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, 2020

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 ☒

As of June 30, 2020, 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 $435.1 million.

As of February 15, 2021, 205,661,239 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 2021 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, 2020.

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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", "plan", "potential", "positioned", "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) the impact of the COVID-19 pandemic on our clinical trials, businesses, operating results, cash flows, and/or financial condition; (ii) the timeliness of regulatory approvals; (iii) our strategy and overall approach to our business model, our recent efforts to realign our business, and our ability to exercise more control and ownership over the development process and commercialization path; (iv) our ability to successfully enter new markets or develop additional product candidates, including the expected timing and results of investigational studies and preclinical and clinical trials, including any delays or potential delays as a result of the COVID-19 pandemic, whether with our collaborators or independently; (v) our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third-party manufacturers; (vi) our ability to successfully enter into optimal strategic relationships with our subsidiaries and operating companies that we may form in the future; (vii) our ability to hold or generate significant operating capital, including through partnering, asset sales, and operating cost reductions; (viii) actual or anticipated variations in our operating results; (ix) actual or anticipated fluctuations in competitors' or collaborators' operating results or changes in their respective growth rates; (x) our cash position; (xi) market conditions in our industry; (xii) the volatility of our stock price; (xiii) the ability, and the ability of our collaborators, to protect our intellectual property and other proprietary rights and technologies; (xiv) our ability, and the ability of our collaborators, to adapt to changes in laws or regulations or policies, including federal, state, and local government responses to the COVID-19 pandemic; (xv) outcomes of pending and future litigation; (xvi) the rate and degree of market acceptance of any products developed by us, our subsidiaries, collaborations, or joint ventures, or JVs, and competition from existing technologies and products or new technologies and products that may emerge; (xvii) our ability to retain and recruit key personnel; (xviii) expectations related to the use of proceeds from public offerings and other financing efforts; (xix) estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; (xx) the challenges inherent in leadership transitions; and (xxi) the effects, duration, and severity of the ongoing COVID-19 pandemic and the actions we and others have taken or may take in response.

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.

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 have a history of net losses, we may not achieve or maintain profitability, and we will need substantial additional capital in the future in order to fund our business.
- Servicing our debt may require a significant amount of cash, and we may not have sufficient cash flows from our business, or otherwise have available cash, to pay our substantial debts when due.
- Despite our current debt levels, we may still incur substantially more debt or take other actions that would intensify the risks discussed above.
- The COVID-19 pandemic has created significant volatility, uncertainty, and economic disruption that could have an adverse effect on our access to capital on favorable terms.

Risks Related to the Discovery and Development of our Product Candidates

- Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and ultimately commercialize them.
- The regulatory process of the U.S. 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.
- Our product candidates may cause undesirable side effects or have other properties that could delay or halt their clinical development, limit their commercial potential, or result in significant negative consequences.
- Even if we complete the necessary clinical trials, we cannot predict 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 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.
- The ongoing COVID-19 pandemic could cause a disruption of the development of our product candidates and adversely impact our healthcare business.
- 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.

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

- Even if a product candidate receives marketing approval, it 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.
- 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. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.
- The successful commercialization of our product candidates will depend in part on the extent to which third-party payers provide coverage and adequate reimbursement levels.
- Our business may be adversely affected by current and potential future healthcare reforms.

Risks Related to our Business Operations and Strategy

- We rely on third parties to develop and commercialize some of our product candidates.
- We have previously entered into strategic collaborations, that we cannot operate solely for our benefit, and which we may fail to successfully manage, or from which disputes may arise.
- We rely on our subsidiaries, our collaborators, and other third parties to deliver timely and accurate information.
- We may be sued for product liability.
- The livestock products of our operating subsidiaries are subject to disease outbreaks.
- Competitors and potential competitors may develop products and technologies that make ours obsolete or garner greater market share than ours.
- If we experience a significant breach of data security or disruption in our information systems, our business could be adversely affected.
- The effects of the COVID-19 pandemic have disrupted, and will likely continue to disrupt, our business operations, which could have a material adverse effect on our results of operations, cash flows, and financial position.
- We may pursue strategic acquisitions and investments that could have an adverse impact on our business.

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 could require us to spend significant time and money and could prevent us from commercializing our technologies or impact our stock price.
- If we do not obtain additional protection under United States or foreign legislation by extending the patent terms and obtaining regulatory exclusivity for our technologies, our business may be materially harmed.
- Enforcing our intellectual property rights may be difficult and unpredictable, within the United States and elsewhere.

Risks Related to 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.
- We do not anticipate paying cash dividends, and accordingly, shareholders will have to rely on any stock appreciation for return on their investment.
- The issuance of our common stock pursuant to a share lending agreement, including sales of the shares that we lend, and other market activity related to the share lending agreement may lower the market price of our common stock.
- As of December 31, 2020, Randal J. Kirk controlled approximately 44 percent of our common stock and may be able to control or significantly influence shareholder votes and other corporate actions.

PART I

Item 1. Business

Overview

We are a dedicated discovery and clinical-stage biopharmaceutical company advancing the next generation of gene and cell therapies with the overall goal of improving outcomes for patients with significant unmet medical needs. 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 have developed an extensive pipeline of therapies across multiple indications within these core focus areas.

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 UltraCAR-T, AdenoVerse immunotherapy, 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 are actively advancing our lead clinical programs, including: PRGN-3005 and PRGN-3006, which are built on our UltraCAR-T platform; PRGN-2009 and PRGN-2012, which are based on our AdenoVerse immunotherapy platform; and AG019, which is built on our ActoBiotics platform. In addition, we recently completed a Phase 1 study of INXN-4001, a non-viral triple-effector plasmid DNA, which is built on our UltraVector platform.

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 UltraPorator device received FDA clearance for manufacturing UltraCAR-T cells in clinical trials in October 2020, and we began dosing patients with UltraCAR-T cells manufactured with UltraPorator in our PRGN-3005 and PRGN-3006 clinical trials in November 2020. We also have a robust pipeline of preclinical programs that we are pursuing in order to drive long-term value creation.

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

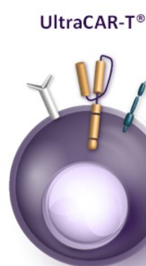
Our strategy is to use our discovery and clinical development infrastructure to continue advancement of our clinical programs with the goal of improving outcomes for patients with significant unmet medical needs. The key elements of our strategy include:

- ***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 have a robust pipeline of preclinical programs that we are pursuing in order to drive long-term value creation. 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.

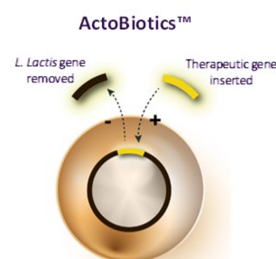
- ***Leveraging our technology and therapeutic platforms across indications.*** Through the application of our suite of proprietary and complementary synthetic biology technologies, we believe we can create optimized biological processes and overcome the limitations of traditional techniques, leading 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 in immuno-oncology, infectious diseases, and autoimmune disorders based on our transformative UltraCAR-T, AdenoVerse immunotherapy, and ActoBiotics 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 manufacturing and have invested in internal manufacturing capabilities to de-risk our clinical production.



- Non-viral multi-gene delivery
- Non-exhausted, stem-like T cell phenotype
- Higher antigen-specific expansion
- Enhanced *in vivo* persistence
- Ability to deplete with kill switch
- Overnight manufacturing process

- Large payload capacity
- Low seroprevalence in humans
- Ability for repeat administration
- Durable antigen-specific immune response
- Highly productive manufacturing process



- Food-grade bacteria, *L. lactis*
- Long history of safe use in humans
- Easy genetic manipulation
- Cost-effective and scalable manufacturing
- Convenient oral or topical delivery
- Local expression of genes at disease site

Our Clinical Pipeline

	PRODUCT	PLATFORM	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Immuno-oncology	PRGN-3005	UltraCAR-T	Ovarian Cancer					
	PRGN-3006	UltraCAR-T	AML, MDS					
	PRGN-2009	OTS AdenoVerse Immunotherapy	HPV⁺ Solid Tumors					

	PRODUCT	PLATFORM	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Autoimmune	AG019	ActoBiotics	Type 1 Diabetes					

	PRODUCT	PLATFORM	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Infectious	PRGN-2012	OTS AdenoVerse Immunotherapy	Recurrent Respiratory Papillomatosis					

	PRODUCT	PLATFORM	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Emerging	INXN-4001	Non-viral UltraVector	Heart Failure					

Our Healthcare Subsidiaries

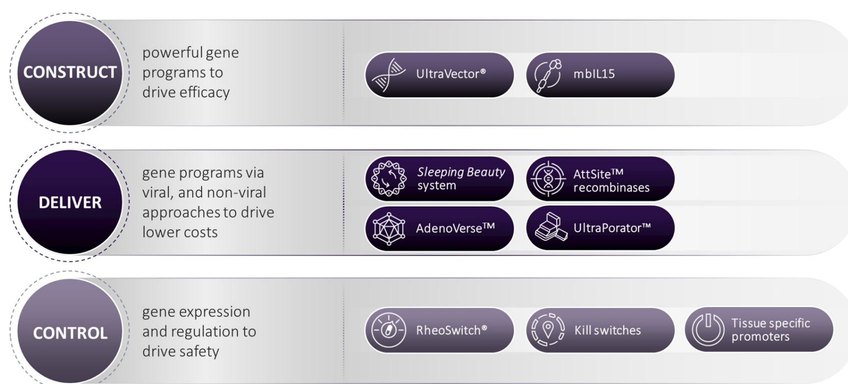
Our healthcare business is operated by our wholly owned subsidiaries PGEN Therapeutics, Inc., or PGEN Therapeutics, Precigen ActoBio, Inc., or ActoBio, and Exemplar Genetics, LLC, doing business as Precigen Exemplar, or Exemplar, and also includes our majority ownership interest in Triple-Gene LLC, doing business as Precigen Triple-Gene, or Triple-Gene, as well as equity and royalty interests in therapeutics and therapeutic platforms from companies not controlled by us.

PGEN Therapeutics

PGEN Therapeutics is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target urgent and intractable diseases in immuno-oncology, autoimmune disorders and infectious diseases. PGEN Therapeutics operates as an innovation engine, progressing a preclinical and clinical pipeline of well-differentiated therapies toward clinical proof-of-concept and commercialization.

PGEN Therapeutics' 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 enable 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 the genome. The *Sleeping Beauty* system has been shown to promote random integration in the genome without insertion bias, which contrasts with the predilection of lentiviral vectors for integration at transcriptionally active sites. We believe that this 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 a unidirectional, irreversible fashion to direct integration of a transgene into the host cell genome, allow for stable, site-specific gene integration. 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 in their large payload capacity, ability for repeat administrations and generation of robust antigen-specific immune responses. 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.

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, we believe is the most clinically advanced gene switch system and provides quantitative dose-proportionate regulation of the amount and timing of target protein expression in response to an orally available activator ligand, veledimex. In addition, we have developed a suite of 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.

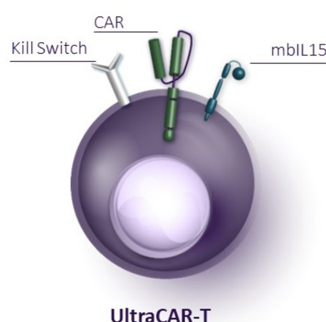
We have leveraged our proprietary and complementary technology platforms discussed above and our expertise in immunology to develop key therapeutic platforms, including UltraCAR-T and AdenoVerse, to address multiple pathways of complex disorders with significant unmet medical needs and to realize our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

PGEN Therapeutics' Therapeutic Platforms

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 modification of T cells with chimeric antigen receptors to enable those 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 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, 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.

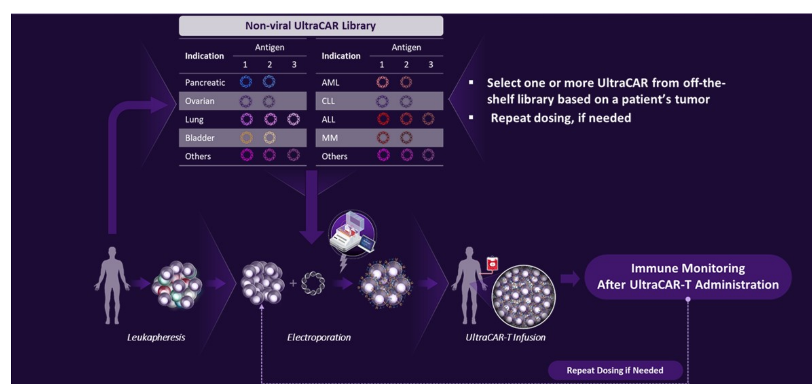
Our UltraCAR-T platform is differentiated from the competition, and we believe it has the potential to address the shortcomings of current technologies and disrupt the CAR-T treatment landscape by increasing patient access through shortening manufacturing time from weeks to days, decreasing manufacturing-related costs, and improving outcomes.



UltraCAR-T Differentiation

- Non-viral multi-gene delivery
- Uniform, multigenic cell product
- Stem-like T cell memory phenotype
- Higher antigen-specific expansion
- Enhanced *in vivo* persistence
- Ability to deplete with kill switch
- Overnight manufacturing process

We recently 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

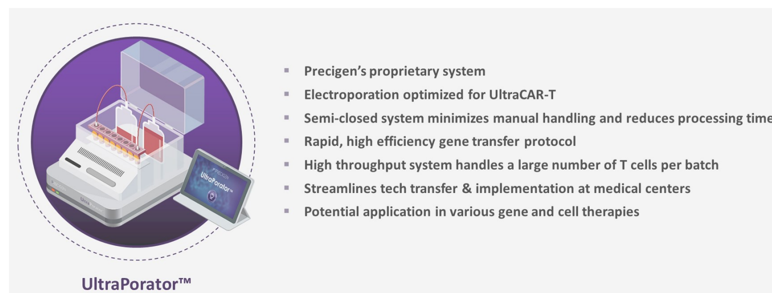
We have optimized and advanced the *Sleeping Beauty* system using our UltraVector DNA construction platform to produce multigenic UltraCAR-T cells. As a result of this optimization, our UltraCAR-T cells are precision-engineered to produce a homogeneous cell product that simultaneously co-expresses antigen-specific CAR, kill switch, and mbIL15 genes in any genetically modified UltraCAR-T cell. 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

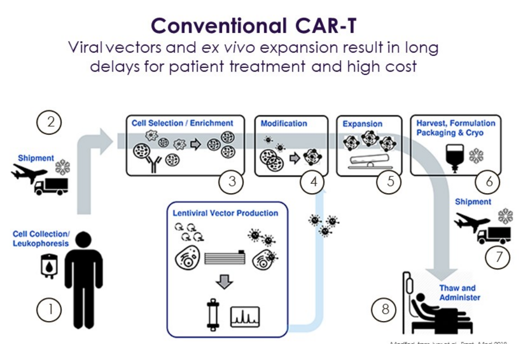
The key driver of improved UltraCAR-T cell performance is mbIL15. The expression of mbIL15 has been shown to enhance *in vivo* expansion of UltraCAR-T cells in the presence of tumor antigens and prevent T cell exhaustion to maintain a less differentiated, stem-cell like memory phenotype leading to longer 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.

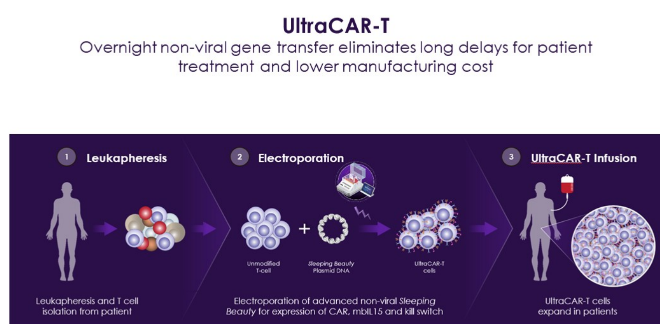
Scalable, rapid, decentralized manufacturing process

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 to achieve clinically relevant cell numbers 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 are the first company to implement non-viral, rapid, decentralized manufacturing of CAR-T cells in the clinic and have validated our proprietary UltraCAR-T manufacturing process in practice by infusing patients one day after gene transfer at two different sites in our ongoing clinical trials. 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 the processing time and contamination risk.



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.





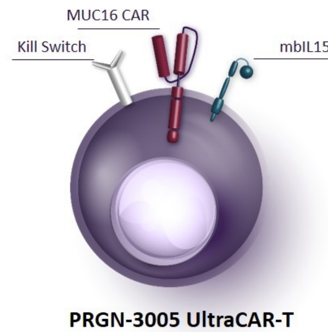
- Reliance on viral vectors
- Long and complex CAR-T cell manufacturing process
  - Lengthy *ex vivo* expansion
  - High cost of manufacturing
- Exhausted T cell phenotype
- Major challenges in solid tumor treatment

- Non-viral gene delivery
- Overnight UltraCAR-T manufacturing process
  - No *ex vivo* expansion necessary
  - Reduced manufacturing cost
- Stem-like memory T cell phenotype
- Enhanced potential for expansion and persistence

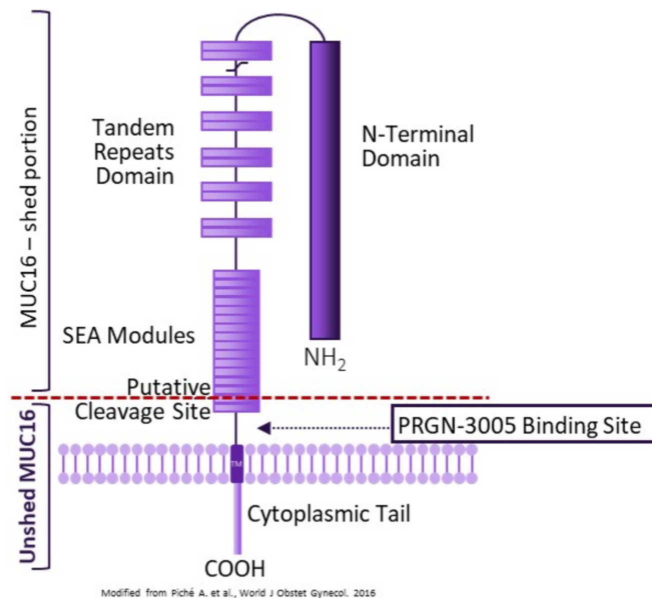
PGEN Therapeutics' most advanced programs based on the UltraCAR-T platform include PRGN-3005, which is in a Phase 1/1b clinical trial for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer, and PRGN-3006, which is in a Phase 1/1b clinical trial for patients with relapsed or refractory acute myeloid leukemia, or AML, high-risk myelodysplastic syndromes, or MDS, and chronic myelomonocytic leukemia, or CMML.

PRGN-3005

PRGN-3005 is a first-in-class, 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.

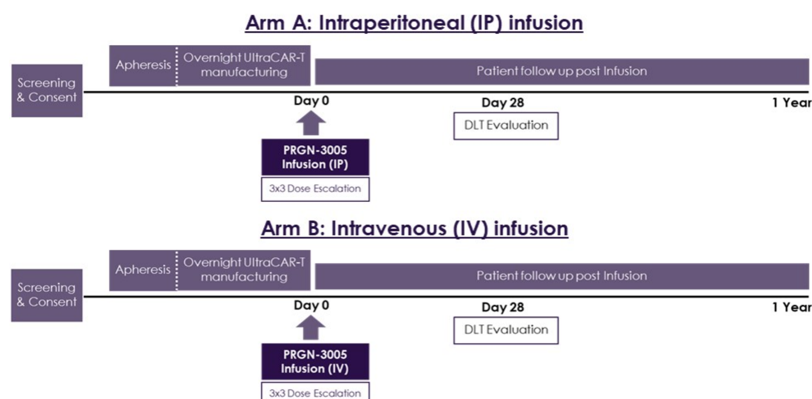


PRGN-3005 is being evaluated for the treatment of advanced ovarian, fallopian tube, and primary peritoneal cancers. Advanced ovarian cancer is often fatal, with Stage IV survival rates as low as 20 percent, and has limited treatment options. Patients with ovarian cancer represent a large population, with approximately 300,000 patients diagnosed worldwide annually, including 22,000 in the United States alone.

In preclinical *in vitro* studies, PRGN-3005 UltraCAR-T cells have shown robust MUC16-specific cytotoxicity of ovarian cancer cell lines, a stem-cell like memory phenotype and significant improvement in their longevity even in the absence of exogenous cytokines as compared to conventional CAR-T cells. PRGN-3005 UltraCAR-T cells have shown significantly superior anti-tumor response in mouse models of ovarian cancer compared to mice treated with a saline solution or conventional MUC16 CAR-T cells lacking mbIL15 expression. Specifically, a single administration of PRGN-3005 one day after non-viral gene transfer showed significantly superior expansion and preferred memory phenotype of UltraCAR-T *in vivo* and significantly

superior efficacy compared to traditional CAR-T resulting in all PRGN-3005 treated mice becoming tumor-free. Furthermore, rechallenging these tumor-free mice three months later with ovarian tumors for a second time (to simulate tumor relapse) led to the elimination of tumor burden without additional PRGN-3005 UltraCAR-T treatment. These data demonstrated the potential of UltraCAR-T cells to persist long-term *in vivo*, prevent CAR-T cell exhaustion, and mount a durable anti-tumor response with the ability to continue to respond upon tumor rechallenge.

PRGN-3005 is currently being evaluated in a Phase 1/1b clinical trial. 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 this investigator-initiated Phase 1 dose escalation trial receive either intraperitoneal, or IP (Arm A), or intravenous, or IV (Arm B), administration of PRGN-3005 without prior lymphodepletion. The primary objectives of the Phase 1 trial are to assess the safety and maximum tolerated dose, or MTD, of PRGN-3005. For both routes of administration, PRGN-3005 will follow a 3+3 dose escalation pattern. We are conducting this trial in collaboration with The University of Washington and The Fred Hutchinson Cancer Research Center, leaders in immunotherapy and CAR-T treatments. We expect to enroll up to 71 patients total in this study.



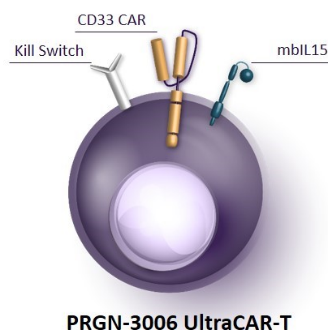
In October 2020, we announced the FDA clearance of our UltraPorator system, a proprietary electroporation device and software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies, as a manufacturing device for clinical trials of our investigational UltraCAR-T therapies in compliance with cGMP. In November 2020, we announced that we have successfully dosed the first patient in the PRGN-3005 Phase 1 trial using UltraCAR-T cells manufactured using the UltraPorator system.

In December 2020, we presented preliminary data from the first six patients treated with PRGN-3005, who were treated at the two lowest dose levels in the IP arm without prior lymphodepletion. The six patients were treated at either Dose Level 1 ($>3x10^4$ - $\leq 1 \times 10^5$ UltraCAR-T cells/kg; N=3) or Dose Level 2 ($>1x10^5$ - $\leq 3 \times 10^5$ UltraCAR-T cells/kg; N=3). Patients had received between 6 and 9 prior therapies before enrolling in the PRGN-3005 study. Preliminary data from these patients showed that PRGN-3005 was well-tolerated, with no dose-limiting toxicities, or DLTs, neurotoxicities, or cytokine release syndromes reported. PRGN-3005 UltraCAR-T cells showed encouraging expansion and persistence after low dose IP infusion without lymphodepletion across both dose levels. In addition, 50 percent (3 out of 6) of the patients experienced regression in total target tumor burden and 33 percent (2 out of 6) patients achieved stable disease according to RECIST v1.1 criteria at their restaging evaluation. In addition, we believe that our consistent ability to successfully manufacture UltraCAR-T cells at a medical center confirms the validity of our rapid, decentralized approach to manufacturing.

Enrollment is ongoing in the IP arm of the trial, and an expansion phase is planned at the MTD. We have received clearance from the FDA to initiate dosing in the IV arm of the trial concurrently with the IP arm.

PRGN-3006

PRGN-3006 is a first-in-class, 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.

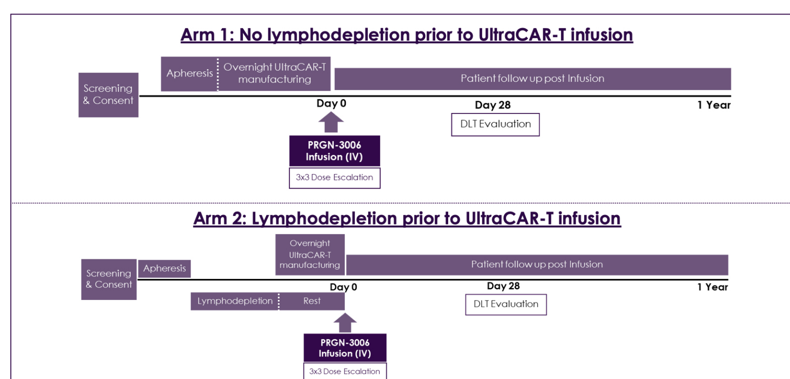


CD33, also known as Siglec-3, is a single pass transmembrane glycoprotein and a member of the sialic acid-binding immunoglobulin-like lectin super-family. CD33 is an attractive target for immunotherapy because it is over-expressed on AML blasts and leukemic stem cells, or LSCs, but is not expressed on 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 20,000 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. 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.

In preclinical studies, PRGN-3006 demonstrated robust expansion in the presence of CD33 antigen, lack of autonomous expansion in the absence of CD33 and prolonged persistence in the absence of exogenous cytokines. PRGN-3006 exhibited target-specific killing of $CD33^+$ tumor cells as well as a significant release of inflammatory cytokines such as IFNγ, upon co-culture with AML tumor cells. PRGN-3006 cells were specifically eliminated by kill switch activator treatment, displaying functionality of the kill switch, which is intended to improve the safety profile of PRGN-3006. *In vivo*, a single administration of PRGN-3006 UltraCAR-T cells only one day after gene transfer effectively eliminated the tumor burden and significantly improved overall survival of tumor bearing mice compared to CAR-T cells lacking mbIL15 expression (conventional CAR-T) in an aggressive xenograft model of AML. PRGN-3006 demonstrated engraftment and significantly higher expansion and persistence in mice compared to conventional CAR-T cells, which lack mbIL15 expression.

PRGN-3006 is currently being evaluated in an investigator-initiated Phase 1/1b 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 includes relapsed or refractory AML, higher-risk MDS, and CMML. In the 3+3 dose escalation phase, patients will be treated in one of the two arms: patients in Arm 1, or No Lymphodepletion arm, will receive UltraCAR-T cell infusion without prior lymphodepletion, and patients in Arm 2, or Lymphodepletion arm, will receive lymphodepleting chemotherapy prior to UltraCAR-T infusion. Because our UltraCAR-T cells have the potential for enhanced *in vivo* expansion and persistence due to expression of mbIL15, we are evaluating the administration of PRGN-3006 in patients without prior lymphodepletion. The primary objective of this trial is to assess the safety of PRGN-3006 and determine the MTD. The Phase 1 trial is being conducted in collaboration with Moffitt Cancer Center, a pioneer in CAR-T clinical development.



In October 2020, we announced the FDA clearance of our UltraPorator system as a manufacturing device for clinical trials of our investigational UltraCAR-T therapies in compliance with cGMP. In November 2020, we announced that we have successfully dosed the first patient in the PRGN-3006 Phase 1 trial using UltraCAR-T cells manufactured using the UltraPorator system.

In December 2020, the Principal Investigator of the PRGN-3006 clinical trial presented clinical progress and preliminary data from the ongoing Phase 1 trial, including a case study of a patient treated at Dose Level 2 of the No Lymphodepletion arm at the 62nd ASH Annual Meeting and Exposition. Later in December, we presented additional data to expand upon the preliminary data presented at the ASH Annual Meeting and Exposition. As of November 10, 2020, the cutoff date for the results, a total of nine patients had been treated in either the No Lymphodepletion arm or the Lymphodepletion arm of the trial. Of the nine patients treated, six were treated at either the Dose Level 1 ($>3x10^4$ - $\leq 1 x 10^5$ UltraCAR-T cells/kg; N=3) or the Dose Level 2 ($>1x10^5$ - $\leq 3 x 10^5$ UltraCAR-T cells/kg; N=3) of the No Lymphodepletion arm, and three were treated at the Dose Level 1 ($>3x10^4$ - $\leq 1 x 10^5$ UltraCAR-T cells/kg; N=3) of the Lymphodepletion arm. Preliminary data from these patients showed that PRGN-3006 was well-tolerated, with no DLTs and no neurotoxicity. Transient grade 1 to 3 cytokine release syndrome was reported in two patients, which was resolved without intervention. There was low incidence of treatment-related adverse events and serious adverse events, and Grade 3 or greater treatment-emergent adverse events included hematologic events, decreased electrolytes, and infections. PRGN-3006 UltraCAR-T showed encouraging expansion and persistence in peripheral blood of patients in both No Lymphodepletion and Lymphodepletion arms and across all dose levels. Furthermore, PRGN-3006 UltraCAR-T cells showed the ability to traffic, expand, and persist in bone marrow. In addition, we believe that our consistent ability to successfully manufacture UltraCAR-T cells at a medical center confirms the validity of our rapid, decentralized approach to manufacturing.

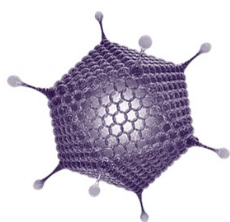
A case study of the patient with the longest follow-up as of the data cutoff was also presented at the ASH Annual Meeting and Exposition. The case study patient was a 69 year old female with secondary AML and four prior lines of therapy, including induction chemotherapy, or IC, allogenic hematopoietic stem cell transplantation, or allo-HSCT, hypomethylating agent plus venetoclax, or HMA+VEN. The patient was refractory to all therapy post allo-HSCT. The patient had approximately 40 percent peripheral blasts and 47 percent bone marrow blasts at baseline. The patient was treated at Dose Level 2 in No Lymphodepletion arm with a total of only 24 million UltraCAR-T cells via IV infusion. Case study findings presented showed that, after a low dose infusion without prior lymphodepletion, PRGN-3006 UltraCAR-T cells demonstrated robust expansion and persistence in blood at seven months post-infusion. PRGN-3006 UltraCAR-T cells demonstrated trafficking to bone marrow and the ability to expand and persist in bone marrow. The patient showed a decline in AML blast levels in blood and bone marrow concomitant with UltraCAR-T expansion and persistence and had durable stable disease.

Enrollment is ongoing simultaneously in both the No Lymphodepletion and the Lymphodepletion arms of this Phase 1 trial. The dose escalation phase of each arm will be followed by a dose expansion phase at the MTD. PRGN-3006 was granted Orphan Drug designation for the treatment of AML by the FDA.

"Off-the-shelf" AdenoVerse Immunotherapy

Our AdenoVerse immunotherapy 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 immunotherapy platform, which we believe are easily scalable for commercial supply. We believe that our proprietary gorilla adenovectors, which are 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.



AdenoVerse Differentiation

- Large genetic payload capacity
- Off-the-shelf availability
- Ability for repeat administration
- Durable antigen-specific immune response
- Non-replicating adenoviruses
- Highly productive manufacturing process

The key advantages of AdenoVerse immunotherapy 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 a significant 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.

Inability to replicate

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

One of our central differentiating factors and competitive gene therapy advantages is our investment in internal cGMP manufacturing capabilities in Germantown, Maryland, with the aim to reduce a myriad of risks that can impact manufacturing of viral vectors. These include technology transfer risks when outsourcing to contract manufacturing organizations as well as process and timing risks. Our modular cGMP facility with a small footprint was designed with agility and control in mind, focusing on rapid manufacturing and the ability to scale production appropriately to meet early-stage clinical trial needs of gene therapy vectors, especially our AdenoVerse-based therapeutics. We are able to generate greater than 1,000 doses of early phase

clinical trial material at this facility at an expedited timeline and reduced cost compared to contract manufacturing organizations. As a result, we feel we are in a position to be in control of meeting our gene therapy manufacturing needs for our early-phase clinical trials.

PGEN Therapeutics' most advanced programs based on the AdenoVerse immunotherapy platform include: (i) PRGN-2009, a first-in-class, "off-the-shelf" investigational immunotherapy utilizing the AdenoVerse platform, is designed to activate the immune system to recognize and target human papillomavirus-positive, or HPV+, solid tumors, which is in a Phase 1/2 clinical trial 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; and (ii) PRGN-2012, a first-in-class, investigational "off-the-shelf" AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV type 6, or HPV6, or HPV type 11, or HPV11, which recently received investigational new drug application, or IND, approval from the FDA to initiate a Phase 1 trial in patients with recurrent respiratory papillomatosis, or RRP.

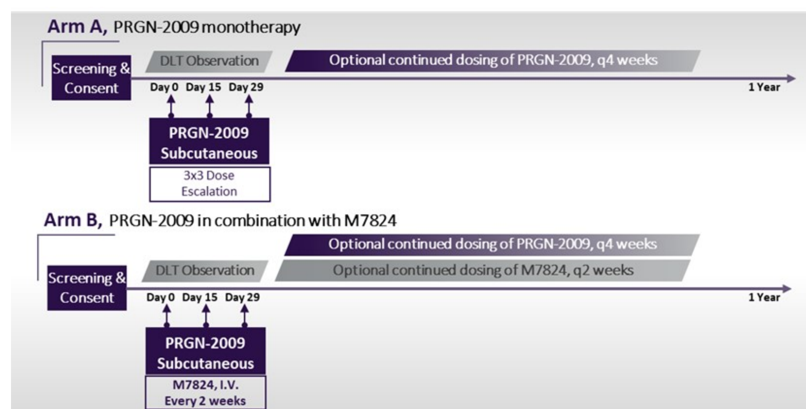
PRGN-2009

PRGN-2009, a first-in-class, "off-the-shelf" investigational immunotherapy, 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 infects the squamous cell carcinoma. Some cervical cancers come from HPV infection of gland cells in the cervix and are referred to as adenocarcinomas. HPV-related cancers include cervical, oropharyngeal, anal, penile, vaginal, and vulvar. Nearly 44,000 HPV-associated cancers occur in the United States each year. Of these, approximately 25,000 occur in women and 19,000 occur in men. HPV is considered responsible for more than 90 percent of anal and cervical cancers, about 70 percent of vaginal and vulvar cancers, and more than 60 percent of penile cancers. Recent studies indicate that about 70 percent of cancers of the oropharynx also may be related to HPV.

In preclinical studies, PRGN-2009 treatment induced strong HPV-specific immune response and effectively controlled solid tumors in a murine model of HPV+ head and neck cancer. In a humanized mouse model of HPV+ cancer, PRGN-2009 treatment led to an increase in CD8 and CD4 T cells in the tumor microenvironment and a reduction in the tumor. In a syngeneic mouse model of HPV+ cancer, repeated injections of PRGN-2009 monotherapy resulted in generation of high levels of HPV-specific T cells, and reduction in tumor burden. The combination of PRGN-2009 with bintrafusp alfa, or M7824, an investigational bifunctional fusion protein, further reduced tumor growth, increased HPV-specific T cells, and increased T-cell infiltration into the tumor microenvironment *in vivo*.

PRGN-2009 is in a Phase 1/2 clinical trial for patients with HPV-associated cancers in collaboration with NCI pursuant to a CRADA. The Phase 1 portion of the study will follow 3+3 dose escalation to evaluate the safety of PRGN-2009 administered as a monotherapy, Arm A, to determine the recommended Phase 2 dose, or R2PD, followed by an evaluation of the safety of the combination of PRGN-2009 at the R2PD and M7824, Arm B. The Phase 1 study population includes patients with recurrent or metastatic HPV-associated cancers. PRGN-2009 will be administered via sub cutaneous injection once every 2 weeks for three administrations and may be continued every 4 weeks for up to one year, as clinically appropriate. M7824 will be administered on Day 1 and then every 2 weeks. The Phase 2 portion of the study will evaluate PRGN-2009 as a monotherapy or in combination with M7824 as a neoadjuvant or induction therapy in patients with newly-diagnosed stage II/III HPV16-positive oropharyngeal cancer and patients with newly diagnosed operable stage II/III/IVA/IVB HPV+ sinonasal squamous cell cancer.



In January 2021, we announced preliminary data from the ongoing Phase 1/2 clinical trial of PRGN-2009 in patients with HPV-associated cancers. Enrollment in the Phase 1 monotherapy dose escalation arm, Arm A, of this trial is complete, and enrollment in the Phase 1 combination arm, Arm B, has been initiated. A total of six patients were treated in the monotherapy arm. All patients in the monotherapy arm have received multiple PRGN-2009 administrations to date. Preliminary data showed that repeated administrations of PRGN-2009 was well-tolerated by these patients with no DLTs. In addition, preliminary correlative analysis by the NCI of peripheral blood mononuclear cells from three patients treated at the initial dose level showed an increase in HPV16 and/or HPV18-specific T-cell response in 100 percent (3 out of 3) patients. Furthermore, an increase in the magnitude and breadth of immune response was seen after repeat administration of PRGN-2009.

PRGN-2012

PRGN-2012, a first-in-class, investigational "off-the-shelf" AdenoVerse immunotherapy for the treatment of RRP. PRGN-2012 is an innovative therapeutic vaccine with optimized antigen design that uses our gorilla adenovector technology, part of our proprietary AdenoVerse platform, to elicit immune responses directed against cells infected with HPV6 and HPV11. Gorilla adenovectors have numerous advantages, including the ability for repeat administration, the inability to replicate *in vivo*, which may improve safety, and the ability to deliver large payload capacity.

RRP is a rare, difficult-to-treat, and sometime fatal neoplastic disease of the respiratory tract caused by infection with HPV6 or HPV11. RRP is classified based on age of onset as juvenile or adult. Juvenile-onset disease has an incidence of 4 per 100,000 and adult-onset RRP has an incidence of 2 to 3 per 100,000. There is no cure for RRP, and the current standard-of-care is repeated endoscopic debulking with ablation or excision of papillomatous lesions. Recurrence of papilloma after surgical removal is very common, and repeated procedures are required to debulk and monitor the disease, which exposes patients to anesthetic and surgical risks and emotional distress. Some patients require a tracheotomy and need a trach tube indefinitely to keep the breathing passage open. RRP morbidity and mortality results from the effects of papilloma mass on the vocal cords, trachea, and lungs, which may cause voice changes, stridor, airway occlusion, loss of lung volume, and/or post-obstructive pneumonia. Although rare, one to three percent of RRP cases can transform into invasive squamous cell carcinoma. In addition, more than 90 percent of genital warts are related to HPV6 and HPV11 infection.

Normal trachea

RRP Patient trachea

In preclinical models, PRGN-2012 has demonstrated strong HPV6 and HPV11-specific T-cell response in RRP patient samples *in vitro*.

In January 2021, we announced that the FDA had cleared the IND to initiate the Phase 1 clinical trial of PRGN-2012 AdenoVerse immunotherapy in adult patients with RRP. The Phase 1 study will follow 3+3 dose escalation of PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomatosis disease. Patients will receive up to four injections of PRGN-2012. The primary objective of the study is to determine safety and tolerability and the recommended Phase 2 dose of PRGN-2012. The study will enroll 3 to 6 subjects at each dose level, and 12 patients will be treated at the MTD. PRGN-2012 is being developed in collaboration with the Center for Cancer Research at the NCI through a CRADA.

Preclinical Programs

We have a robust pipeline of preclinical programs that we are pursuing in order to drive long-term value creation. Our pipeline includes a number of product candidates, including UltraCAR-T therapeutics for various cancers, an "off-the-shelf" AdenoVerse immunotherapy for infectious disease, and a multifunctional therapeutic for solid tumors. We expect to continue development of various preclinical programs to identify product candidates for evaluation in clinical trials.

We are evaluating multiple UltraCAR-T candidates for treatment of hematological and solid tumors in preclinical testing. We recently introduced our vision for a new UltraCAR-T library approach aimed at transforming 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.

We are developing PRGN-2013, a preclinical stage asset based on our "off-the-shelf" AdenoVerse immunotherapy platform, to treat chronic hepatitis B virus, or HBV, infection. HBV can cause serious health problems, including liver damage, cirrhosis, liver cancer, and death. Preclinical studies of PRGN-2013 showed that mice treated with PRGN-2013 saw (i) a more significant cytotoxic T-cell response against more HBV epitopes and (ii) decreased plasma levels of HBsAg, the key marker of chronic HBV infection in mice.

We are also developing immuno-oncology product candidates based on our Multifunctional Therapeutic platform to target solid tumors. Additional preclinical programs under development include an AdenoVerse cytokine therapy candidate for solid tumors and candidates to target autoimmune disorders.

We also have a number of other 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 is pioneering a proprietary class of microbe-based biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics. We refer to these microbe-based biopharmaceuticals as ActoBiotics.

Precigen ActoBio's Therapeutic Platforms

ActoBiotics

Our ActoBiotics platform is a unique therapeutic platform precisely tailored for specific disease modification with the potential for superior efficacy and safety. ActoBiotics combine the advantages of highly selective protein-based therapeutic agents with local delivery by the well-characterized and food-grade bacterium *Lactococcus lactis*, or *L. lactis*. ActoBiotics can be delivered orally in a capsule, through an oral rinse or in a topical solution. We believe ActoBiotics have the potential to provide superior safety and efficacy via the sustained release of appropriate quantities of select therapeutic agents as compared to injectable biologics, while reducing the side effects commonly attributed to systemic delivery and corresponding peaks in concentration. ActoBiotics work via genetically modified bacteria that deliver proteins and peptides at mucosal sites, rather than the insertion of one or more genes into a human cell by means of a virus or other delivery mechanism. By foregoing this insertion, ActoBiotics allow "gene therapy" without the need for cell transformation.

The key advantages of ActoBiotics include:

Food-grade bacterium with easy genetic manipulation

ActoBiotics combine the advantages of highly selective protein-based therapeutic agents with local delivery by the well-

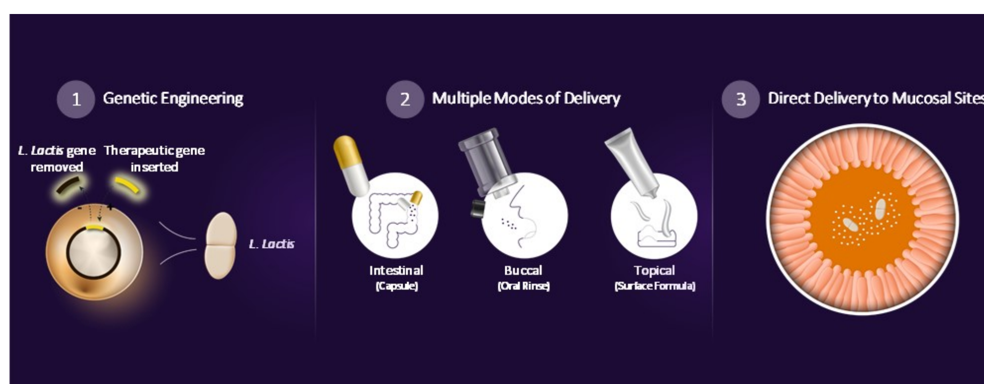
characterized and food-grade bacterium with *L. lactis*, which has a long history of safe use. ActoBiotics are generated by genetically modifying *L. lactis* via chromosomal integration through targeted double homologous recombination to express and release a variety of highly versatile biological moieties. Multiple therapeutic agents, such as proteins, peptides, and antibodies, can be incorporated into a single ActoBiotics therapeutic, enabling the simultaneous targeting of multiple pathways in one disease. The *L. lactis* host is also engineered for environmental containment, thus preventing the spread of bacteria outside the human body.

Cost-effective and scalable manufacturing

We have established an efficient and reliable cGMP manufacturing process for the production of ActoBiotics that we believe is easily scalable for commercial supply. The manufacturing process involves fermentation of genetically modified *L. lactis* to generate significant quantities of the therapeutic agent, followed by concentration and freeze-drying. The process does not require the costly purification required to produce conventional biologics.

Convenient delivery method

ActoBiotics can be delivered to the oral cavity through a mouthwash, intestinally via a capsule, or through a topical formula. Physiological dosing is low, and our ActoBiotics product candidates have been well-tolerated in preclinical and clinical studies. As compared to conventional biologics, we believe ActoBiotics have the potential to provide superior safety and efficacy via the sustained release of appropriate quantities of select therapeutic agents while reducing the side-effects commonly attributed to systemic delivery and corresponding peaks in concentration of conventional biologics.



ActoBio's most advanced internal pipeline candidate, AG019, is a first-in-class disease modifying antigen-specific, investigational immunotherapy for the prevention, delay, or reversal of type 1 diabetes mellitus, or T1D. AG019 is an easy-to-take capsule formulation of ActoBiotics engineered to deliver the autoantigen human proinsulin, or PINS, and the tolerance-enhancing cytokine human interleukin-10 to the mucosal lining of gastro-intestinal tissues in patients with T1D. We believe this design can reduce T1D pathology by reestablishing immunological tolerance to islet antigens via the production of regulatory T, or Treg, cells.

T1D represents a highly unmet medical need, with approximately 132,000 patients, most commonly children and young adults, diagnosed each year. In T1D, the immune system destroys insulin-producing beta cells in the pancreas, creating a blood glucose imbalance and numerous symptoms, including polyuria, polydipsia, polyphagia, weight loss, lassitude, nausea and blurred vision. The current treatment standard for T1D consists of exogenous insulin along with diet and lifestyle modification, but no disease-modifying treatment is available. We believe that AG019 has the potential to address the unmet medical need for disease modifying treatment in T1D.

Preclinical studies in mice have shown that AG019, in association with a short-term treatment with a low-dose anti-CD3 monoclonal antibody, induced stable reversion to normal blood sugar levels and reversed the disease in diabetic mice treated at an early stage. Furthermore, AG019 treatment induced accumulation and proliferation of PINS-specific $FoxP3^{+}$ Treg cells in the pancreas and peripheral lymph nodes.

AG019 is currently in a Phase 1b/2a clinical trial for the treatment of early-onset T1D. The Phase 1b portion of the study evaluates the safety and tolerability of AG019 monotherapy administered as a single dose and repeated daily doses in adult and adolescent patients. Enrollment and dosing in the Phase 1b and Phase 2a portions of the study are complete. The Phase 2a

portion of the study investigates the safety and tolerability of AG019 in combination with teplizumab, or PRV-031. In August 2020, we announced that the primary endpoint of assessing safety and tolerability in the Phase 1b monotherapy portion of the study was met and that preliminary results at six months after AG019 monotherapy treatment initiation showed an encouraging trend in the insulin C-peptide levels, a biomarker for T1D disease progression. In December 2020, we announced additional data from our ongoing Phase 1b portion and initial preliminary data from the Phase 2a portion of our ongoing Phase 1b/2a clinical trial. The additional data from the Phase 1b monotherapy portion of the trial showed that AG019 continued to be well-tolerated, with no discontinuations due to treatment-emergent adverse events. From the perspective of clinical activity, this data showed that 58 percent (7 of 12) of patients aged 17 or older receiving the AG019 monotherapy showed stabilization of C-peptide levels during the first six months of treatment and slower decline in C-peptide levels after being treated for 12 months as compared to treatment with placebo. In addition, a mechanistic analysis performed by an independent research group found the induction of antigen-specific tolerance in conjunction with the reduction of disease-specific T cell responses for adult patients after three months of treatment with AG019. We believe these results indicate the potential of AG019 to preserve insulin production in early-onset T1D through AG019's capacity to induce antigen-specific immune modulation. Data from the Phase 2a combination portion with teplizumab showed that the combination was well-tolerated. This data showed that 70 percent of adult patients (7 of 10) experienced stabilization of C-peptide levels after six months of treatment with a trend toward higher C-peptide levels as compared to baseline levels. Mechanistic data were consistent with the data shown in the monotherapy trial, which we believe indicates the effect may be attributed to AG019. We believe preliminary results in the combination trial point to the potential to boost or prolong teplizumab-induced metabolic effects. No dose-related adverse events or serious adverse events were reported in either portion of this trial.

Precigen Triple-Gene

Triple-Gene is a clinical stage gene therapy company focused on developing advanced treatments for complex cardiovascular diseases. Triple-Gene's approach is to develop a holistic treatment for heart failure through improvements in angiogenesis, calcium homeostasis-associated cellular energetics, reductions in inflammatory signals, and the activation/recruitment of stem cells to support heart remodeling.

Triple-Gene's most advanced candidate, INXN-4001, a non-viral triple effector plasmid based on our UltraVector platform designed for the constitutive expression of human S100A1, SDF-1a, and VEGF-165, is engineered to address multiple pathways of heart failure. Utilizing a single plasmid comprising all three genes, instead of each individual gene on separately delivered plasmids, INXN-4001 can control for delivery and ensure expression of three genes in all transfected cells.

Heart failure represents a significant unmet medical need and a major economic burden worldwide. There are approximately 25 million heart failure patients worldwide, of whom 6 million are in the United States. Heart failure is the number one cause of hospitalization in patients aged 65 years and older, and 50 percent of heart failure patients die within five years after diagnosis. Heart failure is a complex and multifaceted disease most often resulting from the intersection of multiple genetic predispositions with negative environmental factors. Existing treatments improve quality of life in the short-term and offer some improvement in long-term survival at high cost and with associated complications. We believe that developing a holistic and clinically relevant treatment for heart failure will require improvements in numerous areas, including angiogenesis, calcium homeostasis-associated cellular energetics, reductions in inflammatory signals, and the activation or recruitment of stem cells to support heart remodeling.

Preclinical studies of INXN-4001 showed significant improvement in beat rate, contractile duration and contraction rate of human induced pluripotent stem cell-derived cardiomyocytes in a dilated cardiomyopathy model to the levels demonstrated by control cells and did not result in increased cell death compared to controls. Coronary sinus delivery of INXN-4001 in a large animal ischemic heart failure model showed decreased left ventricular end systolic volume and increased absolute mean ejection fraction, which are indicators of myocardial function, as well as no increase in arrhythmias compared to controls.

We recently completed our Phase 1 clinical trial of INXN-4001, which was a first-in-human, open label study designed to evaluate the safety of retrograde coronary sinus infusion, or RCSI, of INXN-4001 in outpatient left ventricular assist device, or LVAD, recipients. Twelve stable patients with implanted LVAD for mechanical support of end stage heart failure were allocated into two cohorts of six subjects for infusion of the same amount of INXN-4001 (80mg) in either 40mL or 80mL via RCSI at a rate of 20mL per minute. The primary objectives of the Phase 1 study are to evaluate the safety of INXN-4001 infusion into the myocardium of LVAD patients and to demonstrate safety and feasibility of RCSI. Secondary endpoints include improvements in the six minute walk test, or 6MWT, duration and distance and quality of life, as assessed by Kansas City Cardiomyopathy Questionnaire, or KCCQ, responses. We have completed dosing and follow-up of patients in this trial.

In August 2020, we provided six-month follow-up data from the Phase 1 study of INXN-4001. Twelve chronic heart failure patients were treated with INXN-4001 in either Cohort 1 (80 mg/40 mL; n=6) or Cohort 2 (80 mg/80 mL; n=6), and ten were

evaluated for six-month follow-up. The study has met the primary endpoints to evaluate safety and feasibility for INXN-4001. The infusions of INXN-4001 were overall well tolerated, with no adverse events attributed to INXN-4001, whereas one serious adverse event was considered related to the infusion procedure. Furthermore, preliminary assessment of the secondary endpoints show improvement by at least five points in total KCCQ score, a validated tool qualified by the FDA for Clinical Outcome Assessment, was observed in 50 percent of patients evaluable (5 out of 10) at the six-month follow-up visit, These included four patients treated in Cohort 1 and one patient treated in Cohort 2. Of the evaluable patients, 50 percent (4 out of 8) had an improvement in the 6MWT (> 50 meters in distance walked) at six months post-infusion compared to pre-treatment baseline. The Phase 1 trial has now been completed, and analysis of final results is ongoing.

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, as well as enabling the production of cells and organs in its genetically engineered swine for regenerative medicine applications. 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.

Partnered Program

We have partnered with Castle Creek Biosciences, Inc. (formerly Fibrocell Science, Inc.), or Castle Creek, to advance product candidates D-Fi (debcoemagene autoficel), formerly designated FCX-007, for the treatment of recessive dystrophic epidermolysis bullosa, or RDEB, and FCX-013 for the treatment of localized scleroderma. In October 2020, Castle Creek announced the dosing of the first patient in the ongoing Phase 3 trial of D-Fi and the dosing of the first patient in the ongoing Phase 1/2 trial of FCX-013. The FDA has granted Orphan Drug designation to D-Fi for the treatment of Dystrophic Epidermolysis Bullosa, which includes RDEB. In addition, D-Fi has been granted Rare Pediatric Disease designation, Fast Track designation, and Regenerative Medicine Advanced Therapy designation by the FDA for treatment of RDEB. The FDA has granted Orphan Drug designation to FCX-013 for the treatment of localized scleroderma. In addition, FCX-013 has been granted Rare Pediatric Disease designation and Fast Track designation for the treatment of moderate to severe localized scleroderma. Pursuant to the collaboration, we licensed our technology platforms to Castle Creek for use in certain specified fields, and in exchange, we received and were entitled to certain access fees, milestone payments, royalties, and sublicensing fees related to the development and commercialization of product candidates. In March 2020, we and Castle Creek terminated the original collaboration agreement by mutual agreement, with the parties agreeing that FCX-007 and FCX-013 would be treated as "Retained Products" under the terms of the original agreement. Castle Creek retains a license to continue to develop and commercialize the Retained Products within the field of use for so long as Castle Creek continues to pursue such development and commercialization, and we are also entitled to certain royalties with respect to the Retained Products. We are also required to perform certain drug product manufacturing activities related to the Retained Products.

Competition: Healthcare Business

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.

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.

Immuno-oncology

Our lead product candidates include PRGN-3005 for the treatment of ovarian cancer and PRGN-3006 for the treatment of AML, which are built on our UltraCAR-T platform, and PRGN-2009, which is based on our AdenoVerse immunotherapy 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 MaxCyte 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, Amgen, Cellectis S.A., and Allogene Therapeutics are also using CAR-T technology to develop product candidates for the treatment of AML. We believe that INOVIO Pharmaceuticals, AstraZeneca, Transgene SA, and Advaxis Immunotherapies are developing immunotherapies against HPV-associated cancers.

Bristol-Myers Squibb's product candidate, JCAR020, is a MUC16-IL-12 armored T-cell therapy being developed to treat ovarian cancer. Similar to our UltraCAR-T platform, this product candidate targets MUC16 on ovarian tumors. JCAR020 is engineered with "armored CAR" technology to co-express CAR and IL-12, a cytokine that can help overcome the inhibitory effects that the tumor micro-environment can have on T cell activity. Tmunity Therapeutics is developing Tm Tn-MUC 01 CAR-T for various solid tumors including ovarian cancer. This candidate targets TnMUC-1 antigen on tumor cells. Tmunity Therapeutics is also developing TmFRα01 CAR-T targeting folate receptor alpha for ovarian cancer. MaxCyte's MCY-M11 is a mesothelin-specific human mRNA CAR-T cell therapy being developed to treat ovarian cancer. MCY-M11 is a non-viral approach that uses repeated infusions of mesothelin-specific messenger RNA (mRNA) transfected T cells transiently expressing CAR to permit prospective control of 'on-target/off-tumor' toxicity. TCR2 Therapeutics' TC-210 targets mesothelin and is based on TCR Fusion Construct T cells, or TRuC-T cells, technology and is manufactured using lentiviral transduction of autologous T cells.

For the treatment of AML using CAR-T therapies, we believe that Celyad and Mustang Bio have product candidates in the most advanced clinical trials. Celyad's product candidate, CYAD-02, is an NKG2D-based CAR-T with co-expression of a single shRNA targeting NKG2DL, MICA and MICB, that uses the OptimAb manufacturing process, which generates a higher frequency of less differentiated CAR-T cells. CYAD-02 is in clinical trials for r/r AML or MDS patients. Mustang Bio's product candidate, MB-102, is an autologous CAR-T cell therapy that is produced by engineering patient T cells to recognize and eliminate CD123-expressing tumors. Amgen is developing AMG 553, an FMS-like tyrosine kinase 3, or FLT3, CAR-T cell therapy utilizing autologous T cells genetically modified *ex vivo* to express a transmembrane CAR to target FLT3 protein on the surface of AML cells irrespective of FLT3 mutational status. Cellectis S.A. is also developing UCART123, an allogeneic anti-CD123 CAR-T cell therapy, which utilizes lentivector transduction followed by TALEN-mediated gene editing to eliminate expression of TCRαβ from donor T cells. Finally, Allogene Therapeutics' allogeneic CAR-T therapies ALLO-316 and ALLO-819, targeting FLT3 and CD70, respectively, which we believe are in preclinical development for AML, are manufactured using healthy donor T-cells that are engineered using lentiviral transduction to express CAR followed by gene editing to eliminate expression of TCR to reduce the potential of rejection of therapy by a patient's immune system.

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 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.

See "Our Therapeutic Platforms - UltraCAR-T," "Our Product Pipeline - PRGN-3005" and "Our Product Pipeline - PRGN-3006" for a discussion of the features that we believe differentiate UltraCAR-T treatments in general and PRGN-3005 and PRGN-3006 specifically from our competitors.

For the treatment of HPV-associated cancers, we believe that INOVIO Pharmaceuticals, AstraZeneca, and Transgene S.A. are developing immunotherapies that are in clinical testing. TG4001 is an investigational therapeutic cancer vaccine candidate using an attenuated and modified poxvirus, or MVA, as a vector expressing the HPV16 E6 and E7 proteins and interleukin-2. We believe TG4001 is in a clinical trial in combination with anti-PD-L1 antibody avelumab for recurrent HPV+ cancers. INOVIO's lead investigational candidate VGX-3100 is a plasmid DNA based vaccine designed to increase T cell immune responses against the E6 and E7 antigens of HPV16 and HPV18. VGX-3100 is in clinical trials for precancerous cervical dysplasia. We believe AstraZeneca's MEDI0457, an investigational DNA vacine designed by INOVIO, is in clinical trials for various HPV-associated cancers. MEDI0457 is a multi-component DNA vaccine that uses different DNA plasmids to express modified sequences for E6 and E7 antigens of HPV16 and HPV18 and immune activator interleukin-12, or IL-12. 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.

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 Advaxis Immunotherapies, Bavarian Nordic, and Altimmune. We also face competition from non-vaccine based approaches being developed by companies such as Kite, Iovance, Bristol-Myers Squibb, and Merck.

Infectious Diseases

Our lead product candidate is PRGN-2012, which is based on our AdenoVerse immunotherapy platform, for the treatment of RRP. While we believe our approach for PRGN-2012 is novel based on the 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 with their investigational DNA vaccine INO-3107 targeting HPV6 and HPV11 antigens.

Autoimmune Disorders

We are also using our suite of proprietary and complementary synthetic biology technologies for the preclinical and clinical development of product candidates for the treatment of autoimmune disorders, including T1D. While we believe AG019 is the first disease-modifying treatment for T1D, there are a number of competitors pursuing immunotherapy product candidates to treat T1D. We believe that our primary competitors with respect to the development of immunotherapies for T1D are Provention Bio, Midatech Pharma, and MerciaPharma.

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, Brazil, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, Philippines, Russia, Singapore, South Africa and Taiwan. In the future, we may file in these or additional jurisdictions as deemed appropriate for the protection of our technologies.

As of December 31, 2020, we owned or in-licensed at least 55 issued United States patents and 40 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 2038; our portfolio around various gene delivery technologies and their use, with a last to expire patent in 2040; 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 2042. 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. We also rely on our collaborators' compliance with laws and regulations applicable to the products they produce. We do not independently monitor whether our collaborators comply with applicable laws and regulations. Please see the risk factor entitled "We rely on third parties, including through collaborations, to develop and commercialize some of our product candidates. Markets in which our collaborators are developing product candidates using our technologies are subject to extensive regulation, and we rely on our collaborators to comply with all applicable laws and regulations."

Environmental regulations affecting us and our collaborators

We and our collaborators 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 and our collaborators 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 and those of our collaborators 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 microorganisms which impact us and our collaborators. Our and our collaborators' 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 and our collaborators to obtain and comply with the EPA's Microbial Commercial Activity Notice process to operate. In the European Union, we and our collaborators 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.

Regulations affecting us and our collaborators

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 and our collaborators. 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.

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 12 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, our subsidiaries, such as PGEN Therapeutics and ActoBio, and our collaborators that are focused on the development of human therapeutic products will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of the products enabled by our technologies. 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.

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 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.

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, or CCPA), govern the collection, use, disclosure, and protection 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 became effective on January 1, 2020 and 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, there are a number of legislative proposals in the United States, at both the federal and state level that 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.

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, or any collaborators, 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 on December 22, 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, due to subsequent legislation, continuing until 2030 (with the exception of a temporary suspension from May 1, 2020, through March 31, 2021) unless Congress takes additional action.

It is possible that the Affordable Care Act, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, and their implementation may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payers. 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.

Transition to Our Core Healthcare Business Model

Historically, we developed technology platforms for application across a variety of diverse end markets, including health, food, energy, and environment. In January 2020, we announced that we were increasing our focus on our healthcare opportunities, which reflected our most advanced platforms, and in connection therewith, we divested a number of our non-healthcare assets and changed our name to Precigen, Inc. These transactions included the sale of a number of our non-healthcare assets, or the TS

Biotechnology Sale, to TS Biotechnology Holdings, LLC, or TS Biotechnology, an entity formed by Third Security, LLC, or Third Security. Randal J. Kirk, who is the former CEO of Precigen and is currently the Executive Chairman and a member of our board of directors, serves as the Senior Managing Director and Chairman of Third Security and owns 100 percent of the equity interests of Third Security. In addition, in January 2020, in a separate transaction, we sold our interest in EnviroFlight, LLC, or EnviroFlight, to Darling Ingredients, Inc., or Darling.

As a result of market uncertainty driven by the COVID-19 pandemic and the state of the energy sector raising significant challenges for the strategic alternatives pursued by MBP Titan, LLC, or MBP Titan, our methane bioconversion business, beginning in the second quarter of 2020 and throughout the remainder of 2020, we suspended MBP Titan's operations, preserved certain of MBP Titan's intellectual property, terminated all of its personnel, and undertook steps to dispose of its other assets and obligations. The wind down of MBP Titan's activities was substantially complete by December 31, 2020, with the final disposition of certain property and equipment and the facility operating lease occurring in January 2021. This discontinuation of operations represented the continuation of a strategic shift that we commenced in early 2020 to becoming a primarily healthcare company advancing technologies and products that address complex healthcare challenges. After the wind down of MBP Titan, certain assets and contractual obligations which were originally related to MBP Titan continue to be managed at the Precigen corporate level. These remaining assets and contractual obligations include our equity interests in and collaboration agreements with Intrexon Energy Partners, LLC, or Intrexon Energy Partners, and Intrexon Energy Partners II, LLC, or Intrexon Energy Partners II, including the associated deferred revenue remaining under each collaboration agreement, as well as the associated intellectual property.

See also "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report for additional discussion of our discontinued operations.

See "Notes to the Consolidated Financial Statements - Note 5" appearing elsewhere in this Annual Report for a discussion of Intrexon Energy Partners and Intrexon Energy Partners II.

Non-Healthcare Business

At December 31, 2020, our only non-healthcare business is our established bovine genetics company, Trans Ova Genetics, L.C., or Trans Ova.

Trans Ova

Trans Ova is internationally recognized as a provider of industry-leading bovine reproductive technologies. Trans Ova offers bovine embryo transfer technologies, in addition to other advanced reproductive technologies, including *in vitro* fertilization, or IVF, sexed-semen, genetic preservation, and cloning. Through extensive research programs and applied science, Trans Ova has developed and implemented new technologies that, we believe, have helped to move the science of bovine genetic improvement forward. We continue to evaluate the optimal means to utilize these technology assets and Trans Ova's broad customer base and deep industry knowledge to maximize the value of the business.

As of December 31, 2020, Trans Ova had 183 production employees. Trans Ova's primary domestic production facilities, including approximately 360 acres of land, are located in Sioux Center, Iowa. The land and facilities are primarily used for our embryo transfer and IVF processes, as well as housing livestock used in such processes. As of December 31, 2020, Trans Ova also leased or owned regional production facilities and land in California, Maryland, Missouri, South Dakota, Texas, Washington, and Wisconsin for these purposes.

Competition: Non-Healthcare Assets

Animal Genetics Market

We believe Trans Ova's focus on continuous research and use of applied science allows Trans Ova to develop and implement new technologies that will help move the science of bovine genetic improvement forward rapidly and differentiate it from its competitors. However, there are a number of companies that compete with Trans Ova, including traditional breeding companies and other companies that use advanced reproductive technologies. These competitors may be larger and have better funding than Trans Ova. In addition, Trans Ova's competitors may be companies that have a predominant focus on developing the newest technologies in animal breeding whereas Trans Ova is one part of our overall strategy. Finally, Trans Ova's competitors that operate using more traditional breeding techniques may enjoy greater market acceptance over Trans Ova, and other companies, that utilize genetic manipulation, semen sorting and cloning techniques.

COVID-19 Impact

COVID-19 has had and continues to have an extensive impact on the global health and economic environments. The health and safety of our employees is of the utmost importance. Our essential employees are practicing appropriate safety measures, including social distancing and use of personal protective equipment. These efforts have permitted us to continue to advance our programs, with the ultimate goal of benefiting patients.

Commencing in the second half of March 2020, our healthcare business began to experience delays to certain of our clinical trials as a result of COVID-19. For example, starting in March 2020, ActoBio temporarily suspended the last cohort of the Phase 1b/2a clinical trial for AG019 as a proactive measure to protect the welfare and safety of patients, caregivers, clinical site staff, our employees, and contractors. The temporary suspension of the AG019 trial was voluntary and was not related to any patient safety issues in the study. The voluntary suspension of the AG019 trial was lifted in June 2020, and the study is recruiting patients again. Additionally, from April to May 2020, enrollment of new patients in our PRGN-3005 Phase 1 trial was temporarily suspended due to a mandated hold on certain early and late-stage clinical trials at the Fred Hutchinson Cancer Research Center in Seattle that was instituted in light of the COVID-19 pandemic. Recruitment resumed in the PRGN-3005 trial in May 2020. At this time, we do not expect that these suspensions will result in significant overall delay. Furthermore, uncertainty regarding the duration and severity of the ongoing pandemic may adversely impact our clinical as well as preclinical pipeline candidates in the future. Notwithstanding the foregoing, as the COVID-19 pandemic continues to evolve, we may experience additional 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 are also closely monitoring the impact of COVID-19 on other aspects of our business. While Trans Ova and Exemplar have not experienced any significant impacts as a result of COVID-19 at this time, we are unable to reliably quantify or estimate what future impacts may be. In addition, we have taken certain steps with respect to our operations of MBP Titan as a result of the impacts of the COVID-19 pandemic and other factors. See "Transition to Our Core Healthcare Business Model" above.

Given the dynamic nature of these circumstances, the full impact of the COVID-19 pandemic on our ongoing business, results of operations, and overall financial performance cannot be reasonably estimated at this time. For more information regarding the risks associated with COVID-19 and its impact on our business, see "Risk Factors - Risks Related to Our Business."

Reportable Segments

As of December 31, 2020, our reportable segments are (i) PGEN Therapeutics, (ii) ActoBio, (iii) Trans Ova, and (iv) the Human Biotherapeutics division. These identified reportable segments met the quantitative thresholds to be reported separately for the year ended December 31, 2020. See "Notes to the Consolidated Financial Statements - Note 20" appearing elsewhere in this Annual Report for a discussion of our reportable segments and Segment Adjusted EBITDA.

Research and Development

As of December 31, 2020, we had 140 employees supporting our research and development functions of our healthcare operations, including operational and facility activities. We incurred expenses of $41.6 million, $66.7 million and $333.0 million in 2020, 2019, and 2018, 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, 2020, our primary domestic research and development operations were located in laboratory facilities in Germantown, Maryland, and our primary international research and development operations were located in a laboratory facility in Ghent, Belgium.

Financial Information

Collaboration revenues, product revenues, service revenues and other revenues and operating loss for each of the last three fiscal years, along with assets as of December 31, 2020 and 2019, 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 20" appearing elsewhere in this Annual Report.

Human Capital Management

As of December 31, 2020, we had 194 employees in support of our healthcare operations, of which 140 support our research and development functions including operational and facility activities. Of these research and development employees, 59 have

advanced degrees, of which 35 are PhDs. Our corporate employees provide support to all of our operating subsidiaries and are responsible for the execution of all corporate functions, including executive, operational, finance, information technology, legal, and corporate communications. In addition to our healthcare operations, Trans Ova employs 229 full-time employees and 54 part-time employees. None of our employees are represented by a collective bargaining agreement.

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

We are proud of the fact that our domestic healthcare operations and corporate functions include 40 percent of employees in ethnic and racial minority groups and also the fact that 46 percent of the same population of employees are women.

Our recent 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. We implemented safety protocols in response to the COVID-19 pandemic including increased cleaning protocols, employee preventative measures, contract tracing, and bi-weekly virus testing. These measures enabled us to have the majority of our research and development employees return to their workplaces by early June 2020.

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

We have incurred net losses since our inception, including net losses attributable to Precigen of $170.5 million, $322.3 million and $509.3 million in 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $1.8 billion. We may incur losses and negative cash flow from operating activities for the foreseeable future. Historically, we have derived a significant portion of our revenues from collaborations and license agreements, but revenues of these types for existing collaborations will continue to decrease as we complete our transition to a discovery and clinical stage biopharmaceutical company. We no longer expect to receive reimbursement of costs incurred by us for new research and

development services other than through existing collaborations or future strategic transactions, nor will we recognize deferred revenues associated with previously terminated collaborations. In addition, certain of our collaborations and license agreements provide for milestone payments, future royalties, and other forms of contingent consideration, the payment of which are uncertain as they are dependent on our collaborators' abilities and willingness to successfully develop and commercialize product candidates.

We anticipate that our expenses will increase substantially as we continue to advance the preclinical and clinical development of our existing product candidates and our research programs, 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. We expect a significant period of time could pass before commercialization of our various product candidates or before the achievement of contractual milestones and the realization of royalties on product candidates commercialized under our collaborations and revenues 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 will need substantial additional capital in the future in order to fund our business.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. We are and will continue to be dependent on public or private financings, new collaborations or licensing arrangements with strategic partners, or additional debt financing sources to fund continuing operations. We expect our future capital requirements will be substantial and will depend on many factors, including:

- progress in our research and development programs, as well as the magnitude of these programs;
- the timing of potential regulatory approval of products of our collaborations and operations;
- 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 additional 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.

If future financings involve the issuance of equity securities, our existing shareholders would suffer further dilution. If we raise additional debt financing, we may be subject to 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, 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 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. If adequate funds are not available, we will not be able to successfully execute our business plan or continue our business.

Servicing our debt may require a significant amount of cash, and we may not have sufficient cash flows from our business, or otherwise have available cash, to pay our substantial debt when due.

Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the 3.50 percent convertible senior notes due 2023, or Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flows from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

The Convertible Notes are our exclusive obligations and are not guaranteed by any of our operating subsidiaries. We believe that a substantial portion of our intrinsic value is represented by assets that are held by our subsidiaries. Accordingly, our ability to service our debt, including the Convertible Notes, depends on the results of operations of our subsidiaries and upon the ability of such subsidiaries to provide us with cash, whether in the form of dividends, loans, or otherwise, to pay amounts due on our obligations, including the Convertible Notes. Our subsidiaries are separate and distinct legal entities and have no obligation, contingent or otherwise, to make payments on the Convertible Notes or to make any funds available for that purpose. In addition, dividends, loans or other distributions to us from such subsidiaries may be subject to contractual and other restrictions and are subject to other business considerations.

Despite our current debt levels, we may still incur substantially more debt or take other actions that would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Convertible Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Convertible Notes that could have the effect of diminishing our ability to make payments on the Convertible Notes when due.

The COVID-19 pandemic has created significant volatility, uncertainty, and economic disruption that could have an adverse effect on the Company's access to capital on favorable terms.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. We are and will continue to be dependent on public or private financings, new collaborations or licensing arrangements with strategic partners, or additional debt financing sources to fund continuing operations. As the COVID-19 pandemic continues to negatively impact the economy, our future access to capital on favorable terms may be materially impacted. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. Given the rapid evolution of the COVID-19 pandemic and the uncertainty surrounding it, its impact to our financial condition, including but not limited to, possible impairment, restructuring, and other changes, cannot be reliably quantified or estimated.

Risks Related to the Discovery and Development of our Product Candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and ultimately commercialize them.

We are early in our development efforts. We initiated our first clinical trial for our lead programs, PRGN-3005 in April 2019, PRGN-3006 in May 2019, PRGN-2009 in August 2020, AG019 in October 2018, and INXN-4001 in May 2018, and currently have a pipeline of preclinical programs. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of some or all of these 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 program 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 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 the 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 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 commercializing of 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.

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 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 ever be able to successfully commercialize a product candidate 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 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 never conducted 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 the COVID-19 pandemic 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.

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.

Cell and gene therapies are novel, complex, and difficult to manufacture.

The manufacturing processes that we use to produce our product candidates for human therapeutics are complex, novel and have not been validated for commercial use. 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 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 may 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 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, if any of our 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 candidates and could significantly harm our business, prospects, financial condition, and results of operations.

Even if we complete the necessary clinical trials, we cannot predict 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 where 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 development of certain of our product candidates, including PRGN-3005 and PRGN-3006. 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. Any resources we expend on one or more of these efforts could be at the expense of other potentially profitable opportunities. If we focus our efforts and resources on one or more of these opportunities or markets and they do not

lead to commercially viable products, our revenues, financial condition, and results of operations could be adversely affected.

The ongoing COVID-19 pandemic could cause a disruption of the development of our product candidates, which could adversely impact our healthcare business.

In response to the COVID-19 pandemic, ActoBio took the initiative to temporarily suspend the last remaining cohort of the Phase1b/2a trial for AG019 as a proactive measure to protect the welfare and safety of patients, caregivers, clinical site staff, and our employees and contractors. This voluntary suspension was lifted in June 2020, and the study is recruiting patients again. Further, from April to May 2020, enrollment of new patients in our PRGN-3005 Phase 1 trial was temporarily suspended due to a mandated hold on certain early and late-stage clinical trials at the Fred Hutchinson Cancer Research Center in Seattle that was instituted in light of the COVID-19 pandemic. As the COVID-19 pandemic continues to evolve, we may experience delays in the development of our product candidates, including as a result of declines in new patient enrollment for new and existing trials, ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography, site closures, reduced availability of other key personnel, availability of supplies, or for other reasons that may be difficult to anticipate. For example, we received IND clearance earlier this year to initiate, and initiated, a Phase 1/2 trial to study PRGN-2009 in participants with HPV+ cancers, but our ability to complete such a trial may be delayed or impeded by any of the foregoing factors as a result of the COVID-19 pandemic. In addition, the FDA or other regulatory authorities may have their resources diverted to responding to, or otherwise may be disrupted by, the COVID-19 pandemic, which could result in delays of reviews, approvals, and communications with regulatory authorities related to our clinical trials and product candidates. As the focus of our business is on healthcare, disruptions to our clinical trials could result in increased costs, delays in advancing product candidates, or ultimately, termination of clinical trials altogether resulting in a material adverse impact to our overall business. Furthermore, a failure to achieve meaningful clinical trial results, or even progress toward those results, could have a material adverse effect on the value of our securities and our ability to secure needed additional capital.

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

Even if a current or future product candidate receives marketing approval, it 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 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 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 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 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.

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 product candidates for human therapeutics, we must obtain regulatory approval from the FDA for the applicable manufacturing process and facility. This likely will 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. If 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 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. 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.

Even if we obtain regulatory approval for our product candidates, these candidates 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 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 current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our 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, 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. 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 candidates will be harmed.

The successful commercialization of our 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 candidates. Failure to obtain or maintain coverage and adequate reimbursement for our 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 candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our product candidates or procedures using our product candidates by third-party payers will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our 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 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 candidates or procedures using our product candidates could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our 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 current or future product candidates, or for any procedures using such 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 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% to 70% off the negotiated price effective as of January 1, 2019. Further legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible.

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 also will be 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.

If we fail to comply with applicable United States privacy and data protection laws and regulation, we may be subject to liabilities that adversely affect our business, operations and financial performance.

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 FTC Act and the CCPA), govern the collection, use, disclosure, and protection 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.

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 became effective on January 1, 2020 and 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, there are a number of legislative proposals in the United States, at both the federal and state level, that 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.

If we, our agents, or our third party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

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, including in Trans Ova, 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

Our efforts to realign our business and divest assets may not be successful and could increase our capital requirements, increase our costs, or otherwise harm our operating results and financial condition.

Our business strategy has evolved, and continues to evolve, toward relationships and structures that provide us with more control and ownership over the development process and commercialization path. This approach entails risks in implementation and operations and there is no guarantee that it will be successful. Furthermore, our focus on a healthcare-oriented business strategy will require additional capital beyond what we have available, and we may incur costs associated with the implementation and execution of our changing business strategy. In addition, as we perform our annual impairment tests, we will evaluate the impact of changes in our business strategy and, as a result, may incur impairment charges and write-offs and other related expenses, any of which, if material, could harm our operating results and financial condition. Market changes and

changes in judgments, assumptions, and estimates that we have made in assessing the fair value of goodwill could cause us to consider some portion or all of certain assets to become impaired, which could adversely impact our financial condition.

In January 2020, we announced and completed a sale of the majority of our non-healthcare assets to TS Biotechnology. We simultaneously announced that Intrexon EF Holdings, Inc., our wholly owned subsidiary, sold its 50 percent membership interest in EnviroFlight. As a result of market uncertainty driven by the COVID-19 pandemic and the state of the energy sector raising significant challenges for the strategic alternatives pursued by MBP Titan, beginning in the second quarter of 2020 and throughout the remainder of 2020, we suspended MBP Titan's operations, preserved MBP Titan's intellectual property, terminated all of its personnel, and undertook steps to dispose of its assets and obligations. We cannot provide any assurances that these recent, or any future, divestitures will achieve the business goals we expect. In addition, any future divestiture activities may present financial and operational risks, including the (1) diversion of management attention from existing core businesses, (2) the challenges associated with separating personnel and financial and other systems, including impaired employee relations, and (3) inefficiencies or increased costs, any of which could adversely affect our business, financial condition, results of operations and cash flows. Finally, as we continue our efforts to focus our business and generate additional capital, we may be willing to enter into transactions involving one or more of our remaining operating segments and reporting units for which we record impairment charges related to the write off of goodwill and intangible assets.

We rely on third parties, including through collaborations, to develop and commercialize some of our product candidates. Markets in which our collaborators are developing product candidates using our technologies are subject to extensive regulation, and we rely on our collaborators to comply with all applicable laws and regulations.

We have entered, and may in the future enter into collaboration arrangements to develop product candidates enabled by our technologies. There can be no guarantee that we can successfully manage these relationships. If our collaborators are not able to successfully develop the 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. Some of our existing collaborators do not themselves have the resources necessary to commercialize product candidates, and they in turn will need to rely on additional sources of financing or third-party collaborations. We may be asked to, or choose to, invest additional funds in these collaborators so that they can execute on their business plans. If we fail to invest such additional funds, the collaborator may not have sufficient capital to continue operations. In addition, we typically have limited or no control over the amount or timing of resources that any collaborator is able or willing to devote to developing product candidates or collaborative efforts. Any of our collaborators may fail to perform its obligations. Our collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner.

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

We have previously entered into strategic collaborations, which we may fail to successfully manage, or from which disputes may arise.

We have previously entered into strategic collaborations to develop products enabled by our technologies. 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, including as we transition away from, or terminate, strategic collaborations. In some cases, our strategic collaborations have resulted in disagreements and disputes with our current and former collaborators, including the Harvest Intrexon Enterprise Fund I, LP, or Harvest, the investors of Intrexon Energy Partners, and the investors of Intrexon Energy Partners II, regarding the relative rights, obligations, and revenues of us and our collaboration partners. In addition, we remain susceptible to future additional disagreements and disputes with any of our current or future collaborators. Disagreements and disputes may result in litigation, unfavorable settlements or concessions by us, or management distraction, that could harm our business operations.

We rely on our subsidiaries, our collaborators, and other third parties to deliver timely and accurate information in order to accurately report our financial results in the time frame and manner required by law.

We need to receive timely, accurate, and complete information from a number of third parties in order to accurately report our financial results on a timely basis. We rely on our subsidiaries and certain collaborators to provide us with complete and accurate information regarding revenues, expenses, and payments owed to or by us on a timely basis. In addition, we intend to

rely on current and future collaborators under our collaboration agreements and JVs to provide us with product sales and cost saving information in connection with royalties, if any, owed to us. If the information that we receive is not accurate, our consolidated financial statements may be materially incorrect and may require restatement, and we may not receive the full amount of consideration to which we are entitled under our collaboration agreements or JVs. Although we have audit rights with these parties, performing such an audit could be expensive and time consuming and may not be adequate to reveal any discrepancies in a timeframe consistent with our reporting requirements. In the future, we may need to consolidate the financial statements of one or more other collaborators into our consolidated financial statements. Although we have contractual rights to receive information and certifications allowing us to do this, such provisions may not ensure that we receive information that is accurate or timely. As a result, we may have difficulty completing accurate and timely financial disclosures, which could have an adverse effect on our business.

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, 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.

A portion of our business is conducted by JVs that we cannot operate solely for our benefit.

In JVs, we share ownership and management of a company with one or more parties who may not have the same goals, strategies, priorities, or resources as we do and may compete with us outside the JV. JVs are intended to be operated for the benefit of all JV partners, rather than for our exclusive benefit. Operating a business as a JV often requires additional organizational formalities as well as time-consuming procedures for sharing information and making decisions. In JVs we are required to foster our relationships with our JV partners as well as promote the overall success of the JV, and if a JV partner changes or relationships deteriorate, our success in the JV may be materially adversely affected. The benefits from a successful JV are shared among the JV partners, so we do not receive all the benefits from our successful JVs. Moreover, as a partial owner of a JV, we are exposed to potential risks and liabilities that we do not face when we enter into collaboration with an independent third party.

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 and may face greater risk if we commercialize any products that we develop. 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.

Additionally, each of our collaborations requires the collaborator to indemnify us for liability related to products produced pursuant to the collaboration and to obtain insurance coverage related to product liability in amounts considered standard for the industry. We believe that these industry-standard coverage amounts range from $10 million to $40 million in the aggregate. Even so, we may be named in product liability suits relating to products that are produced by our collaborators using our technologies. These claims could be brought by various parties, including other companies who purchase products from us or our collaborators or by the end users of the products.

We cannot guarantee that our collaborators will not breach the indemnity and insurance coverage provisions of the collaboration. Further, insurance coverage is expensive and may be difficult to obtain, and may not be available to us or to our collaborators in the future on acceptable terms, or at all. We cannot assure you that we or our collaborators 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 or our collaborators' 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.

The livestock products of our operating subsidiaries 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 subsidiaries, including Trans Ova and Exemplar, are subject to periodic outbreaks of a variety of diseases. Although these companies take measures to protect their stock, there can be no assurance that a disease will not damage or destroy existing livestock. The economic impact of disease to our subsidiaries' production systems can be significant, as farmers 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 in which we are developing candidate products using our technologies 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 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.

Our lead product candidates include PRGN-3005 for the treatment of ovarian cancer and 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 MaxCyte 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, 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.

In the area of infectious diseases, our lead product candidate is PRGN-2012, 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.

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.

There are a number of companies that compete with our subsidiary Trans Ova, including traditional breeding companies and other companies that use advanced reproductive technologies. These competitors may be larger and have better funding than Trans Ova. Trans Ova's competitors may also be companies that have a predominant focus on developing the newest technologies in animal breeding whereas Trans Ova is one part to our overall strategy. Trans Ova's competitors that operate using more traditional breeding techniques may enjoy greater market acceptance over Trans Ova, and other companies, that utilize genetic manipulation, semen sorting and cloning techniques.

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 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 candidates for our target markets and entering into collaborations or licensing arrangements to execute 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. For instance, effective January 1, 2020, our Board appointed Dr. Sabzevari, to the position of President and Chief Executive Officer. Mr. Kirk, our previous Chief Executive Officer, now serves as our Executive Chairman and continues to serve as Chairman of the Board. As with any leadership changes, our past or future 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, viruses, 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 the COVID-19 pandemic have disrupted, and will likely continue to disrupt, our business operations, which could have a material adverse effect on our results of operations, cash flows, and financial position.

We are closely monitoring the impacts of COVID-19 on all aspects of our business. The operations of our businesses may continue to be adversely impacted by COVID-19, 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 COVID-19, which may result in additional delays or otherwise adversely impact our operations.

Trans Ova, our established bovine genetics company, has not been significantly impacted by disruptions from COVID-19 to date. However, ongoing disruptions from COVID-19 and its cascading effects could mean that the business may be materially adversely affected in the future, including by a decrease in sales or overall demand for our products, the inability of our customers to pay for our services and products, similar negative effects on our suppliers, and disruptions to the global supply chain generally. There have already been a number of initial reports regarding such disruptions to the beef and dairy industry as a result of the COVID-19 pandemic, which impact both Trans Ova's potential customers and its sources of certain resources, such as embryos. While Exemplar, our subsidiary that develops MiniSwine models to enable the study of life-threatening diseases, has not been significantly impacted by disruptions from COVID-19 to date, it could face similar types of challenges, including its customers delaying or refusing shipments because of delays in their research and development operations similar to, or more severe than, the challenges and risks we face with our operations.

In addition to the potential impacts to our operations, we have initiated several 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. The increase in remote working may also result in elevated susceptibility to cyber security risks. We have incurred additional costs as a result of these measures and will likely continue to do so as a result of these and any future measures necessary to ensure the safety of our employees and the continuity of our operations. These measures could also lead to reduced efficiency in our operations.

Several of our subsidiaries 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. Certain of our subsidiaries, such as Trans Ova and Exemplar, that operate in industries in which remote working is not possible may be particularly at risk.

Given the dynamic nature of these circumstances, the full impact of the COVID-19 pandemic on our ongoing business, results of operations, and overall financial performance cannot be reasonably estimated at this time, and it could have a material adverse effect on our results of operations, cash flows, and financial position, including resulting in impairments to goodwill and long-lived assets and additional credit losses.

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

Our international operations 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.

Trans Ova operates in an industry that is not a part of our core business, and may require additional resources and capital.

We anticipate advancing opportunities through Trans Ova. Trans Ova may never generate revenue that is significant or large enough to achieve or maintain profitability and may require us to divert the necessary capital and resources away from our core healthcare business. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Alternatively, we may choose to divert the necessary capital and resources from further developing Trans Ova in order to focus on our core healthcare business. The failure of our subsidiaries, including Trans Ova, to become and remain profitable may decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes.

Holders of Convertible Notes have the right to require us to repurchase their Convertible Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100 percent of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*, which has subsequently been codified as Accounting Standards Codification, or ASC, Subtopic 470-20, *Debt with Conversion and Other Options*, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital section of shareholders' equity on our consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we record a greater amount of noncash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Convertible Notes to their face amount over the term of the Convertible Notes. We report lower net income in our financial results because ASC 470-20 requires interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Convertible Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued.

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which will require us to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. As the treasury stock method will no longer be permitted beginning in our fiscal year 2022, our diluted earnings per share could be adversely affected. Additionally, we cannot be sure whether other changes may be made to the current accounting standards related to the Convertible Notes, or otherwise, that could have an adverse impact on our financial statements.

We use estimates in determining the fair value of certain assets and liabilities. If new information or changes in circumstances negatively impact our estimates, we may be required to write down the value of these assets or write up the value of these liabilities, which could adversely affect our financial position.

Our ability to measure and report our financial position and operating results is influenced by the need to estimate the impact or outcome of future events on the basis of information available at the time of the financial statements. An accounting estimate is considered critical if it requires that management make assumptions about matters that were highly uncertain at the time the accounting estimate was made. If actual results differ from management's judgments and assumptions, then they may have an adverse impact on our results of operations and cash flows.

Fair value is estimated based on a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs are inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the

asset or liability developed based on the best information available in the circumstances. The fair value hierarchy prioritizes the inputs to valuation techniques into three broad levels whereby the highest priority is given to Level 1 inputs and the lowest to Level 3 inputs.

Valuations are highly dependent upon the reasonableness of management's assumptions and the predictability of the relationships that drive the results of our valuation methodologies.

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

As of December 31, 2020, we had net operating loss carryforwards of approximately $756.2 million for United States federal income tax purposes available to offset future taxable income, including $503.5 million generated after 2017, United States capital loss carryforwards of $211.5 million, and United States federal and state research and development tax credits of $10.2 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 begin to expire in 2022, and capital loss carryforwards will expire if unutilized beginning in 2024. 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, 2020, we had utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, 2020, approximately $42.1 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, 2020, our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately $82.3 million, most of which do not expire.

The Tax Act introduced certain limitations on utilization of losses that are generated after 2017, generally limiting utilization of those losses to 80 percent of future annual taxable income. However, net operating losses generated after 2017 will generally have an indefinite carryforward period.

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 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 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 have also filed patents and patent applications in other jurisdictions, such as Australia, Brazil, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, Philippines, Russia, Singapore, South Africa and Taiwan. 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. Moreover, the United States Leahy-Smith America Invents Act, enacted in September 2011, brought significant changes to the United States patent system, which include a change to a "first to file" system from a "first to invent" system and changes to the procedures for challenging issued patents and disputing patent applications during the examination process, among other things. These changes could increase the costs and uncertainties surrounding the prosecution of our patent applications and the enforcement or defense of our patent rights. Additional uncertainty may result from legal precedent handed down by the United States Court of Appeals for the Federal Circuit and United States Supreme Court as they determine legal issues concerning the scope and construction of patent claims and inconsistent interpretation of patent laws by the lower courts. Accordingly, 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 licensor 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 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 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. 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.

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.

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. 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.

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. Nevertheless, 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.

Risks Related to 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 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, 2019 through February 15, 2021, our common stock has traded as high as $11.10 per share and as low as $1.26 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.

The issuance of our common stock pursuant to a share lending agreement, including sales of the shares that we lend, and other market activity related to the share lending agreement may lower the market price of our common stock.

In connection with our offering of the Convertible Notes in July 2018, we entered into a share lending agreement with J.P. Morgan Securities LLC (that we refer to when acting in this capacity as the "share borrower"), the underwriter for our offering, pursuant to which we agreed to lend up to 7,479,431 shares of our common stock to the share borrower.

We were informed by the share borrower that it or one of its affiliates intended to use the short position created by the share

loan and the concurrent short sales of the borrowed shares to facilitate transactions by which investors in the Convertible Notes, or the Convertible Notes Investors, hedge their investments through short sales or privately negotiated derivatives transactions.

The existence of the share lending agreement in connection with the offering of the borrowed shares, the short sales of our common stock effected in connection with the sale of the Convertible Notes and the related derivatives transactions, or any unwind of such short sales or derivatives transactions, could cause the market price of our common stock to be lower over the term of the share lending agreement than it would have been had we not entered into that agreement, due to the effect of the increase in the number of outstanding shares of our common stock or otherwise. For example, in connection with any cash settlement of any such derivative transaction, the share borrower or its affiliates may purchase shares of our common stock and the Convertible Notes Investors may sell shares of our common stock, which could temporarily increase, temporarily delay a decline in, or temporarily decrease, the market price of our common stock. The market price of our common stock could be further negatively affected by these or other short sales of our common stock, including other sales by the Convertible Notes Investors hedging their investment therein.

Adjustments by the Convertible Notes Investors of their hedging positions in our common stock and the expectation thereof may have a negative effect on the market price of our common stock.

The borrowed shares are used by the Convertible Notes Investors to establish hedged positions with respect to our common stock through short sale transactions or privately negotiated derivative transactions. The number of borrowed shares may be more or less than the number of shares that will be needed in such hedging transactions. Any buying or selling of shares of our common stock by those Convertible Notes Investors to adjust their hedging positions may affect the market price of our common stock.

In addition, the existence of the Convertible Notes may also encourage short selling by market participants because the conversion of the Convertible Notes could depress our common stock price. The price of our common stock could be affected by possible sales of our common stock by the Convertible Notes Investors who view the Convertible Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect to occur involving our common stock. This hedging or arbitrage trading activity could, in turn, affect the market price of the Convertible Notes.

Changes in the accounting guidelines relating to the borrowed shares or our inability to classify the borrowed shares as equity could decrease our reported earnings per share and potentially our common stock price.

Because the borrowed shares (or identical shares) must be returned to us when the share lending agreement terminates pursuant to its terms (or earlier in certain circumstances), we believe that under generally accepted accounting principles in the United States, or U.S. GAAP, as presently in effect, assuming the borrowed shares issued pursuant to the share lending agreement are classified as equity under U.S. GAAP, the borrowed shares will not be considered outstanding for the purpose of computing and reporting our earnings per share. If accounting guidelines were to change in the future or we are unable to classify the borrowed shares issued pursuant to the share lending agreement as equity, we may be required to treat the borrowed shares as outstanding for purposes of computing earnings per share, our reported earnings per share would be reduced and our common stock price could decrease, possibly significantly.

As of December 31, 2020, Randal J. Kirk controlled approximately 44 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, managed, and principally funded by Randal J. Kirk, our former Chief Executive Officer and current Executive Chairman, and affiliates of Mr. Kirk, including Third Security. As of December 31, 2020, Mr. Kirk and shareholders affiliated with him beneficially owned approximately 44 percent of our voting stock, and our executive officers and directors, as a group, owned approximately 46 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.

We have engaged in transactions with companies in which Randal J. Kirk, our Executive Chairman, and his affiliates have an interest.

We have engaged in a variety of transactions, including collaborations and our sale of our non-healthcare assets to TS Biotechnology, with companies in which Mr. Kirk and affiliates of Mr. Kirk have a direct or indirect interest. See "Notes to the Consolidated Financial Statements - Notes 1, 3, 4, 5, 6, 14, 15, 17, and 18" appearing elsewhere in this Annual Report for a discussion of such transactions. Mr. Kirk serves as the Senior Managing Director and Chairman of Third Security and owns 100 percent of the equity interests of Third Security. We believe that each of these transactions was on terms no less favorable to us than terms we could have obtained from unaffiliated third parties, and each of these transactions was approved by at least a majority of the disinterested members of the audit committee of our board of directors. Furthermore, as we execute on these transactions going forward, a conflict may arise between our interests and those of Mr. Kirk and his affiliates.

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, 2020, there were 11,255,896 shares subject to outstanding options that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, lock-up agreements and Rules 144 and 701 under the Securities Act of 1933, as amended. As of December 31, 2020, there were 1,727,712 Restricted Stock Units, or RSUs, outstanding. Shares issuable upon the exercise of such options and upon vesting of the RSUs can be freely sold in the public market upon issuance and once vested. Additionally, as of December 31, 2020, we had 7,055,010 of shares available for grant under the 2013 Omnibus Incentive Plan and 2,432,624 shares available for grant under the 2019 Incentive Plan for Non-Employee Service Providers.

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 formation of a Preferred Stock Equity Facility, which was subsequently terminated in June 2018, we filed an amendment to our articles of incorporation to set the designations of our Series A Preferred Stock. Effective February 1, 2020, the Series A Preferred Stock designations was terminated. In the future, we may enter into similar facilities or issue 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 2. Properties

We establish the geographic locations of our research and development operations 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, 2020:

Location	Square Footage
Germantown, Maryland (PGEN Therapeutics segment)	61,048
Ghent, Belgium (ActoBio segment)	14,198

Our primary domestic production facilities, for our Trans Ova segment, are located in Sioux Center, Iowa, and include approximately 275,000 square feet of production and office facilities and approximately 360 acres of land. The land and production facilities are primarily used for embryo transfer and IVF processes, as well as housing livestock used in such processes. We also lease or own regional production facilities and land in California, Maryland, Missouri, South Dakota, Texas, Washington, and Wisconsin for these purposes.

Our primary administrative offices are in Germantown, Maryland, and Blacksburg, Virginia. 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. 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 17" 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, 2021, we had 287 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.

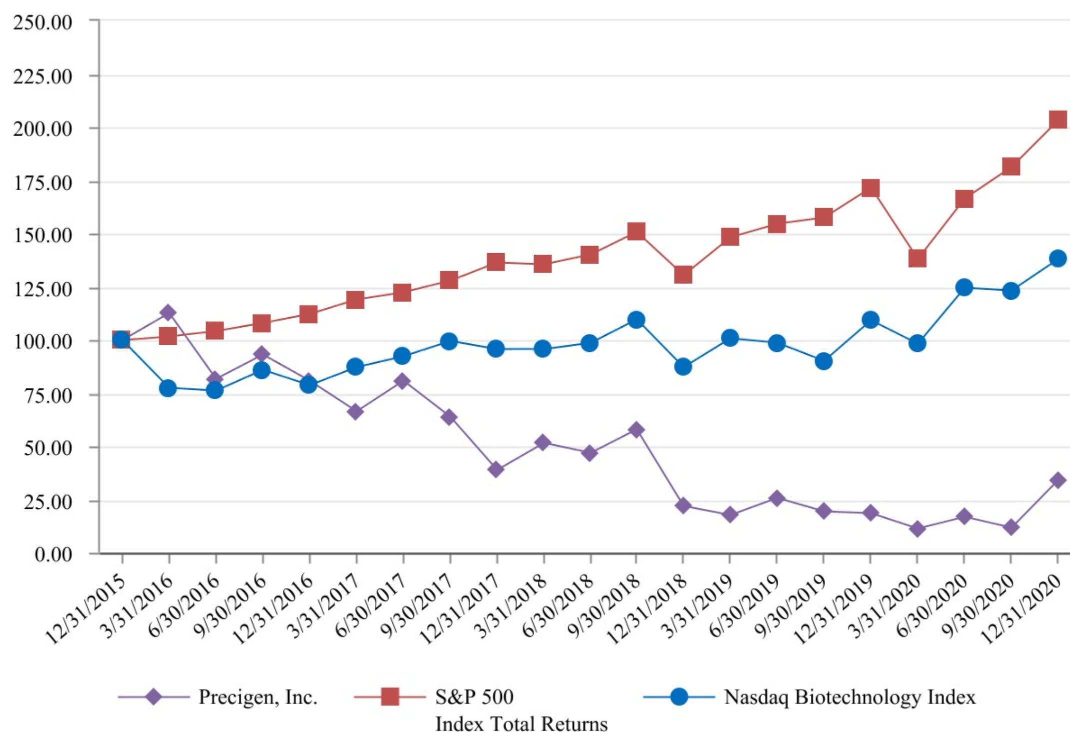
Securities Authorized for Issuance Under Equity Compensation Plans

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, 2015 through December 31, 2020 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, 2015 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 12/31/2015	3/31/2016	6/30/2016	9/30/2016	12/31/2016
Precigen, Inc.	$ **100.00**	$ 112.40	$ 81.63	$ 92.94	$ 80.60
S&P 500 Index	**100.00**	101.35	103.84	107.84	111.96
Nasdaq Biotechnology Index	**100.00**	77.12	76.25	85.78	78.65

Company / Index	3/31/2017	6/30/2017	9/30/2017	12/31/2017	3/31/2018	6/30/2018	9/30/2018	12/31/2018
Precigen, Inc.	$ 66.41	$ 80.72	$ 63.70	$ 38.60	$ 51.36	$ 46.71	$ 57.70	$ 21.91
S&P 500 Index	118.76	122.43	127.92	136.42	135.38	140.03	150.83	130.44
Nasdaq Biotechnology Index	87.17	92.31	99.46	95.69	95.75	98.69	109.74	87.21

Company / Index	3/31/2019	6/30/2019	9/30/2019	12/31/2019	3/31/2020	6/30/2020	9/30/2020	12/31/2020
Precigen, Inc.	$ 17.62	$ 25.67	$ 19.17	$ 18.36	$ 11.39	$ 16.72	$ 11.73	$ 34.18
S&P 500 Index	148.24	154.62	157.24	171.50	137.89	166.22	181.06	203.06
Nasdaq Biotechnology Index	100.76	98.50	90.00	109.11	97.90	124.23	123.21	137.93

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

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds

None.

(c) Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

The following tables set forth our selected consolidated financial data for the periods and as of the dates indicated. You should read the following selected consolidated financial data in conjunction with our audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report.

The selected consolidated financial data set forth below as of December 31, 2020 and 2019, and for the years ended December 31, 2020, 2019 and 2018, are derived from our audited consolidated financial statements included elsewhere in this Annual Report. The selected consolidated financial data set forth below as of December 31, 2018, 2017, and 2016, and for the years ended December 31, 2017 and 2016, are derived from our audited consolidated financial statements contained in reports previously filed with the SEC, not included herein. Our audited consolidated financial statements have been prepared in United States dollars in accordance with U.S. GAAP. The selected consolidated financial data in the below tables have been adjusted to reflect the effects of discontinued operations. See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(In thousands, except share and per share amounts)				
Statements of Operations Data:					
Collaboration and licensing revenues	$ 21,208	$ 14,059	$ 69,540	$ 134,624	$ 97,160
Product revenues	24,349	23,780	28,486	33,585	36,958
Service revenues	56,899	51,803	52,419	50,611	43,049
Total revenues (1)	103,178	90,722	151,178	219,463	177,607
Total operating expenses	189,781	257,511	520,845	285,354	252,424
Operating loss	(86,603)	(166,789)	(369,667)	(65,891)	(74,817)
Loss from continuing operations	(103,773)	(170,334)	(380,487)	(50,420)	(131,838)
Net loss attributable to noncontrolling interests	—	1,592	5,370	9,802	3,662
Net loss from continuing operations attributable to Precigen	(103,773)	(168,742)	(375,117)	(40,618)	(128,176)
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.62)	$ (1.09)	$ (2.90)	$ (0.34)	$ (1.09)
Weighted average shares outstanding, basic and diluted	167,065,539	154,138,774	129,521,731	119,998,826	117,983,836

	December 31,				
	2020	2019	2018	2017	2016
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 51,792	$ 65,793	$ 96,876	$ 59,251	$ 60,217
Short-term and long-term investments	48,325	9,260	119,614	6,273	180,595
Total assets (2)	314,587	455,763	716,177	846,851	949,068
Deferred revenue, current and non-current (1)	25,823	53,833	57,816	226,343	298,842
Long-term debt (3)	171,882	217,991	211,695	8,037	7,948
Other liabilities (4)	49,708	112,228	67,944	65,926	73,030
Total Precigen shareholders' equity	67,174	71,711	362,855	533,631	560,237
Noncontrolling interests	—	—	15,867	12,914	9,011
Total equity	67,174	71,711	378,722	546,545	569,248

(1) Revenues and deferred revenue in 2020, 2019, and 2018 are accounted for under ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, and revenues and deferred revenue prior to 2018 are accounted for under ASC 605, *Revenue Recognition*, or ASC 605. We adopted ASC 606 on January 1, 2018 using the modified retrospective method, which applies the changes in accounting prospectively and does not restate prior periods. See "Notes to the Consolidated Financial Statements - Notes 4, 6, and 18" for discussions of transactions in 2018 resulting in a decrease in the balances of deferred revenue.

(2) Total assets include $191, $161,225, and $129,545 of investments in preferred stock as of December 31, 2018, 2017, and 2016, respectively. In conjunction with the ZIOPHARM License Agreement in 2018, all of our ZIOPHARM preferred shares were returned to ZIOPHARM. See "Notes to the Consolidated Financial Statements - Notes 10 and 11" for discussions of impairment losses on goodwill and other noncurrent assets recognized in 2020 and 2019.

(3) In 2018, we completed a registered underwritten public offering of $200,000 aggregate principal amount of Convertible Notes.

(4) Other liabilities include $8,801 of deferred consideration as of December 31, 2016.

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."

Financial overview

We have incurred significant losses since our inception. We anticipate that we may continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. Our historical collaboration and licensing revenues were generated under a business model from which we have gradually transitioned, and we do not expect to expend significant resources servicing our historical collaborations in the future. We may enter into strategic transactions for individual platforms or programs in the future from which we may generate new collaboration and licensing revenues. We continue to generate product and service revenues through our Trans Ova and Exemplar subsidiaries, and in 2020, both of these subsidiaries generated positive Segment Adjusted EBITDA. Products currently in our clinical pipeline will require regulatory approval and/or commercial scale-up before they may commence significant product sales and operating profits.

In January 2020, as part of our efforts to focus our business on the healthcare industry, we sold a number of our non-healthcare assets to TS Biotechnology and separately sold our interest in EnviroFlight to Darling, referred to collectively as the Transactions. We determined that the assets, liabilities and operations sold in the Transactions collectively met the criteria for discontinued operations and have been reclassified and presented as such for all periods. As a result of market uncertainty driven by the COVID-19 pandemic and the state of the energy sector raising significant challenges for the strategic alternatives pursued by MBP Titan, beginning in the second quarter of 2020 and throughout the remainder of 2020, we suspended MBP

Titan's operations, preserved certain of MBP Titan's intellectual property, terminated all of its personnel, and undertook steps to dispose of its other assets and obligations. The wind down of MBP Titan's activities was substantially complete by December 31, 2020, with the final disposition of certain property and equipment and the facility operating lease occurring in January 2021. As of December 31, 2020, we determined that the assets, liabilities, and expenses related to the discontinued operations of MBP Titan met the criteria for discontinued operations.

See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report for further discussion of discontinued operations.

Additionally, as we continue our efforts to focus our business and generate additional capital, we may be willing to enter into transactions involving one or more of our operating segments and reporting units for which we have goodwill and intangible assets. These efforts could result in us identifying impairment indicators or recording impairment charges in future periods. In addition, market changes and changes in judgments, assumptions and estimates that we have made in assessing the fair value of goodwill could cause us to consider some portion or all of certain assets to become impaired.

Sources of revenue

Historically, we have derived our collaboration and licensing revenues through agreements with counterparties for the development and commercialization of products enabled by our technologies. Generally, the terms of these collaborations provide that we receive some or all of the following: (i) technology access fees upon signing; (ii) reimbursements of costs incurred by us for our research and development and/or manufacturing efforts related to specific applications provided for in the collaboration; (iii) milestone payments upon the achievement of specified development, regulatory and commercial activities; and (iv) royalties on sales of products arising from the collaboration.

Our technology access fees and milestone payments may be in the form of cash or securities of the collaborator. Our collaborations contain multiple arrangements, and we typically defer revenues from the technology access fees and milestone payments received and recognize such revenues in the future over the anticipated performance period. We are also entitled to sublicensing revenues in those situations where our collaborators choose to license our technologies to other parties.

As we continue to shift our focus on our healthcare business, we have and may continue to mutually terminate collaboration agreements or repurchase rights to the exclusive fields from collaborators, relieving us of any further performance obligations under the agreement. Upon such circumstances or when we determine no further performance obligations are required of us under an agreement, we may recognize any remaining deferred revenue as either collaboration revenue or as a reduction of operating expense, depending on the circumstances. See "Notes to the Consolidated Financial Statements - Note 6" appearing elsewhere in this Annual Report for a discussion of changes to our significant collaborations.

We generate product and service revenues primarily through sales of products or services that are created from technologies developed or owned by us. Our primary current offerings arise from Trans Ova and include sales of advanced reproductive technologies, including our bovine embryo transfer and IVF processes and from genetic preservation and sexed semen processes, and applications of such processes to other livestock, as well as sales of livestock and embryos produced using these processes and used in production. Exemplar also 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 is transferred to the customer or when the promised service is completed.

In future periods, in connection with our focus on healthcare, our revenues will primarily depend on our ability to advance and create our own programs and the extent to which we bring products enabled by our technologies to market. Other than for collaboration revenues recognized upon cancellation or modification of an existing collaboration or for revenues generated pursuant to future strategic transactions for any of our existing platforms or programs, we expect our collaboration revenues will continue to decrease in the near term. Our revenues will also depend upon our ability to maintain or improve the volume and pricing of Trans Ova's and Exemplar's current product and service offerings and to develop and scale up production of new offerings from the various technologies of our subsidiaries. As we focus on our healthcare business, we anticipate that our expenses will increase substantially if, and as, we continue to advance the preclinical and clinical development of our existing product candidates and our research programs. We expect a significant period of time could pass before commercialization of our various product candidates or before the achievement of contractual milestones and the realization of royalties on product candidates commercialized under our collaborations and revenues sufficient to achieve profitability. Accordingly, there can be no assurance as to the timing, magnitude, and predictability of revenues to which we might be entitled.

Cost of products and services

Cost of products and services includes primarily labor and related costs, drugs and supplies used primarily in Trans Ova's embryo transfer and IVF processes, livestock and feed used in production, and facility charges, including rent and depreciation. Fluctuations in the price of livestock and feed have not had a significant impact on our operating margins and no derivative financial instruments are used to mitigate the price risk.

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, for personnel in research and development functions;
- 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; and
- facility-related expenses, which include direct depreciation costs and unallocated expenses for rent and maintenance of facilities and other operating costs.

Our research and development expenses are generally incurred by our operating segments and primarily relate to either costs incurred to expand or otherwise improve our technologies or the costs incurred to develop our own products and services. PGEN Therapeutics is progressing preclinical and clinical programs in immuno-oncology, autoimmune disorders and infectious diseases, including PRGN-3005 and PRGN-3006 which are both in Phase 1/1b clinical trials. ActoBio has a portfolio of candidates available for clinical development across a number of potential indications using our ActoBiotics platform, including its most advanced candidate, AG019, that is currently in a Phase 1b/2a clinical trial. Trans Ova's research and development activities support new and improved product and service offerings for its customers. The Human Biotherapeutics division supports our INXN-4001 product candidate with Triple-Gene and our partnered program with Castle Creek. Other operating segment research and development primarily relates to Exemplar's research and development activities related to new and improved pig research models. The following table summarizes our research and development expenses incurred by reportable segment for the years ended December 31, 2020, 2019, and 2018.

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
PGEN Therapeutics	$ 25,245	$ 26,669	$ 151,647
ActoBio	11,110	17,999	35,388
Trans Ova	2,228	2,037	2,481
Human Biotherapeutics	2,452	1,159	—
Total research and development expenses from reportable segments	41,035	47,864	189,516
All Other	625	8,777	23,123
Total research and development expenses from operating segments	$ 41,660	$ 56,641	$ 212,639

The following table reconciles research and development expenses by reportable segments to research and development expenses on the consolidated statements of operations for the years ended December 31, 2020, 2019, and 2018.

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
Total research and development expenses from reportable segments	$ 41,035	$ 47,864	$ 189,516
Other research and development expenses, including from other operating segments (1)	625	19,572	175,803
Eliminations	(16)	(770)	(32,312)
Total consolidated research and development expenses	$ 41,644	$ 66,666	$ 333,007

(1) Includes corporate research and development expenses not allocated to operating segments, as well as certain expenses incurred to reacquire previously licensed technology rights in the year ended December 31, 2018.

The amount of research and development expenses may be impacted by, among other things, the number and nature of our own proprietary programs, and the number and size of programs we may support on behalf of an ECC. We expect that our research and development expenses will increase as we continue to develop our own proprietary programs, including progression of these programs into preclinical and clinical stages. We believe these increases will likely include increased costs paid to consultants and contract research organizations, and increased costs related to laboratory supplies.

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

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist primarily of salaries and related costs, including stock-based compensation expense, for employees in executive, operational, finance, information technology, legal, and corporate communications functions. Other significant SG&A expenses include rent and utilities, insurance, 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, and the outcomes of legal claims and assessments against us.

Other income (expense), net

We historically held equity securities and preferred stock of private and publicly traded companies, including investments received and/or purchased from certain collaborators. These equity securities and preferred stock were recorded at fair value at each reporting date. Unrealized appreciation (depreciation) resulting from fair value adjustments were reported as other income (expense) in the consolidated statements of operations. In January 2020, as part of the TS Biotechnology Sale, we sold our remaining equity securities and investment in preferred stock, and therefore, no future gains (losses) will be incurred.

Interest expense is expected to increase in future periods due to the noncash amortization of the long-term debt discount and debt issuance costs related to the Convertible Notes due July 2023.

Interest income consists of interest earned on our cash and cash equivalents and short-term investments and may fluctuate based on amounts invested and current interest rates. Dividend income historically consisted of the monthly preferred stock dividends received from our investments in preferred stock, all of which have been liquidated as of December 31, 2020.

Equity in net income (loss) of affiliates

Equity in net income or loss of affiliates is our pro-rata share of our equity method investments' operating results, adjusted for accretion of basis difference. We account for investments in our JVs using the equity method of accounting since we have the ability to exercise significant influence, but not control, over the operating activities of these entities. We previously accounted for our investments in start-up entities backed by Harvest using the equity method of accounting. In December 2020, we entered into an agreement with Harvest to resolve matters related to the parties' contractual and equity relationships and our remaining equity interests in start-up entities backed by Harvest were terminated.

Segment performance

We use Segment Adjusted EBITDA as our primary measure of segment performance. We define Segment Adjusted EBITDA as net loss before (i) interest expense, (ii) income tax expense or benefit, (iii) depreciation and amortization, (iv) stock-based compensation expense, (v) loss on settlement agreements where noncash consideration is paid, (vi) adjustments for accrued bonuses paid in equity awards, (vii) loss on impairment of goodwill and other noncurrent assets, (viii) equity in net loss of affiliates, and (ix) recognition of previously deferred revenue associated with upfront and milestone payments as well as cash outflows from capital expenditures and investments in affiliates. Corporate expenses are not allocated to the segments and are managed at a consolidated level. See "Notes to the Consolidated Financial Statements - Note 20" appearing elsewhere in this Annual Report for further discussion of Segment Adjusted EBITDA.

Results of operations

Comparison of the year ended December 31, 2020 to the year ended December 31, 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019, together with the changes in those items in dollars and as a percentage:

	Year Ended December 31,		Dollar Change	Percent Change
	2020	2019		
	(In thousands)			
Revenues				
Collaboration and licensing revenues (1)	$ 21,208	$ 14,059	$ 7,149	50.8 %
Product revenues	24,349	23,780	569	2.4 %
Service revenues	56,899	51,803	5,096	9.8 %
Other revenues	722	1,080	(358)	(33.1)%
Total revenues	103,178	90,722	12,456	13.7 %
Operating expenses				
Cost of products	28,550	31,930	(3,380)	(10.6)%
Cost of services	26,963	29,471	(2,508)	(8.5)%
Research and development	41,644	66,666	(25,022)	(37.5)%
Selling, general and administrative	91,704	98,634	(6,930)	(7.0)%
Impairment of goodwill	—	29,820	(29,820)	(100.0)%
Impairment of other noncurrent assets	920	990	(70)	(7.1)%
Total operating expenses	189,781	257,511	(67,730)	(26.3)%
Operating loss	(86,603)	(166,789)	80,186	(48.1)%
Total other expense, net	(16,114)	(2,059)	(14,055)	>200%
Equity in loss of affiliates	(1,138)	(2,416)	1,278	(52.9)%
Loss from continuing operations before income taxes	(103,855)	(171,264)	67,409	(39.4)%
Income tax benefit	82	930	(848)	(91.2)%
Loss from continuing operations	(103,773)	(170,334)	66,561	(39.1)%
Loss from discontinued operations, net of income tax benefit (2)	(66,748)	(153,582)	86,834	(56.5)%
Net loss	(170,521)	(323,916)	153,395	(47.4)%
Net loss attributable to noncontrolling interests	—	1,592	(1,592)	(100.0)%
Net loss attributable to Precigen	$ (170,521)	$ (322,324)	$ 151,803	(47.1)%

(1) Including $3,053 and $11,832 from related parties for the years ended December 31, 2020 and 2019, respectively.

(2) See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report.

Collaboration and licensing revenues

The following table shows the collaboration and licensing revenue recognized for the years ended December 31, 2020 and 2019, together with the changes in those items.

	Year Ended December 31, 2020	Year Ended December 31, 2019	Dollar Change
	(In thousands)		
ZIOPHARM Oncology, Inc.	$ 200	$ 2,171	$ (1,971)
Oragenics, Inc.	3,053	(564)	3,617
Intrexon Energy Partners, LLC	—	2,596	(2,596)
Intrexon Energy Partners II, LLC	—	1,217	(1,217)
Castle Creek Biosciences, Inc.	17,810	3,713	14,097
Harvest start-up entities (1)	—	4,862	(4,862)
Other	145	64	81
Total	$ 21,208	$ 14,059	$ 7,149

(1) For the year ended December 31, 2019, revenue recognized from collaborations with Harvest start-up entities include Thrive Agrobiotics, Inc.; Exotech Bio, Inc.; and AD Skincare, Inc.

Collaboration and licensing revenues increased $7.1 million, or 51 percent, over the year ended December 31, 2019 primarily due to the accelerated recognition of previously deferred revenue upon the mutual terminations of collaborations with Castle Creek and Oragenics in 2020. This increase was partially offset by a decrease in collaboration revenues related to programs that have been paused since the second half of 2019 while the other parties evaluate the status of the projects and their desired future development activities.

Product revenues and gross margin

Product revenues increased $0.6 million, or 2 percent, over the year ended December 31, 2019. The increase in product revenue was primarily due to higher customer demand for animal products. Gross margin on products improved in the current period as a result of operational efficiencies gained through reductions in workforce and improved inventory management and a decrease in the cost of cows used in production.

Service revenues and gross margin

Service revenues increased $5.1 million, or 10 percent, over the year ended December 31, 2019. Trans Ova's service revenues and gross margins thereon increased due to an increase in services performed for new and existing customers and the expansion of its commercial dairy business. Gross margin also increased due to a reduction in third-party royalty rate obligations for certain licensed technologies and reductions in workforce. Additionally, Exemplar's service revenues increased in the current period due to an increase in services performed resulting from higher demand from existing customers, which also improved gross margin on services performed.

Research and development expenses

Research and development expenses decreased $25.0 million, or 38 percent, from the year December 31, 2019. Salaries, benefits, and other personnel costs decreased $7.3 million and contract research organization costs and lab supplies decreased $13.9 million in 2020 as we deprioritized certain programs at ActoBio and closed two of our operating divisions in 2019.

Selling, general and administrative expenses

SG&A expenses decreased $6.9 million, or 7 percent, from the year ended December 31, 2019, and include a decrease in professional fees payable to certain third-party vendors and reduced personnel costs as we scaled down our corporate functions to support a more streamlined organization. Other corporate expenses decreased $2.6 million as part of the streamlined organization and the impact of the COVID-19 pandemic on travel. These decreases were partially offset by increased share-based compensation expense attributable to equity grants made in the first quarter of 2020, one-time severance costs for

terminated employees, and increased legal fees associated with litigation matters, including our settlements with Harvest and the SEC.

Impairment of goodwill and other noncurrent assets

Impairment losses for the year ended December 31, 2020 of $0.9 million were due to the impairment of the right-of-use assets for certain of our leased facilities. Impairment losses for the year ended December 31, 2019 of $30.8 million arose primarily from a goodwill impairment charge related to Trans Ova.

Total other expense, net

Total other expense, net, which primarily includes interest expense, increased $14.1 million, or over 200 percent, over the year ended December 31, 2019. In 2019, our equity securities and investments in preferred stock, which were fully liquidated by early 2020, had net unrealized and realized appreciation of $8.3 million that partially offset interest expense of $17.7 million. As these investments were fully liquidated by early 2020, there was no such appreciation to offset interest expense of $18.4 million in 2020. Additionally, interest income earned on our short-term investments decreased in 2020 due to lower interest rates.

Segment performance

The following table summarizes Segment Adjusted EBITDA, which is our primary measure of segment performance, for the years ended December 31, 2020 and 2019, for each of our reportable segments and for All Other segments combined, as well as unallocated corporate costs.

	Year Ended December 31,		Dollar Change	Percent Change
	2020	2019		
	(In thousands)			
Segment Adjusted EBITDA:				
PGEN Therapeutics	$ (25,611)	$ (30,164)	$ 4,553	15.1 %
ActoBio	(7,861)	(13,662)	5,801	42.5 %
Trans Ova	2,624	(6,337)	8,961	141.4 %
Human Biotherapeutics	(2,139)	(1,051)	(1,088)	(103.5)%
All Other	4,274	(4,901)	9,175	187.2 %
Unallocated corporate costs	(37,566)	(46,011)	8,445	18.4 %

For a reconciliation of Segment Adjusted EBITDA to net loss from continuing operations before income taxes, see "Notes to the Consolidated Financial Statements - Note 20" appearing elsewhere in this Annual Report.

The following table summarizes revenues from external customers for the years ended December 31, 2020 and 2019, for each of our reportable segments and for All Other segments combined.

	Year Ended December 31,		Dollar Change	Percent Change
	2020	2019		
	(In thousands)			
PGEN Therapeutics	$ 776	$ 2,227	$ (1,451)	(65.2)%
ActoBio	3,053	(364)	3,417	>200%
Trans Ova	71,186	68,672	2,514	3.7 %
Human Biotherapeutics	17,810	3,713	14,097	>200%
All Other	10,299	12,514	(2,215)	(17.7)%

PGEN Therapeutics

Revenues for PGEN Therapeutics declined from 2019 to 2020 because we had no significant collaborations requiring services in 2020. Segment Adjusted EBITDA improved due to higher costs for contract research organizations incurred in 2019 for preclinical activities on certain programs prior to moving to clinical trials and the manufacturing of clinical trial materials in

advance of initiation of the trials. Additionally, fewer costs related to the PRGN-3005 Phase 1 trials were incurred in the second quarter of 2020 as enrollment of new patients in this trial was temporarily suspended due to a mandated hold on certain early and late-stage clinical trials at the Fred Hutchinson Cancer Research Center in Seattle that was instituted in light of the COVID-19 pandemic. Costs related to PGEN Therapeutics' clinical trials are expected to increase in 2021 as the trials progress and as we initiate new clinical trials for new clinical programs. Finally, capital expenditures decreased in the current period as PGEN Therapeutics completed an expansion of its lab facilities in 2019.

ActoBio

Revenues for ActoBio increased primarily due to accelerated recognition of previously deferred revenue upon the mutual termination of a collaboration with Oragenics in July 2020. Segment Adjusted EBITDA has improved as ActoBio incurred fewer costs with contract research organizations due to deprioritizing certain programs in late 2019 and fewer AG019 trial costs in the second quarter of 2020 due to the temporary suspension of the last cohort of the Phase 1b/2a clinical trial.

Trans Ova

Revenues for Trans Ova increased primarily as a result of more procedures performed for new and existing customers and the expansion of its commercial dairy business. The improvement in Segment Adjusted EBITDA was primarily due to operational efficiencies gained through reductions in workforce and improved inventory management, a decrease in the cost of cows used in production, and a reduction in third-party royalty rate obligations for certain licensed technologies.

Human Biotherapeutics

The increase in Human Biotherapeutics' revenues was due to the accelerated recognition of previously deferred revenue upon the mutual termination of a collaboration with Castle Creek in 2020. Segment Adjusted EBITDA declined due to one-time severance costs associated with workforce reductions in the first quarter of 2020 and increased costs for contract research organizations related to our INXN-4001 program.

All Other

Revenues in All Other decreased in 2020 as our partnered programs with Harvest start-up entities were paused since the third quarter of 2019. These decreases were partially offset by an increase in Exemplar's revenues as a result of higher demand from its existing customers. Segment Adjusted EBITDA improved period over period as a result of improved Segment Adjusted EBITDA at Exemplar due to its higher revenues and reduced costs, as well as the closure of two operating segments in 2019.

Unallocated Corporate Costs

Unallocated corporate costs decreased primarily due to a reduction of corporate employees as well as a decrease in certain professional fees as we scaled down our corporate functions to support our more streamlined organization. These decreases were partially offset by an increase in legal fees associated with litigation matters, including our settlement with the SEC.

Comparison of the year ended December 31, 2019 to the year ended December 31, 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018, together with the changes in those items in dollars and as a percentage:

	Year Ended December 31, 2019	Year Ended December 31, 2018	Dollar Change	Percent Change
	(In thousands)			
Revenues				
Collaboration and licensing revenues (1)	$ 14,059	$ 69,540	$ (55,481)	(79.8)%
Product revenues	23,780	28,486	(4,706)	(16.5)%
Service revenues	51,803	52,419	(616)	(1.2)%
Other revenues	1,080	733	347	47.3 %
Total revenues	90,722	151,178	(60,456)	(40.0)%
Operating expenses				
Cost of products	31,930	35,087	(3,157)	(9.0)%
Cost of services	29,471	27,589	1,882	6.8 %
Research and development	66,666	333,007	(266,341)	(80.0)%
Selling, general and administrative	98,634	125,162	(26,528)	(21.2)%
Impairment of goodwill	29,820	—	29,820	N/A
Impairment of other noncurrent assets	990	—	990	N/A
Total operating expenses	257,511	520,845	(263,334)	(50.6)%
Operating loss	(166,789)	(369,667)	202,878	(54.9)%
Total other expense, net	(2,059)	(17,259)	15,200	(88.1)%
Equity in loss of affiliates	(2,416)	(8,986)	6,570	(73.1)%
Loss from continuing operations before income taxes	(171,264)	(395,912)	224,648	(56.7)%
Income tax benefit	930	15,425	(14,495)	(94.0)%
Loss from continuing operations	(170,334)	(380,487)	210,153	(55.2)%
Loss from discontinued operations, net of income tax benefit (2)	(153,582)	(134,219)	(19,363)	14.4 %
Net loss	(323,916)	(514,706)	190,790	(37.1)%
Net loss attributable to noncontrolling interests	1,592	5,370	(3,778)	(70.4)%
Net loss attributable to Precigen	$ (322,324)	$ (509,336)	$ 187,012	(36.7)%

(1) Including $11,832 and $55,573 from related parties for the years ended December 31, 2019 and 2018, respectively.

(2) See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report.

Collaboration and licensing revenues

The following table shows the collaboration and licensing revenue recognized for the years ended December 31, 2019 and 2018, together with the changes in those items.

	Year Ended December 31,		Dollar Change
	2019	2018	
	(In thousands)		
ZIOPHARM Oncology, Inc.	$ 2,171	$ 16,298	$ (14,127)
Ares Trading S.A.	—	11,175	(11,175)
Oragenics, Inc.	(564)	1,353	(1,917)
Intrexon T1D Partners, LLC	—	2,502	(2,502)
Intrexon Energy Partners, LLC	2,596	6,929	(4,333)
Intrexon Energy Partners II, LLC	1,217	2,998	(1,781)
Castle Creek Biosciences, Inc.	3,713	1,394	2,319
Harvest start-up entities (1)	4,862	14,447	(9,585)
Other	64	12,444	(12,380)
Total	$ 14,059	$ 69,540	$ (55,481)

(1) For the years ended December 31, 2019 and 2018, revenue recognized from collaborations with Harvest start-up entities include Thrive Agrobiotics, Inc.; Exotech Bio, Inc.; and AD Skincare, Inc. For the year ended December 31, 2018, revenues recognized from collaborations with Harvest start-up entities also include Genten Therapeutics, Inc. and CRS Bio, Inc.

Collaboration and licensing revenues decreased $55.5 million, or 80 percent, from the year ended December 31, 2018 primarily due to the reacquisition of rights previously licensed to certain collaborators, including ZIOPHARM, Ares Trading, and certain of the Harvest start-up entities, the result of which eliminated or substantially reduced revenues generated from those collaborations. Additionally, in 2018, we recognized additional revenues which arose from the acceleration of previously deferred revenue upon mutual termination of certain collaborations.

Product revenues and gross margin

Product revenues decreased $4.7 million, or 17 percent, from the year ended December 31, 2018. The decrease in product revenues was primarily due to lower customer demand in the beef and dairy industries resulting in fewer sales of pregnant cows and calf products. Gross margin on products declined in the current period as a result of fewer products sold.

Service revenues and gross margin

Service revenues decreased $0.6 million, or 1 percent, from the year ended December 31, 2018. Trans Ova's service revenues and gross margin thereon declined slightly due to fewer services performed and underutilized capacity as a result of lower customer demand.

Research and development expenses

Research and development expenses decreased $266.3 million, or 80 percent, from the year ended December 31, 2018. The 2018 research and development expenses include $236.7 million of expenses related to in-process research and development reacquired from former collaborators.

Selling, general and administrative expenses

SG&A expenses decreased $26.5 million, or 21 percent, from the year ended December 31, 2018. Salaries, benefits and other personnel costs decreased $16.4 million primarily due to decreased share-based compensation expense as a result of the reversal of previously recognized expense for unvested options granted to former employees as well as the conclusion of the vesting period for other previously granted stock options. Legal and professional fees decreased $7.0 million primarily due to fewer legal fees associated with Trans Ova.

Impairment of goodwill and other noncurrent assets

Impairment losses for the year ended December 31, 2019 of $30.8 million arose primarily from a goodwill impairment charge related to Trans Ova following an annual goodwill impairment test where we determined that it was more-likely-than-not that the fair value of Trans Ova was less than its carrying value

Total other expense, net

Total other expense, net, decreased $15.2 million, or 88 percent, over the year ended December 31, 2018. This decrease was primarily attributable to an improvement in unrealized and realized appreciation (depreciation) on our securities portfolio of $36.6 million primarily due to unrealized losses on our ZIOPHARM preferred stock in 2018 and a realized gain on the sale of our common shares held in AquaBounty Technologies, Inc., or AquaBounty, in October 2019, net of a decrease in dividend income of $15.1 million following the return of our investment in ZIOPHARM preferred stock to ZIOPHARM in October 2018. Additionally, these decreases were partially offset by an increase in interest expense of $8.6 million associated with our Convertible Notes issued in July 2018.

Segment performance

The following table summarizes Segment Adjusted EBITDA, which is our primary measure of segment performance, for the years ended December 31, 2019 and 2018, for each of our reportable segments and for All Other segments combined, as well as unallocated corporate costs.

	Year Ended December 31,		Dollar Change	Percent Change
	2019	2018		
	(In thousands)			
Segment Adjusted EBITDA:				
PGEN Therapeutics	$ (30,164)	$ (32,832)	$ 2,668	8.1 %
ActoBio	(13,662)	(12,797)	(865)	(6.8)%
Trans Ova	(6,337)	(5,730)	(607)	(10.6)%
Human Biotherapeutics	(1,051)	—	(1,051)	N/A
All Other	(4,901)	(10,708)	5,807	54.2 %
Unallocated corporate costs	(46,011)	(74,609)	28,598	38.3 %

For a reconciliation of Segment Adjusted EBITDA to net loss from continuing operations before income taxes, see "Notes to the Consolidated Financial Statements - Note 20" appearing elsewhere in this Annual Report.

The following table summarizes revenues from external customers for the years ended December 31, 2019 and 2018, for each of our reportable segments and for All Other segments combined.

	Year Ended December 31,		Dollar Change	Percent Change
	2019	2018		
	(In thousands)			
PGEN Therapeutics	$ 2,227	$ 29,021	$ (26,794)	(92.3)%
ActoBio	(364)	6,684	(7,048)	(105.4)%
Trans Ova	68,672	75,178	(6,506)	(8.7)%
Human Biotherapeutics	3,713	—	3,713	N/A
All Other	12,514	30,213	(17,699)	(58.6)%

PGEN Therapeutics

Revenues for PGEN Therapeutics declined from 2018 to 2019 primarily due to the reacquisition of rights previously licensed to certain collaborators, which eliminated or significantly reduced collaboration revenues from research and development services provided and recognition of previously deferred revenue.

ActoBio

In 2018, ActoBio reacquired rights previously licensed to certain collaborators, including Intrexon T1D Partners, Inc., resulting in the elimination of collaboration revenues from research and development services performed in 2019.

Trans Ova

The decrease in Trans Ova's Segment revenues was primarily attributable to lower product revenues due to lower customer demand.

Human Biotherapeutics

Human Biotherapeutics was a new segment in 2019 and the revenue is associated with our collaboration with Castle Creek. Segment Adjusted EBITDA includes the costs associated with our collaboration with Castle Creek as well as our INXN-4001 program.

All Other

The Segment Adjusted EBITDA of All Other improved period over period due our closure of two reporting units in 2019 and write-downs of certain long-lived assets in 2018. Revenues in All Other declined in 2019 as result of fewer research and development services performed for collaborations with Harvest start-up entities.

Unallocated Corporate Costs

Unallocated corporate costs decreased primarily due to an improvement in unrealized and realized appreciation (depreciation) on our securities portfolio of $36.6 million primarily due to unrealized losses on our ZIOPHARM preferred stock in 2018 and a realized gain on the sale of our common shares held in AquaBounty in October 2019, net of a decrease in dividend income of $15.1 million following the return of our investment in ZIOPHARM preferred stock to ZIOPHARM in October 2018. Additionally, consolidated costs from AquaBounty decreased in 2019 due to our deconsolidation in April 2019.

Liquidity and capital resources

Sources of liquidity

We have incurred losses from operations since our inception, and as of December 31, 2020, we had an accumulated deficit of $1.8 billion. From our inception through December 31, 2020, 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. As of December 31, 2020, we had cash and cash equivalents of $51.8 million and short-term investments of $48.3 million. In January 2021, we closed an underwritten public offering of our common stock, resulting in net proceeds of approximately $121.2 million, after deducting underwriting discounts and estimated offering expenses. Cash in excess of immediate requirements is typically invested primarily in money market funds and United States government debt securities in order to maintain liquidity and preserve capital.

We currently generate cash receipts primarily from sales of products and services and from strategic transactions.

As of December 31, 2020, Trans Ova was in compliance with the debt covenants associated with its line of credit as discussed in "Notes to the Consolidated Financial Statements - Note 12" appearing elsewhere in this Annual Report.

Cash flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	Year Ended December 31,		
	2020	2019	2018
		(In thousands)	
Net cash provided by (used in):			
Operating activities	$ (77,021)	$ (135,927)	$ (124,240)
Investing activities	27,779	86,851	(151,213)
Financing activities	32,705	8,138	309,795
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	353	(810)	295
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (16,184)	$ (41,748)	$ 34,637

Cash flows from operating activities:

In 2020, our net loss was $170.5 million, which includes the following significant noncash expenses totaling $107.9 million from both continuing and discontinued operations: (i) $27.0 million of accumulated foreign currency translation losses that were realized upon the closing of the Transactions, (ii) $23.0 million of impairment losses related to goodwill and long-lived assets, (iii) $18.4 million of stock-based compensation expense, (iv) $17.5 million of depreciation and amortization expense, (v) $11.4 million loss on settlement agreement with Harvest, and (vi) $10.6 million accretion of debt discount and amortization of deferred financing costs. These expenses were partially offset by the recognition of $12.8 million of previously deferred revenue upon the mutual terminations of collaboration agreements with Castle Creek and Oragenics in 2020.

In 2019, our net loss was $323.9 million, which includes the following significant noncash expenses totaling $191.0 million from both continuing and discontinued operations: (i) $120.5 million of impairment loss, (ii) $24.9 million of depreciation and amortization expense, (iii) $19.0 million of stock-based compensation expense, (iv) $10.4 million of shares issued for payment of services, (v) $9.5 million accretion of debt discount and amortization of deferred financing costs, and (vi) $6.7 million of equity in net loss of affiliates. These expenses were partially offset by $7.8 million of unrealized and realized appreciation on equity securities and preferred stock, net.

In 2018, our net loss was $514.7 million, which includes the following significant noncash expenses totaling $440.0 million from both continuing and discontinued operations: (i) $236.7 million of expense related to reacquired in-process research and development previously licensed to certain of our collaborators, (ii) $60.5 million of impairment loss, (iii) $36.3 million of stock-based compensation expense, (iv) $33.1 million of depreciation and amortization expense, (v) $30.2 million of net unrealized and realized losses on our equity securities and preferred stock, (vi) $20.9 million of loss on disposal of assets, (vii) $11.6 million of equity in net loss of affiliates, and (viii) $10.7 million of shares issued as payment for services. These expenses were partially offset by (i) $21.3 million of net changes in deferred income taxes and (ii) $14.8 million of noncash dividend income. Additionally, we had a $20.0 million net increase in our operating assets and liabilities primarily as a result of the recognition of previously deferred revenue.

Our 2020 cash outflows from operations decreased $58.9 million from the year ended December 31, 2019 primarily due to (i) the reduction in cash required to fund the businesses sold in the TS Biotechnology Sale, (ii) the reduction in cash requirements for MBP Titan as we wound down those operations starting in the second quarter of 2020, and (iii) reductions in operating expenses for our ActoBio and corporate operations as we streamlined both in order to further prioritize the use of our capital.

Our 2019 cash outflows from operations increased $11.7 million over the year ended December 31, 2018 due to increased expenses primarily for our clinical programs combined with the lack of reimbursement for research and development services we used to receive under certain key collaborations which we reacquired in 2018.

Cash flows from investing activities:

During 2020, we purchased $171.4 million of investments, primarily using the $64.2 million of proceeds received from the Transactions, net of cash sold, and the private placement discussed below. We also reinvested a portion of the $133.0 million proceeds we received during the year from the maturities of investments.

During 2019, we received proceeds of $111.4 million from the maturities and sales of investments, net of purchases; $21.6 million proceeds from the sale of our AquaBounty securities, and we used $37.9 million for purchases of property, plant and equipment.

During 2018, we used $112.7 million for purchases of short-term investments, net of maturities; $41.6 million for purchases of property, plant and equipment; and $16.6 million for investments in our JVs, and we received $15.5 million in an asset acquisition.

Cash flows from financing activities:

During 2020, we received $35.0 million proceeds from the sale of our common stock in a private placement to TS Biotechnology.

During 2019, we received $6.6 million in net proceeds from underwritten public offerings completed by AquaBounty.

During 2018, we received $219.9 million net proceeds from the issuance of long-term debt and $88.0 million net proceeds from public financings.

Future capital requirements

We believe our existing liquid assets, including the net proceeds from our underwritten public offering in January 2021, will enable us to fund our operating expenses and capital requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

- progress in our research and development programs, as well as the magnitude of these programs;
- any delays or potential delays to our clinical trials as a result of the COVID-19 pandemic;
- the timing of regulatory approval of our product candidates and those of our collaborations;
- the timing, receipt and amount of any payments received in connection with strategic transactions;
- the timing, receipt, and amount of upfront, milestone, and other payments, if any, from present and future collaborators, if any;
- 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 additional 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;
- 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; and
- the effects, duration, and severity of the ongoing COVID-19 pandemic and the actions we have taken or may take in response, any of which could significantly impact our business, operations, and financial results.

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 equity offerings, debt financings, government, or other third-party funding, strategic alliances, sales of assets, and licensing arrangements. As the COVID-19 pandemic continues to negatively impact the economy, our future access to capital on favorable terms may be materially impacted. 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 or convertible debt 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 conducting high-risk, early-stage research and development of product candidates. Principal among these risks are 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 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 ability to achieve what is necessary for our success may be negatively impacted by the uncertainty caused by the COVID-19 pandemic.

See the section entitled "Risk Factors" for additional risks associated with our substantial capital requirements.

Contractual obligations and commitments

The following table summarizes our significant contractual obligations and commitments from continuing operations as of December 31, 2020 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Operating leases (1)	$ 12,911	$ 3,608	$ 5,479	$ 2,957	$ 867
Convertible debt (2)	200,000	—	200,000	—	—
Cash interest payable on convertible debt	21,000	7,000	14,000	—	—
Long-term debt, excluding convertible debt	3,735	360	757	763	1,855
Total	$ 237,646	$ 10,968	$ 220,236	$ 3,720	$ 2,722

(1) See "Notes to the Consolidated Financial Statements - Notes 3 and 23" appearing elsewhere in this Annual Report for further discussion of our operating lease related to MBP Titan which is included in discontinued operations.

(2) See "Notes to the Consolidated Financial Statements - Note 12" appearing elsewhere in this Annual Report for further discussion of our convertible debt.

In addition to the obligations in the table above, as of December 31, 2020 we also have the following significant contractual obligations described below.

In conjunction with the formation of our JVs, we committed to making future capital contributions subject to certain conditions and limitations. As of December 31, 2020, our remaining capital contribution commitments to our JVs were $14.2 million. These future capital contributions are not included in the table above due to the uncertainty of the timing and amounts of such contributions.

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, 2020, we also had research and development commitments with third parties totaling $12.1 million that had not yet been incurred.

Net operating losses

As of December 31, 2020, we had net operating loss carryforwards of approximately $756.2 million for United States federal income tax purposes available to offset future taxable income, including $503.5 million generated after 2017, United States

capital loss carryforwards of $211.5 million, and United States federal and state research and development tax credits of approximately $10.2 million, prior to consideration of annual limitations that may be imposed under Section 382. Net operating loss carryforwards generated prior to 2018 begin to expire in 2022 and capital loss carryforwards will expire if unutilized beginning in 2024. Our foreign subsidiaries included in continuing operations have foreign loss carryforwards of approximately $82.3 million, most of which do not expire. Excluding certain deferred tax liabilities totaling $2.9 million, our remaining net deferred tax assets, which primarily relate to these loss carryforwards, are offset by a valuation allowance due to our history of net losses.

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, 2020, Precigen has utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, 2020, approximately $42.1 million of domestic net operating losses were inherited via acquisitions 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.

The Tax Act introduced certain limitations on utilization of net operating losses that are generated after 2017, generally limiting utilization of those losses to 80 percent of future annual taxable income. However, net operating losses generated after 2017 will generally have an indefinite carryforward period.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

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 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 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.

Collaboration and licensing revenues

We have historically generated collaboration and licensing revenues through agreements with collaborators, known as ECCs, and licensing agreements whereby the collaborators or the licensee obtain exclusive access to our 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 provide that we receive some or all of the following: (i) upfront payments upon consummation of the agreement; (ii) reimbursements for costs incurred by us 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 continues in perpetuity unless terminated and each of our

collaborators retains a right to terminate the agreement upon providing us written notice a certain period of time prior to such termination, generally 90 days.

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

At contract inception, we determine the transaction price, including fixed consideration and any estimated amounts of variable consideration. The upfront payment received upon consummation of the agreement is fixed and nonrefundable. Variable consideration is subject to a constraint and amounts are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include reimbursements for costs incurred by us for research and development efforts; milestone payments upon the achievement of certain development, regulatory and commercial activities; and royalties on sales of products arising from the collaboration or licensing agreement. We determine the initial transaction price and exclude variable consideration that is otherwise constrained pursuant to the guidance in ASC 606.

The transaction price is allocated to the performance obligations in the agreement based on the standalone selling price of each performance obligation. We typically group the promises in our collaboration and licensing agreements into one performance obligation so the entire transaction price relates to this single performance obligation. The technology license included in the single performance obligation is considered a functional license. However, it is typically combined into a single performance obligation as we provide interrelated research and development services along with other obligations over an estimated period of performance. We utilize judgment to determine the most appropriate method to measure our progress of performance under the agreement, primarily based on inputs necessary to fulfill the performance obligation. We evaluate our measure of progress to recognize revenue each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Our measure of performance and revenue recognition involves significant judgment and assumptions, including, but not limited to, estimated costs and timelines to complete our performance obligations. We evaluate modifications and amendments to our contracts to determine whether any changes should be accounted for prospectively or on a cumulative catch-up basis.

Payments received for cost reimbursements for research and development efforts are recognized as revenue as the services are performed, in connection with the single performance obligation discussed above. The reimbursements relate specifically to our efforts to provide services and the reimbursements are consistent with what we would typically charge other collaborators for similar services.

We assess the uncertainty of when and if the milestone will be achieved to determine whether the milestone is included in the transaction price. We then assess whether the revenue is constrained based on whether it is probable that a significant reversal of revenue would not occur when the uncertainty is resolved.

Royalties, including sales-based milestones, received under the agreements will be recognized as revenue when sales have occurred because we apply the sales- or usage-based royalties recognition exception provided for under ASC 606. We determined the application of this exception is appropriate because at the time the royalties are generated, the technology license granted in the agreement is the predominant item to which the royalties relate.

As we receive upfront payments in our collaboration and licensing agreements, we evaluate whether any significant financing components exist in our collaboration and licensing agreements. Based on the nature of our collaboration and licensing agreements, there are no significant financing components as the purpose of the upfront payment is not to provide financing. The purpose is to provide the collaborator with assurance that we will complete our obligations under the contract or to secure the right to a specific product or service at the collaborator's discretion. In addition, the variable payments generally align with the timing of performance or the timing of the consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the collaborator or us.

From time to time, we and certain collaborators may cancel our agreements, relieving us of any further performance obligations under the agreement. Upon such cancellation or when we have determined no further performance obligations are required of us under an agreement, we recognize any remaining deferred revenue as revenue.

We recognized $21.2 million, $14.1 million, and $69.5 million of collaboration and licensing revenues in the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020 and 2019, we have $23.4 million and $50.6 million, respectively, of deferred revenue related to our receipt of upfront and milestone payments.

Product and service revenues

Our product and service revenues are generated primarily through Trans Ova and include sales of advanced reproductive technologies, including our bovine embryo transfer and IVF processes and from genetic preservation and sexed semen processes and applications of such processes to other livestock, as well as sales of livestock and embryos produced using these processes and used in production. Exemplar also generates product and service revenues through the development and sale of genetically engineered miniature swine models. As each promised product or service is distinct, we recognize the transaction price as revenue at a point in time when control of the promised product is transferred to the customer or when the promised service is rendered. Payment terms are typically due within 30 days of invoicing, which occurs prior to or when revenue is recognized. We recognized $81.2 million, $75.6 million, and $80.9 million of product and service revenues for the years ended December 31, 2020, 2019, and 2018, respectively.

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, 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 goodwill impairment test. If this is the case, the 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. 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.

The fair value of the reporting units are primarily determined based on the income approach. The income approach is a valuation technique in which fair value is based from 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. The discount rate utilizes a risk adjusted weighted average cost of capital. To assess the reasonableness of the calculated reporting unit fair values, we compare the sum of the reporting units' fair values to our market capitalization (per share stock price times the number of shares outstanding) and calculate an implied control premium (the excess of the sum of the reporting units' fair values over the market capitalization) and then assess the reasonableness of our implied control premium.

During the years ended December 31, 2020 and 2019, we recorded $0.9 million and $30.8 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 - Notes 10 and 11" appearing elsewhere in this Annual Report.

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, which is incorporated herein by reference.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The following sections provide quantitative information on our exposure to interest rate risk and foreign currency exchange 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 investments of $100.1 million and $75.1 million as of December 31, 2020 and 2019, respectively. Our cash and cash equivalents and short-term investments consist of cash, money market funds, United States government debt securities, and certificates of deposit. The primary objectives of our investment activities are to preserve principal, maintain liquidity, and maximize income without significantly increasing risk. Our investments consist of United States government debt securities and 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.

Foreign currency exchange risk

We have international subsidiaries in Belgium and Germany. These subsidiaries' assets, liabilities, and current revenues and expenses are denominated in their respective foreign currency. We do not hedge our foreign currency exchange rate risk. The effect of a hypothetical 10 percent change in foreign currency exchange rates applicable to our business would not have a material impact on our consolidated financial statements.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-61 of this Annual Report and is incorporated herein by reference.

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, our executive chairman, and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, our chief executive officer, executive chairman, 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, 2020. 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, 2020.

Deloitte & Touche LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2020, as stated in their report, which is included in Part II Item 8 of this Annual Report.

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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

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 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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.

Item 11. Executive Compensation

The information required by this item is hereby incorporated by reference to our Definitive Proxy Statement relating to our 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following consolidated financial statements of Precigen, Inc. and its subsidiaries, and the independent registered public accounting firm reports thereon, are included in Part II, Item 8 of this Annual Report:

1. Financial Statements.

Consolidated Financial Statements of Precigen, Inc. and Subsidiaries

Reports of Independent Registered Public Accounting Firm for the Years Ended December 31, 2020 and 2019

Report of Independent Registered Public Accounting Firm for the Year Ended December 31, 2018

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated Statements of Operations for the Years Ended December 31, 2020, 2019, and 2018

Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2020, 2019, and 2018

Consolidated Statements of Shareholders' and Total Equity for the Years Ended December 31, 2020, 2019 and 2018

Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, 2019, and 2018

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 (17)
3.2*	Amended and Restated Bylaws (20)
4.1*	Specimen certificate evidencing shares of common stock (22)
4.2*	Form of Second Amended and Restated Warrant to Purchase Shares of Common Stock (1)
4.3*	Base Indenture, dated July 3, 2018, by and between the Company and The Bank of New York Mellon Trust Company, N.A. (10)
4.4*	First Supplemental Indenture (including the form of 3.50% convertible senior notes due 2023), dated July 3, 2018, by and between the Company and The Bank of New York Mellon Trust Company, N.A. (10)
4.5	Description of Securities (18)
10.1†*	Amended and Restated 2008 Equity Incentive Plan of the Company (1)
10.2†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 9, 2014 (4)

10.2A†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Restricted Stock Agreement (4)
10.2B†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Incentive Stock Option Agreement (4)
10.2C†*	Amended and Restated 2013 Omnibus Incentive Plan of the Company, Form of Nonqualified Stock Option Agreement (4)
10.2D†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 11, 2015 (5)
10.2E†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 9, 2016 (6)
10.2F†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 28, 2017 (7)
10.2G†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 7, 2018 (9)
10.2H†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 12, 2019 (14)
10.2I†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective January 5, 2020 (19)
10.2J†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 19, 2020 (21)
10.2K†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Officers (8)
10.2L†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Directors (8)
10.3*	2019 Incentive Plan of the Company for Non-Employee Service Providers, effective as of June 12, 2019 (14)
10.4†*	Form of Continuing Employment Agreement (13)
10.5†*	Employment Agreement, dated January 1, 2020, by and between the Company and Helen Sabzevari, Ph.D. (16)
10.6†*	Executive Chairman Compensation Arrangement, by and between the Company and Randal J. Kirk (23)
10.7#*	Exclusive Channel Collaboration Agreement, dated as of March 26, 2014, by and between the Company and Intrexon Energy Partners, LLC (2)
10.8#*	Amended and Restated Limited Liability Company Agreement of Intrexon Energy Partners, LLC, dated as of March 26, 2014, by and among the Company and the parties thereto (2)
10.9*	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 (3)
10.10#*	Exclusive License Agreement, dated October 5, 2018, by and between Precigen, Inc. and ZIOPHARM Oncology, Inc. (11)
10.11†*	Annual Executive Incentive Plan of the Company, adopted as of April 29, 2015 (5)
10.12*	Share Lending Agreement, dated June 28, 2018, by and between the Company, J.P. Morgan Securities LLC and JPMorgan Chase Bank, National Association, New York Branch (10)
10.13#*	Securities Purchase, Assignment and Assumption Agreement, dated December 19, 2018, by and between the Company, ARES TRADING S.A. and Precigen, Inc. (12)
10.14*	Stock and Asset Purchase Agreement, dated January 1, 2020, by and between the Company and TS Biotechnology Holdings, LLC (15)
10.15*	Subscription Agreement, dated January 1, 2020, by and between the Company and TS Biotechnology Holdings, LLC (15)
21.1	List of Subsidiaries of Precigen, Inc.
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of PricewaterhouseCoopers 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 Rick L. Sterling, 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 Rick L. Sterling, 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
101**	Interactive Data File (Precigen, Inc. and Subsidiaries Consolidated Financial Statements for the years ended December 31, 2020, 2019, and 2018, 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, 2020 and 2019, (ii) the Consolidated Statements of Operations for the years ended December 31, 2020, 2019, and 2018, (iii) the Consolidated Statements of Shareholders' and Total Equity for the years ended December 31, 2020, 2019, and 2018, (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019, and 2018 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)	Amendment No. 1 to Registration Statement on Form S-1, filed with the Securities and Exchange Commission on July 29, 2013.
(2)	Current Report on Form 8-K/A, filed with the Securities and Exchange Commission on April 4, 2014.
(3)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 14, 2015.
(4)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2014.
(5)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 17, 2015.
(6)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2016.
(7)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 30, 2017.
(8)	Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2018.
(9)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 8, 2018.
(10)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 3, 2018.
(11)	Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 8, 2018.
(12)	Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2019.
(13)	Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 9, 2019.
(14)	Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 9, 2019.
(15)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 2, 2020.
(16)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 7, 2020.
(17)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 4, 2020.
(18)	Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 2, 2020.
(19)	Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 11, 2020.
(20)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 4, 2020.
(21)	Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 19, 2020.

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

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

** Furnished herewith

† Indicates management contract or compensatory plan.

Portions of the exhibit (indicated by asterisks) have been omitted in compliance with Item 601 of Regulation S-K.

(c) Financial Statement Schedules

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

Item 16. Form 10-K Summary

None.

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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 1, 2021

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)	3/1/2021
/S/ RICK L. STERLING Rick L. Sterling	Chief Financial Officer (Principal Accounting and Financial Officer)	3/1/2021
/S/ RANDAL J. KIRK Randal J. Kirk	Executive Chairman	3/1/2021
/S/ CESAR L. ALVAREZ Cesar L. Alvarez	Director	3/1/2021
/S/ STEVEN FRANK Steven Frank	Director	3/1/2021
/S/ VINITA D. GUPTA Vinita D. Gupta	Director	3/1/2021
/S/ FRED HASSAN Fred Hassan	Director	3/1/2021
/S/ JEFFREY B. KINDLER Jeffrey B. Kindler	Director	3/1/2021
/S/ DEAN J. MITCHELL Dean J. Mitchell	Director	3/1/2021
/S/ ROBERT B. SHAPIRO Robert B. Shapiro	Director	3/1/2021
/S/ JAMES S. TURLEY James S. Turley	Director	3/1/2021

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Precigen, Inc. and Subsidiaries

Consolidated Financial Statements

December 31, 2020, 2019 and 2018

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, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, shareholders' and total equity, and cash flows, for the years then ended, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. 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. 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.

Goodwill - Trans Ova Reporting Unit - Refer to Notes 2 and 11 to the financial statements

Critical Audit Matter Description

The Company's goodwill balance was $54.4 million as of December 31, 2020, of which $16.6 million is allocated to the Trans Ova reporting unit. The Company's evaluation of goodwill for impairment involves the comparison of the fair value of the reporting unit to its carrying amount. 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. Given the significant estimates and assumptions management makes to estimate the fair value of the Trans Ova reporting unit and the sensitivity of Trans Ova's valuation to changes in these estimates, performing audit procedures to evaluate the reasonableness of management's estimates and assumptions required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the forecasts of future revenues, operating margins, and cash flow ("forecasts"), and the selection of the discount rate for the Trans Ova reporting unit included the following, among others:

- We tested the operating effectiveness of controls over management's goodwill impairment evaluation, including those over the determination of the Trans Ova reporting unit fair value, such as controls related to management's forecasts and selection of the discount rate.

- We evaluated management's ability to accurately forecast revenues and operating margins by comparing actual results to management's historical forecasts, as well as external information.

- We evaluated the reasonableness of management’s forecasts by comparing the forecasts to (1) historical results, (2) internal communications to management and the Board of Directors, (3) industry growth projections, and (4) forecasted information prepared in the prior year.

- With the assistance of our fair value specialists, we evaluated the discount rate, including testing the underlying source information and the mathematical accuracy of the calculations, and developing a range of independent estimates and comparing those to the discount rate selected by management.

/s/ Deloitte & Touche LLP

Baltimore, Maryland
March 1, 2021

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Precigen, Inc. and subsidiaries (the "Company") as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2020, of the Company and our report dated March 1, 2021 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the 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.

/s/ Deloitte & Touche LLP

Baltimore, Maryland
March 1, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the consolidated statements of operations, comprehensive loss, shareholders' and total equity and cash flows of Precigen, Inc. (formerly known as Intrexon Corporation) and its subsidiaries (the "Company") for the year ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses, cash outflows from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Atlanta, Georgia

March 1, 2019, except for the effects of discontinued operations discussed in the *Transactions with TS Biotechnology Holdings, LLC and Darling Ingredients, Inc*. section within Note 3 and the change in composition of reportable segments discussed in Note 20, as to which the date is March 2, 2020, and the effects of discontinued operations discussed in the *MBP Titan* section within Note 3, as to which the date is March 1, 2021.

We served as the Company's auditor from 2006 to 2019.

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2020 and 2019

(Amounts in thousands, except share data)	2020	2019
Assets		
Current assets		
Cash and cash equivalents	$ 51,792	$ 65,793
Short-term investments	48,325	9,260
Receivables		
Trade, less allowance for credit losses of $4,825 and $5,201 as of December 31, 2020 and 2019, respectively	16,487	20,650
Related parties, less allowance for credit losses of $1,509 and $2,312 as of December 31, 2020 and 2019, respectively	19	600
Notes	3,689	2,942
Other	232	2,030
Inventory	11,359	16,097
Prepaid expenses and other	7,192	5,827
Current assets held for sale or abandonment	9,853	111,444
Total current assets	148,948	234,643
Property, plant and equipment, net	34,924	43,952
Intangible assets, net	65,396	68,346
Goodwill	54,363	54,119
Investments in affiliates	—	1,461
Right-of-use assets	9,353	11,803
Other assets	1,603	1,349
Noncurrent assets held for sale or abandonment	—	40,090
Total assets	$ 314,587	$ 455,763

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

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2020 and 2019

(Amounts in thousands, except share data)	2020	2019
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,598	$ 5,528
Accrued compensation and benefits	8,097	13,198
Other accrued liabilities	9,549	11,674
Deferred revenue, including $0 and $877 from related parties as of December 31, 2020 and 2019, respectively	2,800	5,697
Lines of credit	—	1,922
Current portion of long-term debt, including $0 and $31,211 to related parties as of December 31, 2020 and 2019, respectively	360	31,670
Current portion of lease liabilities	2,657	2,634
Related party payables	19	51
Current liabilities held for sale or abandonment	14,047	50,538
Total current liabilities	42,127	122,912
Long-term debt, net of current portion, including $0 and $25,000 to related parties as of December 31, 2020 and 2019, respectively	171,522	186,321
Deferred revenue, net of current portion, including $21,205 and $30,182 from related parties as of December 31, 2020 and 2019, respectively	23,023	48,136
Lease liabilities, net of current portion	7,744	10,119
Deferred tax liabilities	2,897	2,834
Other long-term liabilities	100	—
Long-term liabilities held for sale or abandonment	—	13,730
Total liabilities	247,413	384,052
Commitments and contingencies (Note 17)		
Shareholders' equity		
Common stock, no par value, 400,000,000 shares authorized as of December 31, 2020 and 2019; and 187,663,207 shares and 163,274,880 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	1,886,567	1,752,048
Accumulated deficit	(1,823,390)	(1,652,869)
Accumulated other comprehensive income (loss)	3,997	(27,468)
Total shareholders' equity	67,174	71,711
Total liabilities and shareholders' equity	$ 314,587	$ 455,763

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

Precigen, Inc. and Subsidiaries
Consolidated Statements of Operations
Years Ended December 31, 2020, 2019 and 2018

(Amounts in thousands, except share and per share data)	2020	2019	2018
Revenues			
Collaboration and licensing revenues, including $3,053, $11,832, and $55,573 from related parties in 2020, 2019, and 2018, respectively	$ 21,208	$ 14,059	$ 69,540
Product revenues	24,349	23,780	28,486
Service revenues	56,899	51,803	52,419
Other revenues	722	1,080	733
Total revenues	103,178	90,722	151,178
Operating Expenses			
Cost of products	28,550	31,930	35,087
Cost of services	26,963	29,471	27,589
Research and development	41,644	66,666	333,007
Selling, general and administrative	91,704	98,634	125,162
Impairment of goodwill	—	29,820	—
Impairment of other noncurrent assets	920	990	—
Total operating expenses	189,781	257,511	520,845
Operating loss	(86,603)	(166,789)	(369,667)
Other Expense, Net			
Unrealized and realized appreciation (depreciation) in fair value of equity securities and preferred stock, net	—	8,291	(28,273)
Interest expense	(18,400)	(17,666)	(8,473)
Interest and dividend income	2,451	3,871	19,017
Other income (expense), net	(165)	3,445	470
Total other expense, net	(16,114)	(2,059)	(17,259)
Equity in net loss of affiliates	(1,138)	(2,416)	(8,986)
Loss from continuing operations before income taxes	(103,855)	(171,264)	(395,912)
Income tax benefit	82	930	15,425
Loss from continuing operations	(103,773)	(170,334)	(380,487)
Loss from discontinued operations, net of income tax benefit	(66,748)	(153,582)	(134,219)
Net loss	$ (170,521)	$ (323,916)	$ (514,706)
Net loss attributable to the noncontrolling interests	—	1,592	5,370
Net loss attributable to Precigen	$ (170,521)	$ (322,324)	$ (509,336)
Amounts Attributable to Precigen			
Net loss from continuing operations attributable to Precigen	$ (103,773)	$ (168,742)	$ (375,117)
Net loss from discontinued operations attributable to Precigen	(66,748)	(153,582)	(134,219)
Net loss attributable to Precigen	$ (170,521)	$ (322,324)	$ (509,336)
Net Loss per Share			
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.62)	$ (1.09)	$ (2.90)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	(0.40)	(1.00)	(1.03)
Net loss attributable to Precigen per share, basic and diluted	$ (1.02)	$ (2.09)	$ (3.93)
Weighted average shares outstanding, basic and diluted	167,065,539	154,138,774	129,521,731

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, 2020, 2019 and 2018

(Amounts in thousands)	2020	2019	2018
Net loss	$ (170,521)	$ (323,916)	$ (514,706)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments	6	68	(59)
Gain (loss) on foreign currency translation adjustments	4,502	1,087	(13,073)
Release of cumulative foreign currency translation adjustments to net loss from discontinued operations	26,957	—	—
Comprehensive loss	(139,056)	(322,761)	(527,838)
Comprehensive loss attributable to the noncontrolling interests	—	1,581	5,548
Comprehensive loss attributable to Precigen	$ (139,056)	$ (321,180)	$ (522,290)

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

Precigen, Inc. and Subsidiaries
Consolidated Statements of Shareholders' and Total Equity
Years Ended December 31, 2020, 2019 and 2018

(Amounts in thousands, except share data)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Precigen Shareholders' Equity	Noncontrolling Interests	Total Equity
	Shares	Amount						
Balances at December 31, 2017	122,087,040	$ —	$1,397,005	$ (15,554)	$ (847,820)	$ 533,631	$ 12,914	$ 546,545
Cumulative effect of adoption of ASC 606	—	—	—	(104)	26,611	26,507	—	26,507
Stock-based compensation expense	—	—	36,174	—	—	36,174	122	36,296
Shares issued upon vesting of restricted stock units and for exercises of stock options and warrants	70,159	—	297	—	—	297	2,039	2,336
Shares issued as payment for services	909,980	—	10,695	—	—	10,695	—	10,695
Shares and warrants issued in public offerings, net of issuance costs	6,900,000	—	82,374	—	—	82,374	5,616	87,990
Equity component of convertible debt, net of issuance costs and deferred taxes	—	—	36,868	—	—	36,868	—	36,868
Shares issued pursuant to share lending agreement	7,479,431	—	—	—	—	—	—	—
Shares issued for reacquired in-process research and development	22,573,856	—	159,323	—	—	159,323	—	159,323
Adjustments for noncontrolling interests	—	—	(724)	—	—	(724)	724	—
Net loss	—	—	—	—	(509,336)	(509,336)	(5,370)	(514,706)
Other comprehensive loss	—	—	—	(12,954)	—	(12,954)	(178)	(13,132)
Balances at December 31, 2018	160,020,466	$ —	$1,722,012	$ (28,612)	$(1,330,545)	$ 362,855	$ 15,867	$ 378,722

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

Precigen, Inc. and Subsidiaries
Consolidated Statements of Shareholders' and Total Equity
Years Ended December 31, 2020, 2019 and 2018

(Amounts in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Precigen Shareholders' Equity	Noncontrolling Interests	Total Equity
Balances at December 31, 2018	160,020,466	$ —	$1,722,012	$ (28,612)	$(1,330,545)	$ 362,855	$ 15,867	$ 378,722
Stock-based compensation expense	—	—	18,881	—	—	18,881	69	18,950
Shares issued upon vesting of restricted stock units and for exercises of stock options and warrants	1,028,144	—	63	—	—	63	250	313
Shares issued for accrued compensation	150,908	—	1,102	—	—	1,102	—	1,102
Shares issued as payment for services	2,075,362	—	10,446	—	—	10,446	—	10,446
Shares and warrants issued in public offerings, net of issuance costs	—	—	—	—	—	—	6,611	6,611
Adjustments for noncontrolling interests	—	—	(456)	—	—	(456)	456	—
Deconsolidation of subsidiary	—	—	—	—	—	—	(21,672)	(21,672)
Net loss	—	—	—	—	(322,324)	(322,324)	(1,592)	(323,916)
Other comprehensive income	—	—	—	1,144	—	1,144	11	1,155
Balances at December 31, 2019	163,274,880	$ —	$1,752,048	$ (27,468)	$(1,652,869)	$ 71,711	$ —	$ 71,711

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

Precigen, Inc. and Subsidiaries
Consolidated Statements of Shareholders' and Total Equity
Years Ended December 31, 2020, 2019 and 2018

(Amounts in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2019	163,274,880	$ —	$1,752,048	$ (27,468)	$(1,652,869)	$ 71,711
Stock-based compensation expense	—	—	18,366	—	—	18,366
Shares issued upon vesting of restricted stock units and for exercises of stock options	877,249	—	117	—	—	117
Shares issued for accrued compensation	1,955,405	—	5,100	—	—	5,100
Shares issued as payment for services	413,911	—	1,006	—	—	1,006
Shares issued in private placement	5,972,696	—	35,000	—	—	35,000
Shares issued upon conversion of long-term debt	13,051,802	—	56,827	—	—	56,827
Shares issued in conjunction with settlement agreement	2,117,264	—	18,103	—	—	18,103
Net loss	—	—	—	—	(170,521)	(170,521)
Release of cumulative translation adjustment to loss from discontinued operations	—	—	—	26,957	—	26,957
Other comprehensive income	—	—	—	4,508	—	4,508
Balances at December 31, 2020	187,663,207	$ —	$1,886,567	$ 3,997	$(1,823,390)	$ 67,174

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, 2020, 2019 and 2018

(Amounts in thousands)	2020	2019	2018
Cash flows from operating activities			
Net loss	$ (170,521)	$ (323,916)	$ (514,706)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	17,516	24,896	33,112
Loss on abandonment and disposals of assets, net	4,442	3,071	20,928
Impairment of goodwill	9,635	87,862	—
Impairment of other noncurrent assets	13,326	32,627	60,504
Gain on sale of discontinued operations	(672)	—	—
Loss on release of cumulative foreign currency translation adjustments to loss from discontinued operations	26,957	—	—
Reacquisition of in-process research and development	—	—	236,748
Loss on settlement agreement	11,436	—	—
Unrealized and realized (appreciation) depreciation on equity securities and preferred stock, net	106	(7,833)	30,200
Noncash dividend income	—	(48)	(14,841)
Amortization of discounts on investments, net	(699)	(1,005)	(771)
Equity in net loss of affiliates	1,176	6,730	11,608
Stock-based compensation expense	18,366	18,950	36,296
Shares issued as payment for services	1,006	10,446	10,695
Provision for credit losses	899	3,242	1,779
Accretion of debt discount and amortization of deferred financing costs	10,587	9,459	4,378
Deferred income taxes	(156)	(3,674)	(21,278)
Other noncash items	226	837	1,093
Changes in operating assets and liabilities:			
Receivables:			
Trade	2,214	(262)	(2,698)
Related parties	258	967	11,003
Other	1,853	(656)	(542)
Inventory	2,511	4,100	(478)
Prepaid expenses and other	(812)	(2,262)	1,006
Other assets	(142)	333	652
Accounts payable	(1,097)	(5,349)	4,680
Accrued compensation and benefits	(789)	5,186	4,385
Other accrued liabilities	(2,682)	(5,516)	356
Deferred revenue	(21,045)	7,423	(38,578)
Lease liabilities	(887)	(995)	—
Related party payables	(33)	45	(52)
Other long-term liabilities	—	(585)	281
Net cash used in operating activities	(77,021)	(135,927)	(124,240)

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, 2020, 2019 and 2018

(Amounts in thousands)	2020	2019	2018
Cash flows from investing activities			
Purchases of investments	(171,360)	(55,073)	(178,681)
Sales and maturities of investments	133,000	166,495	65,975
Proceeds from sales of equity securities	—	23,456	217
Acquisitions of businesses, net of cash received	—	—	(920)
Investments in affiliates	—	(3,713)	(16,582)
Decrease in cash from deconsolidation of subsidiary	—	(7,244)	—
Return of investment in affiliate	—	125	2,598
Cash received in asset acquisitions	—	—	15,500
Purchases of property, plant and equipment	(7,527)	(37,883)	(41,587)
Proceeds from sale of assets	6,484	688	2,267
Proceeds from sale of discontinued operations, net of cash sold	64,240	—	—
Proceeds from repayment of notes receivable	2,942	—	—
Net cash provided by (used in) investing activities	27,779	86,851	(151,213)
Cash flows from financing activities			
Proceeds from issuance of shares in a private placement	35,000	—	—
Proceeds from issuance of shares and warrants in public offerings, net of issuance costs	—	6,611	87,990
Advances from lines of credit	10,005	11,757	4,561
Repayments of advances from lines of credit	(11,927)	(10,301)	(4,328)
Proceeds from long-term debt, net of issuance costs	—	376	219,859
Payments of long-term debt	(490)	(618)	(623)
Proceeds from stock option and warrant exercises	117	313	2,336
Net cash provided by financing activities	32,705	8,138	309,795
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	353	(810)	295
Net increase (decrease) in cash, cash equivalents, and restricted cash	(16,184)	(41,748)	34,637
Cash, cash equivalents, and restricted cash			
Beginning of year	68,434	110,182	75,545
End of year	$ 52,250	$ 68,434	$ 110,182

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, 2020, 2019 and 2018

(Amounts in thousands)	2020	2019	2018
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 7,202	$ 3,751	$ 3,868
Cash paid during the period for income taxes	48	50	216
Significant noncash activities			
Fair value of stock received as consideration for collaboration agreements	$ —	$ 4,530	$ —
Fair value of stock issued for reacquired in-process research and development	—	—	159,323
Fair value of stock issued upon conversion of long-term debt	56,827	—	—
Fair value of stock issued in conjunction with settlement agreement	18,103	—	—
Long-term debt issued to a related party in an asset acquisition	—	—	30,000
Accrued compensation paid in equity awards	5,100	1,102	—
Purchases of property and equipment included in accounts payable and other accrued liabilities	277	694	2,267
Purchases of equipment financed through debt	—	—	234
Sales of assets included in receivables	4,227	—	—

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of December 31, 2020 and 2019 as shown above:

	2020	2019
Cash and cash equivalents	$ 51,792	$ 65,793
Cash and cash equivalents included in current assets held for sale or abandonment	—	2,223
Restricted cash included in other assets	458	418
Cash, cash equivalents, and restricted cash	$ 52,250	$ 68,434

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

Precigen, Inc. and Subsidiaries
Notes to the Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

1. Organization and Basis of Presentation

Precigen, Inc. ("Precigen"), a Virginia corporation, is a synthetic biology company with an increasing focus on its discovery and clinical stage activities to advance the next generation of gene and cellular therapies to target the most urgent and intractable challenges in immuno-oncology, autoimmune disorders, and infectious diseases.

PGEN Therapeutics, Inc. ("PGEN Therapeutics") is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target urgent and intractable diseases in immuno-oncology, autoimmune disorders, and infectious diseases. PGEN Therapeutics is a wholly owned subsidiary of Precigen with primary operations in Maryland.

Precigen ActoBio, Inc. ("ActoBio") is pioneering a proprietary class of microbe-based biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics and is a wholly owned subsidiary of Precigen with primary operations in Belgium.

Exemplar Genetics, LLC, doing business as 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, as well as enabling the production of cells and organs in its genetically engineered swine for regenerative medicine applications and is a wholly owned subsidiary of Precigen with primary operations in Iowa.

Trans Ova Genetics, L.C. ("Trans Ova") and Progentus, L.C. ("Progentus"), providers of reproductive technologies, including services and products sold to cattle breeders and other producers, are wholly owned subsidiaries with primary operations in California, Iowa, Maryland, Missouri, Texas, Washington, and Wisconsin.

Effective October 1, 2019, Precigen transferred substantially all of its proprietary methane bioconversion platform assets to a wholly owned subsidiary, MBP Titan LLC ("MBP Titan"). MBP Titan's proprietary technology is designed to convert natural gas into more valuable and usable energy and chemical products through novel, highly engineered bacteria that utilize specific energy feedstocks. Prior to October 1, 2019, the operation transferred to MBP Titan was an operating division within Precigen. Beginning in the second quarter of 2020, the Company suspended MBP Titan's operations and began the process to wind down MBP Titan's activities and has substantially completed the wind down by December 31, 2020. With the exception of certain assets and obligations with which the Company has a continuing involvement after the wind down, MBP Titan has been presented as discontinued operations for all periods presented. See Note 3 for further discussion.

Through April 8, 2019, Precigen consolidated AquaBounty Technologies, Inc. ("AquaBounty"), a company focused on improving productivity in commercial aquaculture and whose common stock is listed on the Nasdaq Stock Market. On April 9, 2019, AquaBounty completed an underwritten public offering that resulted in Precigen no longer having the contractual right to control AquaBounty's board of directors, and accordingly, Precigen deconsolidated AquaBounty resulting in a loss on deconsolidation of $2,648, which is included in other income, net, on the accompanying consolidated statement of operations for the year ended December 31, 2019. After deconsolidating the entity in April 2019, Precigen held its AquaBounty equity securities, which was an equity method investment that the Company accounted for using the fair value option, until October 2019 when the independent members of the Company's board of directors, with the recommendation of the audit committee and an independent special committee of the Board, unanimously approved the sale of the Company's common shares held in AquaBounty to an affiliate of Third Security, LLC ("Third Security"), a related party, for $21,587, resulting in the recognition of a realized gain of $7,348 which is included in unrealized and realized appreciation in fair value of equity securities and preferred stock, net, on the accompanying consolidated statement of operations for the year ended December 31, 2019.

On January 31, 2020, Precigen completed the sale of the majority of its non-healthcare assets and operations to an affiliate of Third Security, which are presented as discontinued operations for all periods presented. See Notes 3 and 14 for further discussion.

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

Liquidity and Going Concern

Management believes that existing liquid assets as of December 31, 2020, along with the net proceeds from the underwritten public offering in January 2021 (Note 23), 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 conducting high-risk, early-stage research and development of product candidates. Principal among these risks are 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 and its collaborators' 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. During the year ended December 31, 2020, the Company incurred a net loss of $170,521 and, as of December 31, 2020, had an accumulated deficit of $1,823,390. Management expects operating losses and negative cash flows to continue for the foreseeable future and, as a result, the Company will require additional capital to fund its operations and execute its business plan. In the absence of a significant source of recurring revenue, the Company's long-term success is dependent upon its ability to continue to raise additional capital in order to fund ongoing research and development, reduce uses of cash for operating and investing activities for non-healthcare functions, obtain regulatory approval of its product candidates, successfully commercialize its product candidates, generate revenue, meet its obligations and, ultimately, attain profitable operations.

Upon the original issuance of the Company's financial statements for the year ended December 31, 2018, the Company's resources of cash, cash equivalents, and short-term investments were not sufficient to fund the Company's planned operations through one year after the date the 2018 consolidated financial statements were originally issued and accordingly, there was substantial doubt about the Company's ability to continue as a going concern. The analysis used to determine the Company's ability to continue as a going concern did not include cash sources outside of the Company's direct control that management expected to be available within the twelve months following the original issuance of the 2018 consolidated financial statements.

At the time of the original issuance of the 2018 consolidated financial statements, the Company could not ensure that it would be able to obtain sufficient additional funding through monetizing certain of its existing assets, entering into new license and collaboration agreements, issuing additional equity or debt instruments or any other means, and if it was able to do so, they may not be on satisfactory terms. The Company's ability to raise additional capital in the equity and debt markets, should the Company choose to do so, was dependent on a number of factors, including, but not limited to, the market demand for the Company's common stock, which itself is subject to a number of business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that were favorable to the Company. Should the Company not have been able to secure additional funding through these means, the Company could have had to engage in any or all of the following activities: (i) shift internal investments from subsidiaries and platforms whose potential for value creation was longer-term to near-term opportunities; (ii) sell certain of its operating subsidiaries to third parties; (iii) reduce operating expenditures for third-party contractors, including consultants, professional advisors and other vendors; and (iv) reduce or delay capital expenditures, including non-essential facility expansions, lab equipment, and information technology projects. The 2018 consolidated financial statements were prepared on a going concern basis and did not include any adjustments to the amounts and classification of assets and liabilities that may have been necessary in the event the Company could no longer continue as a going concern.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Risks and Uncertainties

COVID-19 has had and continues to have an extensive impact on the global health and economic environments.

Commencing in the second half of March 2020, the Company's healthcare business began to experience delays to certain of its clinical trials as a result of COVID-19. For example, starting in March 2020, ActoBio temporarily suspended the last cohort of the Phase 1b/2a clinical trial for AG019 as a proactive measure to protect the welfare and safety of patients, caregivers, clinical site staff, its employees, and contractors. The temporary suspension of the AG019 trial was voluntary and was not related to any patient safety issues in the study. The voluntary suspension of the AG019 trial was lifted in June 2020, and the study is recruiting patients again. Additionally, from April to May 2020, enrollment of new patients in the Company's PRGN-3005

Phase 1 trial was temporarily suspended due to a mandated hold on certain early and late-stage clinical trials at the Fred Hutchinson Cancer Research Center in Seattle that was instituted in light of the COVID-19 pandemic. The temporary suspension of the PRGN-3005 trial was not related to safety issues in the studies, and in May 2020, recruitment resumed in the PRGN-3005 Phase 1 trial. Furthermore, uncertainty regarding the duration and severity of the ongoing pandemic may adversely impact the Company's clinical as well as preclinical pipeline candidates in the future.

The Company is closely monitoring the impact of COVID-19 on these and other aspects of its business, including Trans Ova and Exemplar. Given the dynamic nature of these circumstances, the full impact of the COVID-19 pandemic on the Company's ongoing business, results of operations, and overall financial performance in future periods cannot be reasonably estimated at this time, and it could have a material adverse effect on the Company's results of operations, cash flows, and financial position, including resulting impairments to goodwill and long-lived assets and additional credit losses.

See Note 3 for further discussion of the impact of COVID-19 on MBP Titan.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company performs 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) the Company satisfies the performance obligations.

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 obtain 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 provide that the Company receives 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 continues 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 determines whether each of the promises is a distinct performance obligation. As the nature of the promises in the Company's collaboration and licensing agreements are highly integrated and interrelated, the Company typically combines most of its promises into a single performance obligation. Because the Company is performing research and development services during early-stage development, the services are integral to the utilization of the technology license. Therefore, the Company has determined that the technology license and research and development services are typically inseparable from each other during the performance period of its collaboration and licensing agreements. Options to acquire additional services are considered to determine if they constitute material rights. Contingent manufacturing services that may be provided under certain of the Company's agreements are considered to be a separate future contract and not part of the current collaboration or licensing agreement.

At contract inception, the Company determines the transaction price, including fixed consideration and any estimated amounts of variable consideration. The upfront payment received upon consummation of the agreement is fixed and nonrefundable. Variable consideration is subject to a constraint and amounts are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include reimbursements for costs incurred by the Company for research and development efforts; milestone payments upon the achievement of certain development, regulatory, and commercial activities; and royalties on sales of products arising from the collaboration or licensing agreement. The Company determines the initial transaction price and excludes variable consideration that is otherwise constrained pursuant to the guidance in ASC 606.

The transaction price is allocated to the performance obligations in the agreement based on the standalone selling price of each performance obligation. The Company typically groups the promises in its collaboration and licensing agreements into one performance obligation so the entire transaction price relates to this single performance obligation. The technology license included in the single performance obligation is considered a functional license. However, it is typically combined into a single performance obligation as the Company provides interrelated research and development services along with other obligations over an estimated period of performance. The Company utilizes 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. The Company evaluates its measure of progress to recognize revenue each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The Company's measure of performance and revenue recognition involves significant judgment and assumptions, including, but not limited to, estimated costs and timelines to complete its performance obligations. The Company evaluates modifications and amendments to its contracts to determine whether any changes should be accounted for prospectively or on a cumulative catch-up basis.

Payments received for cost reimbursements for research and development efforts are recognized as revenue as the services are performed, in connection with the single performance obligation discussed above. The reimbursements relate specifically to the Company's efforts to provide services and the reimbursements are consistent with what the Company would typically charge other collaborators for similar services.

The Company assesses the uncertainty of when and if the milestone will be achieved to determine whether the milestone is included in the transaction price. The Company then assesses whether the revenue is constrained based on whether it is probable that a significant reversal of revenue would not occur when the uncertainty is resolved.

Royalties, including sales-based milestones, received under the agreements will be recognized as revenue when sales have occurred because the Company applies the sales- or usage-based royalties recognition exception provided for under ASC 606. The Company determined the application of this exception is appropriate because at the time the royalties are generated, the technology license granted in the agreement is the predominant item to which the royalties relate.

As the Company receives upfront payments in its collaboration and licensing agreements, it evaluates whether any significant financing components exist in its collaboration and licensing agreements. Based on the nature of its collaboration and licensing agreements, there are no significant financing components as the purpose of the upfront payment is not to provide financing. The purpose is to provide the collaborator with assurance that the Company will complete its obligations under the contract or to secure the right to a specific product or service at the collaborator's discretion. In addition, the variable payments generally align with the timing of performance or the timing of the consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the collaborator or the Company.

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.

Product and service revenues

The Company's product and service revenues are generated primarily through Trans Ova and include sales of advanced reproductive technologies, including the Company's bovine embryo transfer and *in vitro* fertilization processes and from genetic preservation and sexed semen processes and applications of such processes to other livestock, as well as sales of livestock and embryos produced using these processes and used in production. Exemplar also generates product and service revenues through the development and sale of genetically engineered miniature swine models. As each promised product or service is distinct, the Company recognizes the transaction price as revenue at a point in time when control of the promised product is transferred to the customer or when the promised service is rendered. Payment terms are typically due within 30 days of invoicing, which occurs prior to or when revenue is recognized.

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, 2020 and 2019, the Company had research and development commitments with third parties that had not yet been incurred totaling $12,054 and $14,664, respectively. The commitments are generally cancellable by the Company at any time upon written notice.

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. As of December 31, 2020 and 2019, the Company had cash equivalent investments in highly liquid money market accounts at major financial institutions of $30,164 and $47,238, respectively.

Short-term Investments

As of December 31, 2020, short-term investments include 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. The Company's written investment policy requires investments to be explicitly rated by two of Standard & Poor's, Moody's or Fitch and to have a minimum rating of A1, P1 or F-1, respectively, from those agencies. In addition, the investment policy limits the amount of credit exposure to any one issuer.

Equity Securities

The Company historically held equity securities of private and publicly traded companies, including investments received and/or purchased from certain collaborators. The Company evaluated whether to elect the fair value option on an individual investment basis. The Company elected the fair value option to account for its equity securities held in publicly traded companies. These equity securities were recorded at fair value at each reporting date and were subject to market price volatility. Unrealized gains and losses resulting from fair value adjustments were reported in the consolidated statements of operations. The Company accounts for its investments in private companies using either the equity method, as discussed below, or the measurement alternative method for equity securities without readily determinable fair values, which represented cost and any adjustments for impairment or observable price changes in certain transactions. See Notes 3 and 18 for additional discussion of certain equity securities.

For equity securities received pursuant to a collaboration agreement, the Company recorded the fair value of securities received on the date the collaboration was consummated or the milestone was achieved using the fair value of the collaborator's security on that date, assuming the transfer of consideration was considered perfunctory. If the transfer of the consideration was not considered perfunctory, the Company considered the specific facts and circumstances to determine the appropriate date on which to evaluate fair value. The Company also evaluated whether any discounts for trading restrictions or other basis for lack of marketability should be applied to the fair value of the securities at inception of the collaboration. In the event the Company concluded that a discount should be applied to securities accounted for under the fair value option, the fair value of the securities was adjusted at inception of the collaboration and re-evaluated at each reporting period thereafter.

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 mix of fixed and variable rate securities holdings, the Company's investment portfolio is susceptible to changes in interest rates. As of December 31, 2020, gross unrealized losses on the Company's short-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, or distribute its equity securities to shareholders as a stock dividend. 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 concentrations of credit risk consist primarily of trade and related party receivables. The Company controls 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 accounts for its investments in each of its joint ventures ("JVs") and in start-up entities backed by the Harvest Intrexon Enterprise Fund I, LP ("Harvest"), all of which are related parties, using the equity method of accounting based upon relative ownership interest. The Company's investments in these entities are included in investments in affiliates in the accompanying consolidated balance sheets. See additional discussion related to certain of the Harvest start-up entities in Notes 4 and 17 and to certain of the Company's JVs in Note 5.

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, 2020 and 2019, the Company determined that certain of its collaborators and JVs were VIEs. It also determined Harvest was a VIE as of December 31, 2019. 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 the economic performance of the VIEs. The Company's aggregate investment balances of these VIEs as of December 31, 2020 and 2019, were $0 and $1,461, respectively, which represents the Company's maximum risk of loss related to the identified VIEs. See Note 5 for discussion of the Company's future funding commitments for its significant JVs.

Accounts Receivable

Effective January 1, 2020, the Company applies FASB Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This ASU replaces the incurred loss impairment model with an expected credit loss impairment model for financial instruments, including accounts receivable. The amendment requires entities to consider forward-looking information to estimate expected credit losses, resulting in earlier recognition of losses for receivables that are current or not yet due, which were not considered under the previous accounting guidance.

The Company is exposed to credit losses primarily through sales of products and services by Trans Ova and Exemplar in the normal course of business. 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 customers' accounts receivables. The Company's monitoring activities include timely account reconciliation, routine follow-up

on past due accounts, and consideration of customers' financial condition, as well as macroeconomic conditions. Past due status is determined based upon contractual terms. 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, 2020, 2019, and 2018:

	2020	2019	2018
Beginning balance	$ 7,513	$ 4,991	$ 4,631
Charged to operating expenses	899	3,384	1,627
Write offs of accounts receivable, net of recoveries	(2,078)	(862)	(1,267)
Ending balance	$ 6,334	$ 7,513	$ 4,991

Inventory

The Company's inventory primarily includes adult female cows that are used in Trans Ova's production processes and are recorded at acquisition cost using the first-in, first-out method or net realizable value, whichever is lower. Work-in-process inventory includes allocations of production costs and facility costs for products currently in production and is recorded at the lower of cost or net realizable value. Significant declines in the price of cows could result in unfavorable adjustments to inventory balances.

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 from continuing operations are as follows:

	Years
Land improvements	4–15
Buildings and building improvements	3–23
Furniture and fixtures	1–7
Equipment	1–9
Breeding stock	2–4
Computer hardware and software	1–7

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

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.

If the quantitative goodwill impairment test is performed, first, 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 in the fourth quarter, or sooner if a triggering event occurs prior to the annual impairment review.

The fair value of the reporting units are primarily determined based on the income approach. The income approach is a valuation technique in which fair value is based from 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. To assess the reasonableness of the calculated reporting unit fair values, the Company compares the sum of the reporting units' fair values to its market capitalization (per share stock price times the number of shares outstanding) and calculates an implied control premium (the excess of the sum of the reporting units' fair values over the market capitalization) and then assesses the reasonableness of its implied control premium.

See Notes 3 and 11 for additional discussion regarding goodwill impairment charges recorded in the years ended December 31, 2020 and 2019.

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 three to eighteen years for the patents, developed technologies, and know-how; customer relationships; and trademarks.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment and intangible assets subject to amortization, 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 3 and 10 for additional discussion of impairment of long-lived assets for the three years ended December 31, 2020.

Convertible Notes

The Company allocated the proceeds received in July 2018 from the issuance of Precigen's 3.50% convertible senior notes due 2023 (the "Convertible Notes") between long-term debt (liability component) and additional paid-in capital (equity component) within the consolidated balance sheet. The original value assigned to long-term debt was the estimated fair value as of the issuance date of a similar debt instrument without a conversion option. The original value assigned to additional paid-in capital represented the value of the conversion option and was calculated by deducting the fair value of the long-term debt from the principal amount of the Convertible Notes and is not remeasured as long as it continues to meet the requirements for equity

classification. The original value of the conversion option will accrete to the carrying value of the long-term debt and result in additional noncash interest expense over the expected life of the Convertible Notes using the effective interest method.

Debt issuance costs related to the Convertible Notes were also allocated between long-term debt and additional paid-in capital based on the original value assigned to each. Debt issuance costs allocated to long-term debt reduced the original carrying value and accrete to the carrying value of the long-term debt and result in additional noncash interest expense over the expected life of the Convertible Notes using the effective interest method. Debt issuance costs allocated to additional paid-in capital were recorded as reduction of the original value assigned to the conversion option.

See Note 12 for the further discussion of the Convertible Notes.

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 comprehensive loss. Revenue and expense amounts are translated at average rates during the period.

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.

The Company accounts for the minimum tax on global intangible low-taxed income ("GILTI") as a period charge in the period in which the tax arises. There was no impact from GILTI to the accompanying consolidated financial statements.

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. Through 2019, since Precigen did not have sufficient history to estimate the expected volatility of its common stock price, expected volatility was based on a blended approach that utilized the volatility of Precigen's common stock and the volatility of peer public entities that were similar in size and industry. Beginning in 2020, for stock options with an expected term where there is sufficient history available, expected volatility is based on the volatility of Precigen's common stock. For any stock options where sufficient history is not available for the expected term, expected volatility is based on the blended approach discussed above. 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, 2020, 2019 and 2018 are set forth in the table below:

	2020	2019	2018
Valuation assumptions			
Expected dividend yield	0%	0%	0%
Expected volatility	59%–90%	58%–64%	55%–59%
Expected term (years)	6.00–10.00	6.25	6.25
Risk-free interest rate	0.36%–1.80%	1.53%–2.58%	2.33%–3.06%

Grant date fair value for the Company's restricted stock units ("RSUs") is 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.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents. Diluted net 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 loss per share calculation, shares to be issued pursuant to convertible debt, stock options, RSUs, and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and, therefore, basic and diluted net loss per share were the same for all periods presented.

Segment Information

The Company's chief operating decision maker ("CODM") regularly reviews disaggregated financial information for various operating segments. As of December 31, 2020, the Company's reportable segments were (i) PGEN Therapeutics; (ii) ActoBio; (iii) Trans Ova; and (iv) the Human Biotherapeutics division, which is an operating division of Precigen. All of Precigen's consolidated subsidiaries and operating divisions that did not meet the quantitative thresholds to report separately are combined and reported in a single category, All Other. See Note 1 for a description of PGEN Therapeutics, ActoBio, and Trans Ova. See Note 20 for a description of the Human Biotherapeutics division. Corporate expenses, which are not allocated to the segments and are managed at a consolidated level, include costs associated with general and administrative functions, including the Company's finance, accounting, legal, human resources, information technology, corporate communication, and investor relations functions. Corporate expenses exclude interest expense, depreciation and amortization, stock-based compensation expense, loss on settlement agreement, and equity in net loss of affiliates and include unrealized and realized gains and losses on the Company's securities portfolio as well as dividend income. See Note 20 for further discussion of the Company's segments.

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.

Recently Adopted Accounting Pronouncements

In October 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). The provisions of ASU 2018-18 clarify when certain transactions between collaborative arrangement participants should be accounted for under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), and incorporates unit-of-account guidance consistent with ASC 606 to aid in this determination. The Company adopted this standard effective January 1, 2020, and there was no impact to the accompanying consolidated financial statements.

In October 2018, the FASB issued ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities* ("ASU 2018-17"). The provisions of ASU 2018-17 modify the guidance under ASC Topic 810 related to the evaluation of indirect interests held through related parties under common control when determining whether fees paid to decision makers and service providers are variable interests. Indirect interests held through related parties that are under common control are no longer considered to be the equivalent of direct interests in their entirety and instead should be considered on a proportional basis. This guidance more closely aligns with accounting of how indirect interests held through related parties under common control are considered for determining whether a reporting entity must consolidate a

VIE. The Company adopted this standard effective January 1, 2020, and there was no impact to the accompanying consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). The provisions of ASU 2018-15 clarify the accounting for implementation costs of a hosting arrangement that is a service contract. The new standard requires an entity (customer) in a hosting arrangement that is a service contract to follow existing internal-use software guidance to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. Capitalized implementation costs of a hosting arrangement that is a service contract should be amortized over the term of the hosting arrangement, which might extend beyond the noncancelable period if there are options to extend or terminate. ASU 2018-15 also specifies the financial statement presentation of capitalized implementation costs and related amortization, in addition to required disclosures for material capitalized implementation costs related to hosting arrangements that are service contracts. The Company adopted this standard effective January 1, 2020, on a prospective basis, and there was no material impact to the accompanying consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurements (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurements* ("ASU 2018-13"). The provisions of ASU 2018-13 modify the disclosures related to recurring and nonrecurring fair value measurements. Disclosures related to the transfer of assets between Level 1 and Level 2 hierarchies have been eliminated and various additional disclosures related to Level 3 fair value measurements have been added, modified, or removed. The Company adopted this standard effective January 1, 2020, and there was no impact to the accompanying consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, which modifies the impairment model for receivables to utilize an expected loss methodology in place of the previous incurred loss methodology, and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company adopted this standard effective January 1, 2020, and there was no material impact to the accompanying consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). The provisions of ASU 2020-06 simplify accounting for convertible instruments by removing major separation models required under current U.S. GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for the exception. ASU 2020-06 also simplifies the diluted net income per share calculation in certain areas. The amendments in ASU 2020-06 are effective for annual periods beginning after December 15, 2021. Early adoption is permitted but no earlier than annual periods beginning after December 15, 2020. The guidance must be adopted as of the beginning of the fiscal year of adoption. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). The provisions of ASU 2019-12 are intended to simplify various aspects related to accounting for income taxes by removing certain exceptions to the general principles in ASC Topic 740 and clarifying certain aspects of the current guidance to promote consistency among reporting entities. ASU 2019-12 is effective for annual periods beginning after December 15, 2020 and interim periods within those annual periods, with early adoption permitted. An entity that elects early adoption must adopt all the amendments in the same period. Most amendments within this ASU are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

3. Discontinued Operations

MBP Titan

As a result of market uncertainty driven by the COVID-19 pandemic and the state of the energy sector raising significant challenges for the strategic alternatives pursued by MBP Titan, beginning in the second quarter of 2020 and throughout the remainder of 2020, the Company suspended MBP Titan's operations, preserved certain of MBP Titan's intellectual property, terminated all of its personnel, and undertook steps to dispose of its other assets and obligations. The wind down of MBP Titan's activities was substantially complete by December 31, 2020, with the final disposition of certain property and equipment

and the facility operating lease occurring in January 2021. See Note 23 for further discussion of the facility operating lease. This discontinuation of operations represented the continuation of a strategic shift, that the Company commenced as part of the Transactions defined and discussed below, to becoming a primarily healthcare company advancing technologies and products that address complex healthcare challenges. The assets, liabilities, and expenses related to the discontinued operations of MBP Titan are reclassified and presented as discontinued operations in the accompanying consolidated financial statements for all periods.

After the wind down of MBP Titan, certain assets and contractual obligations which were previously managed by MBP Titan continue to be managed at the Precigen corporate level. These remaining assets and contractual obligations include the Company's equity interest in and collaboration agreements with Intrexon Energy Partners and Intrexon Energy Partners II, including the associated deferred revenue remaining under each collaboration agreement (Notes 5 and 6), as well as the associated intellectual property developed by MBP Titan to date. These assets, liabilities, and related historical revenue and equity losses are included in the Company's operating results from continuing operations in the accompanying consolidated financial statements for all periods presented as a result of the Company's continuing involvement.

The carrying values of the major classes of assets and liabilities included in assets and liabilities held for abandonment for MBP Titan as of December 31, 2020 and 2019, are as follows:

	December 31,	
	2020	2019
Assets		
Property, plant and equipment, net	$ 586	$ 17,017
Goodwill	—	9,635
Right-of-use assets	9,131	13,425
Other assets	136	636
Total assets held for sale or abandonment	$ 9,853	$ 40,713
Liabilities		
Lease liabilities, current	$ 1,890	$ 1,548
Other current liabilities	619	1,657
Lease liabilities, net of current portion	11,538	13,730
Total liabilities held for sale or abandonment	$ 14,047	$ 16,935

The following table presents the financial results of discontinued operations of MBP Titan:

	Year Ended December 31,		
	2020	2019	2018
Operating expenses (1)	$ 40,692	$ 37,423	$ 33,830
Operating loss	(40,692)	(37,423)	(33,830)
Loss before income taxes	(40,692)	(37,423)	(33,830)
Loss from discontinued operations	$ (40,692)	$ (37,423)	$ (33,830)

(1) Includes a goodwill impairment charge of $9,635 and an impairment charge on property, plant and equipment and ROU Assets of $12,406 recorded in 2020 in conjunction with the suspension of MBP Titan's operations discussed above.

The following table presents the significant non-cash items and purchases of property, plant and equipment for the discontinued operations for MBP Titan that are included in the accompanying consolidated statements of cash flows.

	Year Ended December 31,		
	2020	2019	2018
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	$ 2,474	$ 3,647	$ 3,493
Impairment of goodwill	9,635	—	—
Impairment of other noncurrent assets	12,406	—	—
Stock-based compensation expense	(34)	1,345	1,870
Cash flows from investing activities			
Purchases of property, plant and equipment	(88)	(2,114)	(3,558)

Transactions with TS Biotechnology Holdings, LLC and Darling Ingredients, Inc.

On January 1, 2020, the Company and TS Biotechnology Holdings, LLC ("TS Biotechnology"), a related party and an entity managed by Third Security, entered into a Stock and Asset Purchase Agreement pursuant to which the Company agreed to sell a majority of the Company's non-healthcare assets and operations to TS Biotechnology for $53,000 and certain contingent payment rights (the "TS Biotechnology Sale"). The TS Biotechnology Sale closed on January 31, 2020. The assets and operations sold in the TS Biotechnology Sale included the following wholly owned subsidiaries, as well as certain equity securities that were directly related to the subsidiaries sold:

- Intrexon Produce Holdings, Inc., the parent company of two companies focused on the development and sale of non-browning apples, Okanagan Specialty Fruits, Inc. and Fruit Orchard Holdings, Inc.;
- Intrexon UK Holdings, Inc., the parent company of Oxitec Limited and its subsidiaries, which focused on biological insect solutions;
- ILH Holdings, Inc., a company focused on the production of certain fine chemicals focused primarily on microbial production of therapeutic compounds; and
- Blue Marble AgBio LLC which was formed in January 2020 and included certain agriculture biotechnology assets and operations that were previously an operating division within Precigen.

Additionally, on January 2, 2020, the Company sold its equity interest in EnviroFlight, LLC ("EnviroFlight"), a JV with Darling Ingredients, Inc. ("Darling"), and related intellectual property rights to Darling for $12,200 (the "EnviroFlight Sale"). Unless referenced separately, the TS Biotechnology Sale and the EnviroFlight Sale are collectively referred to as the "Transactions".

The Transactions were approved by the Company's independent members of the board of directors in December 2019. The Transactions represented a strategic shift of the Company towards the Company becoming a primarily healthcare company advancing technologies and products that address complex healthcare challenges. The assets, liabilities, and operations related to the Transactions are reclassified and presented as discontinued operations in the accompanying consolidated financial statements for all periods. Immediately prior to the reclassification, the Company evaluated goodwill, long-lived assets, and the equity method investment included in the Transactions for impairment. The Company recorded an impairment charge of $79,396, including $58,042 and $21,354 related to goodwill and other long-lived assets, respectively, at the Okanagan, Oxitec, Fine Chemicals, and AgBio reporting units. Additionally, the Company recorded a $10,283 impairment charge for the write down of the equity method investment and related intangible assets included in the EnviroFlight Sale. These impairment charges are included in loss from discontinued operations in the accompanying consolidated statement of operations for the year ended December, 31, 2019.

Upon the closing of the TS Biotechnology Sale in January 2020, the cumulative foreign currency translation losses totaling $26,957 were released to earnings and included in loss from discontinued operations. See further discussion below.

The carrying values of the major classes of assets and liabilities included in assets and liabilities held for sale for the Transactions as of December 31, 2019 are as follows:

	TS Biotechnology Sale	EnviroFlight Sale	Total
Assets			
Cash and cash equivalents	$ 2,223	$ —	$ 2,223
Other current assets	9,698	—	9,698
Property, plant and equipment, net	51,975	—	51,975
Intangible assets, net	20,891	4,383	25,274
Investments in affiliates	—	7,817	7,817
Right-of-use assets	13,622	—	13,622
Other noncurrent assets	212	—	212
Total assets held for sale	$ 98,621	$ 12,200	$ 110,821
Liabilities			
Deferred revenue, current (1)	$ 8,723	$ —	$ 8,723
Lease liabilities, current	2,459	—	2,459
Other current liabilities	3,058	41	3,099
Deferred revenue, net of current portion (2)	19,410	—	19,410
Lease liabilities, net of current portion	12,623	—	12,623
Other long-term liabilities	1,019	—	1,019
Total liabilities held for sale	$ 47,292	$ 41	$ 47,333

(1) Includes deferred revenue, current, from related parties of $1,243.

(2) Includes deferred revenue, net of current portion, from related parties of $6,836.

The following tables present the financial results of discontinued operations related to the Transactions:

	Year Ended December 31, 2020		
	TS Biotechnology Sale	EnviroFlight Sale	Total
Revenues (1)	$ 1,294	$ —	$ 1,294
Operating expenses	896	—	896
Operating income	398	—	398
Gain on sale of discontinued operations	633	39	672
Loss on release of cumulative foreign currency translation adjustment	(26,957)	—	(26,957)
Other expense, net	(129)	—	(129)
Equity in net loss of affiliates	—	(38)	(38)
Income (loss) before income taxes	(26,055)	1	(26,054)
Income tax expense	(2)	—	(2)
Income (loss) from discontinued operations	$ (26,057)	$ 1	$ (26,056)

(1) Includes revenues recognized from related parties of $436.

	Year Ended December 31, 2019		
	TS Biotechnology Sale	EnviroFlight Sale	Total
Revenues (1)	$ 12,307	$ —	$ 12,307
Operating expenses (2)	116,091	10,794	126,885
Operating loss	(103,784)	(10,794)	(114,578)
Other expense, net	(272)	—	(272)
Equity in net loss of affiliates	—	(4,314)	(4,314)
Loss before income taxes	(104,056)	(15,108)	(119,164)
Income tax benefit	3,005	—	3,005
Loss from discontinued operations	$ (101,051)	$ (15,108)	$ (116,159)

(1) Includes revenue recognized from related parties of $3,042.

(2) Includes the impairment charge of $89,679 related to the Transactions discussed above.

	Year Ended December 31, 2018		
	TS Biotechnology Sale	EnviroFlight Sale	Total
Revenues (1)	$ 9,396	$ —	$ 9,396
Operating expenses (2)	111,039	470	111,509
Operating loss	(101,643)	(470)	(102,113)
Other expense, net	(1,757)	—	(1,757)
Equity in net loss of affiliates	—	(2,622)	(2,622)
Loss before income taxes	(103,400)	(3,092)	(106,492)
Income tax benefit	6,103	—	6,103
Loss from discontinued operations	$ (97,297)	$ (3,092)	$ (100,389)

(1) Includes revenue recognized from related parties of $4,665.

(2) Includes an impairment charge of $60,504 recorded in 2018 related to Oxitec's developed technology targeting the *Aedes Aegypti* mosquito and a $5,057 loss on disposal of certain leasehold improvements, equipment and other fixed assets in conjunction with the closing of one of Oxitec's research and development facilities in Brazil.

The following table presents the significant non-cash items, investments in EnviroFlight and purchases of property, plant and equipment for the discontinued operations for the Transactions that are included in the accompanying consolidated statements of cash flows.

	Year Ended December 31,		
	2020	2019	2018
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	$ —	$ 5,107	$ 9,007
Impairment of goodwill	—	58,042	—
Impairment of other noncurrent assets	—	31,637	60,504
Gain on sale of discontinued operations	(672)	—	—
Loss on release of cumulative foreign currency translation adjustment	26,957	—	—
Unrealized and realized depreciation on equity securities and preferred stock, net	106	458	1,927
Equity in net loss of EnviroFlight	38	4,314	2,622
Stock-based compensation expense	(1,346)	2,507	3,872
Deferred income taxes	—	(2,710)	(5,703)
Cash flows from investing activities			
Investments in EnviroFlight	—	(2,000)	(12,250)
Purchases of property, plant and equipment	(382)	(23,326)	(21,191)

Also see Note 14 below.

Equity Method Investments

The Company accounted for its investment in EnviroFlight using the equity method of accounting.

The Company accounted for certain equity securities held in one of its collaborators using the fair value option, and the collaborator was considered an equity method investment through September 30, 2018.

Summarized financial data for equity method investments included in discontinued operations during the periods below are shown in the following tables.

	December 31, 2019
Current assets	$ 703
Noncurrent assets	30,549
Total assets	31,252
Current liabilities	2,352
Non-current liabilities	88
Total liabilities	2,440
Net assets	$ 28,812

	Year Ended December 31,		
	2020	2019	2018
Revenues	$ 16	$ 510	$ 268
Operating expenses	92	9,159	12,709
Operating loss	(76)	(8,649)	(12,441)
Other, net	—	21	39
Net loss	$ (76)	$ (8,628)	$ (12,402)

Where applicable, the notes to the accompanying consolidated financial statements have been updated to reflect information pertaining to the Company's continuing operations.

Out-of-Period Adjustment

During the year ended December 31, 2020, the Company recorded an out-of-period adjustment of $26,572 to loss from discontinued operations which relates to the effect of cumulative foreign translation losses associated with the entities sold in the TS Biotechnology Sale. This charge, which is entirely noncash, should have been recorded in the year ended December 31, 2019 as an additional impairment charge included in loss from discontinued operations. There was no impact to net loss from continuing operations, cash and short-term investments, cash flows, or Segment Adjusted EBITDA. The error also had no impact on the cash consideration received upon closing of the TS Biotechnology Sale nor the representations and warranties made by the Company in the transaction. The Company evaluated the effects of this out-of-period adjustment, both qualitatively and quantitatively, and concluded that this adjustment was not material to the Company's financial position or results of operations for the years ended December 31, 2020 and 2019.

4. Mergers and Acquisitions

Asset Acquisition of Certain Harvest Entities

In September 2018, the Company, through its wholly owned subsidiary ActoBio, issued $30,000 of convertible promissory notes to Harvest, a related party, to acquire Harvest's ownership in CRS Bio, Inc. ("CRS Bio"); Genten Therapeutics, Inc. ("Genten Therapeutics"); and Relieve Genetics, Inc. ("Relieve Genetics") (collectively the "Harvest entities"). The Company also received $15,500 cash in the transaction from the acquisition of the Harvest entities. Prior to the transaction, the Company held a noncontrolling interest in the Harvest entities, with a combined carrying value for all entities of $4,303, and accounted for its ownership using the equity method of accounting. Following the transaction, the Company owns 100% of the equity interests of the Harvest entities including the rights that had been previously licensed to the Harvest entities by the Company. The Harvest entities did not meet the definition of a business and accordingly, the transaction was accounted for as an asset acquisition.

By reacquiring the rights previously licensed to the Harvest entities, the Company was relieved from its obligations under the original ECCs and therefore wrote off deferred revenue of $10,078 in September 2018 as part of the transaction. The remaining value acquired of $8,721 was considered in-process research and development related to the reacquired rights under the ECCs and expensed immediately.

See Note 12 for additional discussion of the convertible promissory notes.

5. Investments in Joint Ventures

Intrexon Energy Partners

In March 2014, the Company and certain investors (the "IEP Investors"), including an affiliate of Third Security, a related party, entered into a Limited Liability Company Agreement that governs the affairs and conduct of business of Intrexon Energy Partners, LLC ("Intrexon Energy Partners"), a JV formed to optimize and scale-up the Company's methane bioconversion platform technology for the production of certain fuels and lubricants. The Company also entered into an ECC with Intrexon Energy Partners providing exclusive rights to the Company's technology for the use in bioconversion for the production of certain fuels and lubricants, as a result of which the Company received a technology access fee of $25,000 while retaining a 50% membership interest in Intrexon Energy Partners. The IEP Investors made initial capital contributions, totaling $25,000 in the aggregate, in exchange for pro rata membership interests in Intrexon Energy Partners totaling 50%. In addition, Precigen has committed to make capital contributions of up to $25,000, and the IEP Investors, as a group and pro rata in accordance with their respective membership interests in Intrexon Energy Partners, have committed to make additional capital contributions of up to $25,000, at the request of Intrexon Energy Partners' board of managers (the "Intrexon Energy Partners Board") and subject to certain limitations. As of December 31, 2020, the Company's remaining commitment was $4,225. Intrexon Energy Partners is governed by the Intrexon Energy Partners Board, which has five members. Two members of the Intrexon Energy Partners Board are designated by the Company and three members are designated by a majority of the IEP Investors. The Company and the IEP Investors have the right, but not the obligation, to make additional capital contributions above the initial limits when and if solicited by the Intrexon Energy Partners Board.

The Company's investment in Intrexon Energy Partners was $(425) and $(423) as of December 31, 2020 and 2019, respectively, and is included in other accrued liabilities in the accompanying consolidated balance sheets, which represents the Company's equity in losses for contractually committed contributions to Intrexon Energy Partners.

See Note 3 for additional discussion regarding the Company's investment in Intrexon Energy Partners.

Intrexon Energy Partners II

In December 2015, the Company and certain investors (the "IEPII Investors"), including Harvest, entered into a Limited Liability Company Agreement that governs the affairs and conduct of business of Intrexon Energy Partners II, LLC ("Intrexon Energy Partners II"), a JV formed to utilize the Company's methane bioconversion platform technology for the production of 1,4-butanediol, an industrial chemical used to manufacture spandex, polyurethane, plastics, and polyester. The Company also entered into an ECC with Intrexon Energy Partners II that provides exclusive rights to the Company's technology for use in the field, as a result of which the Company received a technology access fee of $18,000 while retaining a 50% membership interest in Intrexon Energy Partners II. The IEPII Investors made initial capital contributions, totaling $18,000 in the aggregate, in exchange for pro rata membership interests in Intrexon Energy Partners II totaling 50%. In December 2015, the owners of Intrexon Energy Partners II made a capital contribution of $4,000, half of which was paid by the Company. Precigen has committed to make additional capital contributions of up to $10,000, and the IEPII Investors, as a group and pro rata in accordance with their respective membership interests in Intrexon Energy Partners II, have committed to make additional capital contributions of up to $10,000, at the request of Intrexon Energy Partners II's board of managers (the "Intrexon Energy Partners II Board") and subject to certain limitations. As of December 31, 2020, the Company's remaining commitment was $10,000. Intrexon Energy Partners II is governed by the Intrexon Energy Partners II Board, which has five members. One member of the Intrexon Energy Partners II Board is designated by the Company and four members are designated by a majority of the IEPII Investors. The Company and the IEPII Investors have the right, but not the obligation, to make additional capital contributions above the initial limits when and if solicited by the Intrexon Energy Partners II Board.

The Company's investment in Intrexon Energy Partners II was $(435) and $(435) as of December 31, 2020 and 2019, respectively, and is included in other accrued liabilities in the accompanying consolidated balance sheets, which represents the Company's equity in losses for contractually committed contributions to Intrexon Energy Partners II.

See Notes 3 and 17 for additional discussion regarding the Company's investment in Intrexon Energy Partners II.

Intrexon T1D Partners

In March 2016, the Company and certain investors (the "T1D Investors"), including affiliates of Third Security, entered into a Limited Liability Company Agreement that governs the affairs and conduct of business of Intrexon T1D Partners, LLC ("Intrexon T1D Partners"), a JV formed to utilize the Company's proprietary ActoBiotics platform to develop and commercialize products to treat type 1 diabetes. The Company also entered into an ECC with Intrexon T1D Partners that provided the exclusive rights to the Company's technology for use in the field, as a result of which the Company received a technology access fee of $10,000 while retaining a 50% membership interest in Intrexon T1D Partners. The T1D Investors made initial capital contributions, totaling $10,000 in the aggregate, in exchange for pro rata membership interests in Intrexon T1D Partners totaling 50%. Precigen committed to make capital contributions of up to $5,000, and the T1D Investors, as a group and pro rata in accordance with their respective membership interests in Intrexon T1D Partners, committed to make additional capital contributions of up to $5,000, at the request of Intrexon T1D Partners' board of managers, which consisted of two members appointed by the Company and three members appointed by a majority of the T1D Investors. The Company satisfied its commitment in 2018.

In November 2018, the Company, together with its wholly owned subsidiary ActoBio, issued 1,933,737 shares of Precigen common stock valued at $18,970 to the T1D Investors to acquire their ownership interest in Intrexon T1D Partners. Following the transaction, the Company owns 100% of the membership interests in Intrexon T1D Partners, including the rights that had been previously licensed to Intrexon T1D Partners by the Company in the ECC. Intrexon T1D Partners did not meet the definition of a business, and accordingly, the transaction was accounted for as an asset acquisition. By reacquiring the rights previously licensed to Intrexon T1D Partners, the Company was relieved from its obligations under the original ECC and therefore wrote off $8,517 of deferred revenue in November 2018 as part of the transaction. The remaining value of $10,453 was considered in-process research and development related to the reacquired rights under the ECC and expensed immediately.

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6. 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.

See Note 2 for additional discussion of the Company's revenue recognition policy related to collaboration and licensing payments.

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, 2020, 2019 and 2018.

	Year Ended December 31,		
	2020	2019	2018
ZIOPHARM Oncology, Inc.	$ 200	$ 2,171	$ 16,298
Ares Trading S.A.	—	—	11,175
Oragenics, Inc.	3,053	(564)	1,353
Intrexon T1D Partners, LLC	—	—	2,502
Intrexon Energy Partners, LLC	—	2,596	6,929
Intrexon Energy Partners II, LLC	—	1,217	2,998
Castle Creek Biosciences, Inc.	17,810	3,713	1,394
Harvest start-up entities (1)	—	4,862	14,447
Other	145	64	12,444
Total (2)	$ 21,208	$ 14,059	$ 69,540

(1) For the years ended December 31, 2019 and 2018, revenue recognized from collaborations with Harvest start-up entities include Thrive Agrobiotics, Inc.; Exotech Bio, Inc.; and AD Skincare, Inc. For the year ended December 31, 2018, revenue recognized from collaborations with Harvest start-up entities also include Genten Therapeutics and CRS Bio.

(2) Collaboration and licensing revenues recognized for the years ended December 31, 2020, 2019 and 2018, include the recognition of $20,205, $7,505, and $39,446, respectively, associated with upfront and milestone payments which were previously deferred.

The following is a summary of the terms of the Company's significant collaborations and licensing agreements from continuing operations.

ZIOPHARM Collaborations

In January 2011, the Company entered into an ECC with ZIOPHARM Oncology, Inc. ("ZIOPHARM"), a related party at the time. Pursuant to the ECC, ZIOPHARM received a license to the Company's technology platform within the field of oncology as defined more specifically in the agreement. The Company received upfront consideration upon execution of the ECC in the form of ZIOPHARM common shares valued at $17,457, shares of ZIOPHARM common stock valued at $18,330 as consideration upon achievement of a milestone in 2012, and reimbursements for research and development services performed during the ECC. In March 2015, in conjunction with the worldwide License and Collaboration Agreement ("Merck Agreement") with Ares Trading S.A. ("Ares Trading"), a wholly owned subsidiary of Merck KGaA, and ZIOPHARM discussed below, the Company and ZIOPHARM amended their existing ECC. The amendment modified the scope of the ECC

in connection with the Merck Agreement and provided that the Company would pay to ZIOPHARM 50% of all payments received for upfront fees, milestones and royalties under the Merck Agreement. See discussion of the Merck Agreement below.

In June 2016, the Company amended the ECC and a prior ECC that was mutually terminated in December 2017 to reduce the rate of royalty that the Company was entitled to receive on certain products commercialized pursuant to the agreements. As consideration for execution of the amendments, ZIOPHARM issued the Company shares of ZIOPHARM's Series 1 Preferred Stock. The Company allocated the consideration received to each ECC based on the cumulative value of upfront and milestone payments previously received pursuant to that ECC. See Note 18 for additional discussion of the terms of the preferred stock and the accounting treatment.

In October 2018, the Company, through its wholly owned subsidiary PGEN Therapeutics, entered into a license agreement (the "ZIOPHARM License Agreement") with ZIOPHARM, which terminated and replaced the terms of the original ZIOPHARM ECC, including the amendments thereto. Pursuant to the terms of the ZIOPHARM License Agreement, the Company granted ZIOPHARM an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize (i) products utilizing the Company's RheoSwitch gene switch ("RTS") to express IL-12 (the "IL-12 Products") for the treatment of cancer, (ii) chimeric antigen receptor ("CAR") products directed to (a) CD19 for the treatment of cancer (the "CD19 Products"), and (b) a second target, subject to the rights of the Company to pursue such target under the Merck Agreement, and (iii) T-cell receptor ("TCR") products (the "TCR Products") designed for neoantigens for the treatment of cancer or the treatment and prevention of human papilloma virus ("HPV") to the extent that the primary reason for such treatment or prevention is to prevent cancer, which is referred to as the HPV Field. The Company has also granted ZIOPHARM an exclusive, worldwide, royalty-bearing, sub-licensable license for certain patents relating to the Company's *Sleeping Beauty* technology to research, develop and commercialize TCR Products for both neoantigens and shared antigens for the treatment of cancer and in the HPV Field. ZIOPHARM will be solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. ZIOPHARM is required to use commercially reasonable efforts to develop and commercialize IL-12 Products and CD19 Products, and after a two-year period, the TCR Products. The Company also granted ZIOPHARM an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize products utilizing an additional construct that expresses RTS IL-12 (the "Gorilla IL-12 Products") for the treatment of cancer and in the HPV Field. ZIOPHARM is responsible for all development costs associated with each of the licensed products, other than Gorilla IL-12 Products. ZIOPHARM and the Company will share the development costs and operating profits for Gorilla IL-12 Products, with ZIOPHARM responsible for 80% of the development costs and receiving 80% of the operating profits, as defined in the ZIOPHARM License Agreement, and the Company responsible for the remaining 20% of the development costs and receiving 20% of the operating profits, except that ZIOPHARM will bear all development costs and the Company will share equally in operating profits for Gorilla IL-12 Products in the HPV Field (the "Gorilla Program").

In consideration of the licenses and other rights granted by the Company, ZIOPHARM will pay the Company an annual license fee of $100 and agreed to reimburse the Company $1,000, paid in four quarterly installments, with respect to historical Gorilla IL-12 Products (the "historical Gorilla reimbursements"). ZIOPHARM will make milestone payments, payable upon the initiation of later stage clinical trials and upon the approval of exclusively licensed programs in various jurisdictions, totaling up to an additional $52,500 for each of four exclusively licensed programs, up to an aggregate of $210,000. In addition, ZIOPHARM will pay the Company tiered royalties ranging from low-single digits to high-single digits on the net sales derived from the sales of any approved IL-12 Products and CAR products. ZIOPHARM will also pay the Company royalties ranging from low-single digits to mid-single digits on the net sales derived from the sales of any approved TCR Products, up to maximum royalty amount of $100,000 in the aggregate. ZIOPHARM will also pay the Company 20% of any sublicensing income received by ZIOPHARM relating to the licensed products.

The Company reacquired rights to research, develop and commercialize CAR products for all other targets. In addition, the Company may research, develop and commercialize products for the treatment of cancer, outside of the products exclusively licensed to ZIOPHARM. The Company will pay ZIOPHARM royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of the Company's CAR products, up to $50,000. The Company also received from ZIOPHARM reimbursement of costs incurred to transition the necessary knowledge and materials for ZIOPHARM programs for a period of one year from the effective date (the "Transition Services").

As between the parties, the Company agreed to perform all of the obligations of ZIOPHARM under the Merck Agreement, other than an obligation of exclusivity thereunder and ZIOPHARM will remain responsible for all payments owed under the Merck Agreement with respect to CD19 and the other target under the Merck Agreement as a result of ZIOPHARM's, its affiliates' or its sublicensees' exploitation of CAR products. Further, the Company is entitled to receive all rights and financial considerations with respect to all other CAR products, subject to the CAR royalties due to ZIOPHARM for such products. The ZIOPHARM License Agreement will terminate on a product-by-product and/or country-by-country basis upon the expiration of

the later to occur of (i) the expiration of the last to expire patent claim for a licensed product, or (ii) 12 years after the first commercial sale of a licensed product in such country. In addition, ZIOPHARM may terminate the ZIOPHARM License Agreement on a country-by-country or program-by-program basis following written notice to the Company, and either party may terminate the ZIOPHARM License Agreement following notice of a material breach.

Pursuant to the ZIOPHARM License Agreement, the 2016 Securities Issuance Agreement between the Company and ZIOPHARM was terminated as of the effective date of the ZIOPHARM License Agreement, all of the benefits, rights, obligations and liabilities thereunder immediately ceased and terminated and the Company returned to ZIOPHARM all of the preferred stock owned by the Company as of the Effective Date, which was valued at $158,376. See Note 18 for additional discussion of the preferred stock.

Prior to the execution of the ZIOPHARM License Agreement, the Company had $51,084 of deferred revenue remaining from the original ECC, which was related to the Company's obligations to perform under that agreement. Replacement of the original ECC with the ZIOPHARM License Agreement was a contract modification under ASC 606 that represented the termination of the original agreement and the creation of a new agreement as the remaining rights, obligations, and services to be exchanged, which were limited to the Transition Services, were distinct from those under the ECC. Therefore, the Company reviewed the various forms of consideration in the ZIOPHARM License Agreement to determine the transaction price. As the Company's obligations under the ZIOPHARM License Agreement were only related to the Transition Services and no other obligations under the ECC remained, a portion of the previously deferred revenue from the ECC was relieved, which the Company determined to be $49,329, and the remaining $1,755 was included in the transaction price. The initial annual license payment of $100 was also included in the transaction price. The remaining annual license payments and potential milestone payments were constrained at the modification date and will only be recognized when the payments become probable of being received. Royalty payments from sales of ZIOPHARM products developed pursuant to the ZIOPHARM License Agreement will be recognized when the sales occur. The Company recognized payments from Transition Services as those services were performed and recognized the transaction price of $1,855 as it performed the Transition Services required under the ZIOPHARM License Agreement.

The Company also reviewed the consideration paid and potential consideration to be paid to ZIOPHARM as part of the ZIOPHARM License Agreement, which included the $158,376 of ZIOPHARM preferred stock returned by the Company and potential royalty payments to ZIOPHARM from sales of the Company's CAR products. The Company determined the exchange of its investment in ZIOPHARM preferred stock for certain CAR rights previously licensed under the ECC (i.e., in-process research and development) and the relief of performance obligations to ZIOPHARM under the ECC constituted an exchange for distinct goods and services. Therefore, the Company wrote off the $49,329 of relieved deferred revenue and recorded an expense of $109,047 for the reacquired in-process research and development. Potential royalty payments to ZIOPHARM will be expensed as incurred as they relate to distinct goods or services.

The Company determined that the Gorilla Program represented a separate collaboration agreement under the scope of ASC 808, *Collaborative Arrangements*, ("ASC 808") and was not included in the accounting for the ZIOPHARM License Agreement under ASC 606. The Company recognized $500 of the historical Gorilla reimbursements on the contract modification date and recognized the remaining amounts when receipt became probable. The development costs and operating profits from the Gorilla Program will be recognized in accordance with ASC 808.

Merck Licensing Agreement

In March 2015, the Company signed the Merck Agreement with Ares Trading and ZIOPHARM through which the parties established a collaboration for the research and development and commercialization of certain products for the prophylactic, therapeutic, palliative or diagnostic use for cancer in humans. Pursuant to the Merck Agreement, the Company received a technology access fee of $115,000 as upfront consideration, of which $57,500 was paid to ZIOPHARM in accordance with the terms of the agreement. Upon the selection of the first two targets by Ares Trading, the Company received $10,000 in equal quarterly installments over two years.

In December 2018, the Company entered into a Securities Purchase, Assignment and Assumption Agreement (the "Merck Purchase Agreement") with Ares Trading pursuant to which the Company reacquired Ares Trading's development and commercialization rights under the Merck Agreement. As consideration for the reacquisition of the Merck Agreement, the Company issued Ares Trading 20,640,119 shares of Precigen common stock valued at $140,353 and agreed to pay Ares Trading a royalty of 10% of the net sales derived from two CAR products specified in the Merck Purchase Agreement. By reacquiring the rights previously licensed to Ares Trading, the Company is relieved of its obligations under the Merck Agreement and therefore wrote off deferred revenue of $31,826. The remaining value acquired of $108,527 was considered in-process research and development related to the reacquired rights under the Merck Agreement and expensed immediately. The

potential future royalty payments to Ares Trading do not represent consideration paid to a customer and will be recorded when the payments are probable. See Note 12 for additional discussion of this transaction.

Oragenics Collaboration

In June 2015, the Company entered into an ECC with Oragenics, a related party at the time. Pursuant to the ECC, at the transaction effective date, Oragenics received a license to the Company's technology platform within the field of biotherapeutics for use in certain treatments of oral mucositis and other diseases and conditions of the oral cavity, throat, and esophagus. Upon execution of the ECC, the Company received a technology access fee of a $5,000 convertible promissory note, which was subsequently converted to shares of Oragenics' common stock. These shares were sold in the TS Biotechnology Sale (Note 3). The Company received reimbursement payments for research and development services provided pursuant to the agreement during the ECC and manufacturing services for Company materials provided to Oragenics during the ECC. In July 2020, the Company and Oragenics mutually agreed to terminate the ECC, and accordingly, the Company recognized the remaining balance of deferred revenue associated with the ECC totaling $2,823. Following the termination of the ECC, Oragenics is no longer a related party.

Intrexon T1D Partners Collaboration

In March 2016, the Company entered into an ECC with Intrexon T1D Partners, a JV between the Company and certain investors and a related party. Pursuant to the ECC, Intrexon T1D Partners received an exclusive license to the Company's technology platform to develop and commercialize products to treat type 1 diabetes. Upon execution of the ECC, the Company received a technology access fee of $10,000. The Company received reimbursement of research and development services provided pursuant to the ECC agreement. In November 2018, the Company completed an asset acquisition with the T1D Investors, resulting in the Company owning 100% of the membership interest of Intrexon T1D Partners including all rights under the ECC (Note 5).

Genten Therapeutics, CRS Bio, and Relieve Genetics Collaborations

In 2016, the Company entered into three separate ECCs with Genten Therapeutics, CRS Bio, and Relieve Genetics, all affiliates of Harvest and related parties. The total upfront consideration received for the three collaborations was $10,933, which mostly consisted of equity interests in these entities. The Company also received reimbursements for research and development services provided pursuant to the ECCs. In September 2018, the Company completed an asset acquisition with Harvest, resulting in the Company owning 100% of the equity interests in these entities, including all rights under the ECCs (Note 4).

Intrexon Energy Partners Collaboration

In March 2014, the Company entered into an ECC with Intrexon Energy Partners, a JV between the Company and certain investors and a related party. The ECC grants Intrexon Energy Partners an exclusive license to the Company's technology platform to optimize and scale-up the Company's methane bioconversion platform for the production of certain fuels and lubricants. Upon execution of the ECC, the Company received a technology access fee of $25,000 as upfront consideration. The Company receives reimbursement payments for research and development services as provided for in the ECC agreement. The term of the ECC commenced in March 2014 and continues until March 2034 unless terminated prior to that date by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Intrexon Energy Partners upon 90 days written notice to the Company. The ECC is not active while the IEP Investors evaluate the status of the project and their desired future development activities.

Intrexon Energy Partners II Collaboration

In December 2015, the Company entered into an ECC with Intrexon Energy Partners II, a JV between the Company and certain investors and a related party. Pursuant to the ECC, Intrexon Energy Partners II received an exclusive license to the Company's technology platform to optimize and scale-up the Company's methane bioconversion platform for the production of 1,4-butanediol (BDO), a key chemical intermediate that is used to manufacture spandex, polyurethane, plastics, and polyester. Upon execution of the ECC, the Company received a technology access fee of $18,000 and is entitled to reimbursement of research and development services as provided for in the ECC agreement. The term of the ECC commenced in December 2015 and continues until December 2035; termination prior to that date may be initiated (i) by either party in the event of certain material breaches defined in the agreement or (ii) may be terminated voluntarily by Intrexon Energy Partners II upon 90 days written notice to the Company. The ECC is not active while the IEPII Investors evaluate the status of the project and their desired future development activities.

Exotech Bio, AD Skincare, and Thrive Agrobiotics Collaborations

In 2015 and 2016, the Company entered into three separate ECCs with Exotech Bio, Inc. ("Exotech Bio"), AD Skincare, Inc. ("AD Skincare"), and Thrive Agrobiotics, Inc. ("Thrive Agrobiotics"), all affiliates of Harvest and related parties at the time. The total upfront consideration received for the three collaborations was $11,000, which consisted of equity interests in each of these entities. The Company also received reimbursements for research and development services provided pursuant to the ECCs. In conjunction with a settlement agreement with Harvest (Note 17), these ECCs were terminated in December 2020, and the previously licensed technology rights reverted to the Company pursuant to the ECCs. The Company wrote off the remaining balance of deferred revenue associated with these ECCs totaling $6,993 as an offset to the loss recognized on the settlement agreement.

Castle Creek Collaborations

In October 2012, the Company entered into an ECC (the "2012 Castle Creek ECC") with Castle Creek Biosciences, Inc. ("Castle Creek", formerly known as Fibrocell Science, Inc.). Castle Creek was a publicly traded cell and gene therapy company focused on diseases affecting the skin and connective tissue and a related party until it was acquired in December 2019 by Castle Creek Pharmaceutical Holdings, Inc. ("Castle Creek Pharmaceutical"), a privately held company focused on developing medicine for rare genetic disorders. Pursuant to the 2012 Castle Creek ECC, at the transaction effective date, Castle Creek received a license to the Company's technology platform to develop and commercialize genetically modified and non-genetically modified autologous fibroblasts and autologous dermal cells in the United States of America. The Company received (i) upfront consideration upon execution of the ECC in the form of Castle Creek common stock valued at $7,576, (ii) shares of Castle Creek common stock valued at $7,612 as consideration for a 2013 amendment which expanded the field of use defined in the agreement, (iii) sublicensing fees totaling $3,750 in the form of cash in 2019, and (iv) reimbursements for research and development services performed during the ECC.

In March 2020, the Company and Castle Creek terminated the 2012 Castle Creek ECC by mutual agreement ("Termination Agreement") with the parties agreeing that the two drug product candidates, FCX-007 and FCX-013, pursuant to the ECC would be treated as "Retained Products" under the terms of the 2012 Castle Creek ECC. As Retained Products, Castle Creek retains a license under the 2012 Castle Creek ECC to continue to develop and commercialize the Retained Products within the field of use of the 2012 Castle Creek ECC for so long as Castle Creek continues to pursue such development and commercialization. No further licenses to the Company's technology within the field of use are provided to Castle Creek. On a quarterly basis, Castle Creek will pay the Company royalties of 7% of net sales up to $25,000 and 14% of net sales above $25,000 on each Retained Product from the 2012 Castle Creek ECC, as defined in the agreement. Additionally, the Termination Agreement provides for the Company to perform certain drug product manufacturing activities related to the Retained Products. The Termination Agreement was accounted for as a new contract, and the remaining deferred revenue from the 2012 Castle Creek ECC is being recognized prospectively as the manufacturing activities are performed.

In December 2015, the Company entered into a second ECC with Castle Creek (the "2015 Castle Creek ECC"). Pursuant to the ECC, at the transaction effective date, Castle Creek received a license to the Company's technology platform to develop and commercialize genetically-modified fibroblasts to treat chronic inflammatory and degenerative diseases of the joint, including arthritis and related conditions. In February 2020, the Company and Castle Creek mutually agreed to terminate the 2015 Castle Creek ECC, and accordingly, the Company recognized the remaining balance of deferred revenue associated with the 2015 Castle Creek ECC totaling $10,000.

Deferred Revenue

Deferred revenue primarily consists of consideration received for the Company's collaboration and licensing agreements. Deferred revenue consisted of the following:

	December 31,	
	2020	2019
Collaboration and licensing agreements	$ 23,420	$ 50,593
Prepaid product and service revenues	2,126	2,805
Other	277	435
Total	$ 25,823	$ 53,833
Current portion of deferred revenue	$ 2,800	$ 5,697
Long-term portion of deferred revenue	23,023	48,136
Total	$ 25,823	$ 53,833

Revenue is recognized under collaboration and licensing agreements as services are performed. Certain of the arrangements are not active while the other party evaluates the status of the project and its desired future development activities. The following table summarizes the remaining balance of deferred revenue associated with upfront and milestone payments for each significant counterparty to a collaboration or licensing agreement as of December 31, 2020 and 2019, as well as the estimated remaining performance period as of December 31, 2020.

	Average Remaining Performance Period (Years)	December 31,	
		2020	2019
Oragenics, Inc.	0.0	$ —	$ 2,864
Intrexon Energy Partners, LLC	3.2	8,362	8,362
Intrexon Energy Partners II, LLC	3.9	12,843	12,843
Castle Creek Biosciences, Inc.	1.0	379	17,697
Harvest start-up entities (1)	0.0	—	6,993
Other	2.2	1,836	1,834
Total		$ 23,420	$ 50,593

(1) As of December 31, 2019, the balance of deferred revenue for collaborations with Harvest start-up entities includes Thrive Agrobiotics, Exotech Bio, and AD Skincare.

7. Short-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, 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
United States government debt securities	$ 48,048	$ 14	$ (1)	$ 48,061
Certificates of deposit	264	—	—	264
Total	$ 48,312	$ 14	$ (1)	$ 48,325

The following table summarizes the amortized cost, gross unrealized gains and losses, and fair value of available-for-sale investments as of December 31, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
United States government debt securities	$ 8,989	$ 7	$ —	$ 8,996
Certificates of deposit	264	—	—	264
Total	$ 9,253	$ 7	$ —	$ 9,260

See Notes 2 and 8 for further discussion on the Company's method for determining the fair value of its assets.

As of December 31, 2020, all of the available-for-sale investments were due within one year based on their contractual maturities.

Changes in market interest rates and bond yields cause certain investments to fall below their cost basis, resulting in unrealized losses on investments. The unrealized losses of the Company's investments were primarily a result of unfavorable changes in interest rates subsequent to the initial purchase of these investments and are not significant as of December 31, 2020.

8. Fair Value Measurements

The carrying amount of cash and cash equivalents, receivables, accounts payable, accrued compensation and benefits, other accrued liabilities, and related party payables approximate fair value due to the short maturity of these instruments.

Assets

The following table presents the placement in the fair value hierarchy of financial assets that are measured at fair value on a recurring basis, including the items for which the fair value option has been elected, as of December 31, 2020:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2020
Assets				
United States government debt securities	$ —	$ 48,061	$ —	$ 48,061
Other	—	264	—	264
Total	$ —	$ 48,325	$ —	$ 48,325

The following table presents the placement in the fair value hierarchy of financial assets that are measured at fair value on a recurring basis, including the items for which the fair value option has been elected, as of December 31, 2019:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2019
Assets				
United States government debt securities	$ —	$ 8,996	$ —	$ 8,996
Other	—	264	—	264
Total	$ —	$ 9,260	$ —	$ 9,260

The method used to estimate the fair value of the Level 2 short-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. During 2019, the Company's equity securities of AquaBounty (Note 1) and preferred stock owned in one of its collaborators (Note 18) were classified as Level 3 within the fair value hierarchy prior to disposition.

The following table summarizes the changes in the Level 3 investments during the year ended December 31, 2019.

	2019
Beginning balance	$ 191
Retained interest in deconsolidated subsidiary	14,239
Dividend income from investments in preferred stock	48
Net unrealized appreciation in the fair value of the investments in equity securities and preferred stock	7,446
Proceeds from sale of equity securities	(21,587)
Proceeds to be received from preferred stock	(337)
Ending balance	$ —

Liabilities

The carrying values of the Company's long-term debt, excluding the Convertible Notes, approximates fair value due to the length of time to maturity and/or the existence of interest rates that approximate prevailing market rates.

The calculated fair value of the Convertible Notes (Note 12) was approximately $165,000 and $126,000 as of December 31, 2020 and 2019, respectively, and is based on the recent third-party trades of the instrument as of the balance sheet date. The fair value of the Convertible Notes is classified as Level 2 within the fair value hierarchy as there is not an active market for the Convertible Notes, however, third-party trades of the instrument are considered observable inputs. The Convertible Notes are reflected on the accompanying consolidated balance sheets at amortized cost, which was $168,147 and $157,560 as of December 31, 2020 and 2019, respectively.

During the year ended December 31, 2020, the Company's contingent consideration liability, which was $585 as of December 31, 2019, was reduced to $0 as the period for potential payment of this contingent consideration expired without payment in June 2020. The contingent consideration liability was remeasured to fair value at each reporting date until the contingency was resolved, and those changes in fair value were recognized in earnings. The changes in the fair value of the Level 3 liability during the years ended December 31, 2020 and 2019 were as follows:

	2020	2019
Beginning balance	$ 585	$ 585
Change in fair value of contingent consideration recognized in selling, general, and administrative expenses	(585)	—
Ending balance	$ —	$ 585

See Notes 10 and 11 for discussion of non-recurring fair value estimates used in calculating impairment charges recorded during the year ended December 31, 2020.

9. Inventory

Inventory consists of the following:

	December 31,	
	2020	2019
Supplies, embryos and other production materials	$ 2,060	$ 2,282
Work in process	2,348	3,702
Livestock	5,047	7,553
Feed	1,904	2,560
Total inventory	$ 11,359	$ 16,097

10. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following:

	December 31,	
	2020	2019
Land and land improvements	$ 9,844	$ 9,814
Buildings and building improvements	12,088	11,765
Furniture and fixtures	1,228	1,025
Equipment	31,150	33,707
Leasehold improvements	6,260	6,607
Breeding stock	868	5,191
Computer hardware and software	5,684	6,877
Construction and other assets in progress	2,754	5,229
	69,876	80,215
Less: Accumulated depreciation and amortization	(34,952)	(36,263)
Property, plant and equipment, net	$ 34,924	$ 43,952

Depreciation expense was $7,449, $8,222 and $8,946 for the years ended December 31, 2020, 2019 and 2018, respectively.

During the year ended December 31, 2020, the Company recorded impairment losses of $920, which is included in impairment of other noncurrent assets on the accompanying consolidated statement of operations, primarily related to right-of-use assets at certain of the Company's leased locations.

During the year ended December 31, 2019, the Company recorded impairment losses of $448, which is included in impairment of other noncurrent assets on the accompanying consolidated statement of operations, related to the impairment of property, plant and equipment in conjunction with the closing of two of its operating units during the third quarter of 2019.

11. Goodwill and Intangible Assets, Net

The changes in the carrying amount of goodwill for the years ended December 31, 2020 and 2019, are as follows:

	2020	2019
Beginning of year	$ 54,119	$ 83,992
Impairment	—	(29,820)
Foreign currency translation adjustments	244	(53)
End of year	$ 54,363	$ 54,119

The Company had $43,643 of cumulative impairment losses as of December 31, 2020 and 2019.

For the year ended December 31, 2019, during the Company's annual goodwill impairment test, the Company determined it was more-likely-than-not that the fair value of the Trans Ova reporting unit was less than its carrying amount. As a result, the Company compared the carrying amount of the Trans Ova reporting unit to the fair value and determined the carrying amount exceeded the fair value resulting in a $29,642 goodwill impairment charge for the excess carrying value. Additionally, the Company recorded $178 of goodwill impairment in conjunction with the closing of two of its reporting units during the third quarter of 2019.

See Note 20 for information regarding goodwill by reportable segment.

Intangible assets consist of the following as of December 31, 2020:

	Weighted Average Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	16.0	$ 96,927	$ (34,412)	$ 62,515
Customer relationships	6.4	10,850	(9,340)	1,510
Trademarks	8.4	5,900	(4,529)	1,371
Total		$ 113,677	$ (48,281)	$ 65,396

Intangible assets consist of the following as of December 31, 2019:

	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	$ 90,659	$ (26,619)	$ 64,040
Customer relationships	10,700	(8,440)	2,260
Trademarks	5,900	(3,854)	2,046
Total	$ 107,259	$ (38,913)	$ 68,346

In the year ended December 31, 2018, the Company recorded a $16,027 loss related to the abandonment of certain developed technologies that the Company ceased using in the fourth quarter of 2018. The Company does not expect to use these technologies as a defensive asset or market them for sale in the future. Because these technologies were used in combination with other technologies, the identifiable cash flows did not result in an impairment loss; however, because the Company made a decision to abandon the assets, it recorded the charge to research and development expense.

Amortization expense was $7,593, $7,920 and $11,666 for the years ended December 31, 2020, 2019 and 2018, respectively. Estimated aggregate amortization expense for definite lived intangible assets is expected to be as follows:

2021	$ 7,704
2022	6,908
2023	5,742
2024	5,432
2025	5,419
Thereafter	34,191
Total	$ 65,396

12. Lines of Credit and Long-Term Debt

Lines of Credit

Trans Ova has a $5,000 revolving line of credit with First National Bank of Omaha that matures on April 1, 2021. The line of credit bears interest at the greater of the U.S. Prime Rate or 3.00%, and the actual rate was 3.25% as of December 31, 2020. As of December 31, 2020, there was no outstanding balance. The amount available under the line of credit is based on eligible accounts receivable and inventory up to the maximum principal amount and was $5,000 as of December 31, 2020. The line of credit is collateralized by certain of Trans Ova's assets and contains certain restricted covenants that include maintaining minimum tangible net worth and working capital and maximum allowable annual capital expenditures.

Exemplar has a $700 revolving line of credit with American State Bank that matures on October 31, 2021. The line of credit bears interest at 4.00% per annum. As of December 31, 2020, there was no outstanding balance.

Long-Term Debt

Long-term debt consists of the following:

	December 31,	
	2020	2019
Convertible debt	$ 168,147	$ 213,771
Notes payable	3,655	4,089
Other	80	131
Long-term debt	171,882	217,991
Less current portion	360	31,670
Long-term debt, less current portion	$ 171,522	$ 186,321

Convertible Debt

Precigen 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 (together with the Base Indenture, the "Indenture"). Precigen received net proceeds of $193,958 after deducting underwriting discounts and offering expenses of $6,042.

The Convertible Notes are senior unsecured obligations of Precigen and bear interest at a rate of 3.50% per year, payable semiannually in arrears on January 1 and July 1 of each year beginning on January 1, 2019. The Convertible Notes mature on July 1, 2023 and are repayable in cash, unless earlier repurchased or converted. Upon conversion by the holders, the Convertible Notes are convertible into cash, shares of Precigen's common stock or a combination of cash and shares, at Precigen's election. The initial conversion rate of the Convertible Notes is 58.6622 shares of Precigen common stock per $1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately $17.05 per share of common stock). The conversion rate is subject to adjustment upon the occurrence of certain events, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date as defined in the Indenture, Precigen will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such a corporate event in certain circumstances. Prior to April 1, 2023, the holders may convert the Convertible Notes at their option only upon the satisfaction of the following circumstances:

- During any calendar quarter commencing after the calendar quarter ended on September 30, 2018, if the last reported sales price of Precigen's common stock for at least 20 trading days (whether or not consecutive) during the last 30 consecutive trading days of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

- During the five business day period after any five consecutive trading day period in which the trading price, as defined in the Indenture, for the Convertible Notes is less than 98% of the product of the last reported sales price of Precigen's common stock and the conversion rate for the Convertible Notes on each such trading day; or

- Upon the occurrence of specified corporate events as defined in the Indenture.

None of the above events allowing for conversion prior to April 1, 2023 occurred during the year ended December 31, 2020. On or after April 1, 2023 until June 30, 2023, holders may convert their Convertible Notes at any time. Precigen may not redeem the Convertible Notes prior to the maturity date.

If Precigen undergoes a fundamental change, as defined in the Indenture, holders of the Convertible Notes may require Precigen to repurchase for cash all or any portion of their Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The Indenture contains customary events of default, as defined in the agreement, and, if any of the events occur, could require repayment of a portion or all of the Convertible Notes, including accrued and unpaid interest. Additionally, the Indenture provides that Precigen shall not consolidate with or merge with or into, or sell, convey, transfer or lease all or substantially all of its properties and assets to, another entity, unless (i) the surviving entity is organized under the laws of the United States and such entity expressly assumes all of Precigen's obligations under the Convertible Notes

and the Indenture; and (ii) immediately after such transaction, no default or event of default has occurred and is continuing under the Indenture.

The net proceeds received from the issuance of the Convertible Notes were initially allocated between long-term debt, the liability component, in the amount of $143,723, and additional paid-in capital, the equity component, in the amount of $50,235. Additional paid-in capital was further reduced by $13,367 of deferred taxes resulting from the difference between the carrying amount and the tax basis of the Convertible Notes that is created by the equity component, which also resulted in deferred tax benefit recognized from the reversal of valuation allowances on the then current year domestic operating losses in the same amount (Note 13). As of December 31, 2020, the outstanding principal balance on the Convertible Notes was $200,000 and the carrying value of long-term debt was $168,147. The effective interest rate on the Convertible Notes, including amortization of the long-term debt discount and debt issuance costs, is 11.02%. As of December 31, 2020, the unamortized long-term debt discount and debt issuance costs totaled $31,853.

The components of interest expense related to the Convertible Notes were as follows:

	Year Ended December 31,		
	2020	2019	2018
Cash interest expense	$ 7,000	$ 7,000	$ 3,462
Non-cash interest expense	10,587	9,459	4,378
Total interest expense	$ 17,587	$ 16,459	$ 7,840

Accrued interest of $3,500 is included in other accrued liabilities on the accompanying consolidated balance sheet as of December 31, 2020.

ActoBio Convertible Notes

In September 2018, ActoBio issued $30,000 of convertible promissory notes (the "ActoBio Notes") to a related party in conjunction with an asset acquisition with Harvest (Note 4). The ActoBio Notes, which accrued interest at 3.0% compounded annually ("accrued PIK interest"), matured in September 2020. The Company issued 6,293,402 shares of Precigen common stock upon conversion of the outstanding principal balance and accrued PIK interest at maturity. Interest expense was $616, $921, and $290 for the years ended December 31, 2020, 2019 and 2018, respectively.

Precigen and PGEN Therapeutics Convertible Note

In December 2018, in conjunction with the Merck Purchase Agreement (Note 6), Precigen and PGEN Therapeutics jointly and severally issued a $25,000 convertible note (the "Merck Note") to Ares Trading in exchange for cash. The Merck Note had a maturity date of June 28, 2021 although it automatically converted to Precigen common stock on the first trading day following the second anniversary of issuance, which is December 2020, if not otherwise converted prior to that date. In October 2020, pursuant to the terms of the Merck Note, Ares Trading voluntarily elected to convert the entire $25,000 outstanding into 6,758,400 shares of Precigen common stock. The shares are restricted from resale by Ares Trading for a period of 180 days from the date of issuance.

Notes Payable

Trans Ova has a note payable to American State Bank that matures in April 2033 and had an outstanding principal balance of $3,655 as of December 31, 2020. Trans Ova pays monthly installments of $39, which includes interest at 3.95%. The note payable is collateralized by certain of Trans Ova's real estate and non-real estate assets.

Future Maturities

Future maturities of long-term debt as of December 31, 2020 are as follows:

2021	$ 360
2022	397
2023	200,360
2024	374
2025	389
Thereafter	1,855
Total	$ 203,735

13. Income Taxes

The components of loss from continuing operations before income taxes are presented below:

	Year Ended December 31,		
	2020	2019	2018
Domestic	$ (97,313)	$ (167,990)	$ (394,580)
Foreign	(6,542)	(3,274)	(1,332)
Loss from continuing operations before income taxes	$ (103,855)	$ (171,264)	$ (395,912)

The components of income tax benefit from continuing operations are presented below:

	Year Ended December 31,		
	2020	2019	2018
United States federal income taxes:			
Current	$ —	$ —	$ (31)
Deferred	37	(561)	(11,855)
Foreign income taxes:			
Current	74	34	68
Deferred	(204)	(230)	635
State income taxes:			
Current	—	—	113
Deferred	11	(173)	(4,355)
Income tax benefit from continuing operations	$ (82)	$ (930)	$ (15,425)

Income tax benefit from continuing operations for the years ended December 31, 2020, 2019 and 2018 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:

	2020	2019	2018
Computed statutory income tax benefit from continuing operations	$ (21,810)	$ (35,965)	$ (83,141)
State and provincial income tax benefit, net of federal income taxes	(5,167)	(5,494)	(21,717)
Nondeductible stock based compensation	5,709	10,303	4,696
Nondeductible officer compensation	728	595	294
Impairment of goodwill	—	273	—
Research and development tax incentives	(524)	(1,772)	(185)
Acquisition and internal restructuring transaction costs	—	260	52
Reacquired in-process research and development	—	—	2,696
Change in deferred state tax rate	—	—	8,666
United States-foreign rate differential	(21)	(76)	215
Other, net	(306)	(72)	(3,517)
	(21,391)	(31,948)	(91,941)
Change in valuation allowance for deferred tax assets	21,309	31,018	76,516
Total income tax benefit from continuing operations	$ (82)	$ (930)	$ (15,425)

The tax effects of temporary differences that comprise the deferred tax assets and liabilities included in continuing operations as of December 31, 2020 and 2019, are as follows:

	2020	2019
Deferred tax assets		
Allowance for doubtful accounts	$ 1,816	$ 2,140
Inventory	289	415
Equity securities and investments in affiliates	570	11,933
Property, plant and equipment	1,882	1,830
Intangible assets	74,981	85,308
Accrued liabilities	1,834	3,385
Lease liabilities	6,140	10,035
Stock-based compensation	16,402	19,389
Deferred revenue	7,423	14,876
Research and development tax credits	10,210	9,686
Investments in subsidiaries included in discontinued operations	—	8,592
Net operating, capital loss, and interest expense carryforwards	275,519	196,663
Total deferred tax assets	397,066	364,252
Less: Valuation allowance	387,348	349,008
Net deferred tax assets	9,718	15,244
Deferred tax liabilities		
Right-of-use assets	5,011	8,091
Long-term debt	7,604	9,987
Total deferred tax liabilities	12,615	18,078
Net deferred tax liabilities included in continuing operations	$ (2,897)	$ (2,834)

Activity within the valuation allowance for deferred tax assets included in continuing operations during the years ended December 31, 2020, 2019 and 2018 was as follows:

	2020	2019	2018
Valuation allowance at beginning of year	$ 349,008	$ 292,217	$ 211,078
Increase (decrease) in valuation allowance as a result of			
Mergers and acquisitions, net	—	—	418
Deconsolidation of AquaBounty	—	(3,504)	—
Establishment of deferred taxes for subsidiaries included in discontinued operations	—	8,592	—
Current year continuing operations	21,309	31,018	98,549
Discontinued operations treated as asset sales	7,977	10,585	3,832
Discontinued operations related to MBP Titan	8,019	9,663	8,735
Adoption of ASC 842	—	512	—
Adoption of ASC 606	—	—	(7,477)
Equity component of long-term debt	—	—	(13,367)
Change in deferred state tax rate	—	—	(8,666)
Foreign currency translation adjustment	1,035	(75)	(885)
Valuation allowance at end of year	$ 387,348	$ 349,008	$ 292,217

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 certain 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 components of the deferred tax assets and liabilities as of the date of the mergers and acquisitions by the Company prior to consideration of the valuation allowance are substantially similar to the components of deferred tax assets presented herein.

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, however as of December 31, 2020, all such limited losses applicable to Precigen, other than losses inherited via acquisition, have been fully utilized. As of December 31, 2020, approximately $42,100 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, 2020, the Company has net operating loss carryforwards for United States federal income tax purposes of approximately $756,200 available to offset future taxable income, including approximately $503,500 generated after 2017, United States capital loss carryforwards of approximately $211,500, and federal and state research and development tax credits of approximately $10,200, prior to consideration of annual limitations that may be imposed under Section 382. Net operating loss carryforwards generated prior to 2018 will begin to expire in 2022, and capital loss carryforwards will expire if unutilized beginning in 2024. The Company's foreign subsidiaries included in continuing operations have foreign loss carryforwards of approximately $82,300, most of which do not expire.

As of December 31, 2020, the Company's direct foreign subsidiaries included in continuing operations had accumulated deficits of approximately $21,200. Future distributions of accumulated earnings of the Company's direct foreign subsidiaries may be subject to United States income and foreign withholding taxes.

The Company and its subsidiaries do not have material unrecognized tax benefits as of December 31, 2020. The Company does not anticipate significant changes in the amount of unrecognized tax benefits in the next 12 months. The Company's tax returns for years 2004 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.

14. Shareholders' Equity

Issuances of Precigen Common Stock

Concurrent with entering into the TS Biotechnology Sale on January 1, 2020, the Company also entered into a subscription agreement with TS Biotechnology pursuant to which TS Biotechnology purchased 5,972,696 shares of the Company's common stock for $35,000 on January 31, 2020.

In January 2018, Precigen closed a public offering of 6,900,000 shares of its common stock, including 1,000,000 shares of common stock purchased by affiliates of Third Security. The net proceeds of the offering were $82,374, after deducting underwriting discounts of $3,688 and offering expenses of $188, all of which were capitalized.

See Notes 12, 17, and 23 for discussion regarding additional issuances of Precigen common stock.

Share Lending Agreement

Concurrently with the offering of the Convertible Notes (Note 12), 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 will terminate, and the Borrowed Shares will be returned to Precigen within five business days of such termination, upon (i) termination by the Share Borrower or (ii) the earliest to occur of (a) October 1, 2023 and (b) the date, if any, on which the Share Lending Agreement is either mutually terminated or terminated by one party upon a default by the other party. The Share Borrower maintains collateral in the form of cash or certain permitted non-cash collateral with a market value at least equal to the market value of the Borrowed Shares as security for the obligation of the Share Borrower to return the Borrowed Shares when required by the terms above. The Borrowed Shares were offered and sold to the public at a price of $13.37 per share under a registered offering (the "Borrowed Shares Offering"). Precigen did not receive any proceeds from the sale of the Borrowed Shares to the public or any lending fees from the Share Lending Agreement. The Share Borrower or its affiliates received all the proceeds from the sale of the Borrowed Shares to the public. Affiliates of Third Security purchased all of the shares of common stock in the Borrowed Shares Offering.

The Share Lending Agreement was entered into at fair value and met the requirements for equity classification. Therefore, the value is netted against the issuance of the Borrowed Shares in additional paid-in capital. Additionally, the Borrowed Shares are not included in the denominator for loss per share attributable to Precigen shareholders unless the Share Borrower defaults on the Share Lending Agreement.

Issuances of AquaBounty Common Stock

In March 2019, AquaBounty completed an underwritten public offering that resulted in net proceeds of $6,611 after deducting discounts, fees, and expenses. See Note 1 for additional discussion of issuances of AquaBounty common stock in April 2019, which resulted in the deconsolidation of AquaBounty.

In January 2018, AquaBounty completed an underwritten public offering that resulted in net proceeds of $10,616 after deducting discounts, fees and expenses. As part of this offering, Precigen purchased $5,000 of additional AquaBounty common stock. In October 2018, certain investors exercised warrants acquired from the January 2018 offering, resulting in additional net proceeds of $4,316, including $3,077 from Precigen.

Components of Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss) are as follows:

	December 31,	
	2020	2019
Unrealized gain on investments	$ 13	$ 7
Income (loss) on foreign currency translation adjustments	3,984	(27,475)
Total accumulated other comprehensive income (loss)	$ 3,997	$ (27,468)

See Note 3 for further discussion of the release of cumulative losses on foreign currency translation adjustments upon the closing of the TS Biotechnology Sale.

15. Share-Based Payments

The Company measures the fair value of stock options and RSUs 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. Stock-based compensation costs included in the consolidated statements of operations are presented below:

	Year Ended December 31,		
	2020	2019	2018
Cost of products	$ 10	$ 20	$ 78
Cost of services	134	220	237
Research and development	1,815	3,478	5,017
Selling, general and administrative	17,787	11,380	25,222
Discontinued operations	(1,380)	3,852	5,742
Total	$ 18,366	$ 18,950	$ 36,296

Precigen Stock Option Plans

In April 2008, Precigen adopted the 2008 Equity Incentive Plan (the "2008 Plan") for employees and nonemployees pursuant to which Precigen's board of directors granted share based awards, including stock options, to officers, key employees and nonemployees. Upon the effectiveness of the 2013 Omnibus Incentive Plan (the "2013 Plan"), no new awards may be granted under the 2008 Plan. As of December 31, 2020, there were 185,078 stock options outstanding under the 2008 Plan.

Precigen adopted the 2013 Plan for employees and nonemployees pursuant to which Precigen's board of directors may grant share-based awards, including stock options, and shares of common stock, to employees, officers, consultants, advisors, and nonemployee directors. The 2013 Plan became effective in August 2013, and as of December 31, 2020, there were 27,000,000 shares authorized for issuance under the 2013 Plan, of which 10,225,570 stock options and 1,176,629 RSUs were outstanding and 7,055,010 shares were available for grant.

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, 2020, there were 5,000,000 shares authorized for issuance under the 2019 Plan, of which 845,248 stock options and 551,083 RSUs were outstanding and 2,432,624 shares were available for grant.

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 if the stock options are replacement options in accordance with certain United States Treasury regulations. Virtually all stock options have ten-year terms 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)
Balances at December 31, 2017	11,382,747	$ 28.99	7.32
Granted	1,470,339	14.26	
Exercised	(45,159)	(6.59)	
Forfeited	(929,596)	(21.48)	
Expired	(785,268)	(26.25)	
Balances at December 31, 2018	11,093,063	27.95	6.81
Granted	1,556,575	6.52	
Exercised	(19,887)	(3.17)	
Forfeited	(1,236,326)	(24.92)	
Expired	(2,371,143)	(38.53)	
Balances at December 31, 2019	9,022,282	21.94	6.10
Granted	5,693,498	10.03	
Exercised	(30,061)	(3.88)	
Forfeited	(976,324)	(15.47)	
Expired	(2,453,499)	(26.53)	
Balances at December 31, 2020	11,255,896	15.53	7.25
Exercisable at December 31, 2020	5,437,667	19.61	5.61

Total unrecognized compensation costs related to unvested awards as of December 31, 2020 were $13,842, and are expected to be recognized over a weighted-average period of approximately 2.75 years.

The weighted average grant date fair value of options granted during 2020, 2019 and 2018 was $2.98, $3.79 and $7.94, respectively. The aggregate intrinsic value of options exercised during 2020, 2019 and 2018 was $51, $66 and $356, 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, 2020:

	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**
$ 1.55 — $ 5.95	3,259,685	$ 4.63	8.92	$ 18,157	1,271,310	$ 3.11	8.73	$ 9,018
$ 6.06 — $ 15.09	2,261,216	11.01	8.23	1,325	345,788	9.09	4.76	689
$ 15.80 — $ 20.94	3,028,309	18.85	7.38	—	1,216,258	19.82	5.62	—
$ 21.13 — $ 36.84	2,303,371	26.33	4.32	—	2,200,996	26.52	4.22	—
$ 37.88 — $ 47.35	403,315	42.26	4.01	—	403,315	42.26	4.01	—
	11,255,896	$ 15.53	7.25	$ 19,482	5,437,667	$ 19.61	5.61	$ 9,707

The following table summarizes additional information about stock options outstanding as of December 31, 2019:

	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
$ 3.17 — $ 8.60	1,612,219	$ 6.40	8.08	$ 473	585,144	$ 5.61	5.95	$ 194
$ 8.77 — $ 20.68	1,278,121	15.55	6.53	—	753,064	15.89	5.20	—
$ 20.94	1,646,500	20.94	6.51	—	892,000	20.94	6.02	—
$ 21.00 — $ 29.47	1,976,645	23.71	6.06	—	1,585,940	23.71	5.79	—
$ 29.56 — $ 65.08	2,508,797	34.46	4.38	—	2,448,046	34.47	4.33	—
	9,022,282	$ 21.94	6.10	$ 473	6,264,194	$ 24.89	5.20	$ 194

RSU activity was as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)
Balances at December 31, 2017	—	$ —	0.00
Granted	1,069,126	13.84	
Vested	(25,000)	(15.82)	
Forfeited	(73,785)	(13.47)	
Balances at December 31, 2018	970,341	13.82	1.43
Granted	2,278,460	6.59	
Vested	(1,159,165)	(8.74)	
Forfeited	(307,654)	(8.99)	
Balances at December 31, 2019	1,781,982	8.71	1.24
Granted	3,157,390	3.09	
Vested	(2,802,593)	(3.99)	
Forfeited	(409,067)	(8.59)	
Balances at December 31, 2020	1,727,712	6.11	0.42

Total unrecognized compensation costs related to unvested RSU awards as of December 31, 2020 were $4,188 and are expected to be recognized over a weighted-average period of approximately 0.75 years.

Precigen currently uses authorized and unissued shares to satisfy share award exercises.

The Company's Executive Chairman ("Executive Chairman"), who previously served as the Company's Chief Executive Officer ("CEO") until January 1, 2020, and as an employee and executive officer until September 24, 2020, received a base salary of $200 per month through March 31, 2020, payable in fully-vested shares of Precigen common stock with such shares subject to a three-year lock-up on resale. The monthly number of shares of common stock was calculated based on the closing price on the last trading day of each month through March 2019 and based on the volume weighted average of the price of Precigen common stock over the 30 day period ending on the last calendar day of each month thereafter, and the shares were issued pursuant to the terms of a Restricted Stock Unit Agreement ("RSU Agreement") between Precigen and the Executive Chairman pursuant to the terms of the 2013 Plan. The RSU Agreement expired March 31, 2020. The fair value of the shares issued as compensation for services is included in selling, general, and administrative expenses in the Company's consolidated statements of operations and totaled $454, $1,868, and $1,956 for the years ended December 31, 2020, 2019 and 2018, respectively.

In September 2020, the Company's board of directors, upon the recommendation of the compensation committee of the board, approved a new compensation arrangement for the Executive Chairman. The new arrangement consists of (i) an annual retainer of $100 payable in cash or, at the Executive Chairman's election, shares of Precigen common stock; (ii) an annual grant of fully

vested stock options having a grant date fair value of $250; and (iii) an annual grant of RSUs having a grant date fair value of $250. The compensation arrangement begins in calendar year 2021, and the foregoing elements were prorated for the nine months of 2020 not covered by the Executive Chairman's previous compensation arrangement discussed above. The terms of the equity awards granted to the Executive Chairman are pursuant to the 2019 Plan.

16. 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 one to nine 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,	
	2020	2019
Operating lease costs	$ 3,578	$ 3,821
Short-term lease costs	1,763	2,042
Variable lease costs	842	845
Lease costs	$ 6,183	$ 6,708

As of December 31, 2020, maturities of lease liabilities, excluding short-term and variable leases, for continuing operations were as follows:

2021	$ 3,608
2022	3,392
2023	2,087
2024	1,841
2025	1,116
Thereafter	867
Total	12,911
Present value adjustment	(2,510)
Total	$ 10,401
Current portion of operating lease liabilities	$ 2,657
Long-term portion of operating lease liabilities	7,744
Total	$ 10,401

Other information related to operating leases in continuing operations was as follows:

	December 31,	
	2020	2019
Weighted average remaining lease term (years)	4.21	4.81
Weighted average discount rate	10.27 %	10.32 %

	Year Ended December 31,	
	2020	2019
Supplemental disclosure of cash flow information		
Cash paid for operating lease liabilities	$ 4,012	$ 3,877
Operating lease right-of-use assets added in exchange for new lease liabilities	417	1,137

17. Commitments and Contingencies

Contingencies

On December 1, 2020, Trans Ova settled one of two patent infringement lawsuits brought by XY, LLC ("XY"). The lawsuit, originally filed in 2012, was tried and appealed between 2016 and 2020. On December 1, 2020, the parties reached a settlement resolving all remaining disputes. As part of that settlement, Trans Ova remitted to XY a settlement payment, which, in addition to all the other monies Trans Ova had previously paid XY, constituted full payment and satisfaction of the judgment, including pre-judgment interest, post-judgment interest, costs, and all past, current and future royalty obligations under the judgment. In exchange, XY released and forever discharged Trans Ova from all obligations arising out of the judgment. In addition, XY dismissed with prejudice its pending appeal. On January 8, 2021, the parties filed a stipulation of case termination with the district court.

The second patent infringement lawsuit brought on by XY was filed in December 2016. On March 20, 2019, the United States District Court for the District of Colorado entered judgment under Rule 54(b) as to ten of the twelve counts of the operative complaint, dismissed those patent counts from the case, and stayed the remaining two counts of patent infringement pending XY's appeal of the Rule 54(b) judgment. While XY's appeal was pending, one of the two patents remaining in the case was separately invalidated in a different district court proceeding, which XY did not appeal. As to the ten dismissed counts in the suit XY brought against Trans Ova, XY appealed dismissal of only four of them, each alleging patent infringement. On July 31, 2020, the United States Court of Appeals for the Federal Circuit reversed the district court's dismissal of those four patent counts and remanded the case for further proceedings. The Court is assessing next steps of the case, including an amended scheduling order.

While this patent infringement lawsuit is pending, Trans Ova shall continue to utilize the technology consistent with the determinations of the court proceedings. Nonetheless, these disputes remain subject to a number of uncertainties, including the outcome of district court and appellate proceedings, the possibility of further claims by XY, and the impact of these matters on Trans Ova's ability to utilize the technology. Trans Ova and the Company could elect to enter into a settlement agreement in order to avoid the further costs and uncertainties of litigation.

In October 2018, the Company received a subpoena from the Division of Enforcement of the SEC informing the Company of a non-public, fact-finding investigation concerning the Company's disclosures regarding its methane bioconversion platform. The Company produced documents to, and met with, the staff of the SEC and voluntarily cooperated with the SEC investigation. In September 2020, the Company reached a final settlement with the SEC regarding the matter. Under the terms of the settlement, the Company, without admitting or denying the allegations of the SEC, consented to the entry of an administrative order requiring that the Company: (i) cease and desist from committing or causing any violations and future violations under Section 13(a) of the Securities Exchange Act of 1934, as amended, and Rules 13a-11 and 12b-20 promulgated thereunder; and (ii) pay a $2,500 civil money penalty to the SEC.

In October 2020, three purported shareholder class action lawsuits, captioned *Abadilla v. Precigen, Inc., F/K/A Intrexon Corp., et al*, *Chen v. Precigen, Inc. F/K/A Intrexon Corp., et al*, and *Seppen v. Precigen, Inc. F/K/A Intrexon Corp., et al*, were filed in the U.S. District Court for the Northern District of California on behalf of certain purchasers of the Company's common stock. The complaints name as defendants the Company and certain of its current and former officers. The plaintiffs' claims track the allegations in the SEC's administrative order described above. The plaintiffs seek compensatory damages, interest, and an award of reasonable attorneys' fees and costs and have filed motions to consolidate these claims. 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 names as defendants current directors and certain officers. The plaintiff's claims track the allegations in the SEC's administrative order described above. The plaintiff seeks damages, forfeiture of benefits received by defendants, and an award of reasonable attorneys' fees and costs. The Company intends to defend the lawsuits vigorously; however, there can be no assurances regarding the ultimate outcome of these lawsuits.

On July 10, 2020, the Company received a notice of arbitration from Harvest pursuant to the Collaboration Investment Opportunity Agreement dated March 13, 2015. In December 2020, the Company entered into an agreement with Harvest to resolve matters related to the parties' contractual and equity relationships and to settle all claims made in connection with the notice of arbitration noted above. Pursuant to the settlement agreement, the Company issued 2,117,264 shares of its common stock to Harvest valued at $18,103 in consideration of (i) the termination of the ECC agreements with Thrive Agrobiotics, Exotech Bio, and AD Skincare, which the Company had $6,993 of deferred revenue remaining related to these ECCs prior to the settlement agreement; (ii) the return of the Company's ownership interest in these Harvest start-up entities that had a total value of $326 prior to the settlement agreement; (iii) the commitment of Harvest to take reasonable commercial efforts to transfer its membership interests in Intrexon Energy Partners II; and (iv) mutual irrevocable and unconditional releases of

claims. The Company wrote off the investment balances and netted the deferred revenue balances associated with the eliminated service obligation against the consideration paid, resulting in a loss on the settlement agreement of $11,436 which is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2020. Outstanding receivables from these Harvest start-up entities related to research and development services performed by the Company under the ECC agreements, which had been fully reserved in 2019, were also forgiven as part of the settlement agreement and written off by the Company. Following the settlement agreement, these Harvest start-up entities are no longer related parties.

The Company has previously entered into strategic collaborations, including ECCs and JVs, to fund and develop products enabled by its technologies. These relationships involve complex interests, and the Company's interests may diverge with those of its collaborators, which can occur as a result of operations under those collaborations, business or technological developments, or as the Company transitions away from, or terminates, certain strategic collaborations. The Company has had, and has, disagreements and disputes with certain collaborators and JV partners, including the IEP Investors and the IEPII Investors. While the Company believes it is entitled to payment for work performed per its collaborations and JVs, consistent with its policy for accounting for accounts receivable, the Company has fully reserved the amount of any disputed accounts receivable that remained outstanding as of December 31, 2020 and 2019. These disagreements and disputes result in management distraction and may result in litigation, unfavorable settlements, or concessions by the Company, or adverse regulatory action, any of which could harm the Company's business or operations.

In the course of its business, the Company is involved in litigation or legal matters, including governmental investigations. 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, 2020, 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.

18. Related Party Transactions

Third Security and Affiliates

The Company's Executive Chairman is also the Senior Managing Director and Chairman of Third Security and owns 100% of the equity interests of Third Security. Through December 2019, the Company was party to a Services Agreement ("Services Agreement") with Third Security pursuant to which Third Security provided the Company with certain professional, legal, financial, administrative, and other support services necessary to support the Company and its Executive Chairman. Under the Services Agreement, as consideration for providing these services, Third Security was entitled to a fee paid in the form of fully-vested shares of Precigen common stock that approximated $800 per month. In 2018, the number of shares of common stock was calculated based on the closing price of the Company's common stock on the 15th day of each month and issued to Third Security at the end of the month. In 2019, the number of shares of common stock was calculated based on the volume weighted average of the closing price of the Company's common stock over the 30-day period ending on the 15th day of the calendar month when the applicable services were provided. For the years ended December 31, 2019 and 2018, the Company issued 1,606,062 shares and 696,033 shares, respectively, with values of $8,233 and $8,324, respectively, to Third Security as payment for services rendered pursuant to the Services Agreement.

Following the expiration of the Services Agreement, the Company entered into a new agreement with Third Security under which the Company reimburses Third Security for certain tax-related services performed by Third Security as requested by the Company. The Company also reimburses Third Security for certain out-of-pocket expenses incurred on the Company's behalf prior to and after the expiration of the Services Agreement under a separate agreement. The total expenses incurred by the Company under these arrangements were $159, $26, and $47 for the years ended December 31, 2020, 2019 and 2018, respectively. The Company also subleases certain administrative offices to Third Security. The significant terms of the lease mirror the terms of the Company's lease with the landlord, and the Company recorded sublease income of $83, $89, and $89 for the years ended December 31, 2020, 2019 and 2018, respectively.

See also Note 15 regarding compensation arrangements between the Company and its Executive Chairman.

In October 2017, the Company entered into a Preferred Stock Equity Facility ("Preferred Stock Equity Facility") with an affiliate of Third Security ("Third Security Affiliate"). Under the Preferred Stock Equity Facility, the Company could, from time to time at its sole and exclusive option, issue and sell to the Third Security Affiliate, up to $100,000 of newly issued Series A Redeemable Preferred Stock ("Series A Preferred Stock"). In conjunction with the Company's July 2018 registered underwritten public offering of Convertible Notes (Note 12), the Preferred Stock Equity Facility was terminated. No shares of Series A Preferred Stock had been issued under the Preferred Stock Equity Facility.

See Notes 1, 3, and 14 regarding additional transactions with affiliates of Third Security.

Transactions with ECC Parties

Collaborators in which the Company holds more than a de minimis equity interest, including interests received as upfront or milestone payments through collaborations, are considered related parties.

The Company held Series 1 Preferred Stock (the "Preferred Shares") of ZIOPHARM previously acquired through collaborations. In conjunction with the ZIOPHARM License Agreement in October 2018 (Note 6), the Company returned to ZIOPHARM all of the Preferred Shares owned or accrued by the Company as of the effective date of the agreement. During the year ended December 31, 2018, the Company recognized $14,793 of dividend income in the accompanying consolidated statement of operations. Following the transaction in October 2018, ZIOPHARM is no longer a related party.

The Company held Series A Convertible Preferred Stock (the "Convertible Preferred Shares"), a convertible note, common shares of Castle Creek, and warrants to purchase shares of Castle Creek common stock previously acquired through collaborations and other transactions. As a result of the acquisition of Castle Creek by Castle Creek Pharmaceutical in December 2019, the Company received $1,280 in December 2019 for its shares of Castle Creek common stock and received a total of $3,311 in January 2020 for the Convertible Preferred Shares and the convertible note, including accrued interest thereon. The $3,311 is included in receivables on the accompanying consolidated balance sheet as of December 31, 2019. The Company recognized a total gain of $3,222 on the change in fair value of these instruments, which is included in total other expense, net, in the accompanying consolidated statement of operations for the year ended December 31, 2019. Subsequent to the acquisition by Castle Creek Pharmaceutical, Castle Creek is no longer a related party.

During 2018, the Company mutually terminated ECC agreements with three separate related parties which resulted in the recognition of the remaining deferred revenue associated with these ECCs totaling $11,877.

19. Net Loss per Share

The following table presents the computation of basic and diluted net loss per share:

	2020	2019	2018
Historical net loss per share:			
Numerator:			
Net loss from continuing operations attributable to Precigen	$ (103,773)	$ (168,742)	$ (375,117)
Net loss from discontinued operations attributable to Precigen	(66,748)	(153,582)	(134,219)
Net loss attributable to Precigen	$ (170,521)	$ (322,324)	$ (509,336)
Denominator:			
Weighted average shares outstanding, basic and diluted	167,065,539	154,138,774	129,521,731
Net loss per share:			
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.62)	$ (1.09)	$ (2.90)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	(0.40)	(1.00)	(1.03)
Net loss attributable to Precigen per share, basic and diluted	$ (1.02)	$ (2.09)	$ (3.93)

The following potentially dilutive securities as of December 31, 2020, 2019, and 2018, have been excluded from the above computations of diluted weighted average shares outstanding for the years then ended as they would have been anti-dilutive:

	December 31,		
	2020	2019	2018
Convertible debt	11,732,440	21,323,068	18,955,668
Options	11,255,896	9,022,282	11,093,063
Restricted stock units	1,727,712	1,781,982	970,341
Warrants	133,264	133,264	133,264
Total	24,849,312	32,260,596	31,152,336

20. Segments

The Company realigned its business in April 2019, and as a result, its CODM began regularly reviewing disaggregated financial information for various operating segments. The Company's CODM assesses the operating performance of and allocates resources for several operating segments using Segment Adjusted EBITDA. Management believes this financial metric is a key indicator of operating results since it excludes noncash revenues and expenses that are not reflective of the underlying business performance of an individual enterprise. The Company defines Segment Adjusted EBITDA as net loss before (i) interest expense, (ii) income tax expense or benefit, (iii) depreciation and amortization, (iv) stock-based compensation expense, (v) loss on settlement agreements where noncash consideration is paid, (vi) adjustments for accrued bonuses paid in equity awards, (vii) loss on impairment of goodwill and other noncurrent assets, (viii) equity in net loss of affiliates, and (ix) recognition of previously deferred revenue associated with upfront and milestone payments as well as cash outflows from capital expenditures and investments in affiliates. For the year ended December 31, 2020, the Company modified the current period definition of Segment Adjusted EBITDA to exclude adjustments recorded to reverse the difference of bonuses accrued as of December 31, 2019 compared to the value of equity awards granted, as the Company determined in March 2020 that those accrued bonuses would be paid through the grant of equity awards instead of cash. The Company also excluded noncash losses associated with settlement agreements. Segment Adjusted EBITDA for the years ended December 31, 2019 and 2018, were not impacted by these changes.

Because the Company uses Segment Adjusted EBITDA as its primary measure of segment performance, it has included this measure in its discussion of segment operating results. The Company has also disclosed revenues from external customers and intersegment revenues for each reportable segment. Corporate expenses are not allocated to the segments and are managed at a consolidated level. The CODM does not use total assets by segment to evaluate segment performance or allocate resources, and accordingly, these amounts are not required to be disclosed. The Company's segment presentation excludes amounts related to the businesses included in the Transactions and the operations of MBP Titan which are reported as discontinued operations (Note 3).

For the year ended December 31, 2020, the Company's reportable segments were (i) PGEN Therapeutics, (ii) ActoBio, (iii) Trans Ova, and (iv) the Human Biotherapeutics division. These identified reportable segments met the quantitative thresholds to be reported separately for the year ended December 31, 2020. See Note 1 for a description of PGEN Therapeutics, ActoBio, and Trans Ova. The Company's Human Biotherapeutics division is an operating division within Precigen which in 2020 and 2019 included the Company's majority-owned subsidiary, Triple-Gene LLC, and its collaborations with Castle Creek (Note 6). The All Other category as reported below reflects Precigen's other operating segments that do not meet the quantitative thresholds to be reported separately.

Information by reportable segment was as follows:

	PGEN Therapeutics	ActoBio	Trans Ova	Human Biotherapeutics	All Other	Total
Goodwill						
Balances at December 31, 2018	$ 15,232	$ 1,788	$ 46,236	$ —	$ 20,736	$ 83,992
Reallocations from changes to reporting units	—	—	—	482	(482)	—
Impairments	—	—	(29,642)	—	(178)	(29,820)
Foreign currency translation adjustments	—	(53)	—	—	—	(53)
Balances at December 31, 2019	15,232	1,735	16,594	482	20,076	54,119
Foreign currency translation adjustments	—	244	—	—	—	244
Balances at December 31, 2020	$ 15,232	$ 1,979	$ 16,594	$ 482	$ 20,076	$ 54,363

	Year Ended December 31, 2020					
	PGEN Therapeutics	ActoBio	Trans Ova	Human Biotherapeutics	All Other	Total
Revenues from external customers	$ 776	$ 3,053	$ 71,186	$ 17,810	$ 10,299	$ 103,124
Intersegment revenues	5,006	(3)	340	—	281	5,624
Total segment revenues	$ 5,782	$ 3,050	$ 71,526	$ 17,810	$ 10,580	$ 108,748
Segment Adjusted EBITDA	$ (25,611)	$ (7,861)	$ 2,624	$ (2,139)	$ 4,274	$ (28,713)

	Year Ended December 31, 2019					
	PGEN Therapeutics	ActoBio	Trans Ova	Human Biotherapeutics	All Other	Total
Revenues from external customers	$ 2,227	$ (364)	$ 68,672	$ 3,713	$ 12,514	$ 86,762
Intersegment revenues	11,341	498	1,361	—	1,270	14,470
Total segment revenues	$ 13,568	$ 134	$ 70,033	$ 3,713	$ 13,784	$ 101,232
Segment Adjusted EBITDA	$ (30,164)	$ (13,662)	$ (6,337)	$ (1,051)	$ (4,901)	$ (56,115)

	Year Ended December 31, 2018					
	PGEN Therapeutics	ActoBio	Trans Ova	Human Biotherapeutics	All Other	Total
Revenues from external customers	$ 29,021	$ 6,684	$ 75,178	$ —	$ 30,213	$ 141,096
Intersegment revenues	617	840	558	—	255	2,270
Total segment revenues	$ 29,638	$ 7,524	$ 75,736	$ —	$ 30,468	$ 143,366
Segment Adjusted EBITDA	$ (32,832)	$ (12,797)	$ (5,730)	$ —	$ (10,708)	$ (62,067)

The table below reconciles total segment revenues from reportable segments to total consolidated revenues:

	Year Ended December 31,		
	2020	2019	2018
Total segment revenues from reportable segments	$ 98,168	$ 87,448	$ 112,898
Other revenues, including from other operating segments	10,634	17,964	40,841
Elimination of intersegment revenues	(5,624)	(14,690)	(2,561)
Total consolidated revenues	$ 103,178	$ 90,722	$ 151,178

The table below reconciles Segment Adjusted EBITDA for reportable segments to consolidated net loss from continuing operations before income taxes:

	Year Ended December 31,		
	2020	2019	2018
Segment Adjusted EBITDA for reportable segments	$ (32,987)	$ (51,214)	$ (51,359)
All Other Segment Adjusted EBITDA	4,274	(4,901)	(10,708)
Remove cash paid for capital expenditures and investments in affiliates	6,970	12,512	15,276
Add recognition of previously deferred revenue associated with upfront and milestone payments	25,005	14,721	33,204
Other expenses:			
Interest expense	(18,400)	(17,666)	(8,473)
Depreciation and amortization	(15,042)	(16,142)	(20,612)
Impairment losses	(920)	(30,810)	—
Reacquisition of in-process research and development	—	—	(236,748)
Loss on settlement agreement	(11,436)	—	—
Stock-based compensation expense	(19,746)	(15,098)	(30,554)
Adjustment related to accrued bonuses paid in equity awards	2,833	—	—
Equity in net loss of affiliates	(1,138)	(2,416)	(8,986)
Other	11	67	—
Unallocated corporate costs	(37,566)	(46,011)	(74,609)
Eliminations	(5,713)	(14,306)	(2,343)
Consolidated net loss from continuing operations before income taxes	$ (103,855)	$ (171,264)	$ (395,912)

As of December 31, 2020 and 2019, the Company had $5,908 and $6,724, respectively, of long-lived assets in foreign countries. The Company recognized revenues derived in foreign countries totaling $595, $1,401, and $6,255 for the years ended December 31, 2020, 2019 and 2018, respectively.

21. Quarterly Financial Information (Unaudited)

The following information has been derived from unaudited consolidated statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information. The information in the tables below reflect the impact of discontinued operations further discussed in Note 3.

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020 (1)
Total revenues	$ 29,838	$ 30,424	$ 23,583	$ 19,333
Operating loss	(16,600)	(11,830)	(23,006)	(35,167)
Loss from continuing operations	(20,846)	(15,709)	(27,536)	(39,682)
Net loss attributable to Precigen	(55,998)	(43,354)	(29,508)	(41,661)
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.13)	$ (0.10)	$ (0.17)	$ (0.22)
Net loss attributable to Precigen per share, basic and diluted	$ (0.35)	$ (0.26)	$ (0.18)	$ (0.23)

(1) During the fourth quarter of 2020, the Company recorded a loss on settlement agreement related to Harvest (Note 17).

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019 (1)
Total revenues	$ 22,585	$ 32,836	$ 18,299	$ 17,002
Operating loss	(41,855)	(21,508)	(34,702)	(68,724)
Loss from continuing operations	(44,539)	(22,440)	(39,119)	(64,236)
Net loss attributable to Precigen	(60,709)	(38,766)	(53,634)	(169,215)
Net loss from continuing operations attributable to Precigen per share, basic and diluted	$ (0.28)	$ (0.14)	$ (0.25)	$ (0.41)
Net loss attributable to Precigen per share, basic and diluted	$ (0.40)	$ (0.25)	$ (0.35)	$ (1.09)

(1) During the fourth quarter of 2019, the Company recorded a goodwill impairment charge related to the Trans Ova reporting unit (Note 11) as well as impairment charges on certain assets held for sale (Note 3).

22. 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 $873, $1,186 and $1,392 for the years ended December 31, 2020, 2019 and 2018, respectively.

23. Subsequent Events

In January 2021, the Company closed a public offering of 17,250,000 shares of its common stock, resulting in net proceeds of approximately $121,200, after deducting underwriting discounts and estimated capitalizable offering expenses.

In January 2021, the Company executed termination and recapture agreements with the landlord of the leased facility used in MBP Titan's operations, thereby relieving the Company of all of its obligations related to the facility which were originally due to expire in July 2025. The Company will record the impact of this termination as discontinued operations in the Company's consolidated financial statements during the first quarter of 2021. As of December 31, 2020, the right-of-use asset related to the lease was $9,131 and the lease liability was $13,428, which are included in current assets held for sale or abandonment and current liabilities held for sale or abandonment, respectively, in the consolidated balance sheet. Following January 2021, the Company has no further payment obligations under the lease.

Exhibit 21.1

List of Subsidiaries of Precigen, Inc.

Domestic	
Exemplar Genetics, LLC	Iowa
Genomatix, Inc.	Delaware
GenVec LLC	Delaware
Intrexon AB, Co.	Delaware
Intrexon CEU, Inc.	Delaware
Intrexon Energy Partners, LLC	Delaware
Intrexon Energy Partners II, LLC	Delaware
MabLogix, LLC	Delaware
MBP Titan LLC	Delaware
PGEN Therapeutics, Inc.	Delaware
Precigen ActoBio, Inc.	Delaware
Precigen ActoBio CED, Inc.	Delaware
Precigen ActoBio CRS, LLC	Delaware
Precigen ActoBio Holdings, Inc.	Delaware
Precigen ActoBio T1D, LLC	Delaware
ProGentus, L.C.	Iowa
Trans Ova Genetics, L.C.	Iowa
Triple-Gene LLC	Delaware
Unicell Bio International, LLC	Delaware
ViaGen, L.C.	Iowa
XON Cells, Inc.	Nevada
International	
ActoBio Laboratories Belgium BVBA *(besloten vennootschap met beperkte aansprakelijkheid)*	Belgium
ER Cell LLC	Russia
Intrexon ActoBiotics NV *(naamloze vennootschap)*	Belgium
Precigen BioInformatics Germany GmbH	Germany
Trans Ova Laboratories India Private Limited	India

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-239366 and 333-249172 on Form S-3 and Registration Statement Nos. 333-190614, 333-196840, 333-205642, 333-213065, 333-219874, 333-226821, 333-233209, 333-233211, and 333-239367 on Form S-8 of our reports dated March 1, 2021, relating to the financial statements of Precigen, Inc. and the effectiveness of Precigen, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Baltimore, Maryland
March 1, 2021

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-190614, 333-196840, 333-205642, 333-213065, 333-219874, 333-226821, 333-239367) and Form S-3 (Nos. 333-220326, 333-239366, 333-239366) of Precigen, Inc. (formerly known as Intrexon Corporation) of our report dated March 1, 2019, except for the effects of discontinued operations discussed in the *Transactions with TS Biotechnology Holdings, LLC and Darling Ingredients, Inc.* section within Note 3 and the change in composition of reportable segments discussed in Note 20, as to which the date is March 2, 2020, and the effects of discontinued operations discussed in the *MBP Titan* section within Note 3, as to which the date is March 1, 2021, relating to the financial statements which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Atlanta, Georgia
March 1, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Helen Sabzevari, certify that:

1. I have reviewed this Annual Report on Form 10-K of Precigen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ HELEN SABZEVARI

Helen Sabzevari
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick L. Sterling, certify that:

1. I have reviewed this Annual Report on Form 10-K of Precigen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ RICK L. STERLING

Rick L. Sterling
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Helen Sabzevari, Chief Executive Officer of Precigen, Inc. (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ HELEN SABZEVARI
Helen Sabzevari
Chief Executive Officer and Director
(Principal Executive Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Rick L. Sterling, Chief Financial Officer of Precigen, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ RICK L. STERLING
Rick L. Sterling
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.