit profile of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted, or may be required to be conducted, after initial approval to further assess the risk/benefit profile of the product and to gain additional experience from treatment of patients in the intended indication, including for long-term safety follow-up.

Additional regulation for gene therapy clinical trials

Additional standards apply to clinical trials involving gene therapy. The FDA has issued guidance documents regarding gene therapies, which relate to, among other things: preclinical assessments; chemistry, manufacturing and controls, or CMC, information that should be included in an IND application; the proper design of tests to measure product potency in support of an application; and long-term follow-up measures to observe delayed adverse effects in subjects exposed to investigational gene therapies when the risk of such effects is not low or when the gene therapy utilizes genome-editing technology, shows signs of persistence, has the potential for latency and reactivation, or genetically alters the human genome.

United States review and approval processes

The results of the preclinical tests and clinical trials, together with detailed information relating to the product's CMC and proposed labeling, among other things, are submitted to the FDA as part of an application requesting approval to market the product for one or more uses, or indications. When an application is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. If the application is not, the FDA may refuse to accept the application for filing and request additional information. A refusal to file, which requires resubmission of the application with the requested additional information, delays review of the application. For gene therapies, selecting patients with applicable genetic defects is often a necessary condition to effective treatment and may require diagnostic devices that the FDA has cleared or approved prior to or contemporaneously with approval of the gene therapy.

Under the Pediatric Research Equity Act, or PREA, certain marketing applications generally must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any product candidate for an indication for which orphan designation has been granted.

On the basis of the marketing application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA

to reconsider the application. If those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA may issue an approval letter.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. In addition, the FDA may require postmarketing clinical trials designed to further assess the risk/benefit profile of the product and to gain additional experience from treatment of patients in the intended indication, including for long-term safety follow-up.

Compliance with cGMP requirements

Drug and biologics manufacturers must comply with applicable cGMP regulations. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing of drugs. Establishments may be subject to periodic, unannounced inspections by the FDA and other government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved product application and may extend to requiring withdrawal of the product from the market.

Orphan Drug Designation in the United States

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs and biological products intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a marketing application or supplement seeking approval for the orphan indication. After the FDA grants orphan drug designation, the common identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA.

Orphan drug designation does not—by itself—convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for that drug or biologic for the indication for which it has been designated, the product is entitled to an orphan exclusivity period in which the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years.

Exceptions to the seven-year exclusivity period may apply in limited circumstances, such as where the sponsor of a different version of the product is able to demonstrate that its product is clinically superior to the approved orphan drug product. This exclusivity does not prevent a competitor from obtaining approval to market a different product that treats the same disease or condition, or the same product to treat a different disease or condition. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the holder of the approved orphan drug application is unable to assure the availability of sufficient quantities of the drug to meet patient needs. Orphan exclusivity operates independently from other regulatory exclusivities and other protections against generic or biosimilar competition.

A sponsor of a product application that has received an orphan drug designation is also granted tax incentives for clinical research undertaken to support the application. In addition, the FDA may coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required, based on the limited size of the applicable patient population. Orphan drug designation does not, however, change the legal standard required for a product candidate to obtain FDA approval.

Fast Track Designation

The FDA has a number of expedited review programs for drugs that are intended for the treatment of a serious or life-threatening condition. As one example, under the agency's Fast Track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND for the product candidate, if nonclinical and clinical data demonstrate the product's potential to address unmet medical needs and the product is intended to treat a serious condition. The FDA must determine if the product candidate qualifies for Fast Track designation within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the agency may initiate review of sections of a Fast Track product's marketing application before the application is complete. This rolling review is available if

the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's review period for a Fast Track application does not begin until the last section of the marketing application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

Regenerative Medicine Advanced Therapy Designation

The FDA may grant regenerative medicine advanced therapy, or RMAT, designation to regenerative medicine therapies, which may include cell therapies, human gene therapies, therapeutic tissue engineering products, and human cell and tissue products, if certain criteria are met. In particular, a drug may be eligible for RMAT designation if the drug is a regenerative medicine therapy as defined in Section 506(g)(8) of the FDCA; the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease and condition. The FDA must determine if the product candidate qualifies for RMAT designation within 60 days after receipt of the sponsor's request.

A grant of RMAT designation includes all of the benefits of Fast Track designation, intensive guidance on efficient drug development beginning as early as Phase 1, and organizational commitment involving senior managers. The RMAT designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

A Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). The FDA may expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. A Breakthrough Therapy designation provides all Fast Track designation features, offers intensive guidance on an efficient drug development program and ensures organizational commitment involving senior management at FDA. The FDA must determine if the product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor’s request.

Platform Technology Designation

Under the Food and Drug Omnibus Reform Act (FDORA), a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under an NDA or BLA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original NDA or BLA for a drug that uses or incorporates the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive FDA approval. In addition, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

Post-approval requirements

Rigorous and extensive FDA regulation of drugs and biologics continues after approval, including requirements relating to recordkeeping, periodic reporting, product sampling and distribution, adverse experiences with the product, cGMP, and advertising and promotion. Changes to the product, manufacturing process, or facility often require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. Additionally, the FDA may require postmarketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the

implementation of other risk management measures, including distribution restrictions, if new safety information emerges. Failure to comply with the applicable requirements may result in administrative, judicial, civil or criminal actions and adverse publicity. These actions may include FDA's refusal to approve or delay in approving pending applications or supplemental applications, withdrawal of approval, clinical hold, suspension or termination of clinical trial, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Regulatory Exclusivity and Biosimilar Competition in the United States

In 2010, the federal Biologics Price Competition and Innovation Act, or BPCIA, was enacted, creating a statutory pathway for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, reference biological products licensed under the Public Health Service Act.

Under the BPCIA, innovator manufacturers of original biological products are granted twelve years of marketing exclusivity after first licensure before biosimilar versions of such products can be licensed for marketing in the United States. This means that the FDA may not approve an application for a biosimilar product that references data in an innovator's Biologics License Application, or BLA, until 12 years after the date of approval of the reference biological product, with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results are reported to the FDA. A biosimilar application may be submitted four years after the date of licensure of the reference biological product, but the FDA cannot approve the application until the full exclusivity period has expired. This 12-year exclusivity period operates independently from other protections that may apply to biosimilar competitors, including patents that are held for those products. Additionally, the BPCIA establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor and by which information about potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

Under the Best Pharmaceuticals for Children Act, which was subsequently made applicable to biological products by the BPCIA, the FDA may also issue a Written Request asking a sponsor to conduct pediatric studies related to a particular active moiety; if the sponsor agrees and meets certain requirements, the sponsor may be eligible to receive an additional six months of marketing exclusivity for its drug product containing such active moiety.

Other regulatory exclusivity may be granted to drugs, including, but not limited to, three-year and five-year exclusivity granted to non-biologic drugs under the Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch-Waxman Amendments.

Depending upon the timing, duration, and specifics of FDA approval of a product candidate, some of a sponsor's United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Only one patent applicable to an approved drug product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent.

Foreign regulation of human therapeutics

In addition to regulations in the United States, Precigen and ActoBio, and any third party service providers or collaborators will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of the products enabled by our technologies outside of the United States. Whether or not the developer obtains FDA approval for a product, they must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before they may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under Regulation (EC) No 141/2000, PRGN-2012 Orphan drug designation in the European Union (EU) was granted by the European Commission in January 2024 based on a positive opinion issued by the EMA adopted by the Committee for Orphan Medicinal Products (COMP).

Anti-Kickback, False Claims, and Other Marketing and Fraud and Abuse Laws

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers, patients and third-party payers will expose us to broadly applicable United States fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and any collaborative partners through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations are discussed in the "Risk Factors" section below.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of our current product and any product candidates for which we may obtain regulatory approval. In the United States, sales of Papzimeos and any other product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the EU, pricing and reimbursement schemes vary widely from member state to member state. While a product may usually be legally placed on the market in the EU once a marketing authorization has been obtained, meaningful market access in many EU member states depends on the completion of national pricing and reimbursement procedures. Some member states may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Privacy Laws

In the United States, we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state data breach notification laws, state health information and/or genetic privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission, or FTC, Act and the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or CCPA), govern the collection, use, disclosure, protection and other processing of health-related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the CCPA establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. Similarly, numerous other states have enacted, or are considering enacting, comprehensive data privacy laws that share similarities with the CCPA, and there are a number of legislative proposals in the United States at the federal level, in each case which could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners.

Internationally, laws and regulations in many jurisdictions also apply broadly to the collection, use, storage, disclosure, protection and other processing of data that identifies or may be used to identify or locate an individual. Please see the risk factor entitled “Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to governmental enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.”

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, has substantially changed the way healthcare is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to repeal, replace, or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act, or Tax Act, enacted in December 2017 eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the "individual mandate," effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act, or portions thereof, will affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, as amended, among other things led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2 percent per fiscal year beginning April 1, 2013, and will remain in effect through 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 eliminated the statutory cap on drug manufacturers' Medicaid drug rebate program liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug’s average manufacturer price, or AMP.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The Inflation Reduction Act (“IRA”) was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (which began in 2024); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of Papzimeos and any other product candidate that we commercialize.

The federal government is presently pursuing a two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how these proposals will be implemented, the policies could have a negative impact on the pharmaceutical industry and on our ability to receive revenues for Papzimeos or any other product candidate that we commercialize. The federal government has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the federal government is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Although the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S pharmaceutical sector and our business.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for Papzimeos or other product candidates that receive approval.

Adoption of other new legislation or regulation at the federal, state, or foreign level could further limit reimbursement for pharmaceuticals, including Papzimeos and our other product candidates if approved. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Research and Development

As of December 31, 2025, we had 47 employees supporting our research and development functions of our healthcare operations, including operational and facility activities. We incurred expenses of $41.3 million, $53.1 million and $48.6 million in 2025, 2024, and 2023, respectively, on research and development activities for continuing operations. We anticipate that our research and development expenditures could increase as we advance our healthcare programs and platforms. As of December 31, 2025, our primary domestic research and development, and production operation was located in laboratory and production facilities in Germantown, Maryland.

Financial Information

Collaboration revenues, product revenues, net, service revenues, and other revenues and operating loss for each of the last three fiscal years, along with assets and liabilities as of December 31, 2025, and 2024, are set forth in the consolidated financial statements, which are included in Item 8 of this Annual Report. Financial information about geographic areas is set forth in "Notes to the Consolidated Financial Statements - Note 16" appearing elsewhere in this Annual Report.

Human Capital Management

As of December 31, 2025, out of 160 employees, 140 support our healthcare operations, of which 47 support our research and development functions including operational and facility activities. Of these research and development employees, 35 have advanced degrees, of which 17 are PhDs. Our corporate employees provide support to our one subsidiary with ongoing operations and are responsible for the execution of all corporate functions, including executive, operational, finance, human resources, information technology, legal, and corporate communications. None of our employees are represented by a collective bargaining agreement.

We structure our compensation packages to compete for the best talent. Our compensation packages include a competitive base salary and bonus, the issuance of equity incentives, a 401(k) plan, and health and wellness benefits, including a health insurance plan with a Platinum actuarial value.

Our 2025 employee development initiatives included employee training targeting specific areas of interest, executive and manager coaching, and performance management, which encompass performance goals and competency evaluations.

Additional Information

Our website is *www.precigen.com*. The information on, or that can be accessed through, our website does not constitute part of and is not deemed to be incorporated by reference into, this Annual Report. We post regulatory filings on this website as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. These filings include annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K; Section 16 reports on Forms 3, 4, and 5; and any amendments to those reports filed with or furnished to the SEC. We also post our press releases on our website. Access to these filings or any of our press releases on our website is available free of charge. Copies are also available, without charge, from Precigen Investor Relations, 20374 Seneca Meadows Parkway, Germantown, Maryland 20876. Reports filed with the SEC may be viewed at *www.sec.gov*.

In addition, our Corporate Governance Guidelines, Code of Business Conduct and Ethics, and charters for the Audit Committee, the Compensation and Human Capital Management Committee and the Nominating and Governance Committee are available free of charge to shareholders and the public through the "Corporate Governance" section of our website. Printed copies of the foregoing are available to any shareholder upon written request to our Communications Department at the address set forth on the cover of this Annual Report or may be requested through our website, *www.precigen.com.*

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report, including our consolidated financial statements and the related notes appearing at the end of this Annual Report, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition, or prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Annual Report. See "Special Note Regarding Forward-Looking Statements" for information relating to these forward-looking statements.

Risks Related to Our Financial Position and Capital Needs

We are substantially dependent on the commercial success of Papzimeos

To date, we have invested substantial efforts and financial resources in the research, development and commercialization of Papzimeos and our product candidates. Our near-term prospects, including our ability to develop our product candidates and generate revenue, and our future growth are substantially dependent on the commercial success of Papzimeos. Although we received approval from the U.S. Food and Drug Administration, or FDA, we are pursing regulatory approval from the European Commission, and are preparing to file for approval from other foreign regulatory bodies, for Papzimeos for the treatment of RRP in adults, we can provide no assurances that we will obtain regulatory approval in any jurisdiction other than the U.S., which could have an adverse impact on our results of operations. In addition, the successful commercialization of Papzimeos will depend on a number of factors and involves risk, including some of the risks identified in these “Risk Factors.” One or

more of these risks, many of which are beyond our control, could cause significant delays or an inability to successfully commercialize Papzimeos.

We have a history of net losses, and we may not achieve or maintain profitability.

We have incurred net losses since our inception, with the exception of 2022 where we had $28.3 million in net income due to the sale of TransOva, which generated a gain on divestiture of $94.7 million. As of December 31, 2025, we had an accumulated deficit of $2.3 billion. We expect to incur losses and negative cash flows from operating activities for the foreseeable future.

On August 14, 2025, we received FDA approval for Papzimeos for adults with RRP. We anticipate that our expenses will increase substantially as we commercialize Papzimeos, continue to advance the preclinical and clinical development of our existing product candidates and continue our research activities, and there is a significant risk that our product candidates will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval, or become commercially viable. As we commercialize Papzimeos and if we obtain regulatory approval of Papzimeos in other jurisdictions or indications or for our other product candidates, we expect we will incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We have and are devoting substantial resources to the commercial infrastructure for Papzimeos and have not yet achieved significant product revenue. A significant period of time could pass before Papzimeos generates significant product revenue, or commercialization of our various product candidates or before the execution of contractual relationships providing for up-front payments, milestones or royalties sufficient to achieve profitability. As a result, our expenses may exceed revenues for the foreseeable future, and we may not achieve profitability. If we fail to achieve profitability, or if the time required to achieve profitability is longer than we anticipate, we may not be able to continue our business. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We expect our future capital requirements will be substantial and will depend on many factors.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to commercialize Papzimeos, continue the preclinical and clinical development of our current and future programs and commercialize other product candidates. We expect our future capital requirements will be substantial and will depend on many factors, including:

- the timing, receipt, and amount of sales of Papzimeos;
- progress in our research and development programs, as well as the magnitude of these programs;
- capital expenditures related to building out our manufacturing capabilities, further commercialization of Papzimeos and preparing for commercial readiness for product candidates;
- the timing of potential regulatory approval of products;
- the timing, receipt, and amount of any payments received in connection with strategic transactions;
- the timing, receipt, and amount of sales and royalties, if any, from our product candidates;
- the timing and capital requirements to scale up our various product candidates and service offerings and customer acceptance thereof;
- our ability to maintain and establish collaborative arrangements and/or new strategic initiatives;
- the resources, time, and cost required for the preparation, filing, prosecution, maintenance, and enforcement of our intellectual property portfolio;
- strategic mergers and acquisitions, if any, including both the upfront acquisition cost as well as the cost to integrate, maintain, and expand the strategic target; and
- the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes.

We raised approximately $30.9 million in net proceeds in an offering of equity securities in August 2024 and approximately $78.5 million in net proceeds in an offering of equity securities in December 2024 and we entered into a Loan Agreement (as defined below) that provides for a 5-year senior secured term loan facility of up to $125.0 million in September 2025. If future financings involve the issuance of equity securities, our existing shareholders would suffer further dilution. If we raise further debt financing, we may be subject to additional restrictive covenants that limit our ability to conduct our business. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. If we fail to raise sufficient funds and continue to incur losses, our ability to fund our operations, take advantage of strategic opportunities, develop product candidates or technologies, commercialize or otherwise respond to competitive pressures could be significantly limited. If this happens, we may be forced to delay or terminate research or development programs or the commercialization of our product and product candidates resulting from our technologies, curtail or cease operations or obtain funds through strategic transactions or other collaborative and licensing arrangements that may require us to relinquish commercial rights, or grant licenses on terms that are not favorable to us. In addition, raising funds in the current macroeconomic and geopolitical environment may present additional challenges. For example, adverse macroeconomic or geopolitical conditions, such as the disruption and uncertainty caused by heightened inflation and interest rates and slower economic growth or recession, uncertainty caused by tariffs and trade policies, and geopolitical conflicts such as the war between Russia and Ukraine and the conflict in the Middle East, could result in a sustained disruption in the capital markets. We cannot predict the extent or duration of such macro-economic and geopolitical disruptions, and if they deepen or persist, this could negatively impact our ability to raise capital on favorable terms, or at all. If adequate funds are not available, we will not be able to successfully execute our business plan or continue our business.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

On September 3, 2025, we and certain of our subsidiaries party thereto as guarantors entered into a Loan Agreement (the "Loan Agreement") with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership as the lenders thereunder (the "Lenders") and BioPharma Credit PLC as the collateral agent, each of which are investment entities managed by Pharmakon Advisors, LP. The Loan Agreement provides for a 5-year senior secured term loan facility of up to $125.0 million, composed of two committed tranches: (i) an initial tranche in an aggregate principal amount of $100.0 million, which was funded on September 3, 2025; and (ii) a delayed draw tranche in an aggregate principal amount of $25.0 million, which is available, subject to certain conditions, until June 29, 2027 (such tranches, collectively, the "Term Loans"). The Term Loans mature on September 3, 2030 (the "Maturity Date"). The Term Loans bear interest at Term SOFR (three-month tenor), subject to a 3.75% floor, plus 6.50%, payable quarterly. The Term Loans amortize in eight equal quarterly installments beginning on September 29, 2028 through the Maturity Date. The Term Loans may be voluntarily prepaid in whole (but not in part), and are subject to make-whole, prepayment premium and exit fees, and must be prepaid upon a Change in Control (as defined in the Loan Agreement).

Our indebtedness could also have important negative consequences for our security holders and our business, results of operations and financial condition, including:

- we will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of cash available to finance our operations, our research and development efforts and other general corporate activities;
- our failure to comply with the obligations of our affirmative and restrictive covenants in the Loan Agreement could result in an event of default that, if not cured or waived, would permit the Lenders to accelerate our obligation to repay this indebtedness, and the Lenders could seek to enforce their security interest in the assets securing such indebtedness; and
- we may be more vulnerable to downturns in our business, our industry or the economy in general.

In addition, we may borrow additional capital in the future to fund clinical development and our future growth, including pursuant to the Loan Agreement or potentially pursuant to new arrangements with different lenders. To the extent additional debt is added to our current debt levels, the risks described above could increase.

Failure of the U.S. federal government to manage its fiscal matters or to raise or further suspend the debt ceiling may expose us to increased financial and operational risk.

Congressional disagreement over the federal budget and the maximum amount of debt the federal government is permitted to have outstanding (commonly referred to as the "debt ceiling") has previously caused the U.S. federal government to shut down for periods of time. Generally, if effective legislation to fund government operations and manage the level of federal debt is not enacted, the federal government may suspend its investments for certain government accounts, among other available options, in order to prioritize payments on its obligations. A failure by the U.S. Congress to pass spending bills or address the debt

ceiling at any point in the future would increase the risk of default by the U.S. on its obligations, the risk of a lowering of the U.S. federal government's credit rating, and the risk of other economic dislocations. Such a failure, or the perceived risk of such a failure, could consequently have a material adverse effect on the financial markets and economic conditions in the U.S. and globally. For example, over the last several years, the U.S. government has shut down several times, including for 43 days beginning in October 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown or other disruption occurs again in the future, it may have negative consequences for us, including:

- devaluation in any U.S. government bond investments held by the Company;
- inability to access capital markets, or increased difficulty in doing so; or
- government shutdown, or reduced operation, of agencies such as the FDA, which could impede our ability to progress our planned clinical development of product candidates.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the successful commercialization of Papzimeos in the U.S. and other jurisdictions, where we may obtain regulatory approval, and our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and ultimately commercialize them.

We currently have one product approved for commercial sale, Papzimeos, which was approved by the FDA on August 14, 2025, for adults with RRP and are otherwise early in our development efforts. We initiated our first clinical trial for our lead programs in October 2018 and, other than Papzimeos, currently have a pipeline of clinical and preclinical programs. Our ability to generate product revenues, will depend heavily on the successful commercialization of Papzimeos in the United States and in other jurisdictions, if approved. as well as the successful development and eventual commercialization of some or all of our existing product candidates, and any future product candidates we develop, which may never occur. Our current and future product candidates will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, coverage from pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment, and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- timely and successful completion of preclinical studies and clinical trials;
- acceptance of INDs for future product candidates;
- successful enrollment in and completion of clinical trials;
- data from our clinical programs that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third-party manufacturers that can do so;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- the ongoing build up of our commercialization organization and successful launch of commercial sales of our product

candidates, if approved;

- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;
- our ability to obtain and maintain patent and other intellectual property protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community, and third-party payers;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as postmarketing studies, a REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive;
- our ability to compete effectively with other therapies; and
- our ability to obtain and maintain healthcare coverage and adequate reimbursement from third-party payers.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that any of our current or future product candidates will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

The market opportunities for our product and product candidates may be smaller than we estimate.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases who are in a position to receive our product and product candidates, and who have the potential to benefit from treatment with our product and product candidates, are based on our own estimates. These estimates may be inaccurate or based on imprecise data. We do not have verifiable internal marketing data regarding the potential size of the commercial market for any of our product and product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product and product candidates or any future product candidates. Since our current product and product candidates and any future product candidates represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from product and product candidates.

For example, our estimates of the number of people who have recurrent respiratory papillomatosis, or RRP, the indication for Papzimeos, is based on our own internal estimates including, commissioned research which reviewed a variety of sources, including scientific literature, surveys of treating physicians, analogous products based on disease severity, prevalent population and efficacy of therapy and other forms of market research. These estimates may be inaccurate or based on imprecise data. As RRP is a rare disease and there are currently no approved therapeutics for RRP other than Papzimeos, limited research is available regarding its prevalence and severity and the market opportunity for a therapeutic. In addition, the addressable market opportunity for Papzimeos will depend on, among other things, the labeling for Papzimeos as agreed with the U.S. Food and Drug Administration or comparable regulatory authorities in other jurisdictions, acceptance by the medical community and patient access and drug pricing and reimbursement. In addition, the prevalence of RRP could be reduced as a result of the increased use of vaccines like Gardasil. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product or product candidate or new patients may become increasingly difficult to identify or gain access to, all of which could materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. There can be no assurance that we will not experience problems or delays in developing new product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We also may experience unanticipated problems or delays in expanding our manufacturing capacity, which may delay or prevent the completion of clinical trials and the commercialization of our product and product candidates on a timely or profitable basis, if at all. For example, we, a collaborator, or another group may uncover a previously unknown risk with any of our product candidates, which may prolong the period of observation required for obtaining regulatory approval, may necessitate additional clinical testing, or may otherwise result in a change in the requirements for approval of any of our product candidates. For example, although Papzimeos has been approved by the FDA for the treatment of adults with RRP, we may be unable to obtain approval for Papzimeos in any jurisdiction outside the United States, including in the European Union.

In addition, the clinical trial requirements of the FDA, European Medicines Agency, or EMA, and other regulatory authorities and the criteria these regulators use when evaluating product candidates vary substantially according to the type, complexity, novelty, and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied product candidates. Even if we are successful in developing product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals in either the United States or jurisdictions outside the United States or how long it will take to commercialize these product candidates.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA has established the Office of Tissues and Advanced Therapies and the Division of Cellular and Gene Therapies within the Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its marketing application review process.

We may be unable to obtain FDA approval of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact on our potential to generate revenue, our business, and our results of operations.

To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity, and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive, and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs.

The field of gene therapy is still early in development. The FDA first approved a gene therapy for use in humans in 2017, and to date has only approved a limited number. Clinical trials with gene therapies have encountered a multitude of significant technical problems in the past, including unintended integration with host DNA leading to serious adverse events, poor levels of protein expression, transient protein expression, viral overload, immune reactions to either viral capsids utilized to deliver DNA, DNA itself, proteins expressed or cells transfected with DNA. There can be no assurance that our development efforts will be timely or successful, that we or our collaborators will receive the regulatory approvals necessary to initiate clinical trials, where applicable, or that we will be able to successfully commercialize a product candidate other than Papzimeos enabled by our technologies. To the extent that we utilize viral constructs or other systems to deliver gene therapies and the same or similar delivery systems demonstrate unanticipated and/or unacceptable side effects in preclinical or clinical trials conducted by ourselves or others, we may be forced to, or elect to, discontinue development of such product candidates.

Additionally, we are pursuing the development and commercialization of adoptive cell therapies based on CAR T-cell therapies targeting a variety of cancer malignancies. Because this is a newer approach to cancer immunotherapy and cancer treatment generally, developing and commercializing such product candidates subjects us to a number of challenges, including:

- developing and deploying consistent and reliable processes for engineering a patient's T-cells *ex vivo* and infusing the engineered T-cells back into the patient;

- possibly conditioning patients with chemotherapy in conjunction with delivering each of the potential product candidates, which may increase the risk of adverse side effects of the potential products;

- educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release;
- developing processes for the safe administration of these potential products, including long-term follow-up for all patients who receive the potential products;
- sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the potential products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval required to gain market access and acceptance;
- developing therapies for types of cancers beyond those addressed by the current potential products;
- not infringing, misappropriating or otherwise violating the intellectual property rights, in particular, the patent rights, of third parties, including competitors developing alternative CAR T-cell therapies; and
- avoiding any applicable regulatory barriers to market, such as data and marketing exclusivities held by third parties, including competitors with approved CAR T-cell therapies.

We cannot be sure that T-cell immunotherapy technologies that we may develop will yield satisfactory products that are safe and effective, scalable, or profitable.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

Clinical development involves a lengthy and expensive process with uncertain outcomes. Results from preclinical studies or previous clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired results in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials and failure may occur at any stage due to a multitude of factors both within and outside our control. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects. If clinical trials result in negative or inconclusive results, we may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies.

As an organization, we have limited experience designing and implementing clinical trials and we have limited experience conducting pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect our ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payers. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding.

We may find it difficult to enroll patients in clinical trials, which could delay or prevent us from proceeding with clinical trials.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to success. The timing of clinical trials depends on the ability to recruit patients to participate as well as completion of required follow-up periods. If patients are unwilling to participate in our clinical studies for any number of reasons, such as because of negative publicity from adverse events related to the biotechnology or gene therapy fields, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval may be delayed. Additionally, any shelter-in-place orders from local, state, or federal governments or clinical trial site policies resulting from pandemics may impact our ability to enroll patients in clinical trials. These delays could result in increased costs, delays in advancing product candidates, or termination of the clinical trials altogether. For example, we experienced delays and suspensions in our trials in 2020 due to the COVID-19 pandemic. Although these suspensions did not result in significant overall delay, if future pandemics occur, we may experience significant delays to our clinical trials, including related to enrollment, site closures, reduced availability of key personnel, or our ability to receive the necessary approvals from the FDA or other regulatory agencies to advance our programs.

We may be required to suspend, repeat, or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current good clinical practices requirements or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs, or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows, and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Papzimeos and our product candidates are novel, complex, and difficult to manufacture.

The manufacturing processes that we use to produce our product and product candidates for human therapeutics are complex and novel. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, or disruptions in the operations of our suppliers. Our synthetic biology product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic often cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, it is necessary to employ multiple steps to control our manufacturing process to assure that the product or product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, or insufficient inventory. We have developed our proprietary electroporation device, UltraPorator, to permit the rapid and cost-effective manufacturing of our

UltraCAR-T therapies, but we may face challenges in the production and implementation of this device, which may, in turn, adversely impact the therapeutic candidates. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA, or other applicable standards or specifications with consistent and acceptable production yields and costs.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation, and verification procedures that could result in material changes in the final data.

From time to time, we publish interim data, including interim top-line results or preliminary results from our clinical trials. Interim data and results from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit, validation, and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our product and our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia and death seen in other trials. While new approaches have been developed to reduce these side effects, gene therapy and synthetic biology therapy in general is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to these product candidates due to persistent biological activity of the genetic material or other components of products used to carry the genetic material.

Other possible adverse side effects that could occur with treatment using cell and gene therapy products include an immunologic reaction early after administration that, while not necessarily adverse to the patient's health, could substantially limit the effectiveness of the treatment. In previous clinical trials involving adeno-associated virus, vectors for gene therapy, some subjects experienced the development of a T-cell response, whereby after the vector is within the target cell, the cellular immune response system triggers the removal of transduced cells by activated T-cells. If a similar effect occurs with our product candidates, we may decide or be required to halt or delay further clinical development of our product candidates.

Additionally, for Papzimeos or if any of our other product candidates receive marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, and provider certification. Such requirements could prevent us from achieving or maintaining market acceptance of our product or product candidates and could significantly harm our business, prospects, financial condition, and results of operations.

Even if we complete the necessary clinical trials, we cannot be certain when, or if, we will obtain regulatory approval to commercialize a product candidate, and the approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even when product candidates meet their endpoints in clinical trials, the clinical trial results may not support approval of our product candidates if they fail to demonstrate that our product candidates are both safe and effective for their intended uses. Similarly, the regulatory authorities may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require precautions or contraindications with respect to conditions of use or they may grant approval subject to the performance of costly postmarketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations, and prospects.

We have chosen to prioritize commercialization of Papzimeos and the selective development of certain of our product candidates. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other opportunities for which there may be a greater likelihood of success or may be more profitable.

Because we have limited resources, we are required to strategically prioritize our application of resources to particular development efforts, including the commercialization of Papzimeos for the treatment of RRP. As part of the strategic prioritization, we decided to minimize spending on our UltraCAR-T programs, and have paused enrollment in PRGN-3005 and PRGN-3007 UltraCAR-T clinical trials. We have also reduced our focus on preclinical programs, while continuing select projects we believe could provide future near-term validation of our technology platforms. We have also shut down our ActoBio subsidiary operations. Though we have started to commercialize Papzimeos, there is no assurance that Papzimeos will be profitable and by deprioritizing the other programs and product candidates, we may be failing to capitalize on opportunities for which there may be a greater likelihood of success or be more profitable, and our revenues, financial condition, and results of operations may be adversely affected.

We may seek designation for our AdenoVerse platform technology as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

We may seek designation for our AdenoVerse platform technology as a designated platform technology. Under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if: (1) the platform technology is incorporated in, or utilized by, a drug approved under an NDA or BLA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original NDA or BLA for a drug that uses or incorporates the platform technology. Even if we believe our AdenoVerse platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a drug will be developed more quickly or receive a faster FDA review or approval process. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation. For example, in July 2025, the FDA revoked Sarepta Therapeutics' platform technology designation for AAVrh74 given new safety information that suggested the preliminary evidence on which the designation was based was insufficient to demonstrate that its platform technology had the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on safety.

Risks Related to the Commercialization of our Product and Product Candidates and Other Legal Compliance Matters

Our product and product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payers, and others in the medical community necessary for commercial success.

Ethical, social, and legal concerns about gene and cell therapies could result in additional regulations restricting or prohibiting our product and product candidates. Even with the requisite approvals from the FDA in the United States, the EMA in the European Union, and other regulatory authorities internationally, the commercial success of Papzimeos and of our product candidates will depend, in part, on their acceptance by physicians, patients, and healthcare payers as medically necessary, cost-effective, and safe. Public perception may be influenced by claims that gene and cell therapies are unsafe, and Papzimeos and any product candidate that we commercialize may not gain acceptance by physicians, patients, healthcare payers, and others in the medical community. In particular, our success will depend upon appropriate physicians prescribing treatments that involve the use of our product and product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue to make the products profitable.

Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply Papzimeos for commercial and future clinical uses would adversely affect our ability to commercialize Papzimeos and our business and business prospects could be severely harmed.

The manufacture of Papzimeos must comply with applicable regulatory standards for commercial uses and current and potential future clinical trials. The process of manufacturing Papzimeos is complex and subject to several risks, including:

- the ability to consistently manufacture and attain sufficient production yields with acceptable quality control and quality assurance to meet market demand for our commercialization of Papzimeos, as well as the needs for continuing clinical trials;
- our ability to maintain existing commercial supply agreements and to establish additional or alternative supply agreements if necessary, including our ability to successfully transfer manufacturing technology and attain regulatory approval at any such additional or alternative suppliers;
- supply chain issues, including the timely availability of product and management of shelf-life, including raw materials, active pharmaceutical ingredient, or API, and drug product and other supplies, and the cost of procuring the foregoing, any of which may be impacted by a number of factors, including the effects of macroeconomic or other global conditions, such as increased tariffs, renegotiation of existing international trade agreements, escalating trade tensions and other trade restrictions;
- shortage of qualified personnel internally or at any of our third party suppliers;
- our ability to safeguard our manufacturing facilities from harm by physical or cyber threats; and
- ongoing compliance with regulatory requirements, which vary in each country.

As a result of these and other risks, we may be unable to maintain a manufacturing infrastructure and supply chain capable of providing Papzimeos for commercial use, which could delay or adversely affect our product commercialization efforts; result in lost sales; delay or result in a cessation of our current or potential future clinical trials; delay or preclude potential future regulatory approvals of Papzimeos in other jurisdictions or indications; and could cause financial and reputational harm.

We rely on third parties for certain aspects of the manufacture of our product, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or potential future commercialization efforts.

While we currently use our internal cGMP manufacturing capabilities in Germantown, Maryland for the commercial manufacturing of Papzimeos bulk drug substance, we rely, and expect to continue to rely, on third parties for certain aspects of commercial manufacture, packaging and distribution. This reliance on third parties increases the risk that we will not have sufficient quantities of our product on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development ongoing commercialization efforts.

We rely on third-party manufacturers, which entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- failure of third-party manufacturers to perform the manufacturing process adequately;
- breach of supply agreements by the third-party manufacturers;
- failure to supply components, intermediates, services, or product according to our specifications;
- failure to supply components, intermediates, services, or product according to our schedule or at all;
- misappropriation or disclosure of our proprietary information, including our trade secrets and know-how; and
- termination or non-renewal of agreements by third-party manufacturers at times that are costly or inconvenient for us.

For example, our third party vendors have, from time to time, experienced a number of deviations with respect to the production of our product. Although such incidents have not. to date, had a material impact on our commercialization efforts, developments of this type, or other failures by our third party vendors, could adversely impact our business.

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product. If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre-approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States that might be capable of manufacturing our product, and our product candidates if and when approved. Therefore, our product and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the commercialization of our product or the clinical development, marketing approval and potential future commercialization of our product candidates.

Furthermore, if we breach or are perceived to breach our contractual obligations or otherwise default under our agreements with third parties, or if we otherwise have contractual disputes with such third parties, it may lead to adverse outcomes, including potential delays, unforeseen expenses, or the termination of those contracts. We do not currently have a second source for certain required materials used for the manufacture of finished product and we are dependent upon certain third parties for certain steps in our manufacture and distribution process for Papzimeos. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of Papzimeos and our product candidates could delay, prevent or impair our development and both our current and potential future commercialization efforts.

Delays in obtaining regulatory approval of manufacturing processes and facilities or disruptions in manufacturing processes may delay or disrupt our commercialization efforts.

Before we can begin to commercially manufacture our additional product candidates for human therapeutics, we must obtain regulatory approval from the FDA for the applicable manufacturing process and facility. This will likely require the manufacturing facility to pass a pre-approval inspection by the FDA. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities.

In order to obtain FDA approval, we will need to ensure that all of the processes, methods, and equipment are compliant with cGMP and perform extensive audits of vendors, contract laboratories, and suppliers. While we currently use our internal cGMP manufacturing capabilities in Germantown, Maryland for the commercial manufacturing of Papzimeos, we may rely on third parties to commercially manufacture our other product candidates. If we, any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation(s) or while we work to identify suitable replacement vendors. The cGMP requirements govern, among other things, quality control of the manufacturing process, raw materials, containers/closures, buildings and facilities, equipment, storage and shipment, labeling, laboratory activities, data integrity, documentation policies and procedures, and returns. In complying with cGMP, we will be obligated to expend time, money, and effort in production, record keeping, and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action that could adversely affect our business, results of operations, financial condition, and cash flows, including the inability to sell any products that we may develop.

Even after we receive marketing approval, we remain subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Papzimeos and other product candidates we obtain regulatory approval for, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other postmarket information. Regulatory approvals also may be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly postmarketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the

product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures.

If we fail to comply with applicable regulatory requirements for Papzimeos or following approval of any of our product candidates, a regulatory authority may take a range of adverse actions, including, among other things, issuing a warning letter, imposing monetary penalties, restricting or suspending manufacturing, or causing us to withdraw the product from the market.

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations, and prospects.

Obtaining and maintaining marketing approval of our product and current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our product and current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our product and current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, as for Papzimeos, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. For example, we have submitted a MAA for zopapogene imadenovec-drba for the treatment of adults with RRP to the EMA in November 2025. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product and product candidates will be harmed.

We have limited experience as a commercial company and the sales, marketing, and distribution of Papzimeos or any future approved products may be unsuccessful or less successful than anticipated..

Though we have obtained regulatory approval from the FDA for Papzimeos, as a company, we have no prior experience commercializing a product for any indication. The success of our commercialization efforts is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal and contracted sales, marketing, manufacturing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities. Further, given our lack of experience commercializing products, we do not have a track record of successfully executing a commercial launch. There is a risk that we underestimate the level of demand for a product, which could require us to change a manufacturing process to increase production yields and changes to a manufacturing process are time consuming and subject to regulatory, financial, and operational risks. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize Papzimeos and any

future approved products, we may require significant additional capital and financial resources, we may not achieve or maintain profitability, and we may not be able to compete against more established companies in our industry.

Although we have been developing our commercial infrastructure for the commercialization of Papzimeos, we have chosen to utilize a contracted sales force. We may choose, in the future, to develop our own sales force for Papzimeos or other product candidates. There are costs and risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We must also compete with other biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

Alternatively, we may wish to establish collaborations with third parties to maximize the potential of Papzimeos or our product candidates in jurisdictions in which Papzimeos or a product candidate has been approved. Our industry is characterized by intense competition. Therefore, we may not be successful in entering into such commercialization arrangements with third parties on favorable terms, or at all. In addition, we may have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

There can be no assurance that we will be able to develop the necessary commercial infrastructure and capabilities to successfully commercialize Papzimeos or our other product candidates or be able to establish or maintain relationships with third parties necessary to perform these services. As a result, we may not successfully commercialize any product in any jurisdiction.

The successful commercialization of our product and product candidates will depend in part on the extent to which third-party payers, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product and product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product and product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by third-party payers, including managed care plans, governmental healthcare programs, such as Medicare and Medicaid and private health insurers is essential for most patients to be able to afford medical services and pharmaceutical products such as our product and product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our product and product candidates or procedures using our product and product candidates by third-party payers will have an effect on our ability to successfully commercialize our product and product candidates. Obtaining coverage and adequate reimbursement for our product and product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product or product candidate is used may not be available. A decision by a third-party payer not to cover or not to separately reimburse for our product or product candidates or procedures using our product or product candidates could reduce physician utilization of our products once approved. Assuming there is coverage for our product and product candidates, or procedures using our product or product candidates by a third-party payer, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union, or elsewhere will be available for our product or current or future product candidates, or for any procedures using such product or product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. The Medicare and Medicaid programs are increasingly used as models in the United States for how private third-party payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. Some third-party payers may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payers will decide with respect to the coverage and reimbursement for our product or product candidates.

No uniform policy for coverage and reimbursement for products exist among third-party payers in the United States. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by third-party payers in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Our business may be adversely affected by current and potential future healthcare reforms.

In the United States, federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our product candidates, if approved, are prescribed and purchased. For example, the Affordable Care Act has changed the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. In addition, the Tax Act eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50 percent to 70 percent off the negotiated price effective as of January 1, 2019.

Significant developments that may adversely affect pricing in the United States include proposed drug pricing and Medicare reforms by Congress and regulatory changes to Medicare Part B and Medicare Part D, additional changes to the Affordable Care Act under the current Administration and trends in the practices of managed care groups and institutional and governmental purchasers, including consolidation of our customers. The Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2 percent Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030.On August 16, 2022, the Inflation Reduction Act of 2022, was signed into law, which among other things, includes prescription drug provisions that have significant implications for the pharmaceutical industry and beneficiaries, including extending enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries. On August 29, 2023, the Department of Health and Human Services announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. For example, on July 4, 2025, the annual reconciliation bill, the “One Big Beautiful Bill Act” (“OBBBA”), was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

The current administration is pursuing policies to reduce regulations and expenditures across the U.S. government, including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Some these actions include (1) directing agencies to reduce workforce and make program cuts, (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMMI, to consider new payment and healthcare models to limit drug spending, (3) eliminating the Biden administration’s executive order that directed HHS to establish an AI task force, developing a strategic plan directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program, (4) directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans; (5) imposing tariffs on imported pharmaceutical product; (6) directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans; and (7) as part of the Make America Healthy Again (MAHA) Commission’s recent Strategy Report, working cross government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. For example, on April 15, 2025, outlining several

actions the Secretary of HHS must take to optimize healthcare regulations that will provide access to prescription drugs at lower costs; on May 5, 2025, aiming to promote domestic production of critical medicines; and on May 12, 2025, aiming to establish a "most favored nation" drug pricing policy that would tie US drug prices to the prices paid for drugs in other countries. Since the May 12, 2025 "most favored nation" executive order, the Trump administration has continued to exert pressure on drug manufacturers to implement "most favored nation" pricing and has suggested that it may impose significant tariffs on pharmaceuticals if such pricing is not implemented. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. Additionally, the U.S. Supreme Court's recent Loper Bright decision described above could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass healthcare-related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for certain drugs. In recent years, some states have considered legislation and ballot initiatives that would control the prices of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the United States and laws intended to impose price controls on state drug purchases. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our product candidates, if approved. In addition, under the Affordable Care Act, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our future product candidates, if approved, which could have an adverse impact on our sales and results of operations. In addition, if we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained.

Our relationships with customers, third-party payers, and others may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending the purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal civil False Claims Act, which imposes liability, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment of governmental funds that are false or fraudulent, making a false statement material to an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government;

- HIPAA's fraud provisions, which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are now required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by non-governmental third-party payers, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers in those jurisdictions; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers, and others restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; other states and cities require identification or licensing of sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Although compliance programs can help mitigate the risk of investigations and prosecution for violations of these laws, the risks cannot be eliminated entirely. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Defending against actions or investigations for violations of these laws and regulations, even if ultimately successful, will incur significant legal expenses and divert management's attention from the operation of our business.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to governmental enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We or our collaborators may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure, protection and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. For example, the CCPA imposes stringent data privacy and data protection requirements for the personal information of California residents, provides for civil penalties for violations, as well as a private right of action for data breaches. State laws are changing rapidly, as numerous other states have enacted, or are considering enacting, comprehensive data privacy laws that share similarities with the CCPA. The CCPA and evolving legislation may require us, among other things, to incur additional costs and expenses in an effort to comply.

Foreign data protection laws, including the European Union, or EU, General Data Protection Regulation, or the GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR introduced new data protection requirements in the EU, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4 percent of annual global revenue. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain.

Further, the vote in the United Kingdom in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR, or the U.K. GDPR, which took effect in January 2021. While the U.K. GDPR currently imposes substantially the same obligations as the GDPR, the UK Data (Use and Access) Act, which received Royal Assent in June 2025 modifies the U.K. GDPR in a manner that deviates from the GDPR and permits further deviations in the form of regulatory guidance or secondary legislation, creating further risk of divergent parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for violations. The GDPR and U.K. GDPR also impose strict rules on the transfer of personal data to countries outside the European Economic Area or the United Kingdom, respectively, including the United States. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from the European Economic Area to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in December 2031 unless the European Commission re-assesses and renews or extends that decision. We and many other companies may need to implement different or additional measures (such as the European Commission-approved Standard Contractual Clauses or the U.K. Government-approved International Data Transfer Agreement) to establish or maintain legitimate means for the transfer and receipt of personal data from the European Economic Area and the United Kingdom to the United States.

Compliance with United States and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts; restrict our ability to collect, use, and disclose data; or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators to comply with United States and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity, and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may incur significant costs complying with environmental, health, and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and radioactive and biological materials in our business and are subject to a variety of federal, state, local and international laws and regulations governing, among other matters, the use, generation, manufacture, transportation, storage, handling, disposal of, and human exposure to these materials both in the United States and overseas, including regulation by governmental regulatory agencies, such as the Occupational Safety and Health Administration and the EPA. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

We are subject to certain United States and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, United States and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-United States activities to increase in time. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the United States Foreign Corrupt Practices Act of 1977, as amended, or FCPA. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, United States

companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws.

Violations of these laws and regulations could result in fines, criminal sanctions, including imprisonment, against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, debarment, reputational harm, prohibitions on the conduct of our business, and other consequences. Any such violations could also result in prohibitions on our ability to offer our product candidates in one or more countries as well as difficulties in manufacturing or continuing to develop our product candidates, and could materially damage our reputation, our brand, our ability to attract and retain employees and our business, prospects, operating results, and financial condition.

Risks Related to Our Business Operations and Strategy

We may rely on third parties to develop and commercialize some of our product candidates, and we may fail to successfully manage, or disputes may arise from, any such collaborations. Markets in which collaborators develop product candidates using our technologies will be subject to extensive regulation, and we may rely on our collaborators to comply with all applicable laws and regulations.

We have previously entered into, and may in the future enter into, collaboration arrangements to develop product candidates enabled by our technologies. For example, because of our strategic reprioritization of our pipeline to focus on Papzimeos, we have minimized UltraCAR-T spend and instead have focused on strategic partnerships to further advance such UltraCAR-T programs. We may face significant competition in seeking appropriate partners for our product candidates, and the negotiation process may be time-consuming and complex. There can be no guarantee that we can successfully manage these relationships, as they involve complex interests and our interests and our collaborators' interests may diverge.

Our collaborators may fail to perform their obligations under the collaboration agreements or may not perform their obligations in a timely manner. If our collaborators are not able to successfully develop product candidates enabled by our technologies, none of these enabled product candidates will become commercially available, and we will receive no back-end payments under these arrangements.

If conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Furthermore, our collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. In addition, we cannot control the amount and timing of resources our collaborators may devote to our product candidates or other collaborative efforts.They may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates.

If our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations successfully or in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive anticipated revenues from the collaboration. In some cases, our past strategic collaborations have resulted in disagreements and disputes regarding the relative rights, obligations, and revenues of us and our collaboration partners. Disagreements and disputes with future collaborators may result in litigation, unfavorable settlements or concessions by us, or management distraction, that could harm our business operations.

Our technologies are used in product candidates that are subject to extensive regulation by governmental authorities. We may depend on our collaborators to comply with these laws and regulations with respect to product candidates they produce using our technologies, and we may not independently monitor whether our collaborators comply with applicable laws and regulations. If our collaborators fail to comply with applicable laws and regulations, we may be subject to substantial financial and operating risks because, in addition to our own compliance, we may depend on our collaborators to produce the end products enabled by our technologies for sale.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, if required in conjunction with the financial statement audit, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We may be sued for product liability.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials as well as any product liability claims related to the use of Papzimeos. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering, or selling our products.

Insurance coverage for product liability claims is expensive and may be difficult to obtain, and may not be available to us in the future on acceptable terms, or at all. We cannot assure you that we will have adequate insurance coverage against potential claims. In addition, although we currently maintain product liability insurance for our technologies in amounts we believe to be commercially reasonable, if the coverage limits of these insurance policies are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition, and cash flows or even cause us to go out of business.

Regardless of the merits or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for products enabled by our technologies;
- injury to our reputations and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products using our technologies.

Our insurance policies are expensive and protect only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risks that our business may encounter, and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. Required coverage limits for such insurances are difficult to predict and may not be sufficient. If potential losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we

could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product or product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product or product candidates that we may develop.

The livestock products of Exemplar are subject to disease outbreaks that can increase the cost of production and/or reduce production harvests, and the loss of existing livestock would result in the loss of commercial technology.

Several of the products of our operating subsidiary, Exemplar, are subject to periodic outbreaks of a variety of diseases. Although Exemplar takes measures to protect their animals, there can be no assurance that a disease will not damage or destroy existing animals. The economic impact of disease to Exemplar can be significant, as we must incur the cost of preventive measures, such as vaccines and antibiotics, and then if infected, the cost of lost or reduced production.

The markets for our product and product candidates are highly competitive. Competitors and potential competitors may develop products and technologies that make ours obsolete or garner greater market share than ours.

While we believe that our novel approach to developing the next generation of gene and cell therapies to target the most urgent and intractable challenges in immuno-oncology, autoimmune disorders, and infectious diseases provides us with competitive advantages, our industry is highly competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical, and human resource capabilities than we do, and certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. In addition, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of the resources available to our competitors, our competitors may be able to develop competing and/or superior technologies and processes, and compete more aggressively and sustain that competition over a longer period of time than we can. The availability of reimbursement from the government and other third-party payers will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In the area of infectious diseases, we have Papzimeos, which is based on our AdenoVerse immunotherapy platform, for the treatment of RRP. We believe there are competitors in this area, including INOVIO Pharmaceuticals with their investigational DNA vaccine INO-3107 targeting HPV6 and HPV11 antigens.

Our other lead product candidates include PRGN-3006 for the treatment of AML, which are built on our UltraCAR-T platform, and PRGN-2009, which is based on our AdenoVerse platform. While we are employing a novel approach, there are a number of competitors pursuing CAR-T cell therapies for the treatment of cancer. We believe that, among others, Bristol-Myers Squibb, Tmunity Therapeutics, and Anixa Biosciences are developing CAR-T based treatments for ovarian cancer and TCR2 Therapeutics is developing TCR-T based treatment for ovarian cancer. We believe that Celyad, Mustang Bio, Kite, Amgen, Cellectis S.A., and Allogene Therapeutics are also using CAR-T technology to develop product candidates for the treatment of AML. The CAR-T technology space also has significant other competition including from multiple companies and their collaborators, such as Novartis and University of Pennsylvania, Kite and Gilead, Adaptimmune and GSK, Autolus Therapeutics, Poseida Therapeutics, and Bellicum Pharmaceuticals. We also face competition from non-cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Incyte, Merck, Abbvie, and Roche.

We are also using our suite of proprietary and complementary technologies for the preclinical and clinical development of product candidates for the treatment of autoimmune disorders, including T1D. We believe that our primary competitors with respect to the development of immunotherapies for T1D are Provention Bio, Midatech Pharma, and MerciaPharma.

Our ability to compete successfully will depend on our ability to develop proprietary technologies that can be used to produce products that reach the market in a timely manner and are technologically superior to and/or are less expensive than other products on the market. As more companies develop new intellectual property in our markets, a competitor could acquire patent or other rights that may limit products using our technologies, which could lead to litigation. To the extent that any of our competitors are more successful with respect to any key competitive factor or we are forced to reduce, or are unable to raise, the price of any products enabled by our technologies in order to remain competitive, our operating results and financial condition could be materially adversely affected.

If we lose key personnel, including key management personnel, or are unable to attract and retain additional personnel, it could delay our product development programs, harm our research and development efforts, and we may be unable to continue to commercialize our product and product candidates.

Our business involves complex operations and requires a management team and employee workforce that is knowledgeable in the many areas in which we operate. The loss of any key members of our management, including our Chief Executive Officer, Helen Sabzevari Ph.D., or the failure to attract or retain other key employees who possess the requisite expertise for the conduct of our business, could prevent us from developing and commercializing our product and product candidates for our target markets and executing on our business strategy.

In addition, the loss of any key scientific staff, or the failure to attract or retain other key scientific employees, could prevent us from developing our technologies for our target markets or from further developing and commercializing our products and services offerings to execute on our business strategy. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among biotechnology, synthetic biology and other technology-based businesses, or due to the unavailability of personnel with the qualifications or experience necessary for our business. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience staffing constraints that will adversely affect our ability to support our internal research and development programs or meet other demands.

We have had a number of executive officers depart from our Company over the last several years, and we continually evaluate our leadership structure. Our past or future leadership changes could lead to strategic and operational challenges and uncertainties, distractions of management from other key initiatives, inefficiencies or increased costs, any of which could adversely affect our business, financial condition, results of operations, and cash flows.

We depend on sophisticated information technology and infrastructure.

We rely on various information systems to manage our operations. These systems are complex and include software that is internally developed, software licensed from third parties, and hardware purchased from third parties. These products may contain internal errors or defects, particularly when first introduced or when new versions or enhancements are released. Failure of these systems could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition.

If we experience a significant breach of data security or disruption in our information systems, our business could be adversely affected.

We rely on various information systems to manage our operations and to store information, including sensitive data such as confidential business information and personally identifiable information. These systems have been and continue to be vulnerable to interruption or malfunction, including due to events beyond our control, and to unauthorized access, computer hackers, ransomware, malware, viruses. fraudulent use attempts, phishing attacks, and other security problems. Failure of these systems or any significant breach of our data security could have an adverse effect on our business and may materially adversely affect our operating results and financial condition.

Data security breaches could result in loss or misuse of information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, compelled compliance with breach notification laws, interruption to our operations, damage to our reputation or could otherwise have a material adverse effect on our business, financial condition and operating results. Companies throughout our industry have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access to networks or sensitive information. While we have implemented and continue to implement cybersecurity safeguards and procedures, these safeguards have been vulnerable to attack. As cyber threats continue to evolve, we may be required to expend additional resources to enhance our cybersecurity measures or to investigate or remediate any vulnerabilities or breaches.

Although we maintain insurance to protect ourselves in the event of a breach or disruption of certain of our information systems, we cannot ensure that the coverage is adequate to compensate for any damages that may be incurred.

The effects of health epidemics, including the COVID-19 pandemic, could adversely affect our business operations, which could have a material adverse effect on our results of operations, cash flows, and financial position.

The operations of our business could be adversely affected by health epidemics, including, for example, if we are unable to secure necessary supplies, including personal protection equipment for our employees. We also rely on third parties for various

aspects of our business, including developing some of our product candidates. These third parties may experience similar disruptions or negative impacts to their businesses due to epidemics, which may result in additional delays or otherwise adversely impact our operations.

In addition to the potential impacts to our operations, we may be required to implement, or reinstitute, precautions to mitigate the spread of the illness across our businesses, which may impact our ability to carry out our business as usual, including additional sanitation and cleaning procedures in our laboratories and other facilities, instituting remote working when possible, and implementing social distancing and staggered worktime requirements for our employees that must work on-site. An increase in remote working may also result in elevated susceptibility to cyber security risks. For example, during the COVID-19 pandemic, we had incurred additional costs as a result of these measures. These measures could also lead to reduced efficiency in our operations.

Several of our operations are leanly staffed and rely on key personnel to manage operations. The loss of our key scientific staff, personnel, or other key employees, as a result of illness or otherwise, could negatively impact our business and operations, particularly if we are unable to adequately find or train replacements.

A significant outbreak of infectious diseases in the future could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

We have international assets and may have international operations and additional international assets in the future. Our international operations and assets may be subject to various economic, social, and governmental risks.

Our international assets and any future international operations may expose us to risks that could negatively impact our future results. Our operations may not develop in the same way or at the same rate as might be expected in a country with an economy similar to the United States. The additional risks that we may be exposed to in these cases include, but are not limited to:

- tariffs and trade barriers;
- currency fluctuations, which could decrease our revenues or increase our costs in United States dollars;
- regulations related to customs and import/export matters;
- tax issues, such as tax law changes and variations in tax laws;
- limited access to qualified staff;
- inadequate infrastructure;
- cultural and language differences;
- inadequate banking systems;
- different and/or more stringent environmental laws and regulations;
- restrictions on the repatriation of profits or payment of dividends;
- disease outbreaks, environmental catastrophes, crime, strikes, riots, civil disturbances, terrorist attacks or wars;
- nationalization or expropriation of property;
- law enforcement authorities and courts that are weak or inexperienced in commercial matters; and
- deterioration of political relations among countries.

Additionally, we are exposed to risks associated with changes in foreign currency exchange rates. We present our consolidated financial statements in United States dollars. Our international subsidiaries have assets and liabilities denominated in currencies other than the United States dollar. Future expenses and revenues of our international subsidiaries are expected to be denominated in currencies other than in United States dollars. Therefore, movements in exchange rates to translate from foreign

currencies may have an impact on our reported results of operations, financial position, and cash flows.

We may pursue strategic acquisitions and investments that could have an adverse impact on our business if they are unsuccessful.

We have made acquisitions in the past and, if appropriate opportunities become available, we may acquire additional businesses, assets, technologies, or products to enhance our business in the future. In connection with any future acquisitions, we could:

- issue additional equity securities, which would dilute our current shareholders;
- incur substantial debt to fund the acquisitions; or
- assume significant liabilities.

Although we conduct due diligence reviews of our acquisition targets, such processes may fail to reveal significant liabilities. Acquisitions involve numerous risks, including:

- problems integrating the purchased operations, facilities, technologies, or products;
- unanticipated costs and other liabilities;
- the potential disruption of our ongoing business and diversion of management resources;
- adverse effects on existing business relationships with current and/or prospective collaborators, customers and/or suppliers;
- unanticipated expenses related to the acquired operations;
- risks associated with entering markets in which we have no or limited prior experience;
- potential unknown liabilities associated with the acquired business and technology;
- potential liabilities related to litigation involving the acquired companies;
- potential periodic impairment of goodwill and intangible assets acquired; and
- potential loss of key employees or potential inability to retain, integrate, and motivate key personnel.

We cannot be certain that any acquisition will be successful or that we will realize the anticipated benefits of the acquisition. In particular, we may not be able to realize the strategic and operational benefits and objectives we had anticipated.

Acquisitions also may require us to record goodwill and non-amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, and incur large and immediate write-offs and restructuring and other related expenses, all of which could harm our operating results and financial condition. In addition, we may acquire companies that have insufficient internal financial controls, which could impair our ability to integrate the acquired company and adversely impact our financial reporting. If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business, and financial condition may be adversely affected.

As a result of the Company's decision to shutdown ActoBio's operations and Exemplar's reporting unit’s annual goodwill impairment test, the Company recorded a $3.9 million goodwill impairment charge in the year ended December 31, 2025. See Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report for additional discussion.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we had net operating loss carryforwards of approximately $1.12 billion for United States federal income tax purposes available to offset future taxable income, including $911.9 million generated after 2017, United States capital loss carryforwards of $1.4 million, and United States federal and state research and development tax credits of $17.9

million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or ("Section 382"). Net operating loss carryforwards generated prior to 2018 will expire if unutilized from 2025 to 2037, and capital loss carryforwards will expire if unutilized from 2025 to 2027. As a result of our past issuances of stock, as well as due to prior mergers and acquisitions, certain of our net operating losses have been subject to limitations pursuant to Section 382. As of December 31, 2025, we had utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, 2025, approximately $31.5 million of domestic net operating losses were acquired via acquisition and are limited based on the value of the target at the time of the transaction. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation. As of December 31, 2025, our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately $80.1 million, most of which do not expire.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary technologies or if we lose some of our intellectual property rights through costly litigation or administrative proceedings.

Our success depends in part on our ability to obtain patents and maintain adequate protection of our intellectual property in the United States and abroad for our suite of technologies and products and product candidates. We have adopted a strategy of seeking patent protection in the United States and abroad with respect to certain of the technologies used in or relating to our technologies and product pipeline. We have also in-licensed rights to additional patents and pending patent applications in the United States and abroad. We intend to continue to apply for patents relating to our technologies, methods, and products as we deem appropriate.

For instance, we pursue protection of switch technologies, gene delivery technologies, and genetic componentry related to our pipeline products. In addition, we seek patents covering specific collaborator's products. We have also filed patents and patent applications in other jurisdictions, such as Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, Oman, Qatar, Saudi Arabia, Singapore, South Africa, Taiwan, and United Arab Emirates. In the future we may file in these or additional jurisdictions as deemed appropriate for the protection of our technologies.

The enforceability of patents, as well as the actual patent term and expiration thereof, involves complex legal and factual questions and, therefore, the extent of enforceability cannot be guaranteed. Issued patents and patents issuing from pending applications may be challenged, invalidated, or circumvented. We cannot ensure that any of our pending patent applications will result in issued patents, or even if issued, predict the breadth of the claims upheld in our and other companies' patents. Given that the degree of future protection for our proprietary rights is uncertain, we cannot ensure that we were the first to invent the inventions covered by our pending patent applications; we were the first to file patent applications for these inventions; the patents we have obtained, particularly certain patents claiming nucleic acids, proteins, or methods, are valid and enforceable; and the proprietary technologies we develop will be patentable.

In addition, unauthorized parties may attempt to copy or otherwise obtain and use our products or technology. Monitoring unauthorized use of our intellectual property is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our technologies, particularly in certain foreign countries where the local laws may not protect our proprietary rights as fully as in the United States. Moreover, third parties could practice our inventions in territories where we do not have patent protection. Such third parties may then try to import into the United States or other territories products, or information leading to potentially competing products, made using our inventions in countries where we do not have patent protection for those inventions. If competitors are able to use our technologies, our ability to compete effectively could be harmed. Moreover, others may independently develop and obtain patents for technologies that are similar to or superior to our technologies. If that happens, we may need to license these technologies, and we may not be able to obtain licenses on reasonable terms, if at all, which could harm our business.

We also rely on trade secrets to protect our technologies, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require our employees, academic collaborators, collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. If we cannot maintain the confidentiality of our proprietary and licensed technologies and other confidential information, our ability, and that of our licensors, to receive patent protection and our ability to protect valuable information owned or licensed by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other

violation could require us to spend significant time and money and could prevent us from commercializing our technologies or impact our stock price.

Our commercial success also depends in part on not infringing patents and proprietary rights of third parties and not breaching any licenses or other agreements that we have entered into with regard to our technologies, products, and business. We cannot ensure that patents have not been issued to third parties that could block our or our collaborators' ability to obtain patents or to operate as we would like. There may be patents in some countries that, if valid, may block our ability to make, use or sell our products in those countries, or import our products into those countries, if we are unsuccessful in circumventing or acquiring the rights to these patents. There also may be claims in patent applications filed in some countries that, if granted and valid, also may block our ability to commercialize products or processes in these countries if we are unable to circumvent or license them.

The biotechnology industry is characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many companies have employed intellectual property litigation as a way to gain a competitive advantage. Our involvement in litigation, interferences, opposition proceedings or other intellectual property proceedings inside and outside of the United States, to defend our intellectual property rights or as a result of alleged infringement, misappropriation or violation of the rights of others, may divert management's time from focusing on business operations and could cause us to spend significant amounts of money. Some of our competitors may have significantly greater resources and, therefore, they are likely to be better able to sustain the cost of complex patent or intellectual property litigation than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our business or to enter into additional collaborations with others. Furthermore, any potential intellectual property litigation also could force us or our collaborators to do one or more of the following:

- stop selling, incorporating or using products that use the intellectual property at issue;
- obtain from the third party asserting its intellectual property rights a license to sell or use the relevant technology, which license may not be available on reasonable terms, if at all; or
- redesign those products or processes that use any allegedly infringing technology, or relocate the operations relating to the allegedly infringing technology to another jurisdiction, which may result in significant cost or delay to us, or that could be technically infeasible.

The patent landscape in the field of biotechnology is particularly complex. We are aware of United States and foreign patents and pending patent applications of third parties that cover various aspects of cell and gene biology including patents that some may view as covering aspects of our technologies. In addition, there may be patents and patent applications in the field of which we are not aware. In many cases, the technologies we develop are early-stage technologies, and we are just beginning the process of designing and developing products using these technologies. Although we will seek to avoid pursuing the development of products that may infringe any patent claims that we believe to be valid and enforceable, we and our collaborators may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of synthetic biology and the complexities and uncertainties associated with them, third parties may allege that we are infringing upon patent claims even if we do not believe such claims to be valid and enforceable.

Except for claims we believe will not be material to our financial results, no third party has asserted a claim of infringement against us. Others may hold proprietary rights that could prevent products using our technologies from being marketed. Any patent-related legal action against persons who license our technologies or us claiming damages and seeking to enjoin commercial activities relating to products using our technologies or our processes could subject us to potential liability for damages and require our licensee or us to obtain a license to continue to manufacture or market such products or any future product candidates that use our technologies. We cannot predict whether we or our licensor would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, we cannot be sure that any such products or any future product candidates or processes could be redesigned to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us or our licensees from developing and commercializing products using our technologies, which could harm our business, financial condition, and operating results. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

If any of our competitors have filed patent applications or obtained patents that claim inventions also claimed by us, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention and, thus, the right to

the patents for these inventions in the United States. These proceedings could result in substantial cost to us even if the outcome is favorable. Even if successful, an interference may result in loss of certain of our important claims.

Any litigation or proceedings could divert our management's time and efforts. Even unsuccessful claims could result in significant legal fees and other expenses, diversion of management's time, and disruption in our business. Uncertainties resulting from initiation and continuation of any patent or related litigation could harm our ability to compete. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. Given the size of our intellectual property portfolio, compliance with these provisions involves significant time and expense. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we do not obtain additional protection under the Hatch-Waxman Amendments, other United States legislation, and similar foreign legislation by extending the patent terms and obtaining regulatory exclusivity for our technologies, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of products using our technologies, one or more of the United States patents we own or license may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Some of our products may not have patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. We may rely on trade secrets and other unpatented proprietary information to protect our commercial position with respect to such products, which we may be unable to do. In some instances, we may also rely on regulatory exclusivity, including orphan drug exclusivity, to protect our products from competition. Some of our or our collaborators' products may be subject to the BPCIA, which may provide those products exclusivity that prevents approval of a biosimilar product that references the data in one of our BLAs in the United States for 12 years after approval. However, the BPCIA and other regulatory exclusivity frameworks may evolve over time based on statutory changes, FDA issuance of new regulations, and judicial decisions. In addition, the BPCIA exclusivity period does not prevent another company from independently developing a product that is highly similar to an approved product, generating all the data necessary for a full BLA and seeking approval.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties and may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product and product candidates.

Enforcing our intellectual property rights may be difficult and unpredictable.

If we were to initiate legal proceedings against a third party to enforce a patent claiming one of our technologies, the defendant could counterclaim that our patent is invalid and/or unenforceable or assert that the patent does not cover its manufacturing processes, manufacturing components or products. Proving patent infringement may be difficult, especially where it is possible to manufacture a product by multiple processes. Furthermore, in patent litigation in the United States, defendant counterclaims alleging both invalidity and unenforceability are commonplace. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of our patent rights, we cannot be certain, for example, that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would not be able to exclude others from practicing the inventions claimed therein. Such a loss of patent protection could have a material adverse impact on our business. Even if our patent rights are found to be valid and enforceable, patent claims that survive litigation may not cover commercially valuable products or prevent competitors from importing or marketing products similar to our own, or using manufacturing processes or manufacturing components similar to those used to produce the products using our technologies.

Although we believe we have obtained assignments of patent rights from all inventors, if an inventor did not adequately assign their patent rights to us, a third party could obtain a license to the patent from such inventor. This could preclude us from enforcing the patent against such third party.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to synthetic biology. This could make it difficult for us to stop the infringement of our patents or misappropriation of our other intellectual property rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If our technologies or products using our technologies are stolen, misappropriated, or reverse engineered, others could use the technologies to produce competing technologies or products.

Third parties, including our collaborators, contract manufacturers, contractors and others involved in our business, often have access to our technologies. If our technologies, or products using our technologies, were stolen, misappropriated, or reverse engineered, they could be used by other parties that may be able to reproduce our technologies or products using our technologies, for their own commercial gain. If this were to occur, it would be difficult for us to challenge this type of use, especially in countries with limited intellectual property protection.

Confidentiality agreements with employees and others may not adequately prevent disclosures of trade secrets and other proprietary information.

We have taken measures to protect our trade secrets and proprietary information, but these measures may not be effective. We require our new employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting arrangement with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements also generally provide that inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our proprietary information may be disclosed, third parties could reverse engineer our technologies or products using our technologies, and others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence (AI) into our business processes. Use of this technology presents risks and challenges that could affect our business both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect its adoption, and therefore our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

Additionally, we expect to see increasing government and supranational regulation related to AI use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict.

Our vendors may incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Our Common Stock

We have failed in the past and may fail in the future to meet all applicable continued listing requirements of Nasdaq Global Select Market, which could result in a delisting of our common stock. Delisting could negatively affect the price of our common stock which, could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.

Our common stock is currently listed on the Nasdaq Global Select Market of The Nasdaq Stock Market, LLC ("Nasdaq"), which has qualitative and quantitative continued listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we are required to meet the continued listing requirements of Nasdaq and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of $1.00 per share. We have in the past, and may in the future, be unable to comply with these continued listing requirements; if we do not meet these continued listing requirements, our common stock could be delisted.

On November 1, 2024, we received a deficiency letter (the "Deficiency Letter") from the Listing Qualifications Department (the "Staff") of Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Rule"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until April 30, 2025, to regain compliance. To regain compliance, the bid price of our common stock must close at $1.00 per share or more for a minimum of ten consecutive business days during such 180-day compliance period. The Deficiency Letter had no immediate effect on the listing or trading of our common stock.

On January 16, 2025, we received written notification from Nasdaq indicating that the Company's common stock had a closing price at or greater than $1.00 per share for the last 10 consecutive business days, from December 31, 2024 to January 15, 2025, and that, as a result, we have regained compliance with the Bid Price Rule and the matter is closed.

However, there can be no assurance that we will be able to maintain compliance with the Nasdaq listing requirements, including the minimum bid price requirement. If we fail to maintain compliance with the minimum bid price requirement or to meet the other applicable continued listing requirements in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock, reduce our ability to raise additional capital and result in operational challenges and damage to investor relations and market reputation.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline.

Our financial condition and operating results have varied significantly in the past and may continue to fluctuate from quarter to quarter and year to year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this Annual Report:

- our ability to achieve or maintain profitability;
- the outcomes of our research programs, clinical trials, or other product development and approval processes;
- our ability to develop and successfully commercialize our products;
- the timing, receipt, and amount of any payments received in connection with upfront, milestone, and sale and royalty payments, if any;
- our ability to successfully scale up production of our commercial products and customer acceptance thereof;
- our ability to enter into strategic transactions;
- our ability to develop and maintain our technologies;
- our ability to manage our growth;
- risks associated with the international aspects of our business;

- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management, and other personnel;
- our ability to obtain, protect and enforce our intellectual property rights;
- our ability to prevent the theft or misappropriation of our intellectual property, know-how or technologies;
- the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes;
- potential advantages that our competitors and potential competitors may have in securing funding or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- business interruptions such as power outages and other natural disasters;
- our ability to integrate any businesses or technologies we may acquire with our business;
- negative public opinion and increased regulatory scrutiny of gene and cell therapies;
- the impact of new accounting pronouncements on our current and future operating results;
- our ability to use our net operating loss carryforwards to offset future taxable income; and
- the results of our consolidated subsidiaries.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

Our stock price is volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by media or industry analysts, investor perceptions or negative announcements by our collaborators regarding their own performance, as well as industry conditions and general financial, economic and political instability. From January 1, 2024 through February 15, 2026, our common stock has traded as high as $5.23 per share and as low as $1.11 per share. The stock market in general, as well as the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- announcements of acquisitions, collaborations, financings, divestitures, or other transactions by us;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel; and
- the other factors described in this "Risk Factors" section.

In addition, we believe there has been and may continue to be substantial off-market transactions in derivatives of our stock, including short selling activity or related similar activities, which are beyond our control and which may be beyond the full control of the SEC and Financial Institutions Regulatory Authority, or FINRA. While SEC and FINRA rules prohibit some forms of short selling and other activities that may result in stock price manipulation, such activity may nonetheless occur without detection or enforcement. Significant short selling or other types of market manipulation could cause our stock trading price to decline, to become more volatile, or both.

Additionally, we have historically, and may from time to time in the future, own equity interests in our collaborators. Owning equity in our collaborators increases our exposure to the risks of our collaborators' businesses beyond the products of those collaborations. Any equity ownership in our collaborators exposes us to volatility and the potential for negative returns. We may have restrictions on resale and/or limited markets to sell our equity ownership. If our equity position is a minority position, we are exposed to further risk as we will not be able to exert control over the companies in which we hold securities.

We do not anticipate paying cash dividends, and accordingly, shareholders will have to rely on any stock appreciation for return on their investment.

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying cash dividends in the future and intend to retain all of our future earnings, if any, to finance the operations, development, and growth of our business. As a result, appreciation of the price of our common stock, which may never occur, will provide a return to shareholders. Investors seeking cash dividends should not invest in our common stock. We have twice distributed equity securities of affiliated entities to our shareholders as a special stock dividend, most recently in 2017, but it is possible that we may never declare a special dividend again, and shareholders should not rely upon potential future special dividends as a source of return on their investment.

If securities or industry analysts do not publish research or reports, or publish inaccurate or unfavorable research or reports about our business, our share price and trading volume could decline.

The trading market for our shares of common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If securities or industry analysts do not continue to cover us, the trading price for our shares of common stock may be negatively impacted. If one or more of the analysts who covers us downgrades our shares of common stock, changes their opinion of our shares or publishes inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares of common stock could decrease and we could lose visibility in the financial markets, which could cause our share price and trading volume to decline.

As of December 31, 2025, Randal J. Kirk controlled approximately 34 percent of our common stock. If our executive officers and directors choose to act together, they may be able to significantly influence our management and operations, acting in their own best interests and not necessarily those of other shareholders.

We have historically been controlled and principally funded by Randal J. Kirk, our Executive Chairman, and affiliates of Mr. Kirk, including Third Security. As of February 15, 2026, Mr. Kirk and shareholders affiliated with him beneficially owned approximately 34 percent of our voting stock, and our executive officers and directors, as a group, owned approximately 37 percent of our voting common stock. Mr. Kirk may be able to control or significantly influence all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions, and he may be able to exert significant influence on other corporate actions as a result of his role as our Executive Chairman and status as a significant shareholder. Further, our executive officers and directors, acting together as shareholders, would be able to significantly influence all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions, as well as our management and affairs. The interests of this group of shareholders may not always coincide with the interests of other shareholders, and they may act in a manner that advances their best interests and not necessarily those of other shareholders. This concentration of ownership control may:

- delay, defer, or prevent a change in control;
- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover, or other business combination involving us that other shareholders may desire.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. If Mr. Kirk or any of his affiliates were to sell a substantial portion of the shares they hold, it could cause our stock price to decline.

In addition, as of December 31, 2025, there were 28,153,192 shares subject to outstanding options that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, other contractual limitations and federal securities law limitations. As of December 31, 2025, there were 3,367,051 restricted stock units and performance stock units outstanding. Shares issuable upon the exercise of such options and upon vesting of the restricted stock units and performance stock units can be freely sold in the public market upon issuance and once vested. Additionally, as of December 31, 2025, we had 2,048,892 shares available for grant under the 2019 Incentive Plan for Non-Employee Service Providers and 11,458,631 shares available for grant under the 2023 Omnibus Incentive Plan. In addition, as of December 31, 2024, there were approximately 70,222,215 shares of common stock initially underlying the Series A Preferred Stock and 52,666,669 shares of common stock initially underlying the Warrants. The exercisability of the Series A Preferred Stock and the Warrants is contingent upon us obtaining stockholder approval to increase the number of authorized shares of common stock.

Our articles of incorporation authorize us to issue preferred stock with terms that are preferential to those of our common stock.

Our articles of incorporation authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred stock having such designations, preferences, limitations and relative rights, including preferences over our common stock respecting dividends and distributions, as our board of directors may determine. For example, in connection with the issuance in December 2024 of 79,000 shares of Series A Preferred Stock described elsewhere in this Annual Report, we filed an amendment to our articles of incorporation to set the designations of the Series A Preferred Stock. In the future, we may issue additional preferred stock that has greater rights, preferences, and privileges than our common stock.

We are subject to anti-takeover provisions in our articles of incorporation and bylaws and under Virginia law that could delay or prevent an acquisition of our Company, even if the acquisition would be beneficial to our shareholders.

Certain provisions of Virginia law, the commonwealth in which we are incorporated, and our articles of incorporation and bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions:

- include a provision allowing our board of directors to issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at shareholder meetings;
- provide for the inability of shareholders to convene a shareholders' meeting without the support of shareholders owning together 25 percent of our common stock;
- provide for the application of Virginia law prohibiting us from entering into a business combination with the beneficial owner of 10 percent or more of our outstanding voting stock for a period of three years after the 10 percent or greater owner first reached that level of stock ownership, unless we meet certain criteria;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which shareholders can remove directors from the board;
- require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent; and
- limit who may call a special meeting of shareholders.

These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders, should they choose to do so, to remove our board of directors or management.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity Risk Management

At Precigen, cybersecurity risk management is an integral part of our overall enterprise risk management processes. Our cybersecurity risk management program is managed by our security steering team. Designed to align with industry's best practices, our program provides a framework for identifying, monitoring, assessing and responding to cybersecurity threats and incidents and facilitates coordination across different departments of the Company. This framework includes steps for identifying the source of a cybersecurity threat or incident, including whether such cybersecurity threat or incident is associated with a third-party vendor or service provider, assessing the severity and risk of a cybersecurity threat or incident, implementing cybersecurity countermeasures and mitigation strategies and informing management and our board of directors of potentially material cybersecurity threats and incidents or other significant changes in the evolving cybersecurity threat landscape.

Our security steering team is responsible for assessing and maintaining our cybersecurity risk program and engages third-party cybersecurity experts for risk assessment and system enhancements. In addition, we provide training to all employees both during the initial onboarding process and on an annual basis. We also conduct tabletop exercises to assess our cybersecurity readiness on an annual basis.

However, despite our efforts, we cannot eliminate all risks from cybersecurity threats or incidents, or provide assurances that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see "Risk Factors-If we experience a significant breach of data security or disruption in our information systems, our business could be adversely affected." in this annual report on Form 10-K.

Cybersecurity Governance

Management is responsible for identifying and assessing cybersecurity risks on an ongoing basis, establishing processes designed to ensure that such potential cybersecurity risk exposures are monitored, putting in place appropriate mitigation and remediation measures, and maintaining cybersecurity programs. Our cybersecurity programs are managed under the direction of our Chief Operating Officer ("COO") who serves as the chairman of the security steering team and monitors the prevention, detection, mitigation, and remediation of cybersecurity risks. The security steering team also includes the leadership of our Information Technology ("IT") team. The IT team consists of seasoned security professionals well-versed in emerging cybersecurity risks and solutions used to mitigate and remediate loss due to cybersecurity incidents. Precigen also employs the use of cybersecurity vendors to actively monitor and remediate cybersecurity threats and incidents. Management, including the COO, regularly updates the board of directors on the Company’s cybersecurity programs, material cybersecurity risks and mitigation strategies and provides quarterly cybersecurity updates. Such updates cover, among other topics, third-party assessments of the Company’s cybersecurity programs, developments in cybersecurity and updates to the Company’s cybersecurity programs and mitigation strategies.

Our board of directors has overall oversight responsibility for our risk management and is charged with oversight of our cybersecurity risk management program. The board is responsible for ensuring that management has policies and processes in place designed to identify, monitor, assess and respond to cybersecurity, data privacy and other information technology risks to which the Company is exposed and implement processes and programs to manage cybersecurity risks and mitigate cybersecurity threats and incidents.

Item 2. Properties

We establish the geographic locations of our research and development operations and production facilities based on proximity to the relevant market expertise and access to available talent pools. The following table shows information about our primary lab operations used in our healthcare operations as of December 31, 2025:

Location	Square Footage
Germantown, Maryland	61,048

Our primary domestic production and lab facilities for Exemplar are located in Sioux County and Johnson County, Iowa, and include approximately 57,711 square feet of production, lab, and office facilities.

Our primary administrative offices, including our manufacturing facility for Papzimeos, are located in Germantown, Maryland. See also "Management's Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments" appearing elsewhere in this Annual Report.

Item 3. Legal Proceedings

In the course of our business, we are involved in litigation and legal matters, including governmental investigations. Such matters are subject to many uncertainties and outcomes are not predictable with assurance. We accrue liabilities for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. As of December 31, 2025, we do not believe that any such matters, individually or in the aggregate, will have a material adverse effect on our business, financial condition, results of operations, or cash flows.

See "Notes to the Consolidated Financial Statements - Note 15" appearing elsewhere in this Annual Report for further discussion of ongoing legal matters.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information and Holders of Record

Our common stock trades on the Nasdaq Global Select Market, or Nasdaq, under the symbol "PGEN".

As of February 15, 2026, we had 271 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business and do not expect to pay any cash dividends on our common stock in the foreseeable future.

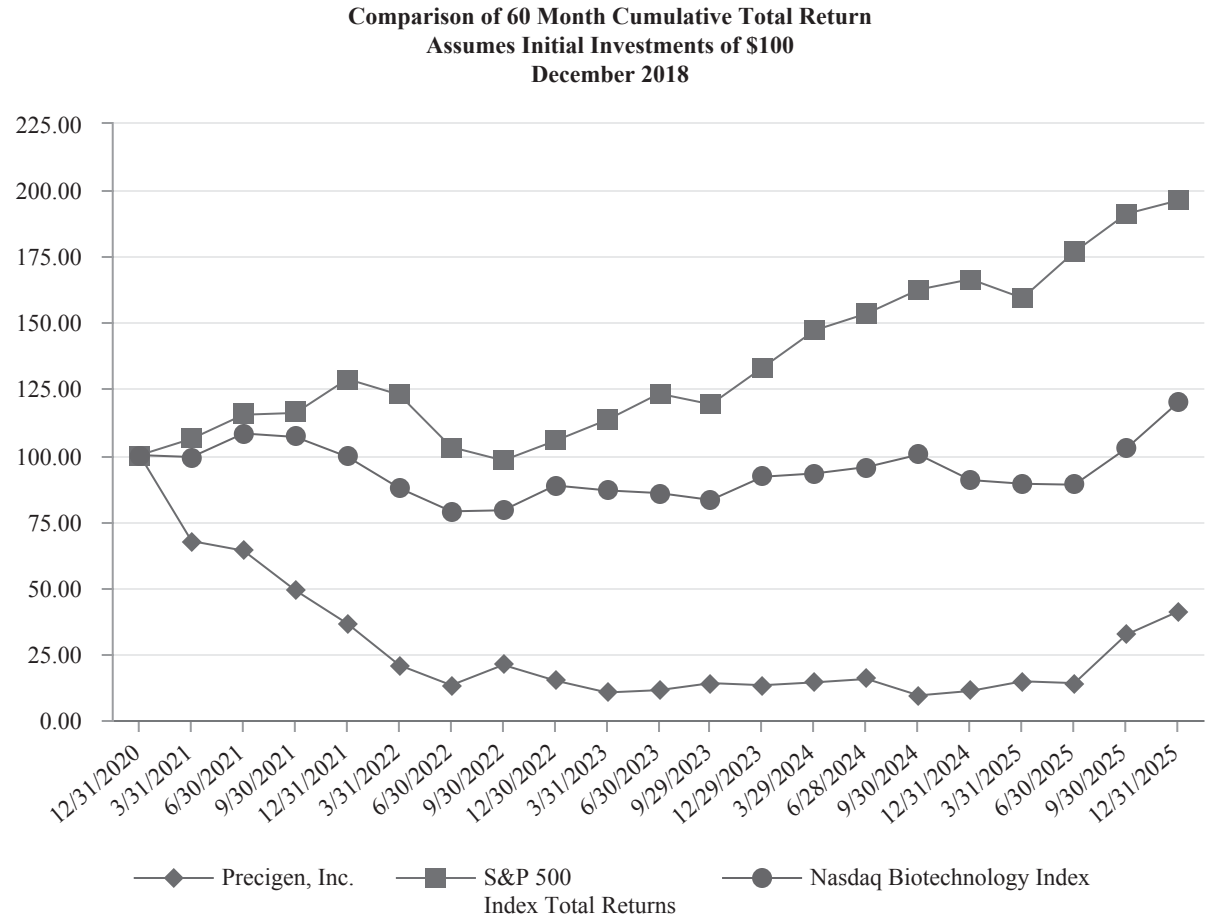
Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Precigen, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph shows a comparison from December 31, 2020, through December 31, 2025 of the cumulative total return for our common stock; the Standard & Poor's 500 Stock Index, or the S&P 500 Index; and the Nasdaq Biotechnology Index. The graph assumes that $100 was invested at the market close on December 31, 2020, in the common stock of Precigen, Inc., the S&P 500 Index, and the Nasdaq Biotechnology Index, and data for the S&P 500 Index and the Nasdaq Biotechnology Index assumes reinvestments of dividends. The stock price performance of the following graph is not necessarily indicative of future stock price performance.



Company / Index	Base Period 12/31/2020	3/31/2021	6/30/2021	9/30/2021	12/31/2021
Precigen, Inc.	**$ 100.00**	$ 67.55	$ 63.92	$ 48.92	$ 36.37
S&P 500 Index	**100.00**	106.17	115.25	115.92	128.71
Nasdaq Biotechnology Index	**100.00**	99.28	108.17	106.85	99.37

Company / Index	3/31/2022	6/30/2022	9/30/2022	12/30/2022	3/31/2023	6/30/2023	9/29/2023	12/29/2023
Precigen, Inc.	$ 20.69	$ 13.14	$ 20.78	$ 14.90	$ 10.39	$ 11.27	$ 13.92	$ 13.14
S&P 500 Index	122.79	103.02	97.99	105.40	113.30	123.20	119.17	133.10
Nasdaq Biotechnology Index	87.54	78.77	79.17	88.53	86.68	85.67	83.07	91.84

Company / Index	3/29/2024	6/28/2024	9/30/2024	12/31/2024	3/31/2025	6/30/2025	9/30/2025	12/31/2025
Precigen, Inc.	$ 14.22	$ 15.49	$ 9.29	$ 10.98	$ 14.61	$ 13.92	$ 32.25	$ 40.98
S&P 500 Index	147.15	153.46	162.49	166.40	159.29	176.72	191.08	196.16
Nasdaq Biotechnology Index	93.08	95.51	100.18	90.58	89.18	88.83	102.54	119.92

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

(a) Sales of Unregistered Securities

On September 15, 2025, the holders of Precigen, Inc.'s 8.00% Series A Convertible Perpetual Preferred Stock ("Preferred Stock") converted 79,000 shares of Preferred Stock (with an aggregate stated value of $79.0 million) into 54,937,411 shares of

common stock of the Company, which were delivered to such holders on September 17, 2025 pursuant to the terms of our Amended and Restated Articles of Incorporation and such Preferred Stock at the then-current conversion rate of 695.4103 shares of our common stock per $1,000 of stated value of Preferred Stock.

The shares of our common stock issued upon conversion of the Preferred Stock were issued in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended, as involving an exchange by us exclusively with our existing security holders in a transaction where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

(b) Use of Proceeds

None.

(c) Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, "Business" and Item 8, "Financial Statements and Supplementary Data." For information on risks and uncertainties related to our business that may make past performance not indicative of future results, or cause actual results to differ materially from any forward-looking statements, see "Special Note Regarding Forward-Looking Statements," and Part I, Item 1A, "Risk Factors." Refer to Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2024 Annual Report on Form 10-K for management's discussion and analysis of financial condition and results of operations for the fiscal year 2024 compared to fiscal year 2023.

Overview

We are a biopharmaceutical company specializing in the advancement of innovative precision medicines to address difficult-to-treat diseases with high unmet patient need. Precigen is dedicated to advancing scientific breakthroughs from proof-of-concept through commercialization. We are leveraging our proprietary technology platforms to develop product candidates designed to target urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases.

We believe that our array of technology platforms uniquely positions us among other biotechnology companies to advance precision medicine. Our proprietary and complementary technology platforms provide a strong foundation to realize the core promise of precision medicine by supporting our efforts to construct powerful gene programs to drive efficacy, deliver these programs through viral, non-viral, and microbe-based approaches to drive lower costs, and control gene expression to drive safety. Our therapeutic platforms, including AdenoVerse immunotherapy, UltraCAR-T, and ActoBiotics, are designed to allow us to precisely control the level and physiological location of gene expression and modify biological molecules to control the function and output of living cells to treat underlying disease conditions. We have developed a proprietary electroporation device, UltraPorator, designed to further streamline and ensure the rapid and cost-effective manufacturing of UltraCAR-T therapies.

Our commercial product, Papzimeos (zopapogene imadenovec-drba, PRGN-2012), is the first and only US Food and Drug Administration ("FDA") approved therapy for the treatment of adults with recurrent respiratory papillomatosis ("RRP"). Papzimeos is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of human papillomavirus (HPV) types 6 and 11 proteins. Papzimeos is designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP. Discovered and designed in Precigen's labs using Precigen's proprietary AdenoVerse therapeutic platform, Papzimeos represents a new therapeutic paradigm for RRP.

Our clinical pipeline includes PRGN-2009, which are based on our AdenoVerse immunotherapy platform; and PRGN-3005, PRGN-3006 and PRGN-3007, which are built on our UltraCAR-T platform. We have completed enrollment in the Phase 1b clinical trial of PRGN-3006. As part of the strategic prioritization of our pipeline announced in August 2024, we paused enrollment in the PRGN-3005 and PRGN-3007 clinical trials, minimized UltraCAR-T spending and plan to focus on strategic

partnerships to further advance UltraCAR-T programs. In addition, we previously announced plans to continue PRGN-2009 Phase 2 clinical trials under a cooperative research and development agreement ("CRADA") with the National Cancer Institute ("NCI") in recurrent/metastatic cervical cancer and in newly diagnosed HPV-associated oropharyngeal cancer.

Fiscal Year 2025 Business Update

In August 2025, the U.S. Food and Drug Administration ("FDA") granted full approval of Papzimeos for the treatment of adults with RRP. RRP is a rare, debilitating, and potentially life-threatening disease caused by chronic human papillomavirus ("HPV") 6 or HPV 11 infection, which results in recurrent benign tumors in the respiratory tract. RRP can lead to severe voice disturbance, a compromised airway, and recurrent post-obstructive pneumonias. Management of RRP has primarily consisted of repeated surgeries, which do not address the root cause of the disease and can be associated with significant morbidity as well as significant patient and health system burden. The approval of Papzimeos marks a historic milestone for the RRP patient community as the first and only FDA-approved therapy for the treatment of adults with RRP. As a result of Papzimeos receiving full FDA approval, a confirmatory clinical trial is not required.

Papzimeos is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of HPV types 6 and 11 proteins—the root cause of RRP. Papzimeos is delivered via four subcutaneous injections over a 12-week interval. Papzimeos approval is supported by safety and efficacy data from the pivotal Phase 1/2 clinical trial published in the Lancet Respiratory Medicine. The pivotal study successfully met its primary safety and pre-specified primary efficacy endpoints. Papzimeos was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2. Of the patients in our study, 51% (18 out of 35) achieved complete response, requiring no surgeries in the 12 months after treatment with Papzimeos. These complete responses have been durable after Papzimeos treatment with median follow-up of 36 months as of a September 19, 2025 data cutoff.

See further discussion of 2025 financing transactions below under the Liquidity and capital resources section of Item 7.

Financial operations overview

Sources of revenue

Exemplar generates product and service revenues through the development and sale of genetically engineered miniature swine models. We recognize revenue when control of the promised product or service is transferred to the customer. In 2025, revenues generated by Exemplar became less significant to the Company, and we expect this significance to greatly diminish into the future.

During the fourth quarter of 2025, we began generating revenue from commercial sales of Papzimeos, our FDA-approved immunotherapy for RRP. While revenues from Papzimeos were limited in the year due to the timing of our commercial launch, we anticipate our future revenue to primarily be generated from Papzimeos product sales.

As we transition to a commercial-stage company, our future revenues will increasingly depend on our ability to successfully commercialize Papzimeos, advance our proprietary programs, and bring additional products enabled by our technology platforms to market.

We anticipate that collaboration revenue will remain minimal in the near term, except in cases of future strategic transactions involving our platforms or programs. Should new collaboration agreements or strategic transactions be executed, revenue could be positively impacted.

Accordingly, there can be no assurance as to the timing, magnitude, and predictability of revenues, if any, to which we might be entitled.

Cost of products and services and gross margin

Cost of products and services consists of manufacturing costs, transportation and freight-in, and indirect overhead costs (including salary and benefits related and stock-based compensation expenses) associated with the commercial manufacturing and distribution of Papzimeos, and costs related to our Exemplar business, which includes primarily labor, supplies, feed used in production, and facility charges. Approximately $4.4 million of our cost of products and services in 2025 relates to our Exemplar business.

For the year ended December 31, 2025, the cost of products and services includes the costs of Papzimeos sales. Prior to August 14, 2025, regulatory approval and subsequent commercialization of Papzimeos and thus the possibility of future economic benefits from Papzimeos sales were not considered probable and inventory-related costs were expensed as incurred. As such, the inventory recognized on the Consolidated Balance Sheet at December 31, 2025 does not include any costs incurred prior to August 14, 2025, which is referred to as pre-launch inventory. In addition, the cost of products related to Papzimeos on the Consolidated Statement of Operations for the year ended December 31, 2025 is comprised of the sale of pre-launch inventory, which only includes costs incurred subsequent to August 14, 2025, including period costs that were not absorbed into inventory. As of December 31, 2025, the amount of future estimated net revenues represented by existing physical pre-launch inventories is approximately $85 million based on our current pricing assumptions and projected demand for our recently approved commercial product. Due to the fact that commercialization began in late 2025, these estimates are inherently subject to significant uncertainty.

The Company expects that it will finish selling all of the pre-launch inventories in 2026. Projected sales derived from pre-launch inventories depend on several factors that could materially impact actual realized results, including the timing and scale of product adoption within our target patient population, and payer coverage. As a result, the cost of products sold related to Papzimeos will initially reflect a lower average per unit cost of materials (excluding period costs that are expensed as incurred), as pre-launch inventory is utilized for commercial production and sold to customers. As pre-launch inventory continues to absorb costs through the manufacturing process, we expect the current gross margins (exclusive of period costs expensed as incurred) will gradually decrease as pre-launch inventory is sold and will stabilize between high 80 percentages and low 90 percentages when pre-launch inventories are expected to be completely sold based on current forecasts, which include significant risks given that Papzimeos is the first therapy available to patients with RRP.

Research and development expenses

We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and benefits, including stock-based compensation expense, as well as severance costs related to personnel in research and development functions, if such costs exist;
- fees paid to consultants and contract research organizations who perform research on our behalf and under our direction;
- costs related to laboratory supplies used in our research and development efforts and acquiring, developing, and manufacturing preclinical study and clinical trial materials;
- costs related to certain in-licensed technology rights or reacquired in-process research and development;
- amortization of patents and related technologies acquired in mergers and acquisitions;
- facility-related expenses, which include direct depreciation costs and unallocated expenses for rent and maintenance of facilities and other operating costs; and
- other manufacturing costs related to the manufacture of drug products that have not yet been approved by the FDA.

Our research and development expenses primarily relate to either costs incurred to expand or otherwise improve our technologies or the costs incurred to develop our own products and services. Prior to August 2024, the Company was progressing preclinical and clinical programs that targeted urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases, including PRGN-3005, PRGN-3006, PRGN-3007, PRGN-2009, PRGN-2012 and AG019. As discussed in "Notes to the Consolidated Financial Statements - Note 1 " appearing elsewhere in this Annual Report, in August 2024, we announced a strategic prioritization of our clinical portfolio and streamlining of resources, to focus on potential commercialization of the PRGN-2012 AdenoVerse® immunotherapy for the treatment of RRP. We also continue to advance PRGN-2009, and we have completed enrollment in the Phase 1b clinical trial of PRGN-3006. Exemplar's research and development activities relate to new and improved pig research models. Following the FDA approval of Papzimeos in August 2025, we no longer expect to record research and development expenses related to PRGN-2012 for adults. Future costs associated with this product for adults are expected to be classified as costs of products or capitalized as inventory.

We currently track external research and development ("R&D") expenses by platform, although we do not accumulate or track R&D expenses by individual product candidate or program. Preparing such information solely for external reporting would not

reflect management's view of the business or how R&D activities are managed. A significant portion of our R&D spending supports the development, optimization, and operation of our core therapeutic platforms and shared technologies rather than any single drug candidate.

Management evaluates R&D activities and makes resource allocation decisions based on the nature of the underlying expenses, which align with how our R&D operations are structured and managed.The table below presents R&D expenses by nature of cost for the periods presented.

	2025	2024
External development expense:		
AdenoVerse immunotherapy platform	$ 11,550	$ 11,347
UltraCAR-T therapeutics platform	1,131	4,713
ActoBiotics Platform	—	810
Other	2,207	3,079
Total Direct external research and development expense	14,888	19,949
R&D personnel expense	19,859	25,493
R&D facility and depreciation expense	5,888	7,254
Other R&D expense	698	374
Total research and development expense	$ 41,333	$ 53,070

In addition to the strategic prioritization in 2024, the amount of research and development expenses may be impacted by, among other things, the number and nature of our own proprietary programs.

Research and development expenses may also increase as a result of in-licensing of technologies or ongoing research and development operations that we might assume through mergers and acquisitions.

Selling, general and administrative expenses

Selling, general and administrative expenses consist of salaries and related costs, including stock-based compensation expense and severance benefits, for employees in executive, commercial (including sales), operational, finance, information technology, legal, and corporate communications functions. Other significant SG&A expenses include rent and utilities, insurance, marketing and promotion activities, sales operations, accounting, and legal services (including the cost of settling any claims and lawsuits), and expenses associated with obtaining and maintaining our intellectual property.

SG&A expenses may fluctuate in the future depending on the scaling of our corporate functions required to support our corporate initiatives, the strategic prioritization of assets, the build-up of our commercialization efforts and the outcomes of legal claims and assessments against us.

Other income (expense), net

Other income and expense, net consists primarily of changes in the fair value of warrant liabilities (until the warrants were classified into equity in 2025), interest expense related to the term loans entered into in 2025 that mature in 2030, and interest earned on our cash and cash equivalents and short-term and long-term investments, which may fluctuate based on amounts invested and changing interest rates. See "Notes to the Consolidated Financial Statements - Notes 10 and 12 " appearing elsewhere in this Annual Report for further discussion.

Results of operations

Comparison of the year ended December 31, 2025 to the year ended December 31, 2024

The following table summarizes our results of operations for the years ended December 31, 2025, and 2024, together with the changes in those items in dollars and as a percentage (dollar amounts in thousands):

	Year Ended December 31,		Dollar Change	Percent Change
	2025	2024		
		(In thousands)		
Revenues				
Collaboration and licensing revenues	$ 1,818	$ —	$ 1,818	N/A
Product revenues, net	3,975	422	3,553	>200%
Service revenues	3,891	3,503	388	11.1 %
Total revenues	9,684	3,925	5,759	146.7 %
Operating expenses				
Cost of products and services	4,823	4,267	556	13.0 %
Research and development	41,333	53,070	(11,737)	(22.1)%
Selling, general and administrative	70,128	41,293	28,835	69.8 %
Impairment of goodwill	3,907	7,409	(3,502)	(47.3)%
Impairment of other noncurrent assets	—	32,915	(32,915)	(100.0)%
Total operating expenses	120,191	138,954	(18,763)	(13.5)%
Operating loss	(110,507)	(135,029)	24,522	(18.2)%
Total other income (expense), net	(140,132)	7,001	(147,133)	>(200)%
Loss before income taxes	(250,639)	(128,028)	(122,611)	95.8 %
Income tax benefit (expense)	(3)	1,793	(1,796)	(100.2)%
Net Loss	(250,642)	(126,235)	(124,407)	98.6 %
Deemed dividend on preferred stock	(179,000)	—	(179,000)	N/A
Net loss attributable to common shareholders	$ (429,642)	$ (126,235)	$ (303,407)	>200%
Net loss per share attributable to common shareholders, basic and diluted	$ (1.37)	$ (0.47)	$ (0.90)	192 %

Collaboration and licensing revenues

Collaboration and licensing revenues increased by $1.8 million, compared to the year ended December 31, 2024. In September 2025, the Company and PTC Therapeutics mutually agreed to terminate their existing exclusive channel collaboration ("ECC") agreement. As a result, the Company recognized the remaining deferred revenue associated with the agreement, totaling $1.8 million. There was no comparable revenue recognized in the prior year period.

Product and services revenues

Product and service revenues increased $3.9 million or 100.4%, compared to the year ended December 31, 2024. The increase was primarily driven by the commencement of Papzimeos product revenue, which totaled $3.4 million in 2025 following its commercial launch, and no such revenue existed in 2024. Exemplar service revenue increased by $0.5 million, reflecting growth in service activity.

Cost of products and services

Cost of products and services increased $0.6 million or 13.0%, compared to the year ended December 31, 2024. The increase was primarily as a result of higher service revenues at our Exemplar subsidiary compared to the prior year and Papzimeos cost of products, which approximated $0.4 million, and was not present in the prior year. Papzimeos cost of products recognized in the period relates to inventory manufactured prior to FDA approval and includes 2025 fourth quarter period costs that were not included in inventory

Research and development expenses

Research and development expenses decreased by $11.7 million, or 22.1%, compared to the year ended December 31, 2024. The decrease was primarily driven by a $5.4 million reduction in costs associated with ActoBio, including depreciation, amortization, personnel and other research and development costs after its operations were closed in 2024. External services also declined by approximately $4.0 million, due to reduced activity for contract research organizations as a result of the strategic prioritization of our pipeline announced in the third quarter of 2024. In addition, in August 2025, manufacturing related costs began to be classified as inventory with the FDA approval of Papzimeos. These costs were classified as research research and development expenses prior to the FDA approval.

Selling, general and administrative expenses

SG&A expenses increased by $28.8 million, or 69.8%, compared to the year ended December 31, 2024. This increase was primarily driven by a $27.3 million increase in costs incurred related to Papzimeos commercial readiness, including sales force expansion, marketing and advertising as well as professional and other fees associated with the commercial launch of Papzimeos.

Impairment of goodwill and other noncurrent assets

In connection with the suspension of ActoBio's operations, we recorded $34.5 million of impairment charges related to goodwill and long-lived assets in the second quarter of 2024. Additionally, in the second quarter of 2025, we recorded $3.9 million of impairment charge related to the Exemplar reporting unit, compared to $5.8 million of impairment charge related to the Exemplar reporting unit in the prior year. See "Notes to the Consolidated Financial Statements - Note 9" appearing elsewhere in this Annual Report for further discussion of ActoBio long-lived assets and goodwill impairment and Exemplar goodwill impairment.

Total other income (expense), net

Total other income (expense) net, changed from income of $7.0 million to expense of $140.1 million, resulting in a decrease of $147.1 million, or >(200)% compared to the year ended December 31, 2024. This decrease was primarily driven by a $139.5 million increase in the fair value of warrant liabilities prior to their reclassification into permanent equity in the third quarter of 2025. Substantially all of the increase in the fair value of warrant liabilities was as a result of an increase in our common stock price at the valuation date compared to December 31, 2024.

In addition, the prior year included an $8.5 million gain on the sale of intellectual property and royalty rights related to FCX-007 in December 2024, which did not recur in the current year. See "Notes to the Consolidated Financial Statements - Note 2" appearing elsewhere in this Annual Report for further discussion on gain on transfers of nonfinancial assets.

Deemed dividend on preferred stock

On September 15, 2025, all Series A Preferred Stockholders converted their 79,000 shares (stated value of $79.0 million) into 54,937,411 shares of common stock at the then-current conversion rate of 695.4103 shares per $1,000. Because the conversion feature resulted in a variable number of common shares to be issued, the conversion was accounted for as a redemption under Accounting Standards Codification ("ASC") 260, resulting in the recording of a $179.0 million non-cash deemed dividend as a reduction to additional paid-in capital (and an increase in net loss attributable to common shareholders when computing net loss per share).

Net loss per share attributable to common shareholders

Net loss per share attributable to common shareholders (basic and diluted) increased to $1.37 for the year ended December 31, 2025 , compared to $0.47 for the year ended December 31, 2024. The increase was primarily driven by the changes noted above (including the $139.5 million change in fair value of warrant liabilities, representing $0.45 per basic and diluted share) plus the deemed dividend, as discussed above (representing $0.57 per basic and diluted share), partially offset by a higher weighted-average number of shares outstanding, primarily due to the conversion of preferred shares into common shares during the third quarter of 2025.

Liquidity and capital resources

Sources of liquidity

We have incurred losses from operations since our inception, and as of December 31, 2025, we had an accumulated deficit of $2.3 billion. From our inception through December 31, 2025, we have funded our operations principally with proceeds received from private and public equity and debt offerings, cash received from our collaborators, and through product and service sales made directly to customers, and sales of non-core businesses. As of December 31, 2025, we had cash and cash equivalents of $30.2 million and short-term and long-term investments of $70.1 million. Cash in excess of immediate requirements is typically invested primarily in money market funds, United States government debt securities, and certificates of deposit in order to maintain liquidity and preserve capital.

In January 2023, we closed a public offering of 43,962,640 shares of our common stock, resulting in net proceeds to us of $72.8 million, after deducting underwriting discounts, fees, and other offering expenses.

In August 2024, we closed a public offering of 39,878,939 shares of our common stock, resulting in net proceeds to us of $30.9 million, after deducting underwriting discounts, fees, and an estimate of other offering expenses.

In December 2024, we issued 79,000 shares of 8.00% Series A Convertible Perpetual Preferred Stock with an initial liquidation preference and stated value of $1,000 per share, together with warrants to purchase 52,666,669 shares of common stock for net proceeds of approximately $78.5 million, after deducting offering expenses, which expenses had not been paid as of December 31, 2025.

In September 2025, the Company entered into a loan agreement with investment entities managed by Pharmakon Advisors, LP. The Company received net proceeds of $92,818 after deducting fees and expenses of $7,182. See "Notes to the Consolidated Financial Statements - Note 10" appearing elsewhere in this Annual Report for further discussion on this loan agreement.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below (dollar amounts in thousands):

	Year Ended December 31,		
	2025	2024	2023
		(In thousands)	
Net cash provided by (used in):			
Operating activities	$ (87,831)	$ (68,173)	$ (66,930)
Investing activities	(1,535)	(20,714)	(3,087)
Financing activities	90,048	110,583	29,589
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	35	(27)	(320)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 717	$ 21,669	$ (40,748)

Cash flows from operating activities:

In 2025, our net loss was $250.6 million, which includes the following significant noncash expenses and benefits totaling $156.2 million: (i) $139.5 million of appreciation in the fair value of warrant liabilities prior to their reclassification to permanent equity in the third quarter of 2025, (ii) $3.9 million impairment losses, (iii) $10.9 million of stock-based compensation expense, (iii) $3.2 million of depreciation and amortization expense, (iv) $0.5 million of shares issued as payment for services, and (v) $0.4 million of accretion of debt discount and amortization of deferred financing costs, partially offset by non-cash benefits of $2.2 million due to amortization of discounts on investments. In addition, changes in operating assets and liabilities provided $6.6 million of cash for operating activities.

In 2024, our net loss was $126.2 million, which includes the following significant noncash expenses and benefits totaling $55.1 million: (i) $40.3 million impairment losses, (ii) $9.5 million of stock-based compensation expense, (iii) $4.5 million of depreciation and amortization expense, (iv) $2.9 million due to reclassification of cumulative translation losses, and (v) $0.6 million of shares issued as payment for services, partially offset by non-cash benefits of $1.8 million due to deferred income

taxes and $0.9 million due to amortization of discounts on investments. In addition, changes in operating assets and liabilities provided $2.7 million of cash for operating activities.

In 2023, our net loss was $95.9 million, which includes the following significant noncash expenses: (i) $9.9 million of stock-based compensation expense, (ii) $10.8 million impairment losses, (iii) $6.7 million of depreciation and amortization expense, offset by (iv) $1.8 million due to amortization of discounts on investments. In addition, changes in operating assets and liabilities increased cash from operating activities by $3.4 million.

Our 2025 cash used in operations increased by $19.7 million from the year ended December 31, 2024, primarily due to increased cash outflows associated with commercialization expenses for Papzimeos.

Our 2024 cash used in operations increased by $1.2 million from the year ended December 31, 2023, primarily due to increase in cash outflows related to ActoBio during 2024 as we ceased operations and paid severance costs.

Cash flows from investing activities:

During 2025, we purchased $0.5 million of investments, net, and invested $2 million in property plant and equipment, primarily related to the completion of our cGMP manufacturing facility.

During 2024, we purchased $12.2 million of investments, net, and invested $8.6 million in property plant and equipment, primarily related to the build-out of our cGMP manufacturing facility.

During 2023, we purchased $185.0 million of investments, using both the proceeds received from the underwritten public offering discussed below under cash flows from financing activities, as well as reinvesting a portion of the proceeds received from the $183.4 million sales and maturities of investments. The Company also purchased $1.5 million of property plant and equipment during 2023.

Cash flows from financing activities:

During 2025, we received $92.8 million under the term loan with entities managed by Pharmakon Advisors, LP, and $1.2 million from the exercises of stock options, and made the following financing activity payments: $0.4 million for costs related to a prior year equity issuance, $0.5 million for costs related to the prior year preferred stock issuance, $1.8 million to taxing authorities related to vesting of equity awards, and $1.3 million for performance share units settled in cash.

During 2024, we received $31.2 million of proceeds, net of certain issuance costs, from the sale of our common stock in an underwritten public offering, $79.0 million of gross proceeds from the issuance of the Series A Preferred Stock and the Warrants and $0.3 million of proceeds from stock option exercises.

During 2023, we received $72.8 million of proceeds from the sale of our common stock in an underwritten public offering and retired $43.2 million of our Convertible Notes using restricted cash.

Future capital requirements

Our future capital requirements will depend on many factors, including:

- the successful commercialization of Papzimeos and the level of revenue generated from its sales;
- progress in our research and development programs, as well as the magnitude and speed of development of these programs;
- capital expenditures to expand our manufacturing capabilities, including the potential manufacturing of other product candidates;
- the speed and scale of continuing to build our commercial operations;
- adequate third-party coverage and reimbursement for Papzimeos;
- selling and marketing activities undertaken in connection with the commercialization of Papzimeos, potential

commercialization of any future product candidates, if approved, and costs involved in creating and maintaining an effective sales and marketing organization;

- the timing of regulatory approval of our product candidates;
- the timing, receipt, and amount of any payments received in connection with strategic transactions;
- the timing, receipt, and amount of sales and royalties, if any, from our product candidates;
- the timing and capital requirements to scale up our various product candidates and service offerings and customer acceptance thereof;
- the timing of and amount of payments under our indemnification accrual;
- the resources, time, and cost required for the preparation, filing, prosecution, maintenance, and enforcement of our intellectual property portfolio;
- strategic mergers and acquisitions, if any, including both the upfront acquisition cost as well as the cost to integrate, maintain, and expand the strategic target; and
- the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes.

Until such time, if ever, as we can regularly generate positive operating cash flows, we plan to finance our cash needs through a combination of collection of accounts receivables from the sale of Papzimeos, debt and/or royalty financings, equity offerings, government, or other third-party funding, strategic alliances, sales of assets, and licensing arrangements. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. To the extent that we raise additional capital through the sale of equity, convertible debt, warrants or preferred securities, the ownership interests of our common shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common shareholders. Our current stock price may make it more difficult to pursue equity financings and lead to substantial dilution if the price of our common stock does not increase. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through strategic transactions, collaborations, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or to grant licenses on terms that may not be favorable to us.

We are subject to a number of risks similar to those of other companies launching their first FDA approved drug, while conducting high-risk, early-stage research and development of product candidates. Principal among these risks are market demand for Papzimeos, dependence on key individuals and intellectual property, competition from other products and companies, and the technical risks associated with the successful research, development, and clinical manufacturing of its product candidates. Our success is dependent upon our ability to continue to generate and/or raise additional capital in order to fund ongoing research and development, obtain regulatory approval of our products, successfully commercialize our products, generate revenue, meet our obligations, and, ultimately, attain profitable operations.

Our consolidated financial statements as of and for the year ended December 31, 2025 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Based on current projections, management believes that its existing cash, cash equivalents and short and long-term investments, combined with anticipated potential revenue from the commercialization of Papzimeos, will enable us to continue our operations for at least one year from the date of this filing. We are subject to all of the risks inherent in the development of new products (including manufacturing and commercialization of Papzimeos), and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Contractual obligations and commitments

The following table summarizes our significant contractual obligations and commitments from operations as of December 31, 2025 and the effects such obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Operating leases	$ 6,512	$ 1,680	$ 2,891	$ 1,941	$ —
Cash interest payable on long term debt (*)	40,177	10,392	20,813	8,972	—
Long-term debt	100,000	—	12,500	87,500	—
Purchase Commitments	249	115	134	—	—
Total	$ 146,938	$ 12,187	$ 36,338	$ 98,413	$ —

(*) Interest is calculated using static annual rate of 10.25%, although our long-term debt carries a variable interest rate (see "Notes to the Consolidated Financial Statements - Note 10" appearing elsewhere in this Annual Report on Form 10-K).

In addition to the obligations in the table above, as of December 31, 2025, we are party to in-licensed research and development agreements with various academic and commercial institutions where we could be required to make future payments for annual maintenance fees as well as for milestones and royalties we might receive upon commercial sales of products that incorporate their technologies. These agreements are generally subject to termination by us and therefore no amounts are included in the tables above. As of December 31, 2025, we also had research and development commitments with third parties totaling $6.2 million that had not yet been incurred.

Net operating losses

As of December 31, 2025, we had net operating loss carryforwards of approximately $1,120.4 million for United States federal income tax purposes available to offset future taxable income, including $911.9 million generated after 2017, United States capital loss carryforwards of $1.4 million, and United States federal and state research and development tax credits of approximately $17.9 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, ("Section 382"). Net operating loss carryforwards generated prior to 2018 will expire if unutilized from 2026 to 2037, and capital loss carryforwards will expire if unutilized from 2027 to 2029. As a result of our past stock issuances, as well as due to prior mergers and acquisitions, certain of our net operating losses have been subject to limitations pursuant to Section 382. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation. As of December 31, 2025, our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately $80.1 million, most of which do not expire.

Our net deferred tax assets, which primarily relate to these loss carryforwards, are offset by a valuation allowance due to our history of net losses.

Critical accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in "Notes to the Consolidated Financial Statements - Note 2" appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue recognition

We recognize revenue when our customer obtains control of the promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification ("ASC") 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the promises and distinct performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) we satisfy the performance obligations.

Product and service revenues

Product and service revenues are generated through both Papzimeos, our newly commercialized biopharmaceutical product (Papzimeos), and Exemplar, which provides genetically engineered miniature swine models and related services. Although our underlying revenue recognition policies are described in Note 2 to the Consolidated Financial Statements appearing elsewhere in this Annual Report, the application of those policies requires management to make significant estimates and judgments as described below.

Papzimeos Commercial Product Revenue

We began commercial sales of Papzimeos in the fourth quarter of 2025 following FDA approval. Revenue from Papzimeos is recognized when the performance obligation to provide units of Papzimeos is satisfied, which occurs upon delivery to the site of care or specialty pharmacy. Because Papzimeos is in its first commercial year, revenue recognition involves significant estimation uncertainty, specifically relating to variable consideration, which includes:

- Chargebacks and contractual commitments requiring us to provide products at discounted prices compared with wholesale acquisition cost
- Government and payer rebates associated with Medicaid, Medicare, managed care programs, and commercial payers
- Product returns, which are estimated based on historical data, expected prescription demand, distribution channel inventory, and benchmarking for newly launched specialty products

These estimates require judgment due to limited historical experience, evolving payer and provider utilization, and the inherent uncertainty of a new product launch. Changes in these assumptions could materially affect net revenue recognized in future periods.

Exemplar Product and Service Revenues

We recognize product and service revenue at a point in time when control of the promised product is transferred to the customer or over time when the promised service is rendered. We typically recognize revenue using an out-based measure, generally time elapsed or days of service, to measure progress and transfer of the control of the performance obligation to the customer. When recognizing revenue, we utilize judgments in determining whether individual products and services in a contract are distinct, the appropriate measure of progress for services performed over time, and any adjustments for expected discounts or price concessions, when applicable.

Valuation of goodwill and long-lived assets

We evaluate long-lived assets to be held and used, which include property, plant and equipment and intangible assets subject to amortization, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable.

Goodwill is tested for impairment annually at December 31, or more frequently if events or circumstances between annual tests indicate that the assets may be impaired. We perform a qualitative assessment to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount prior to performing the quantitative goodwill impairment test. If this is the case, the quantitative goodwill impairment test is required. If the quantitative goodwill impairment test is

required or elected to be performed, first, the fair value of the reporting unit is compared with its carrying amount (including goodwill). Impairment losses on goodwill are recognized based solely on a comparison of their fair value to carrying value, without consideration of any recoverability test.

When we perform quantitative evaluations, the fair value of the reporting units is primarily determined based on the income approach. The income approach is a valuation technique in which fair value is based on forecasted future cash flows, discounted at the appropriate rate of return commensurate with the risk as well as current rates of return for equity and debt capital as of the valuation date. The forecast used in our estimation of fair value was developed by management based on historical operating results, incorporating adjustments to reflect management's planned changes in operations and market considerations.

During the years ended December 31, 2025 and 2024, we recorded $3.9 million and $40.3 million, respectively, of impairment charges from continuing operations to write down the values of goodwill and other long-lived assets. See additional discussion regarding these impairments in "Notes to the Consolidated Financial Statements - Note 8 and 9" appearing elsewhere in this Annual Report.

Research and Development Expense, Including Clinical Trial Accruals/Expenses

We consider that regulatory requirements inherent in the research and development of new products preclude us from capitalizing such costs. Research and development costs consist of salaries and related costs of research and development personnel, including stock-based compensation expense, costs to acquire technology rights, contract research organizations and consultants, facilities, materials and supplies associated with research and development projects as well as various laboratory studies.

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, and data management costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid expenses and other or other accrued liabilities. These third-party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze the progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made. The historical clinical accrual estimates have not been materially different from the actual costs.

Recent accounting pronouncements

See "Notes to the Consolidated Financial Statements - Note 2" appearing elsewhere in this Annual Report for a description of recent accounting pronouncements applicable to our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The following section provides quantitative information on our exposure to interest rate risk. We make use of sensitivity analyses that are inherently limited in estimating actual losses in fair value that can occur from changes in market conditions.

Interest rate risk

We had cash, cash equivalents and short-term and long-term investments of $100.4 million and $97.9 million as of December 31, 2025 and 2024, respectively. The primary objectives of our investment activities are to preserve principal, maintain liquidity, and maximize income without significantly increasing risk. Our investments consist of corporate bonds, United States government debt securities,certificates of deposit, which may be subject to market risk due to changes in prevailing interest rates that may cause the fair values of our investments to fluctuate. We believe that a hypothetical 100 basis point increase in interest rates would not materially affect the fair value of our interest-sensitive financial instruments and any such losses would only be realized if we sold the investments prior to maturity.

In addition to our investment portfolio, as of December 31, 2025, our long-term debt totaled $93.2 million and is subject to interest rate risk. Our long-term debt bears interest at a floating rate based upon the secured overnight financing rate ("SOFR"), plus a margin of 6.5% per annum. The SOFR is subject to a 3.75% floor. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. Based on the outstanding principal balance as of December 31, 2025, a hypothetical 100 basis point increase in the SOFR would result in an approximate $1.0 million increase in annual interest expense.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-47 of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on their evaluation of our disclosure controls and procedures as of December 31, 2025, our chief executive officer and chief financial officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) and Rule 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework* (2013). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2025, certain of our officers and directors adopted Rule 10b5-1 trading arrangements as follows.

On December 31, 2025, Helen Sabzevari, Precigen's Chief Executive Officer, adopted a stock trading plan. Ms. Sabzevari's trading plan provides for the sale of up to 130,424 shares. The first sale will not occur until March 31, 2026 at the earliest. Ms. Sabzevari's trading plan is scheduled to terminate on December 31, 2026.

The Rule 10b5-1 trading arrangements described above were adopted and pre-cleared in accordance with Precigen’s Insider Trading Policy and actual transactions made pursuant to such trading arrangements will be disclosed publicly in future Section 16 filings with the SEC. Other than disclosed above, no other officer adopted, modified or terminated a Rule 10b5-1 trading arrangement or “non-Rule 10b5-1 trading arrangement” (as defined in Item 408 of Regulation S-K) during the three months ended December 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all officers, directors, and employees, which is available on our website (*investors.precigen.com*) under "Corporate Governance." We will provide a copy of this document, without charge, upon request, by writing to us at Precigen, Inc., 20374 Seneca Meadows Parkway, Germantown, Maryland 20876, Attention: Investor Relations. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the address and location specified above.

Insider Trading Policies and Procedures

The Company has insider trading policies and procedures that govern the purchase, sale, and other dispositions of its securities by directors, officers, and employees, and by the Company itself/and have implemented processes for the Company. We believe these policies and procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable listing standards.

Item 11. Executive Compensation

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report:

1. Financial Statements.

   Consolidated Financial Statements of Precigen, Inc. and Subsidiaries

   Report of Independent Registered Public Accounting Firm

   Consolidated Balance Sheets as of December 31, 2025 and 2024

   Consolidated Statements of Operations for the Years Ended December 31, 2025, 2024, and 2023

   Consolidated Statements of Comprehensive (Loss) Income for the Years Ended December 31, 2025, 2024, and 2023

   Consolidated Statements of Mezzanine Equity and Shareholders' Equity for the Years Ended December 31, 2025, 2024, and 2023

   Consolidated Statements of Cash Flows for the Years Ended December 31, 2025, 2024, and 2023

   Notes to the Consolidated Financial Statements

2. Financial Statement Schedules.

   All financial statement schedules have been omitted because either the required information is not applicable or the information required is included in the consolidated financial statements and notes thereto included in this Annual Report.

3. Exhibits.

   The exhibits are listed in Item 15(b) below.

(b) Exhibits

The following exhibits are filed with this Annual Report or incorporated by reference:

Exhibit No.	Description
3.1*	Amended and Restated Articles of Incorporation (11)
3.1A*	Articles of Amendment to the Amended and Restated Articles of Incorporation - December 30, 2024 (18)
3.1B*	Articles of Amendment to the Amended and Restated Articles of Incorporation - July 28, 2025 (20)
3.2*	Amended and Restated Bylaws (14)
4.1*	Specimen certificate evidencing shares of common stock (16)
4.3	Description of Securities (12)
4.4*	Form of Certificate for the 8.00% Series A Convertible Perpetual Preferred Stock (18)
10.1†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 9, 2014 (2)
10.1A†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Restricted Stock Agreement (2)
10.1B†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Incentive Stock Option Agreement (2)

10.1C†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Nonqualified Stock Option Agreement (2)
10.1D†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 11, 2015 (3)
10.1E†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 9, 2016 (4)
10.1F†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 28, 2017 (5)
10.1G†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 7, 2018 (7)
10.1H†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 12, 2019 (9)
10.1I†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective January 5, 2020 (13)
10.1J†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 19, 2020 (15)
10.1K†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Officers (6)
10.1L†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Directors (6)
10.2*	2019 Incentive Plan of the Company for Non-Employee Service Providers, effective as of June 12, 2019 (9) Amendment No.1 to Precigen, Inc. 2019 Incentive Plan for Non-Employee Service Providers Amendment No.2 to Precigen, Inc. 2019 Incentive Plan for Non-Employee Service Providers
10.3†*	Form of Continuing Employment Agreement (2019) (8)
10.4†*	Employment Agreement, dated January 1, 2020, by and between the Company and Helen Sabzevari, Ph.D. (11)
10.5†*	Executive Chairman Compensation Arrangement, by and between the Company and Randal J. Kirk (17)
10.6*	Securities Issuance Agreement by and among the Company, The University of Texas System Board of Regents on behalf of The University of Texas MD Anderson Cancer Center dated as of January 13, 2015 (1)
10.7†*	Precigen, Inc. 2023 Omnibus Incentive Plan (10) Amendment No.1 to Precigen, Inc. 2023 Omnibus Incentive Plan Amendment No.2 to Precigen, Inc. 2023 Omnibus Incentive Plan
10.8†*	Form of Restricted Stock Unit Agreement under the 2023 Omnibus Incentive Plan (19)
10.9†**	Form of Incentive Stock Option Agreement under the 2023 Omnibus Incentive Plan (19)
10.10†**	Form of Continuing Employment Agreement (19)
10.11†*	Form of Performance Stock Unit Agreement under the 2023 Omnibus Incentive Plan (17)
10.12††	Product Commercialization Agreement with Eversana Life Science Services, LLC, dated March 19, 2025 (19)
10.13††	Loan Agreement dated as of September 3, 2025, among Precigen, Inc., the guarantors signatory thereto, Biopharma Credit PLC as Collateral Agent, BPCR Limited Partnership and Biopharma Credit Investments V (21)
10.14††	Commercial Supply Agreement, dated August 13, 2025, by and between Precigen, Inc. and Catalent Maryland, Inc. (21)
19.1	Insider Trading Policy (19)
21.1	List of Subsidiaries of Precigen, Inc.
23.1	Consent of Deloitte & Touche LLP

31.1	Certification of Helen Sabzevari, Chief Executive Officer (Principal Executive Officer) of Precigen, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Harry Thomasian Jr., Chief Financial Officer (Principal Financial Officer) of Precigen, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Helen Sabzevari, Chief Executive Officer (Principal Executive Officer) of Precigen, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Harry Thomasian Jr., Chief Financial Officer (Principal Financial Officer) of Precigen, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97**	Precigen, Inc. Financial Statement Compensation Recoupment Policy
101**	Interactive Data File (Precigen, Inc. and Subsidiaries Consolidated Financial Statements for the years ended December 31, 2025, 2024, and 2023, formatted in Inline XBRL (eXtensible Business Reporting Language)). Attached as Exhibit 101 are the following documents formatted in XBRL: (i) the Consolidated Balance Sheets as of December 31, 2025 and 2024, (ii) the Consolidated Statements of Operations for the years ended December 31, 2025, 2024, and 2023, (iii) the Consolidated Statements of Shareholders' and Total Equity for the years ended December 31, 2025, 2024, and 2023, (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2025, 2024, and 2023 and (v) the Notes to the Consolidated Financial Statements.
104**	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Previously filed and incorporated by reference to the exhibit indicated in the following filings by the Company:

(1) Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 14, 2015.

(2) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2014.

(3) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 17, 2015.

(4) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2016.

(5) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 30, 2017.

(6) Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2018.

(7) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 8, 2018.

(8) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 9, 2019.

(9) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 9, 2019.

(10) Registration Statement on Form S-8, filed with the Securities and Exchange Commission on July 6, 2023.

(11) Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 4, 2020.

(12) Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 2, 2020.

(13) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 11, 2020.

(14) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 4, 2020.

(15) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 19, 2020.

(16) Registration Statement on Form S-3, filed with the Securities and Exchange Commission on June 22, 2020.

(17) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 9, 2020.

(18) Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 30, 2024

(19) Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 19, 2024.

(20) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 12, 2025.

(21) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 13, 2025.

** Furnished herewith

† Indicates management contract or compensatory plan.

†† Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

(c) Financial Statement Schedules

The response to Item 15(a)2 is incorporated herein by reference as applicable.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 25, 2026

PRECIGEN, INC.

By: /S/ HELEN SABZEVARI
Helen Sabzevari
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ HELEN SABZEVARI Helen Sabzevari	Chief Executive Officer and Director (Principal Executive Officer)	3/25/2026
/S/ HARRY THOMASIAN JR. Harry Thomasian Jr.	Chief Financial Officer (Principal Accounting and Financial Officer)	3/25/2026
/S/ RANDAL J. KIRK Randal J. Kirk	Executive Chairman	3/25/2026
/S/ NANCY H. AGEE Nancy H. Agee	Director	3/25/2026
/S/ CESAR L. ALVAREZ Cesar L. Alvarez	Director	3/25/2026
/S/ STEVEN FRANK Steven Frank	Director	3/25/2026
/S/ VINITA D. GUPTA Vinita D. Gupta	Director	3/25/2026
/S/ FRED HASSAN Fred Hassan	Director	3/25/2026
/S/ JEFFREY B. KINDLER Jeffrey B. Kindler	Director	3/25/2026
/S/ JAMES S. TURLEY James S. Turley	Director	3/25/2026

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Precigen, Inc. and Subsidiaries

Consolidated Financial Statements

December 31, 2025, 2024, and 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Precigen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Precigen, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, mezzanine equity and shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Conversion of Preferred Shares – Refer to Notes 6 and 12 to the financial statements

Critical Audit Matter Description

On September 15, 2025, all of the holders of the Series A Preferred Stock converted 79,000 shares of Preferred Stock (with an aggregate stated value of $79,000) into 54,937,411 shares of common stock of the Company, which were delivered to such holders on September 17, 2025 pursuant to the terms of the Amended and Restated Articles of Incorporation and such Preferred Stock at the then-current conversion rate of 695.4103 shares of common stock of the Company per $1,000 of stated value of Preferred Stock. The Company determined that following the conversion of Preferred Stock and PIK Preferred Shares, the Company no longer holds convertible securities, qualifying them for the equity scope exception under ASC 815. The Warrants were reclassified from liability to equity at the date of settlement, September 17, 2025.

We identified the classification and recognition for conversion of preferred shares as a critical audit matter because of the judgments necessary to determine the impact on the consolidated financial statements and the fair value of the warrant liability and PIK preferred shares. This required a high degree of auditor judgment and an increased extent of effort, including the need

to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's expected volatility of common stock, including selection of the comparable public companies.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification and recognition for conversion of preferred shares included the following, among others:

- We evaluated the adequacy of management's accounting assessment and their conclusion to account for the conversion of preferred shares and classify warrants as permanent equity considering the following authoritative literature:
  - ASC 815, Derivatives and Hedging
  - ASC 480, Distinguishing Liabilities from Equity
  - ASC 470, Debt with Conversion and Other Options
  - ASC 260, Presentation - Earnings Per Share
- With the assistance of our fair value specialists, we evaluated the fair value measurement of the warrant liability and PIK preferred shares, as follows:
  - Evaluated management's valuation methodology used to arrive at the amount of warrant liability and paid-in-kind preferred shares.
  - Evaluated the incorporation of the applicable estimates and assumptions into the Black-Scholes model and risk-free interest rate as well as testing the model's mathematical accuracy.
  - Tested the underlying source information used by management in making the estimates and assumptions, including the selection of the comparable public companies used in the expected volatility of the common stock.
  - Developed an independent estimate of the warrant liability and paid-in-kind preferred shares and compared our estimate to that used by management.
  - Evaluated the change in fair value of warrants at redemption
- We evaluated the presentation and disclosure of the conversion of preferred shares and warrants in the financial statements.
  - Evaluated the value of common shares at conversion and deemed dividend of preferred shares in accordance with ASC 260.

/s/ Deloitte & Touche LLP

Baltimore, Maryland
March 25, 2026

We have served as the Company's auditor since 2019.

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2025, and 2024

(Amounts in thousands, except share data)	2025	2024
Assets		
Current assets		
Cash and cash equivalents	$ 30,234	$ 29,517
Short-term investments	67,624	68,393
Receivables		
Trade, less allowance for credit losses of $0 as of December 31, 2025 and 2024.	3,916	926
Other	446	237
Inventory	9,581	—
Prepaid expenses and other	3,434	3,341
Total current assets	115,235	102,414
Long-term investments	2,511	—
Property, plant and equipment, net	13,758	13,831
Intangible assets, net	3,182	4,455
Goodwill	15,232	19,139
Right-of-use assets	4,679	5,056
Other assets	908	371
Total assets	$ 155,505	$ 145,266

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2025 and 2024

(Amounts in thousands, except share data)	2025	2024
Liabilities, Mezzanine Equity and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 11,985	$ 3,531
Accrued compensation and benefits	10,199	8,417
Other accrued liabilities	10,993	4,812
Indemnification accrual	2,476	3,213
Deferred revenue	517	589
Current portion of lease liabilities	1,136	956
Total current liabilities	37,306	21,518
Long-term debt	93,174	—
Deferred revenue, net of current portion	—	1,934
Lease liabilities, net of current portion	3,980	4,546
Other long-term liabilities	134	—
Warrant liabilities	—	50,537
Total liabilities	134,594	78,535
Commitments and contingencies (Note 15)		
Mezzanine Equity		
Series A Preferred Stock, no par value, 81,000 shares authorized as of December 31, 2025 and December 31, 2024; zero and 79,000 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively (aggregate liquidation preference of zero as of December 31, 2025 and $79,000 as of December 31, 2024).	—	28,218
Shareholders' equity		
Common stock, no par value, 700,000,000 shares authorized as of December 31, 2025 and 400,000,000 authorized as of December 31, 2024; 353,910,926 shares and 292,869,097 shares issued as of December 31, 2025 and 2024, 353,910,926 shares and 292,869,097 shares outstanding as of December 31, 2025 and 2024, respectively.	—	—
Additional paid-in capital	2,362,252	2,129,207
Accumulated deficit	(2,341,348)	(2,090,706)
Accumulated other comprehensive income	7	12
Total shareholders' equity	20,911	38,513
Total liabilities, mezzanine equity and shareholders' equity	$ 155,505	$ 145,266

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Operations
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands, except share and per share data)	2025	2024	2023
Revenues			
Collaboration and licensing revenues	$ 1,818	$ —	$ 75
Product revenues, net	3,975	422	840
Service revenues	3,891	3,503	5,310
Total revenues	9,684	3,925	6,225
Operating Expenses			
Cost of products and services	4,823	4,267	6,119
Research and development	41,333	53,070	48,614
Selling, general and administrative	70,128	41,293	40,415
Impairment of goodwill	3,907	7,409	10,390
Impairment of other noncurrent assets	—	32,915	445
Total operating expenses	120,191	138,954	105,983
Operating loss	(110,507)	(135,029)	(99,758)
Other Income (Expense), Net			
Change in fair value of warrant liabilities	(139,523)	—	—
Interest expense	(3,867)	(6)	(468)
Interest income	3,215	1,418	3,237
Other income, net	43	5,589	627
Total other (expense) income, net	(140,132)	7,001	3,396
Loss before income taxes	(250,639)	(128,028)	(96,362)
Income tax (expense) benefit	(3)	1,793	458
Net loss	$ (250,642)	$ (126,235)	$ (95,904)
Deemed dividend on preferred stock	(179,000)	—	—
Net loss attributable to common shareholders	$ (429,642)	$ (126,235)	$ (95,904)
Net loss per share attributable to common shareholders			
Net loss per share attributable to common shareholders, basic and diluted	$ (1.37)	$ (0.47)	$ (0.39)
Weighted average shares outstanding, basic and diluted	312,980,562	267,727,426	244,536,221

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands)	2025	2024	2023
Net loss	$ (250,642)	$ (126,235)	$ (95,904)
Other comprehensive income (loss):			
Unrealized (loss) gain on investments	(5)	43	727
Gain (loss) on foreign currency translation adjustments	—	(999)	814
Release of cumulative foreign currency translation adjustments to other income (expense), net	—	2,915	—
Comprehensive loss	(250,647)	(124,276)	(94,363)
Deemed dividend on preferred stock	(179,000)	—	—
Comprehensive loss attributable to common shareholders	$ (429,647)	$ (124,276)	$ (94,363)

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Mezzanine Equity and Shareholders' Equity
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands, except share data)	Mezzanine Equity		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	—	$ —	208,150,021	$ —	—	$ —	$ 1,998,314	$ (3,488)	$ (1,868,567)	$ 126,259
Stock-based compensation expense	—	—	—	—	—	—	9,888	—	—	9,888
Shares issued upon vesting of restricted stock units and for exercises of stock options	—	—	751,233	—	—	—	—	—	—	—
Shares issued for accrued compensation	—	—	3,068,825	—	—	—	3,361	—	—	3,361
Shares issued as payment for services	—	—	465,808	—	—	—	545	—	—	545
Shares issued in public offering, net of issuance costs			43,962,640	—			72,808	—	—	72,808
Shares returned pursuant to share lending agreement			(7,479,431)	—	7,479,431		—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(95,904)	(95,904)
Other comprehensive income	—	—	—	—	—	—	—	1,541	—	1,541
Balances at December 31, 2023	—	$ —	248,919,096	$ —	7,479,431	$ —	$ 2,084,916	$ (1,947)	$ (1,964,471)	$ 118,498

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Mezzanine Equity and Shareholders' Equity
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands, except share data)	Mezzanine Equity		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	—	$ —	248,919,096	$ —	7,479,431	$ —	$ 2,084,916	$ (1,947)	$ (1,964,471)	$ 118,498
Stock-based compensation expense	—	—	—	—	—	—	9,471	—	—	9,471
Shares issued upon vesting of restricted stock units and for exercises of stock options	—	—	1,514,394	—	(1,514,394)	—	346	—	—	346
Shares issued for accrued compensation	—	—	2,170,885	—	(2,170,885)	—	3,039	—	—	3,039
Shares issued as payment for services	—	—	385,783	—	(385,783)	—	553	—	—	553
Shares issued in public offering, net of issuance costs	—	—	39,878,939	—	(3,408,369)	—	30,882	—	—	30,882
Issuance of Series A Preferred Stock	79,000	$28,218	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(126,235)	(126,235)
Reclassification of cumulative foreign currency translation adjustments to other income (expense), net			—	—	—	—	—	2,915	—	2,915
Other comprehensive loss	—	—	—	—	—	—	—	(956)	—	(956)
Balances at December 31, 2024	79,000	$28,218	292,869,097	$ —	—	$ —	$ 2,129,207	$ 12	$ (2,090,706)	$ 38,513

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Mezzanine Equity and Shareholders' Equity
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands, except share data)	Mezzanine Equity		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2024	79,000	$ 28,218	292,869,097	$ —	—	$ —	$ 2,129,207	$ 12	$ (2,090,706)	$ 38,513
Stock-based compensation expense	—	—	—	—	—	—	11,238	—	—	11,238
Shares issued upon vesting of restricted stock units, performance stock units and for exercises of stock options	—	—	3,510,139	—		—	1,202	—	—	1,202
Shares issued for accrued compensation	—	—	3,566,563	—		—	4,880	—	—	4,880
Shares issued as payment for services	—	—	302,582	—		—	527	—	—	527
Repurchase of shares to satisfy tax withholding	—	—	(1,274,866)	—		—	(1,776)	—	—	(1,776)
Vested Performance stock units paid in cash	—	—	—	—	—	—	(1,304)	—	—	(1,304)
Preferred stock deemed dividend upon conversion	—	179,000	—	—	—	—	(179,000)	—	—	(179,000)
Net loss	—	—	—	—	—	—	—	—	(250,642)	(250,642)
Preferred stock conversion to common stock	(79,000)	(209,883)	54,937,411	—	—	—	209,883	—	—	209,883
Other	—	2,665	—	—	—	—	(2,665)	—	—	(2,665)
Warrant liability reclassified to permanent equity	—	—	—	—	—	—	190,060		—	190,060
Other comprehensive loss	—	—	—	—	—	—	—	(5)	—	(5)
Balances at December 31, 2025	—	$ —	353,910,926	$ —	—	$ —	$ 2,362,252	$ 7	$ (2,341,348)	$ 20,911

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands)	2025	2024	2023
Cash flows from operating activities			
Net loss	$ (250,642)	$ (126,235)	$ (95,904)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,199	4,526	6,668
Gain (Loss) on disposals of assets, net	14	(2)	(72)
Impairment of goodwill	3,907	7,409	10,390
Impairment of other noncurrent assets	—	32,915	445
Gain on debt retirement	—	—	(60)
Loss on reclassification of cumulative foreign currency translation adjustments	—	2,915	—
Change in fair value of warrant liabilities	139,523	—	—
Amortization of discounts on investments, net	(2,205)	(883)	(1,809)
Stock-based compensation expense	10,866	9,471	9,888
Shares issued as payment for services	527	553	545
Accretion of debt discount and amortization of deferred financing costs	356	—	60
Deferred income taxes	—	(1,795)	(479)
Issuance cost related to Warrants	—	292	—
Other noncash items	—	—	2
Changes in operating assets and liabilities:			
Receivables:			
Trade	(2,990)	(24)	76
Other	(209)	438	12,153
Inventory	(9,209)	—	—
Prepaid expenses and other	(93)	981	748
Other assets	(556)	120	129
Accounts payable	8,768	1,549	(2,421)
Accrued compensation and benefits	6,662	3,145	5,227
Other accrued liabilities	6,869	(1,827)	782
Deferred revenue	(2,006)	196	484
Lease liabilities	(9)	(55)	(107)
Other long-term liabilities	134	—	—
Indemnification Accruals	(737)	(1,862)	(13,675)
Net cash used in operating activities	(87,831)	(68,173)	(66,930)

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands)	2025	2024	2023
Cash flows from investing activities			
Purchases of investments	(208,006)	(187,206)	(185,026)
Sales and maturities of investments	208,466	175,016	183,377
Purchases of property, plant and equipment	(1,995)	(8,584)	(1,536)
Proceeds from sale of assets	—	60	98
Net cash used in investing activities	(1,535)	(20,714)	(3,087)
Cash flows from financing activities			
(Payments) Proceeds from issuance of common stock, net of issuance costs	(355)	31,237	72,808
Proceeds from long-term debt, net of issuance costs	92,818	—	—
Payments of long-term debt, including cost to retire of $120 in 2023	—	—	(43,219)
(Payments) Proceeds from issuance of Series A Preferred Stock and Warrants, net of issuance cost	(537)	79,000	—
Cash Settlement of Performance Stock Units	(1,304)	—	—
Payments to taxing authorities in connection with shares directly withheld from employees	(1,776)	—	—
Proceeds from stock option exercises	1,202	346	—
Net cash provided by financing activities	90,048	110,583	29,589
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	35	(27)	(320)
Net increase (decrease) in cash, cash equivalents, and restricted cash	717	21,669	(40,748)
Cash, cash equivalents, and restricted cash			
Beginning of year	29,517	7,848	48,596
End of year	$ 30,234	$ 29,517	$ 7,848

The accompanying notes are an integral part of these consolidated financial statements.

Precigen, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
Years Ended December 31, 2025, 2024, and 2023

(Amounts in thousands)	2025	2024	2023
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 3,510	$ 7	$ 1,171
Cash paid during the period for income taxes	3	4	21
Significant noncash activities			
Accrued compensation paid in equity awards	3,578	3,039	3,361
Conversion of preferred stock to common stock	209,883	—	—
Settlement of warrants to equity	190,060	—	—
Purchases of property and equipment included in accounts payable and other accrued liabilities	214	341	566
Issuance costs included in accounts payable and other accrued liabilities	—	892	—

1. Organization and Basis of Presentation

Precigen, Inc. ("Precigen"), a Virginia corporation, is a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to improve the lives of patients. Precigen is leveraging its proprietary technology platforms to develop product candidates designed to target urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. Precigen's primary operations are located in the state of Maryland. In August 2025, Precigen announced that Papzimeos (Zopapogene Imadenovec-drba, PRGN-2012), an AdenoVerse immunotherapy, had received full approval by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with recurrent respiratory Papillomatosis ("RRP"), and a confirmatory clinical trial is not required. Papzimeos is the first immunotherapy approved for the treatment of RRP. Papzimeos has also received Orphan Drug designation from the European Commission. The FDA approval of Papzimeos transitions Precigen from a development-stage to a commercial-stage company.

Precigen also has one wholly owned operating subsidiary, Exemplar Genetics, LLC ("Exemplar"). Exemplar is committed to enabling the study of life-threatening human diseases through the development of MiniSwine Yucatan miniature pig research models and services. Exemplar's primary operations are located in the State of Iowa.

Precigen's other historical operating subsidiary, Precigen ActoBio, Inc. ("ActoBio") ceased operations during 2024. ActoBio utilized a proprietary class of microbe-based biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics, with its primary operations having been located in Ghent, Belgium. As part of a continuing effort to strategically prioritize the application of resources to particular development efforts, in 2024, the Company initiated a shutdown of ActoBio's operations. This included terminating leases and employees, and the disposition of certain of its assets and obligations with a focus on the preservation of ActoBio's intellectual property. See Notes 8 and 9 for further discussion related to non-cash impairment charges recorded during 2024, and Note 12 for discussion of cumulative translation losses reclassified into operations in the year ended 2024 in relation to these activities. During the year ended 2024, the Company also recorded a charge related to employee severance and termination benefits related to ActoBio employees of $2,100, fully paid during 2024, of which $1,700 is included in research and development expenses and $400 is included in selling, general and administrative expenses included in the accompanying consolidated statement of operations for the year ended December 31, 2024.

In addition to the 2024 actions taken at ActoBio noted above, in August 2024 the Company also began undertaking a strategic prioritization of its clinical portfolio and streamlining of its resources, including a reduction of over 20% of its workforce, to focus on the potential commercialization of PRGN-2012, now Papzimeos. These strategic changes were designed to reduce required resources for non-priority programs and enable the Company to focus on pre-commercialization efforts regarding Papzimeos, including supporting the submission of a rolling biologics license application ("BLA") under an accelerated approval pathway which was filed in the fourth quarter of 2024 and manufacturing commercial product. As a result of the actions taken related to this reduction in its workforce, the Company recorded a charge in 2024 related to employee severance and termination benefits of $1,639, of which $594 is included in research and development expenses and $1,045 is included in selling, general and administrative expenses included in the accompanying consolidated statement of operations for the year ended December 31, 2024.

Precigen and its consolidated subsidiaries are hereinafter collectively referred to as the "Company".

Liquidity

As of December 31, 2025, the Company had $100,369 in cash, cash equivalents and investments, which includes proceeds from the non-dilutive financing agreement entered into in the third quarter of 2025 (see Note 10).

Management believes that existing liquid assets as of December 31, 2025, as well as proceeds from past and future sales of Papzimeos, will allow the Company to continue its operations for at least a year from the issuance date of these consolidated financial statements. These consolidated financial statements are presented in United States dollars and are prepared under accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company is subject to a number of risks similar to those of other companies launching their first commercial product as well as conducting high-risk, early-stage research and development of therapeutic product candidates. Additionally, the accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As the Company continues to incur losses, its transition to profitability will depend on the successful commercialization of Papzimeos and potential other product candidates and on the achievement of sufficient revenues to support the Company's cost structure. In addition, the Company may decide, or be required, to raise additional capital. This additional capital could be raised through a combination of non-dilutive financings (including debt financings, collaborations, strategic alliances, monetization of core and non-core assets, marketing, distribution or licensing arrangements, and/or dilutive financings including equity and/or debt financings which may include an equity component). Also, any collaborations, strategic alliances, monetization of assets or marketing, distribution or licensing arrangement may require the Company to give up some or all of its rights to a product or technology, which in some cases may be at less than the full potential value of such rights.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of Precigen and its majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Risks and Uncertainties

The Company is subject to a number of risks similar to those of other companies launching their first commercial product as well as conducting high-risk, early-stage research and development of therapeutic product candidates. Principal among these risks are the forecasted demand for Papzimeos, dependence on key individuals and intellectual property, competition from products and companies, the technical risks associated with the manufacturing of Papzimeos, and the technical risks associated with the successful research, development and manufacturing of therapeutic product candidates.

Revenue recognition

Under Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers (“Topic 606”), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer’s discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The Company assesses whether each promised good or service is distinct to identify the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices (“SSP”) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the adjustment period.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue generating arrangements to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

Product revenue - Papzimeos

In 2025, the Company received FDA approval for Papzimeos and initiated commercial sales during the fourth quarter of 2025. Product revenue represents the consideration that the Company expects to receive from the sale of Papzimeos to customers, net of variable consideration. The Company entered into a limited number of arrangements with specialty distributors in the United States to distribute Papzimeos to certain medical centers or hospitals and specialty pharmacy providers. The Company recognizes revenue on product sales when the performance obligation to provide units of Papzimeos is satisfied, which occurs upon delivery to the site of care or specialty pharmacy. In addition to distribution agreements with customers, the Company enters into arrangements with health care providers and payers that obligate the Company to have government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company’s products. Product revenue is recorded at the wholesale acquisition cost that the Company charges their customers less amounts the Company is required to remit back to customers, including chargebacks, trade discounts and allowances, product returns, government and payer rebates, and patient assistance. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results in the future vary from the Company’s estimates, the Company will adjust these estimates, which would affect net product sales and earnings in the period of the adjustment. Payment terms for Papzimeos generally require customers to remit payment between 60 and 127 days from the date of sale.

Product and service revenues - Exemplar

The Company generates product and service revenues through Exemplar, which consists of the development and sale of genetically engineered miniature swine models and related service offerings. The Company evaluates each promised product or service under its contracts and identifies performance obligations for each distinct product or service. The Company then allocates the transaction price of the contract to each performance obligation, recognizing the transaction price as revenue at a point in time when control of the promised product or over time when the promised service is rendered. The Company typically recognizes revenue using an output-based measure, generally time elapsed or days of service, to measure progress and transfer of the control of the performance obligation to the customer. Payment terms are typically due within 30 days of invoicing, which occurs prior to or when revenue is recognized.

Exemplar revenues primarily consist of over-time service revenue and point-in-time product sales, whereas Papzimeos is recognized exclusively at a point in time upon delivery to the patient.

Collaboration and licensing revenues

The Company has historically generated collaboration and licensing revenues through agreements with collaborators (known as exclusive channel collaborations or "ECCs") and licensing agreements whereby the collaborators or the licensee obtained exclusive access to the Company's proprietary technologies for use in the research, development and commercialization of products and/or treatments in a contractually specified field of use. Generally, the terms of these agreements provided that the Company received some or all of the following: (i) upfront payments upon consummation of the agreement;
(ii) reimbursements for costs incurred by the Company for research and development and/or manufacturing efforts related to

specific applications provided for in the agreement; (iii) milestone payments upon the achievement of specified development, regulatory, and commercial activities; and (iv) royalties on sales of products arising from the collaboration or licensing agreement. The agreement typically continued in perpetuity unless terminated and each of the Company's collaborators retain a right to terminate the agreement upon providing the Company written notice a certain period of time prior to such termination, generally 90 days.

The Company's collaboration and licensing agreements typically contain multiple promises, including technology licenses, research and development services and, in certain cases, manufacturing services. The Company determined whether each of the promises is a distinct performance obligation. As the nature of the promises in the Company's collaboration and licensing agreements were highly integrated and interrelated, the Company typically combined most of its promises into a single performance obligation. Because the Company was performing research and development services during early-stage development, the services were integral to the utilization of the technology license. Therefore, the Company determined that the technology license and research and development services were typically inseparable from each other during the performance period of its collaboration and licensing agreements. Options to acquire additional services were considered to determine if they constituted material rights. Contingent manufacturing services that may be provided under certain of the Company's agreements were considered to be a separate future contract and not part of the collaboration or licensing agreement.

At contract inception, the Company determined the transaction price, including fixed consideration and any estimated amounts of variable consideration. The transaction price was allocated to the performance obligations in the agreement based on the standalone selling price of each performance obligation. The Company utilized judgment to determine the most appropriate method to measure its progress of performance under the agreement, primarily based on inputs necessary to fulfill the performance obligation.

From time to time, the Company and certain collaborators may cancel their agreements, relieving the Company of any further performance obligations under the agreement. Upon such cancellation or when the Company has determined no further performance obligations are required of the Company under an agreement, the Company recognizes any remaining deferred revenue as revenue.

Research and Development

The Company considers that regulatory requirements inherent in the research and development of new products preclude it from capitalizing such costs. Research and development expenses include salaries and related costs of research and development personnel, including stock-based compensation expense, costs to acquire or reacquire technology rights, contract research organizations and consultants, facilities, materials and supplies associated with research and development projects as well as various laboratory studies. Costs incurred in conjunction with collaboration and licensing arrangements are included in research and development. Indirect research and development costs include depreciation, amortization, and other indirect overhead expenses.

The Company has research and development arrangements with third parties that include upfront and milestone payments. As of December 31, 2025 and 2024, the Company had research and development commitments with third parties that had not yet been incurred totaling $6,220 and $5,885, respectively. The commitments are generally cancellable by the Company by providing written notice at least sixty days before the desire termination date.

Cash and Cash Equivalents

All highly liquid investments with an original maturity of three months or less at the date of purchase are considered to be cash equivalents. Cash balances at a limited number of banks may periodically exceed insurable amounts. The Company believes that it mitigates its risk by investing in or through major financial institutions. Recoverability of investments is dependent upon the performance of the issuer.

Short-term and Long-term Investments

As of December 31, 2025 and 2024, short-term and long-term investments include corporate bonds, United States government debt securities and certificates of deposit. The Company determines the appropriate classification as short-term or long-term at the time of purchase based on original maturities and management's reasonable expectation of sales and redemption. The Company reevaluates such classification at each balance sheet date.

Fair Value of Financial Instruments

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset and liability. As a basis for considering such assumptions, the Company uses a three-tier fair value hierarchy that prioritizes the inputs used in its fair value measurements. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

Level 1: Quoted prices in active markets for identical assets and liabilities;

Level 2: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly; and

Level 3: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available.

Concentrations of Risk

Due to the Company's fixed rate securities holdings, the Company's investment portfolio is susceptible to changes in interest rates. As of December 31, 2025, gross unrealized losses on the Company's short-term and long-term investments were not material. From time to time, the Company may liquidate some or all of its investments to fund operational needs or other activities, such as capital expenditures or business acquisitions. Although the Company has no intent to liquidate such investments, depending on which investments the Company liquidates to fund these activities, the Company could recognize a portion, or all, of the gross unrealized losses.

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of trade and other receivables. The Company manages credit risk through credit approvals, credit limits, and monitoring procedures. The Company performs ongoing credit evaluations of its customers but generally does not require collateral to support accounts receivable.

Equity Method Investments

The Company has accounted for its investment in its joint ventures ("JVs") using the equity method of accounting based upon relative ownership interest. At December 31, 2025 and 2024, the Company does not hold any material investments in JVs.

Variable Interest Entities

The Company identifies entities that (i) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIEs"). The Company performs an initial and on-going evaluation of the entities with which the Company has variable interests to determine if any of these entities are VIEs. If an entity is identified as a VIE, the Company performs an assessment to determine whether the Company has both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, the Company is identified as the primary beneficiary of the VIE.

As of December 31, 2025 and 2024, the Company determined that certain of its collaborators and JVs were VIEs. The Company was not the primary beneficiary for these entities since it did not have the power to direct the activities that most significantly impact on the economic performance of the VIEs. As of December 31, 2025 and 2024, the Company had no risk of loss related to the identified VIEs.

Accounts Receivable

The Company's expected loss allowance methodology for accounts receivable is developed using historical collection experience, current and future economic and market conditions, and a review of the current status of accounts receivables. Balances are written off at the point when collection attempts have been exhausted.

Estimates are used to determine the loss allowance, which is based on assessment of anticipated payment and other historical, current, and future information that is reasonably available.

The following table shows the activity in the allowance for credit losses for the years ended December 31, 2025, 2024, and 2023:

	2025	2024	2023
Beginning balance	$ —	$ 184	$ 184
Write offs of accounts receivable, net of recoveries	—	(184)	—
Ending balance	$ —	$ —	$ 184

Inventory

Prior to an initial regulatory authorization for our drug product candidates, we expense costs related to raw materials and inventory production as research and development expenses in our consolidated statements of operations in the period incurred. We capitalize the costs of production as inventory once regulatory authorization has been obtained and commercialization is considered probable, as we expect to realize future economic benefit from the sales of the drug product candidate.

The Company began capitalizing inventory in the third quarter of 2025 upon the receipt of the regulatory approval of Papzimeos. Prior to that point, all related costs were expensed as incurred and classified as research and development expenses. Inventories include the cost of materials, third-party contract manufacturing and packaging services, and overhead associated with manufacturing. Inventory is stated at the lower of cost or net realizable value, and is determined using the first-in, first-out method.

The Company evaluates inventory recoverability at each reporting period and adjusts net realizable value for excess, slow-moving or obsolete inventory based on projected sales activity compared to product shelf-life. If the net realizable value is lower than costs, the inventory is written down accordingly, and the resulting charge is recognized as a component of cost of goods sold in the Company's consolidated statements of operations. Write-downs are recorded in the period identified and are not subsequently reversed.

Inventory used for clinical development purposes is expensed to research and development expense when consumed.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Major additions or betterments are capitalized, and repairs and maintenance are expensed as incurred. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of these assets are as follows:

	Years
Land improvements	9–15
Buildings and building improvements	9–15
Furniture and fixtures	2–7
Equipment	3–7
Breeding stock	2
Computer hardware and software	1–5

Leasehold improvements are amortized over the shorter of the useful life of the asset or the applicable lease term, generally one to seven years.

Operating Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included as right-of-use assets ("ROU Assets") and lease liabilities on the consolidated balance sheets. The Company has elected not to recognize ROU Assets or lease liabilities for leases with lease terms of one year or less.

Lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The initial measurement of the ROU Asset also includes any lease payments made, adjusted for lease incentives. For leases that contain fixed non-lease payments, the Company accounts for the lease and non-lease components as a single lease component. Variable lease payments, which primarily include payments for non-lease components such as maintenance costs, are excluded from the ROU Assets and lease liabilities and are recognized in the period in which the obligation for those payments is incurred. As the Company's operating leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate at the lease commencement date, which is the estimated rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over the term of the lease, in determining the present value of future payments. The lease term for all of the Company's leases includes the noncancelable period of the lease plus any additional periods covered by options that the Company is reasonably certain to exercise, either to extend or to not terminate the lease. Lease expense is recognized on a straight-line basis over the lease term.

Intangible Assets

Intangible assets subject to amortization consist of patents, developed technologies and know-how; customer relationships; and trademarks acquired as a result of mergers and acquisitions. These intangible assets are subject to amortization, were recorded at fair value at the date of acquisition, and are stated net of accumulated amortization.

The Company amortizes long-lived intangible assets to reflect the pattern in which the economic benefits of the intangible asset are expected to be realized. The intangible assets are amortized over their estimated useful lives, ranging from seven to thirteen years with an average of ten years for the patents and developed technologies, and know-how.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment, ROU Assets, and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable.

See Notes 8 and 9 for additional discussion of impairment of long-lived assets for the years ended December 31, 2024 and 2023.

Goodwill

Goodwill represents the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. Goodwill is reviewed for impairment at least annually. The Company may elect to perform a qualitative assessment to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount prior to performing the goodwill impairment test. If this is the case, the quantitative goodwill impairment test is required. If it is more-likely-than-not that the fair value of a reporting unit is greater than the carrying amount, the quantitative goodwill impairment test is not required.

When a quantitative goodwill impairment test is performed, the fair value of the reporting unit is compared with its carrying amount (including goodwill). If the fair value of the reporting unit is less than its carrying amount, the entity must record the impairment charge for the excess carrying amount, which is limited to the amount of goodwill allocated to the reporting unit. If the fair value of the reporting unit exceeds its carrying amount, no goodwill impairment charge is necessary.

The Company performs its annual impairment review of goodwill on December 31 and performs incremental impairment reviews if a triggering event occurs prior to the annual impairment review.

When the Company performs quantitative evaluations, the fair value of the reporting units is primarily determined based on the income approach. The income approach is a valuation technique in which fair value is based on forecasted future cash flows, discounted at the appropriate rate of return commensurate with the risk as well as current rates of return for equity and debt capital as of the valuation date. The forecast used in the Company's estimation of fair value was developed by management based on historical operating results, incorporating adjustments to reflect management's planned changes in operations and market considerations. The discount rate utilizes a risk adjusted weighted average cost of capital.

See Note 9 for additional discussion regarding goodwill impairment charges recorded in the years ended December 31, 2025, 2024 and 2023.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment, ROU Assets, and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable.

See Notes 8 and 9 for additional discussion of impairment of long-lived assets for the years ended December 31, 2024 and 2023.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to both differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases as well as operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date of the change. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company identifies any uncertain income tax positions and recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest, if any, related to unrecognized tax benefits as a component of interest expense. Penalties, if any, are recorded in selling, general and administrative expenses.

Long-term debt

The Company's term loans are initially recognized at fair value, net of any directly attributable transaction costs. Subsequent to initial recognition, debt is measured at amortized cost using the effective interest method. Interest expense is recognized in the consolidated statements of operations using the effective interest rate, which allocates interest over the relevant period.

The Company evaluates the classification of debt instruments based on their contractual terms and features, including any embedded derivatives or conversion options. As of December 31, 2025, the Company’s outstanding long-term debt (Note 10) includes a five-year term loan entered into on September 3, 2025, which is accounted for at amortized cost. The loan does not contain any equity conversion features and is not designated at fair value. As of December 31, 2025, the entire outstanding balance of the Company’s debt was classified as long-term, as no principal payments are due within twelve months of the reporting date.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant’s specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity (“ASC 480”) and ASC 815, Derivatives and Hedging (“ASC 815”). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company’s own common stock and whether the warrant holders could potentially require “net cash settlement” in a circumstance outside of the Company’s control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For warrants that are liability-classified, changes in fair value are included in Change in fair value of warrant liabilities in the consolidated statements of operations. If facts and circumstances lead the warrant liability to be reclassified to shareholders' equity, warrant liabilities are remeasured as of the event date and reclassified from liabilities to shareholders' equity. In the third quarter of 2025, the Warrant liabilities were reclassified to shareholders' equity and will no longer be adjusted to fair value at each reporting period.

Mezzanine Equity

Where ordinary or preferred shares are determined to be conditionally redeemable upon the occurrence of certain events that are not solely within the control of the Company, and upon such event, the shares would become redeemable at the option of the holder, or when the Company currently does not have a sufficient number of authorized and unissued shares available to share settle the instrument, they are classified as "mezzanine equity" (temporary equity). The purpose of this classification is to convey that such a security may not be permanently part of equity and could result in a demand for cash, securities or other assets of the entity in the future.

The Company evaluates whether the contingent redemption provisions are probable of becoming redeemable to determine whether the carrying value of the redeemable convertible preferred units is required to be remeasured to their respective redemption values. All instruments that are classified as mezzanine equity are evaluated for embedded derivative features by evaluating each feature against the nature of the host instrument (e.g., more equity-like or debt-like). Features identified as freestanding instruments or bifurcated embedded derivatives that are material are recognized separately as a derivative asset or liability in the consolidated financial statements. In the event convertible preferred shares utilize a conversion term that results in the delivery of a variable number of shares of common stock upon conversion as compared to the original terms of the agreement, such conversion will be treated as a redemption. If classification of an equity instrument as temporary equity is no longer required, the existing carrying amount of the equity instrument should be reclassified to permanent equity at the date of the event that caused the reclassification.

In the third quarter of 2025, all of the holders of the outstanding shares of preferred stock converted their shares to common stock (see Note 12).

Share-Based Payments

Precigen uses the Black-Scholes option pricing model to estimate the grant-date fair value of all stock options. The Black-Scholes option pricing model requires the use of assumptions for estimated expected volatility, estimated expected term of stock options, risk-free rate, estimated expected dividend yield, and the fair value of the underlying common stock at the date of grant. Expected volatility is based on the volatility of Precigen's common stock. Precigen estimates the expected term of options based on previous history of exercises unless certain terms of the stock option require a different expected term that more appropriately reflects the estimated life of the stock option. The risk-free rate is based on the United States Treasury yield curve in effect at the time of grant for the expected term of the option. The expected dividend yield is 0% as Precigen does not expect to declare cash dividends in the near future. The fair value of the underlying common stock is determined based on the quoted market price on the Nasdaq Global Select Market ("Nasdaq"). Forfeitures are recorded when incurred. The assumptions used in the Black-Scholes option pricing model for the years ended December 31, 2025, 2024, and 2023 are set forth in the table below:

	2025	2024	2023
Valuation assumptions			
Expected dividend yield	0%	0%	0%
Expected volatility	86%–98%	85%–95%	85%–95%
Expected term (years)	6.00-10.00	6.00-10.00	6.00-10.00
Risk-free interest rate	3.74%–4.48%	3.55%–4.56%	3.52%–4.80%

Grant date fair value for the Company's restricted stock units ("RSUs") and performance based restricted stocks units ("PSUs") are based on the fair value of the underlying common stock as determined based on the quoted market price on the Nasdaq on the date of grant.

Foreign Currency Translation

The assets and liabilities of foreign subsidiaries, where the local currency is the functional currency, are translated from their respective functional currencies into United States dollars at the exchange rates in effect at the balance sheet date, with resulting foreign currency translation adjustments recorded in the consolidated statement of operations after the closure of ActoBio in 2024. Prior to that, foreign currency translations adjustments were recorded in the consolidate statements of comprehensive loss. Revenue and expense amounts are translated at average rates during the period.

Net Income (Loss) per Share

Basic net income (loss) per share is calculated by dividing net income (loss) attributable to common shareholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents. Diluted net income (loss) per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, using the treasury-stock method. For purposes of the diluted net income (loss) per share calculation, shares to be issued pursuant to stock options, RSUs, PSUs, and the Warrants (see Note 12 for further discussion regarding the Warrants) are considered to be common stock equivalents but are excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive as described in the next paragraph, therefore, basic and diluted net income (loss) per share were the same for all periods presented. See Note 12 for further discussion of the Company's Share Lending Agreement, which was terminated in October 2023.

The following potentially dilutive securities as of December 31, 2025, 2024, and 2023, have been excluded from the computations of diluted weighted average shares outstanding for the years then ended as they would have been anti-dilutive:

	December 31,		
	2025	**2024**	**2023**
Options	28,153,192	25,924,734	22,057,340
Restricted stock units	2,342,051	826,057	961,534
Performance stock units	1,025,000	3,178,000	—
Warrants	52,666,669	52,666,669	—
Total	84,186,912	82,595,460	23,018,874

Gain on transfers of nonfinancial assets

The Company accounts for dispositions of intellectual and property rights, which are considered nonfinancial assets, in accordance with ASC 610-20, *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* (“ASC 610-20”) and recognizes a gain or loss on sale upon transferring control of the nonfinancial asset to the purchaser, which is generally satisfied at the time of sale. The Company has concluded that the assets are not an output of the entity's ordinary activities, so the transaction is not within the scope of ASC 606. In connection with the sale in December 2024 of intellectual property rights and royalty rights related to FCX-007, a clinical stage product candidate being developed by Castle Creek Biosciences, LLC, the Company recognized a gain of $8,500 recorded in the consolidated statement of operations within Other Income (Expense), net, for the year ended December 31, 2024.

Segment Information

In the first quarter of 2025, the Company realigned its former two operating segments, Biopharmaceuticals and Exemplar, into one operating segment, although both components (Biopharmaceuticals and Exemplar) remain as separate reporting units. This decision was made to streamline operations and enhance focus on core business activities in preparation for the commercial launch of Papzimeos. The Company implemented this change to better reflect how the Company is managed and to align with its strategic initiative to concentrate resources on its core business. This change also reflects a shift in the manner in which the chief operating decision maker (“CODM”) reviews information to assess the Company’s performance and make resource allocation decisions, in accordance with ASC 280, *Segment Reporting*. The Company's CODM is its President and Chief Executive Officer ("CEO"). The CODM manages and allocates resources at a consolidated level.

Recently Adopted Accounting Pronouncements

As of January 1, 2025, we adopted Accounting Standards Update No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”). ASU 2023-09 requires enhanced disclosures surrounding income taxes, particularly related to rate reconciliation and income taxes paid information. The standard is effective for the Company for annual periods beginning January 1, 2025 on a prospective basis, with retrospective application permitted for all prior periods presented. We adopted this guidance using the retrospective method, which had no impact on our consolidated financial statements but expanded our income tax disclosures reflected in Note 11 herein.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03, in order to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions. The amendments in ASU 2024-03 require disclosure, in the notes to the financial statements, of specified information about certain costs and expenses in interim and year-end reporting periods. The amendments in this ASU apply to all public business entities and are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of this ASU and does not expect it to have a material effect on its financial statements.

In November 2024, the FASB issued ASU 2024-04 to improve the relevance and consistency in the application of induced conversion guidance in Subtopic 470-20, Debt— Debt with Conversion and Other Options. The amendments in this Update affect entities that settle convertible debt instruments for which the conversion privileges were changed to induce conversion. The amendments in this ASU are effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods.

There are no other new accounting standards which have not yet been adopted that are expected to have a significant impact on our financial statements and related disclosures.

3. Product and Service Revenue and Reserves

For the years ended December 31, 2025, 2024 and 2023, the company recorded $7,866, $3,925 and $6,150, respectively, of product and service revenue. Product and Service revenue by source represents:

	2025	2024	2023
Papzimeos	$ 3,413	$ —	$ —
Exemplar	562	422	840
Product revenue, net	**3,975**	**422**	**840**
Exemplar	3,891	3,503	5,310
Service revenue	**3,891**	**3,503**	**5,310**
Total Product and Service revenues, net	**$ 7,866**	**$ 3,925**	**$ 6,150**

For the years ended December 31, 2025, 2024, and 2023, 22.0%, 58.1%, and 74.6% of total revenue, excluding Collaboration and Licensing revenue, was attributable to two customer in 2025 and four for 2024 and 2023, respectively.

The Company considers there to be revenue concentration risks for customers that represent product and service revenues that exceed 10% of total product and service revenue. The concentration of the Company's product and service revenue with a particular customer may have a material adverse effect on the Company's revenue and results of operations if sales with the respective customer experience difficulties. All product and service revenue during 2024 and 2023 were within the United States. In 2025, $241 of product and service revenue was generated in foreign country, with the remainder generated within the United States.

4. Collaboration and Licensing Revenue

The Company's collaborations and licensing agreements may provide for multiple promises to be satisfied by the Company and typically include a license to the Company's technology platforms, participation in collaboration committees, and performance of certain research and development services. Based on the nature of the promises in the Company's collaboration and licensing agreements, the Company typically combines most of its promises into a single performance obligation because the promises are highly interrelated and not individually distinct. Options to acquire additional services are considered to determine if they constitute material rights. At contract inception, the transaction price is typically the upfront payment received and is allocated to the performance obligations. The Company has determined the transaction price should be recognized as revenue based on its measure of progress under the agreement primarily based on inputs necessary to fulfill the performance obligation.

The Company determines whether collaborations and licensing agreements are individually significant for disclosure based on a number of factors, including total revenue recorded by the Company pursuant to collaboration and licensing agreements,

collaborators or licensees with equity method investments, or other qualitative factors. Collaboration and licensing revenues generated from consolidated subsidiaries are eliminated in consolidation.

The following table summarizes the amounts recorded as revenue in the consolidated statements of operations for each significant counterparty to a collaboration or licensing agreement for the years ended December 31, 2025 and 2023. There was no such revenue in the year ended December 31, 2024.

	Year Ended December 31,		
	2025	2024	2023
Other	1,818	—	75
Total	$ 1,818	$ —	$ 75

The following is a summary of the terms of the Company's significant collaborations and licensing agreements, all of which have been terminated as of December 31, 2025.

Agilis Biotherapeutics Collaboration

In October 2013, the Company entered into an exclusive channel collaboration agreement ("ECC") with Agilis Biotherapeutics, Inc. (Agilis), a then privately held synthetic biology-based company focused on rare genetic diseases, which was subsequently acquired by PTC Therapeutics, Inc. ("PTC") in August 2018. Upon execution of the ECC, the Company received a technology access fee of $2,500 as upfront consideration. Additionally, the Company historically received reimbursement payments for research and development services provided pursuant to the agreement during the ECC. Although services under the agreement had paused in 2016, the Company withheld recognizing a portion of the upfront payment as the ECC was perpetual and Agilis had the right and ability to resume the program at any time. In September 2025, the Company and PTC mutually agreed to terminate the ECC agreement and accordingly, the Company recognized the remaining balance of deferred revenue associated with the agreement as collaboration and licensing revenue totaling $1,818.

Alaunos License Agreement

On April 3, 2023, the Company entered into an amended and restated exclusive license agreement (the “License Agreement”), with Alaunos Therapeutics (“Alaunos”). The License Agreement amended and replaced an Exclusive License Agreement by and between the Company and Alaunos, dated October 5, 2018.

On October 4, 2024, the License Agreement was terminated. Following the termination of the License Agreement, Precigen has regained all rights previously licensed to Alaunos and Alaunos retains no rights to utilize any of Precigen’s technology.

Deferred Revenue

Deferred revenue primarily consists of consideration received for the Company's collaboration and licensing agreements. The arrangements classified as long-term are not active while the respective counterparties evaluate the status of the project and its desired future development activities since the Company cannot reasonably estimate the amount of service to be performed over the next year.

Deferred revenue consisted of the following:

	December 31,	
	2025	2024
Collaboration and licensing agreements	$ —	$ 1,818
Prepaid product and service revenues	517	15
Other	—	690
Total	$ 517	$ 2,523
Current portion of deferred revenue	$ 517	$ 589
Long-term portion of deferred revenue	—	1,934
Total	$ 517	$ 2,523

5. Short-term and Long-term Investments

The Company's investments are classified as available-for-sale. The following table summarizes the amortized cost, gross unrealized gains and losses, and fair value of available-for-sale investments as of December 31, 2025:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
United States government debt securities	$ 66,670	$ 36	$ (30)	$ 66,676
Certificates of deposit	3,397	1	—	3,398
Corporate Bonds	61	—	—	61
Total	$ 70,128	$ 37	$ (30)	$ 70,135

The estimated fair value of available-for-sale investments classified by their contractual maturities as of December 31, 2025 was:

Due within one year	$ 67,624
After one year through two years	2,511
Total	$ 70,135

The following table summarizes the amortized cost, gross unrealized gains and losses, and fair value of available-for-sale investments as of December 31, 2024:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
United States government debt securities	$ 67,464	$ 15	$ (5)	$ 67,474
Certificates of deposit	848	3	—	851
Corporate Bonds	69	—	(1)	$ 68
Total	$ 68,381	$ 18	$ (6)	$ 68,393

The estimated fair value of available-for-sale investments classified by their contractual maturities as of December 31, 2024 was:

Due within one year	$ 68,393
After one year through two years	—
Total	$ 68,393

In addition, at December 31, 2025 and December 31, 2024, the Company held U.S. government debt securities valued at $19,083 and $24,169, respectively, which was included in cash and cash equivalents in the consolidated balance sheets as these investments had an original maturity of less than three months when purchased.

See Notes 2 and 6 for further discussion on the Company's method for determining the fair value of its assets.

Changes in market interest rates and bond yields cause certain investments to fall below their cost basis, resulting in unrealized losses on investments.

6. Fair Value Measurements

The carrying amount of cash and cash equivalents, receivables, accounts payable, accrued compensation and benefits, and other accrued liabilities approximate fair value due to the short maturity of these instruments.

The following table presents the placement in the fair value hierarchy of financial assets that are measured at fair value on a recurring basis as of December 31, 2025 (there were no financial liabilities measured at fair value on a recurring basis as of December 31, 2025):

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2025
Assets				
United States government debt securities	$ —	$ 66,676	$ —	$ 66,676
Certificates of deposit	—	3,398	—	3,398
Corporate Bonds	—	61	—	61
Total assets	$ —	$ 70,135	$ —	$ 70,135

The following table presents the placement in the fair value hierarchy of financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2024:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2024
Assets				
United States government debt securities	$ —	$ 67,474	$ —	$ 67,474
Certificates of deposit	—	851	—	851
Corporate Bonds	—	68	—	68
Total assets	$ —	$ 68,393	$ —	$ 68,393
Liabilities				
Warrant Liabilities-2024 Warrants	$ —	$ —	$ 50,537	$ 50,537
Total liabilities	$ —	$ —	$ 50,537	$ 50,537

The method used to estimate the fair value of the Level 2 short-term and long-term debt investments in the tables above is based on professional pricing sources for identical or comparable instruments, rather than direct observations of quoted prices in active markets.

Term Loans

Due to the variable rate nature of the Term Loans, the Company believes that the carrying amount approximates fair value at December 31, 2025.

Warrant liabilities

The Warrant liabilities as of December 31, 2024 (as defined below) are comprised of outstanding warrants to purchase 52,666,669 shares of common stock, no par value per share at an exercise price of $0.75 per share issued in a private placement in December 2024 (the "Warrants").

As of December 31, 2024, the Warrants were accounted for as liabilities as the Warrants provided the holder the right to acquire, via a paid in kind ("PIK") dividend on the Series A Preferred Stock for the first two years following the issue date of the Series A Preferred Stock (see Note 12), a number of additional warrants to purchase shares of common stock equal to 50% of the amount of such PIK dividends divided by the $0.75 exercise price ("PIK Warrants"), which failed the requirement of the indexation guidance under ASC 815-40. The Warrants and PIK Warrants (together the "Warrant liabilities") were measured at fair value at inception and the fair value of the outstanding Warrants were re-measured at the end of each of the previous reporting periods and then again at the date of which the Warrant liabilities were reclassified to shareholders' equity, which occurred in the third quarter of 2025.

In connection with the Series A Preferred Stock conversion in September 2025 (see Note 12 for further discussion), the preferred shareholders forfeited their rights to the PIK dividends as the conversion occurred prior to the first of the two stated PIK dividend dates. As a result, as of the conversion date and going forward, the warrants met the equity scope exception to be classified in shareholders' equity and are not subject to remeasurement, provided that the Company continues to meet the criteria for equity classification.

For the Year Ended December 31, 2025, the Company recorded a non-cash expense representing the change in the fair value of the Warrant liabilities in the amount of approximately $139,523 on the accompanying consolidated statements of operations, resulting in Warrant liabilities of $190,060 as of September 17, 2025, when the Series A Preferred Stock was converted to common stock. The Warrant liabilities, after being remeasured, were reclassified to additional paid-in capital within shareholders' equity.

The changes in the fair value of the Warrant liabilities measured utilizing Level 3 inputs for the Year Ended December 31, 2025 were as follows:

Warrant liabilities as of December 31, 2024	$	50,537
Change in fair value of Warrant liabilities		139,523
Reclassification of Warrant liabilities to equity		(190,060)
Warrant liabilities as of December 31, 2025	$	—

Prior to the reclassification of the Warrant liabilities to equity, the Company used various option pricing models, such as the Black-Scholes option pricing model and the Monte Carlo simulation model, to estimate the fair value of the Warrant liabilities. In using these models, the Company made certain assumptions about risk-free interest rates, dividend yields, volatility, expected term of the Warrants and other assumptions. Risk-free interest rates are derived from the yield on U.S. Treasury debt securities. Dividend yields are based on our historical dividend payments, which have been zero to date. Volatility is estimated from the historical volatility of our common stock as traded on the Nasdaq Stock Market Exchange. The expected term of the Warrants was based on the time to expiration of the Warrants from the date of measurement.

The fair value of the Warrants was estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the Warrant liabilities as of September 17, 2025 (the date the Warrant liabilities qualified for permanent equity classification), include (i) volatility of 88.5% (discounted for lack of marketability), (ii) risk free interest rate of 4.0%, (iii) strike price ($0.75), (iv) fair value of common stock ($3.82), and (v) expected life of 9 years, 3 months, 15 days. As of December 31, 2024, the significant assumptions included (i) volatility of 86% (discounted for lack of marketability), (ii) risk free interest rate of 4.5%, (iii) strike price ($0.75), (iv) fair value of common stock ($0.93), and (v) expected life of 10 years.

The fair value of the PIK Warrants was estimated using a Black-Scholes option pricing model within a Monte Carlo simulation model framework. As of December 31, 2024 , the significant assumptions included (i) volatility of 86% (discounted for lack of marketability), (ii) risk free interest rate range of 4.1% to 4.2%, (iii) strike price ($0.75), (iii) term to PIK Warrant payment date of one to two years, and (vii) expected Company's stock price range to the corresponding PIK Warrant payment date of $0.06 to $3.05.

Preferred Stock - PIK Dividends

On December 30, 2024, the Company issued in a private placement 79,000 shares of its 8.00% Series A Convertible Perpetual Preferred Stock (the "Series A Preferred Stock") and warrants to purchase an aggregate of 52,666,669 shares of its common stock (the "Warrants") at an exercise price of $0.75, for gross proceeds of $79,000. In accordance with the Articles of Amendment to the Company's amended and restated articles of incorporation, on each PIK dividend payment date, the stated value of the Series A Preferred Stock shall automatically be increased by the accumulated PIK dividend amount. The PIK dividends were determined to be discretionary and as such, they are measured at fair value as of the date they accumulate. Due to the absence of retained earnings, the adjustment to record the value of the PIK dividends was recorded as a reduction to additional paid-in capital. No PIK dividend was required to be accrued as of December 31, 2025 as a result of the Series A Preferred Stock conversion that occurred in September 2025. See Note 12 for further discussion on the Series A Preferred Stock conversion and PIK dividends.

7. Inventory

On August 14, 2025, the FDA approved Papzimeos (zopapogene imadenovec-drba), marking the first immunotherapy approved for treatment of RRP, and the Company commenced capitalization of inventory from that date.

Prior to August 14, 2025, regulatory approval and subsequent commercialization of Papzimeos and thus the possibility of future economic benefits from Papzimeos sales were not considered probable and inventory-related costs were expensed as incurred; as such, the inventory recognized on the balance sheet at December 31, 2025 does not include any costs incurred prior to August 14, 2025.

The components of inventory are as follows:

	December 31,	
	2025	2024
Raw Material	$ 144	$ —
Work in process	9,265	—
Finish Goods	172	—
Total inventory	$ 9,581	$ —

The shelf life of our inventory is twenty-four months from the date the drug product is manufactured. As of December 31, 2025, the Company has not recorded an adjustment for excess or obsolete inventory.

8. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following:

	December 31,	
	2025	2024
Land and land improvements	$ 164	$ 164
Buildings and building improvements	2,629	2,629
Furniture and fixtures	650	364
Equipment	19,444	16,774
Leasehold improvements	11,934	4,478
Breeding stock	74	88
Computer hardware and software	2,408	3,186
Construction and other assets in progress	278	9,019
	37,581	36,702
Less: Accumulated depreciation and amortization	(23,823)	(22,871)
Property, plant and equipment, net	$ 13,758	$ 13,831

Depreciation expense was $1,926, $1,467, and $1,820 for the years ended December 31, 2025, 2024, and 2023, respectively.

Recorded impairment losses of $598 and $445 for the years ended December 31, 2024, and 2023, respectively, are included in impairment of other noncurrent assets on the accompanying consolidated statements of operations and are primarily related to right-of-use assets and fixed assets at certain of the Company's leased locations.

As discussed in Note 1, during 2024, the Company suspended ActoBio's operations. As a result, the Company reviewed the related property, plant and equipment and right-of-use assets for impairment. Based on the estimated undiscounted cash flows, the Company determined that the related asset values were not fully recoverable and calculated estimated fair values using market participant assumptions. The estimated fair values were lower than the carrying values, and the Company recorded impairment losses of $110 related to property, plant, and equipment and $488 related to the right-of-use assets, which are included in impairment of other noncurrent assets in the accompanying consolidated statements of operations for the year ended December 31, 2024.

9. Goodwill and Intangible Assets, Net

The changes in the carrying amount of goodwill for the years ended December 31, 2025, and 2024, are as follows:

	2025	2024
Beginning of year	$ 19,139	$ 26,612
Impairment	(3,907)	(7,409)
Foreign currency translation adjustments		(64)
End of year	$ 15,232	$ 19,139

The Company had $36,189 and $32,282 of cumulative goodwill impairment losses as of December 31, 2025, and 2024.

For the year ended December 31, 2025, and December 31, 2024, the Company recorded $3,907 and $5,779 of impairment charges related to the Exemplar reporting unit, respectively.

The Company completes its annual goodwill impairment test during the fourth quarter of each year, or more frequently if triggering events indicate a possible impairment in one or more of its reporting units.

During the second quarter of 2025, the Company lowered its financial expectations related to the Exemplar reporting unit for the remainder of 2025 and into 2026 due to projected delays in the timing of planned product and services rendered to existing and new customers. These factors constituted an interim triggering event as of the end of the Company's second quarter of 2025, and the Company performed an impairment analysis with regard to its goodwill.

The revised projections were used as a key input into Exemplar's reporting unit’s annual goodwill impairment test performed as of June 30, 2025. The impairment charge of $3,907 represented the estimated excess of carrying value over fair value of this reporting unit. The Company estimated the fair value of its reporting unit utilizing a combination of a discounted present value cash flow model as well as a market earnings multiple approach. As a result of this impairment charge, no goodwill remains within the Exemplar reporting unit subsequent to June 30, 2025.

As part of its annual impairment evaluation in 2024, the Company determined the fair value of the Exemplar reporting unit was less than its carrying amount. The Company determined the fair value of the Exemplar reporting unit in 2024 using the income approach, discounted at the appropriate rate of return as well as current rates of return for equity and debt capital as of the valuation date. As a result, the Company recorded a goodwill impairment charge of $5,779, which represented the estimated excess of carrying value over fair value of this reporting unit.

During the second quarter of 2024, in connection with the suspension of ActoBio's operations, as discussed in Note 1, the Company determined the fair value of the ActoBio reporting unit was less than its carrying amount. As a result, the Company recorded a goodwill impairment charge of $1,630, which represented the full amount of goodwill associated with the ActoBio reporting unit.

Intangible assets consist of the following as of December 31, 2025:

	Weighted Average Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	10.7	$ 15,912	$ (12,730)	$ 3,182

Intangible assets consist of the following as of December 31, 2024:

	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	$ 15,912	$ (11,457)	$ 4,455

During 2024, in connection with the suspension of ActoBio's operations, the Company determined the fair value of ActoBio's certain developed technologies was less than their carrying amount. As a result, the Company recorded an impairment charge of $32,317, which is included in impairment of other noncurrent assets in the accompanying consolidated statements of operations for the year ended December 31, 2024.

Amortization expense was $1,273, $3,059, and $4,848 for the years ended December 31, 2025, 2024, and 2023, respectively. Estimated aggregate amortization expense for definite lived intangible assets is expected to be as follows:

2026	$ 1,273
2027	1,273
2028	636
2029	—
Total	$ 3,182

10. Debt

Long Term Debt

On September 3, 2025, the Company entered into a Loan Agreement (the "Loan Agreement") with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership as the lenders thereunder (the "Lenders") and BioPharma Credit PLC as the collateral agent, each of which are investment entities managed by Pharmakon Advisors, LP. The Company received net proceeds of $92,818 after deducting underwriting discounts and offering expenses of $7,182.

The Loan Agreement provides for a 5-year senior secured term loan facility of up to $125.0 million, composed of two committed tranches: (i) an initial tranche in an aggregate principal amount of $100.0 million, which was funded on September 3, 2025; and (ii) a delayed draw tranche in an aggregate principal amount of $25.0 million, which is available, subject to certain conditions, until June 29, 2027 (such tranches, collectively, the "Term Loans"). The Term Loans mature on September 3, 2030 (the "Maturity Date"). Beginning on December 31, 2028, the Term Loans require eight equal quarterly principal payments of $12.5 million (adjusted for any borrowings under the second tranche, if any) until maturity, and all remaining outstanding amounts, if any, become due and payable on September 3, 2030. Interest rates for borrowings under the Loan Agreement are determined by a secured overnight financing rate ("SOFR") plus a margin. The interest rate for the Term Loans is based upon the sum of (a) the applicable margin (6.50%), and (b) the 3-month forward-looking term rate based on SOFR, subject to a floor of 3.75%. Interest is payable quarterly in arrears. The effective interest rate of the Term Loan, including amortization of debt issuance costs was 12.5% for the twelve months ended December 31, 2025. No repayment of principal was made during the twelve months ended December 31, 2025.

The Company's obligations under the Loan Agreement are secured by substantially all of its U.S. assets, including intellectual property, and are guaranteed by certain of its subsidiaries, each of which has pledged substantially all of its assets to secure such guarantee.

The following table reflects the Company's long-term debt as of December 31, 2025 and December 31, 2024, respectively:

	December 31, 2025	December 31, 2024
Outstanding principal balance	$ 100,000	$ —
Unamortized debt discount and issuance costs	(6,826)	—
Carrying value	$ 93,174	$ —

The Company incurred $7,182 of debt discount and debt issuance costs in 2025 for the Term Loans, which were capitalized and deferred when incurred and are being amortized over the term of the Term Loans. Interest expense in relation to the Term Loans, including the amortization of debt discount and debt issuance costs is as follows:

	Year Ended December 31,
	2025
Cash interest expense	$ 3,510
Non-cash interest expense	356
Total interest expense	$ 3,866

The Company determined that all of the embedded features identified in the Loan Agreement were either clearly and closely related to the debt host and did not require bifurcation as a derivative liability, or the fair value of the bifurcated features was immaterial to the Company's consolidated financial statements.

The Term Loans contain customary affirmative and restrictive covenants and representations and warranties including, without limitation, (i) information delivery requirements, (ii) obligations to maintain insurance, (iii) preservation of intellectual property and regulatory approvals, and (iv) compliance with applicable laws. Additionally, there are certain restrictive covenants, including, without limitation, (i) limitations on the incurrence of additional indebtedness, (ii) limitations on the incurrence of liens, (iii) restrictions on the payment of dividends and other restricted payments, (iv) restrictions on investments, (v) restrictions on asset transfers, (vi) restrictions on mergers and similar transactions, (vii) restrictions on amendments to organizational documents and material contracts, in each case subject to specified exceptions, (viii) minimum net sales and (ix) minimum liquidity. The Loan Agreement also contains customary representations and warranties, including, without limitation, with respect to (i) organization, authority and enforceability, (ii) financial condition, (iii) compliance with laws, (iv) intellectual property and regulatory matters, and (v) the absence of a material adverse change. The Term Loans may be voluntarily prepaid in whole (but not in part) and must be prepaid upon change in control, and are subject to make-whole, prepayment premium and exit fee provisions. Proceeds of the Term Loans are being used to fund the Company's commercial launch of Papzimeos as well as other general corporate and working capital requirements. The Term Loans include customary events of default, which may require the Company to pay an additional 3% interest on the outstanding loans under the Term Loan facility. As of December 31, 2025, the Company was in compliance with its debt covenants under the Loan Agreement.

Line of Credit

Exemplar had a $5,000 revolving line of credit with American State Bank that matured on November 1, 2025 and was not renewed. As of December 31, 2024, the line of credit bore interest at a stated rate of 8% per annum and there was no outstanding balance.

Convertible Notes

In July 2018, Precigen completed a registered underwritten public offering of $200,000 aggregate principal amount of Convertible Notes and issued the Convertible Notes under an indenture (the "Base Indenture") between Precigen and The Bank of New York Mellon Trust Company, N.A., as trustee, as supplemented by the First Supplemental Indenture.

The Convertible Notes matured on July 1, 2023, although certain notes were repurchased prior to their maturity beginning in third quarter of 2022. On June 30, 2023, the Company repurchased all remaining outstanding Convertible Notes at par plus accrued interest.

The components of interest expense related to the Convertible Notes were as follows:

	Year Ended December 31,
	2023
Cash interest expense	$ 397
Non-cash interest expense	60
Total interest expense	$ 457

Future Maturities of Long-Term Debt

Future maturities of long-term debt as of December 31, 2025 are as follows:

2026	$ —
2027	—
2028	12,500
2029	50,000
2030	37,500
Thereafter	—
Total	100,000

11. Income Taxes

The components of loss from continuing operations before income taxes are presented below:

	Year Ended December 31,		
	2025	**2024**	**2023**
United States	$ (250,719)	$ (85,879)	$ (93,522)
Foreign	80	(42,149)	(2,840)
Total	$ (250,639)	$ (128,028)	$ (96,362)

The components of income tax expense (benefit) from continuing operations are presented below:

	Year Ended December 31,		
	2025	**2024**	**2023**
Current tax expense			
US federal	—	—	—
US state and local	3	2	21
Foreign	—	—	—
Total current tax expense	3	2	21
Deferred tax (benefit)			
US federal	—	(41)	(247)
US state and local	—	(11)	(80)
Foreign	—	(1,743)	(152)
Total deferred tax (benefit)	—	(1,795)	(479)
Total income tax expense (benefit)			
US federal	—	(41)	(247)
US state and local	3	(9)	(59)
Foreign	—	(1,743)	(152)
Total income tax expense (benefit)	$ 3	$ (1,793)	$ (458)

There were no significant tax payments made to any jurisdiction, or state income tax expense incurred, during the periods presented above.

Income tax expense (benefit) for the years ended December 31, 2025, 2024, and 2023 differed from amounts computed by applying the applicable United States federal corporate income tax rate of 21% to loss before income taxes as a result of the following:

	Year Ended December 31,					
	2025		2024		2023	
	Amount	Percent	Amount	Percent	Amount	Percent
US federal statutory income tax rate	(52,634)	21.0 %	(26,886)	21.0 %	(20,236)	21.0 %
Domestic federal						
Research and development tax credits	(1,200)	0.5 %	(1,750)	1.4 %	(1,146)	1.2 %
Nontaxable and nondeductible items						
Stock based compensation	3	— %	313	(0.2)%	3,417	(3.5)%
Change in fair value of warrants	29,300	(11.7)%	61	— %	—	— %
Other	1,631	(0.7)%	333	(0.3)%	324	(0.3)%
Change in valuation allowance	23,820	(9.5)%	19,831	(15.5)%	15,758	(16.4)%
Other	(903)	0.4 %	(794)	0.6 %	867	(0.9)%
Domestic state and local income taxes, net of federal effect	3	— %	(7)	— %	(42)	— %
Foreign						
Belgium						
Statutory income tax rate differential	3	— %	(1,081)	0.8 %	34	— %
Impairment of goodwill	—	— %	551	(0.4)%	—	— %
Other	—	— %	770	(0.6)%	(414)	0.4 %
Change in valuation allowance	(20)	— %	6,866	(5.4)%	895	(0.9)%
Other foreign jurisdictions	—	— %	—	— %	85	(0.1)%
Total income tax expense (benefit)	$ 3	— %	$ (1,793)	1.4 %	$ (458)	0.5 %

The tax effects of temporary differences that comprise the deferred tax assets and liabilities as of December 31, 2025, and 2024, are as follows:

	2025	2024
Deferred tax assets		
Equity securities and investments in affiliates	517	472
Property, plant and equipment	302	237
Intangible assets	47,753	56,113
Accrued liabilities	2,789	2,478
Lease liabilities	1,220	1,383
Stock-based compensation	13,472	14,205
Deferred revenue	56	503
Capitalized research and development cost	21,224	29,796
Research and development tax credits	17,928	16,232
Net operating, capital loss, and interest expense carryforwards	285,791	283,926
Total deferred tax assets	391,052	405,345
Less: Valuation allowance	389,936	404,074
Net deferred tax assets	1,116	1,271
Deferred tax liabilities		
Right-of-use assets	1,116	1,271
Total deferred tax liabilities	1,116	1,271
Net deferred tax liabilities included in continuing operations	$ —	$ —

Activity within the valuation allowance for deferred tax assets included in continuing operations during the years ended December 31, 2025, 2024, and 2023 was as follows:

	2025	2024	2023
Valuation allowance at beginning of year	$ 404,074	$ 424,432	$ 401,086
Increase (decrease) in valuation allowance as a result of			
Current year operations	10,069	30,783	23,065
Expired attributes	(26,394)	(50,269)	—
Foreign currency translation adjustment	2,187	(872)	281
Valuation allowance at end of year	$ 389,936	$ 404,074	$ 424,432

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Due to the Company and its subsidiaries' histories of net losses incurred from inception, any corresponding net domestic and foreign deferred tax assets have been fully reserved as the Company and its subsidiaries cannot sufficiently be assured that these deferred tax assets will be realized.

The Company's past issuances of stock and mergers and acquisitions have resulted in ownership changes as defined in Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). As a result, utilization of portions of the net operating losses may be subject to annual limitations. As of December 31, 2025, approximately $31,466 of the Company's domestic net operating losses were inherited via acquisition and are limited based on the value of the target at the time of the transaction.

As of December 31, 2025, the Company had net operating loss carryforwards of approximately $1,120,424 for United States federal income tax purposes available to offset future taxable income, including $911,880 generated after 2017, United States capital loss carryforwards of $1,372, and United States federal and state research and development tax credits of approximately $17,880, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or ("Section 382"). Net operating loss carryforwards generated prior to 2018 will expire if unutilized from 2026 to 2037, and capital loss carryforwards will expire if unutilized from 2027 to 2029. As a result of our past stock issuances, as well as due to prior mergers and acquisitions, certain of our net operating losses have been subject to limitations pursuant to Section 382. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation. As of December 31, 2025, our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately $80,104, most of which do not expire.

The Company and its subsidiaries do not have material unrecognized tax benefits as of December 31, 2025. The Company's U.S. tax returns for the years 2006 and forward are subject to examination by federal or state tax authorities due to the carryforward of unutilized net operating and capital losses and research and development tax credits.

12. Mezzanine Equity and Shareholders' Equity

As of December 31, 2025, under the Company’s amended and restated articles of incorporation, the Company is authorized to issue 700,000,000 shares of common stock and 25,000,000 shares of preferred stock.

Amendment to the Articles of Incorporation - Series A Preferred Stock

In December 2024, Precigen filed articles of amendment (the “Articles of Amendment”) to its amended and restated articles of incorporation with the State Corporation Commission of the Commonwealth of Virginia ("SCC"), including a form of certificate for the Series A Preferred Stock, designating 81,000 shares of its authorized and unissued preferred stock as 8.00% Series A Convertible Perpetual Preferred Stock (the "Series A Preferred Stock") and establishing the preferences, limitations and relative rights of the Series A Preferred Stock. The Articles of Amendment became effective following the issuance of a Certificate of Amendment by the SCC to Precigen in December 2024.

Amendment to the Articles of Incorporation - Increase of authorized shares

In July 2025, Precigen filed articles of amendment to its amended and restated articles of incorporation with the SCC, to increase Precigen's authorized shares of common stock from 400,000,000 as of December 31, 2024 to 700,000,000 shares of common stock, which became effective in the same month.

Issuances of Preferred Stock and Warrants

On December 30, 2024, the Company issued 79,000 shares of the Series A Preferred Stock with an initial liquidation preference and stated value of $1,000 per share, together with the Warrants (see Note 6), for gross proceeds of $79,000 and net proceeds of $78,463, after deducting offering expenses, which had not been paid as of December 31, 2024. The aggregate exercise price of the Warrants is approximately $39,500, exercisable for an aggregate of 52,666,669 shares of common stock. The Series Preferred Stock was converted to common stock in 2025 as described below.

Mezzanine Classification

ASC 480-10-S99-3A(2) of the SEC's Accounting Series Release N0. 268 ("ASR 268") requires preferred securities that are redeemable for cash or other assets to be classified outside of permanent equity if they are redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the control of the issuer. Preferred securities that are mandatorily redeemable are required to be classified by the issuer as liabilities whereas under ASR 268, a company should classify a preferred security whose redemption is contingent on an event not entirely in control of the issuer as mezzanine equity. The Series A Preferred Stock was redeemable at the option of the holder upon a "fundamental change" (as defined in the agreements) that is not solely within control of the Company, and accordingly, the Company determined that mezzanine treatment was appropriate for the Series A Preferred Stock prior to their conversion to common stock in 2025.

The Series A Preferred Stock was initially measured at the amount of total proceeds less any offering costs and proceeds allocated to the Warrants, and is presented as such in our consolidated balance sheets as of December 31, 2024. Additionally, during the six months ended June 30, 2025, the Company recorded an increase of $2,665 to the Series A Preferred Stock, which represented the fair value of the ratable portion of accumulated PIK dividends that would have increased the stated value of the Series A Preferred stock upon subsequent PIK dividend payment dates. Due to the absence of retained earnings, these adjustments to record the value of the PIK dividends were recorded as a reduction to additional paid-in capital.

Conversion of Preferred Stock

In September 2025, all of the holders of the Series A Preferred Stock converted their 79,000 shares of Preferred Stock (with an aggregate stated value of $79,000) into 54,937,411 shares of common stock of the Company pursuant to the terms of the Amended and Restated Articles of Incorporation and such Preferred Stock at the then-current conversion rate of 695.4103 shares of common stock of the Company per one thousand dollars of stated value of Preferred Stock.

As the shares of Series A Preferred Stock were converted at the then-current conversion rate and therefore resulted in the delivery of a variable number of shares of the Company's common stock as compared to the original conversion terms at the time the Series A Preferred Stock agreement was entered into, the conversion was required to be treated as a redemption. In accordance with ASC 260, the Company compared (1) the fair value of the consideration transferred to the holders of the Series A Preferred Stock and (2) the carrying amount of the Series A Preferred Stock immediately before the exchange, with the difference treated as a return to the holders of the Series A Preferred Stock in a manner similar to dividends paid on preferred stock. Therefore, during September 2025, the Company recorded a $179,000 non-cash preferred stock deemed dividend as a reduction to additional paid-in capital, due to the absence of retained earnings.

Issuances of Precigen Common Stock

In August 2024, the Company closed a public offering of 39,878,939 shares of its common stock, resulting in net proceeds to the Company of $30,882, after deducting underwriting discounts, fees, and other offering expenses. This included the sale of 4,584,821 shares of the Company’s common stock pursuant to the underwriter’s exercise of its option to purchase additional shares. Of the 39,878,939 shares, 23,588,234 shares were purchased by related parties and their affiliates, including the Company's Chairman of the Board of Directors and his affiliates, and one of the Company's executive officers.

In January 2023, the Company closed a public offering of 43,962,640 shares of its common stock, resulting in net proceeds of $72,808, after deducting underwriting discounts, fees, and other underwriting expenses. Of the 43,962,640 shares issued,

11,517,712 shares were purchased by related parties and their affiliates, including the Company's Chief Executive Officer, its Chairman of the Board of Directors and his affiliates, and certain other of the Company's officers.

The Company completed the January 2023 offering of shares of common stock, utilizing a number of underwriters, with J.P. Morgan Securities LLC acting as representative of the underwriters. The services provided by JP Morgan Securities LLC were in the ordinary course of their role as lead underwriter, for which they received customary fees and commissions.

Share Lending Agreement

Concurrently with the offering of the Convertible Notes (Note 10), Precigen entered into a share lending agreement (the "Share Lending Agreement") with J.P. Morgan Securities LLC (the "Share Borrower") pursuant to which Precigen loaned and delivered 7,479,431 shares of its common stock (the "Borrowed Shares") to the Share Borrower. The Share Lending Agreement terminated in October 2023, and the Borrowed Shares were returned to Precigen and were recorded as treasury shares at that time.

Components of Accumulated Other Comprehensive income

The components of accumulated other comprehensive income are as follows:

	December 31,	
	2025	2024
Unrealized income on investments	$ 7	$ 12
Total accumulated other comprehensive income	$ 7	$ 12

During the year ended December 31, 2024, the Company reclassified $2,915 of cumulative foreign translation losses associated with ActoBio upon the final closing of its facilities, which is included in other income (expenses) in the accompanying consolidated statements of operations. These translation losses were previously recorded within accumulated other comprehensive (loss) income.

13. Share-Based Payments

The Company measures the fair value of stock options, RSUs and PSUs issued to employees and nonemployees as of the grant date for recognition of stock-based compensation expense. Stock-based compensation expense for employees and nonemployees is recognized over the requisite service period, which is typically the vesting period. Adjustments to stock-based compensation expense for RSUs and PSUs are made, as needed, each reporting period based on changes in the Company’s estimate of the number of units that are probable of vesting. Stock-based compensation costs included in the consolidated statements of operations are presented below:

	Year Ended December 31,		
	2025	2024	2023
Cost of products and services	$ 72	$ 41	$ 72
Research and development	2,953	2,828	2,237
Selling, general and administrative	7,841	6,602	7,579
Total	$ 10,866	$ 9,471	$ 9,888

The Company capitalized stock-based compensation associated with the allocation of labor costs related to work performed to manufacture Papzimeos of $372 for the year ended December 31, 2025.

Precigen Equity Incentive Plans

In August 2013, Precigen adopted the 2013 Omnibus Incentive Plan (the "2013 Plan"), for employees and nonemployees pursuant to which Precigen's board of directors granted share-based awards, including stock options, restricted stock units, shares of common stock and other awards, to employees, officers, consultants, advisors, and nonemployee directors. Upon the effectiveness of the 2023 Omnibus Incentive Plan (the "2023 Plan") by Precigen's shareholders in June 2023, as discussed in the next paragraph, no new awards may be granted under the 2013 Plan and any awards granted under the 2013 Plan prior to the effectiveness of the 2023 Plan will remain outstanding under such plan and will continue to vest and/or become exercisable in accordance with their original terms and conditions. As of December 31, 2025, there were 14,865,149 stock options and no RSUs outstanding under the 2013 Plan.

In April 2023, Precigen adopted the 2023 Plan, which became effective upon shareholder approval in June 2023. The 2023 Plan permits the grant of share-based awards, including stock options, restricted stock awards, RSUs, PSUs and other awards, to officers, employees and nonemployees. The 2023 Plan initially authorized for issuance pursuant to awards under the 2023 Plan an aggregate of 16,418,137 shares, which included shares remaining available for issuance under the 2013 Plan. In July 2024, shareholders approved an additional 2,000,000 shares to be authorized under the 2023 Plan and in June 2025, shareholders approved an additional 11,500,000 shares to be authorized under the 2023 Plan. As of December 31, 2025, there were 9,051,962 stock options, 1,025,000 PSUs and 1,695,500 RSUs outstanding under the 2023 Plan and 11,458,631 shares were available for future grants.

In April 2019, Precigen adopted the 2019 Incentive Plan for Non-Employee Service Providers (the "2019 Plan"), which became effective upon shareholder approval in June 2019. The 2019 Plan permits the grant of share-based awards, including stock options, restricted stock awards, and RSUs, to non-employee service providers, including board members. As of December 31, 2025, there were 13,100,000 shares authorized for issuance under the 2019 Plan. The 2019 Plan initially authorized for issuance pursuant to awards under the 2019 Plan an aggregate of 5,000,000 shares. In June 2022, shareholders approved an additional 7,000,000 shares to be authorized under the 2019 Plan and in June 2025, shareholders approved an additional 1,100,000 shares to be authorized under the 2019 Plan. As of December 31, 2025, the 2019 Plan had 4,236,081 stock options and 646,551 RSUs outstanding, and 2,048,892 shares were available for future grants.

Stock Options

Stock options may be granted with an exercise price equal to or greater than the stock's fair market value at the date of grant. Stock options may be granted with an exercise price less than the stock's fair market value at the date of grant only if the stock options are replacement options in accordance with certain United States Treasury regulations. All stock options have terms of up to ten-year and vest four years from the date of grant.

Stock option activity was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance at December 31, 2022	15,201,276	$ 10.41	6.87
Granted	7,847,869	1.19	
Exercised	—	—	
Forfeited	(275,250)	(2.65)	
Expired	(716,555)	(20.41)	
Balance at December 31, 2023	22,057,340	6.90	7.12
Granted	7,361,674	1.40	
Exercised	(265,448)	(1.30)	
Forfeited	(1,586,732)	(1.72)	
Expired	(1,642,100)	(17.10)	
Balance at December 31, 2024	25,924,734	5.07	7.05
Granted	4,322,403	1.44	
Exercised	(786,282)	(1.53)	
Forfeited	(334,076)	(1.66)	
Expired	(973,587)	(14.62)	
Balance at December 31, 2025	28,153,192	4.32	6.74
Exercisable at December 31, 2025	18,804,310	5.76	5.90

Total unrecognized compensation costs related to unvested awards as of December 31, 2025 were $8,040 and are expected to be recognized over a weighted-average period of approximately 2.19 years.

The weighted average grant date fair value of options granted during 2025, 2024, and 2023 was $1.15, $1.12, and $0.92, respectively. The aggregate intrinsic value of options exercised during 2025, 2024, and 2023 was $1,704, $60, and $0, respectively. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of Precigen's common stock for those shares where the exercise price was lower than the fair value of Precigen's common stock on the date of exercise.

The following table summarizes additional information about stock options outstanding as of December 31, 2025

	Options Outstanding				Options Exercisable			
Range of Exercise Prices	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$0.67 — $1.40	14,831,973	$ 1.29	8.17	$ 42,799	6,533,916	$ 1.24	7.61	$ 19,225
$1.41 — $2.50	5,711,476	$ 1.97	6.88	12,606	4,684,151	$ 1.96	6.83	10,394
$2.51 — $6.00	2,287,356	$ 5.47	4.23	131	2,263,856	$ 5.50	4.19	109
$6.01 — $12.00	2,773,056	$ 10.14	4.44	—	2,773,056	$ 10.14	4.44	—
$12.01 — $34.85	2,549,331	$ 19.80	2.91	—	2,549,331	$ 19.80	2.91	—
	28,153,192	$ 4.32	6.74	$ 55,536	18,804,310	$ 5.76	5.90	$ 29,728

PSUs and RSUs

In 2024, the Company’s Compensation and Human Capital Management Committee of the Board of Directors (the "Compensation Committee") approved the grant of 3,178,000 PSUs under the 2023 Plan to certain key employees of the Company. Of the PSUs granted, 2,978,000 were subject to vesting in two equal 50% installments based upon the achievement of two specified operational milestones relating to (i) the Company’s good faith submission to the U.S. Food and Drug Administration (the “FDA”) of a complete BLA for the Company’s PRGN-2012 investigational product and (ii) the approval of the BLA by the FDA. The remaining 200,000 PSUs granted in 2024 are subject to vesting in two equal 50% installments based on (i) the achievement of the approval of the BLA by the FDA and (ii) continued employment with the Company on the six-month anniversary of the approval of the BLA by the FDA. In May 2025, the Compensation Committee approved the grant of 950,000 PSUs under the 2023 Plan to non-executive employees of the Company, which are scheduled to vest one year from the grant date, on the condition that that the BLA for PRGN-2012 was approved by the FDA.

In January 2025, the Compensation Committee certified the achievement of the performance milestone of the submission of the BLA to the FDA, and as such, approximately 1,500,000 PSUs vested in January 2025.

In September 2025, the Compensation Committee certified the achievement of the performance milestone related to the approval of the BLA by the FDA. As such, approximately 1,600,000 PSUs vested in September 2025.

With respect to the initial 2,978,000 PSUs, as of the award grant date, the underlying performance milestone relating to the Company's submission of a BLA to the FDA was considered probable of achievement and stock-based compensation expense was recognized during the year ended December 31, 2024 related to that milestone.

As of the award grant date, the underlying performance milestone related to the approval of the BLA by the FDA was determined to be not probable of achievement, as such approval is outside of the Company's control. Therefore, no stock-based compensation expense was recognized related to that milestone of the PSUs for the six months ended June 30, 2025 and during 2024 related to this milestone.

Upon approval of the BLA by the FDA, the performance condition was determined to be probable of being satisfied and therefore the Company recognized cumulative expense of $2,266 to reflect the portion of the employee's requisite service that had been provided to date. For those PSUs with a continued service condition, the Company is continuing to recognize stock-based compensation cost over the remaining requisite service period.

Additionally, in September 2025, the Company elected to settle in cash the portion of the original 2,978,000 PSUs held by certain executive officers that were to vest upon the approval of the BLA by the FDA. This was accounted for as cash settlements of equity-classified awards as it is not expected that the Company will have further settlements of equity awards in cash. As such, the Company recorded compensation cost of $3,404, which represented the additional settlement consideration that exceeded the fair-value-based measure of the equity-classified award on the settlement date.

RSU and PSU activity was as follows:

	Number of RSUs and PSUs	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)
Balance at December 31, 2022	697,815	$ 2.66	0.13
Granted	4,083,777	1.01	
Vested	(3,820,058)	(1.27)	
Forfeited	—	—	
Balance at December 31, 2023	961,534	1.17	0.19
Granted	7,769,484	1.29	
Vested	(4,726,961)	(1.37)	
Forfeited	—	—	
Balance at December 31, 2024	4,004,057	1.16	0.55
Granted	6,872,289	1.42	
Vested	(6,290,420)	(1.29)	
PSUs settled in cash	(1,154,000)	(1.13)	
Forfeited	(64,875)	(1.24)	
Balance at December 31, 2025	3,367,051	1.45	0.70

Total unrecognized compensation costs related to unvested RSU and PSU awards as of December 31, 2025 were $2,284 and are expected to be recognized over a weighted-average period of approximately 1.8 years.

Precigen uses treasury shares (to the extent available) and authorized and unissued shares to satisfy share award vesting.

14. Operating Leases

The Company leases certain facilities and equipment under operating leases. Leases with a lease term of twelve months or less are considered short-term leases and are not recorded on the balance sheet, and expense for these leases is recognized over the term of the lease. All other leases have remaining terms of less than one year to five years, some of which may include options to extend the lease and some of which may include options to terminate the lease within one year. The Company uses judgment to determine whether it is reasonably possible to extend the lease beyond the initial term or terminate before the initial term ends and the length of the possible extension or early termination. The leases are renewable at the option of the Company and do not contain residual value guarantees, covenants, or other restrictions.

The components of lease costs were as follows:

	Year Ended December 31,		
	2025	2024	2023
Operating lease costs	$ 1,593	$ 2,379	$ 2,234
Short-term lease costs	33	55	52
Variable lease costs	390	368	384
Lease costs	$ 2,016	$ 2,802	$ 2,670

As of December 31, 2025, maturities of lease liabilities, excluding short-term and variable leases, for continuing operations were as follows:

2026	$	1,680
2027		1,489
2028		1,402
2029		1,341
2030		600
Thereafter		—
Total		6,512
Present value adjustment		(1,396)
Total	$	5,116
Current portion of operating lease liabilities	$	1,136
Long-term portion of operating lease liabilities		3,980
Total	$	5,116

Other information related to operating leases in continuing operations was as follows:

	December 31,	
	2025	2024
Weighted average remaining lease term (years)	4.05	4.83
Weighted average discount rate	11.47 %	11.57 %

	Year Ended December 31,		
	2025	2024	2023
Supplemental disclosure of cash flow information			
Cash paid for operating lease liabilities	$ 1,601	$ 2,662	$ 2,326
Operating lease right-of-use assets obtained in exchange for new lease liabilities (includes new leases or modifications of existing leases)	724	572	399

During the year ended December 31, 2024 the Company recorded an impairment charge related to right-of-use assets. See Note 8 for further discussion.

15. Commitments and Contingencies

Contingencies

In December 2020, a derivative shareholder action, captioned *Edward D. Wright, derivatively on behalf of Precigen, Inc. F/K/A Intrexon Corp. v. Alvarez et al*, was filed in the Circuit Court for Fairfax County in Virginia on behalf of Precigen, Inc. The complaint named as defendants certain of the Company' directors and certain of the Company's current and former officers. The complaint's claims related to disclosures made by the Company about MBP program from May 10, 2017 to March 1, 2019. The plaintiff seeks damages, forfeiture of benefits received by defendants, and an award of reasonable attorneys' fees and costs. The case was stayed by an order entered on June 14, 2021. On September 24, 2021, an individual shareholder filed a lawsuit in the Circuit Court for Henrico County styled *Kent v. Precigen*, Inc., Case CL21-6349. The *Kent* action, also related to disclosures regarding MBP program, demands inspection of certain books and records of the Company pursuant to Virginia statutory and common law. On April 1, 2022, the court denied the demurrer and referred the matter to a hearing on the merits. The Company intends to defend the lawsuits vigorously; however, there can be no assurances regarding the ultimate outcome of these lawsuits.

In connection with the sale of the Company's Trans Ova subsidiary in 2022, the Company is required to indemnify the buyer for certain expenses incurred post close (related to covenants and certain additional specified liabilities including certain patent infringement lawsuits), if incurred, in amounts not to exceed $5,750. Such indemnification was recorded as a reduction of the gain on divestiture in 2022. As of December 31, 2025 and December 31, 2024, $2,476 and $3,213, respectively, were included in indemnification accruals on the consolidated balance sheets related to this indemnification liability. In 2025, the Company

paid an indemnification claim of $737 for expenses incurred by the buyer for the period from January 2024 to September 2025. During 2024, the Company paid $1,862 for expenses incurred by the Buyer for the period from July 2023 through December 2023. In addition, during 2023, the Company paid $675 for indemnification claims related to the period from the date of sale through June 2023. During 2025, the Company was notified by the buyer that the underlying claim related to the Company's indemnification was fully settled, and the Company will be required to further indemnify the buyer for approximately $2,000 plus associated legal fees. The Company expects to make final payments in 2026 which will discontinue the on going indemnification obligation.

In the course of its business, the Company is involved in litigation or legal matters, including governmental investigations. Such matters may result in adverse judgments, unfavorable settlements, or concessions by the Company, or adverse regulatory action, any of which could harm the Company’s business or operations. Moreover, such matters are subject to many uncertainties and outcomes are not predictable with assurance. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2025, the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations, or cash flows.

16. Segments

While the Company has historically generated revenues from multiple sources, including collaboration agreements and products and services associated with animal research models, management is organized around a singular focus which is developing and commercializing product candidates in its core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases.

In February 2025, the FDA granted priority review to Company’s BLA for PRGN-2012, with a PDUFA target action date set for August 27, 2025. On August 14, 2025, the FDA fully approved Papzimeos, marking the Company’s transition from a development-stage to a commercial-stage biopharmaceutical company.

In anticipation of this transition, during the first quarter of 2025, the Company realigned its former two operating segments, Biopharmaceuticals and Exemplar, into one operating segment. This decision was made to streamline operations and enhance focus on core business activities in preparation for the commercial launch of Papzimeos. The Company implemented this change to better reflect how the Company is managed and to align with its strategic initiative to concentrate resources on its core business. This change also reflects a shift in the manner in which the chief operating decision maker (“CODM”) reviews information to assess the Company’s performance and make resource allocation decisions, in accordance with ASC 280, *Segment Reporting*. The Company's CODM is its President and Chief Executive Officer ("CEO"). The CODM manages and allocates resources at a consolidated level. Although the change in operating segments was made in the first quarter of 2025, the Company still maintains two reporting units for the purpose of goodwill impairment testing.

Also, beginning in the first quarter of 2025, the CEO began using net loss in accordance with generally accepted accounting principles to assess performance and decide how to allocate resources. The CEO uses net loss to evaluate the allocation of resources across functions and research and development projects in line with our overarching long-term company-wide strategic goals as well as to monitor budget versus actual results. The CEO does not use total assets to evaluate segment performance or allocate resources, and accordingly, these amounts are not required to be disclosed. All prior period segment data has been retrospectively adjusted to reflect the way the Company's CODM internally receives information and manages and monitors our operating segment performance starting in fiscal year 2025.

The accounting policies of the Company's single operating segment are the same as those described in the summary of significant accounting policies as described in Note 2. As of December 31, 2025, substantially all of the Company's long-lived assets were held in the United States and there were no revenues derived in foreign countries for any periods presented. Expenditures for the addition of long-lived assets are reported on the consolidated statements of cash flows as purchases of property and equipment.

Total segment net loss, which equals consolidated net loss per the consolidated statements of operations was as follows:

	Year Ended December 31,		
	2025	2024	2023
Revenues from external customers	$ 9,684	$ 3,925	$ 6,225
Less:			
Salaries, benefits and other payroll expenses, including severance costs	(44,093)	(46,281)	(44,097)
Rent and utilities	(3,716)	(3,877)	(3,898)
Change in fair value of warrant liabilities	(139,523)	—	—
Impairment of goodwill	(3,907)	(7,408)	(10,390)
Impairment of assets	—	(32,915)	(445)
Other segment expenses, net	(69,084)	(39,679)	(43,299)
Net loss	$ (250,639)	$ (126,235)	$ (95,904)

Other segment expenses, net in the table above includes external R&D, SG&A and cost of good sold, including third-party commercialization and manufacturing costs, laboratory supplies, consultant costs, legal and professional fees, insurance, and certain other overhead expenses.

17. Defined Contribution Plans

The Company sponsors defined contribution plans covering employees who meet certain eligibility requirements. The Company makes contributions to the plans in accordance with terms specified in the plan agreement. The Company's contributions to the plans were $505, $417, and $178 for the years ended December 31, 2025, 2024, and 2023, respectively.

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