
**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, 2019

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

(State or other jurisdiction of
incorporation or organization)

26-0084895

(I.R.S. Employer
Identification Number)

20374 Seneca Meadows Parkway

Germantown, Maryland

(Address of principal executive offices)

20876

(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

[Table of Contents](#)

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 28, 2019, 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 \$659.7 million.

As of February 15, 2020, 169,669,195 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 2020 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, 2019.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	
Item 1. Business	6
Item 1A. Risk Factors	30
Item 1B. Unresolved Staff Comments	58
Item 2. Properties	58
Item 3. Legal Proceedings	59
Item 4. Mine Safety Disclosures	59
<u>PART II</u>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	60
Item 6. Selected Financial Data	62
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	64
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	82
Item 8. Financial Statements and Supplementary Data	82
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	82
Item 9A. Controls and Procedures	82
Item 9B. Other Information	83
<u>PART III</u>	
Item 10. Directors, Executive Officers and Corporate Governance	84
Item 11. Executive Compensation	84
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	84
Item 13. Certain Relationships and Related Transactions, and Director Independence	84
Item 14. Principal Accountant Fees and Services	84
<u>PART IV</u>	
Item 15. Exhibits and Financial Statement Schedules	85
Item 16. Form 10-K Summary	88

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relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names, and service marks appearing in this Annual Report are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report to "Precigen", "we", "us", and "our" refer to Precigen, Inc.

Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report, including statements regarding our strategy; future events, including their outcome or timing; future operations; future financial position; future revenue; projected costs; prospects; plans; objectives of management; and expected market growth, are forward-looking statements. The words "aim", "anticipate", "assume", "believe", "continue", "could", "due", "estimate", "expect", "intend", "may", "plan", "predict", "potential", "positioned", "project", "seek", "should", "target", "will", "would", and the negative of these terms or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to successfully enter new markets or develop product candidates, including the expected timing and results of investigational studies and preclinical and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings for any product candidates we develop and our ability to obtain and maintain regulatory approvals for such product candidates for any indication;
- our intentions and ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of any products developed by us;
- our ability to successfully execute and achieve benefits from our leadership transition plan and organizational restructuring, and to manage the transition to a new chief executive officer;
- our efforts to hold or generate significant operating capital, including through partnering, potential asset sales of our non-healthcare assets, and operating cost reductions;
- our cash position;
- our estimates regarding expenses, future revenue, capital requirements, and need for additional financing;
- our strategy and overall approach to our business model, including our efforts to focus our business in the healthcare industry;
- our ability to adapt to changes in laws, regulations, and policies;
- our reliance on and the performance of third parties, including exclusive channel collaborations, or ECCs, and joint ventures, or JVs;
- competition from existing technologies and products or new technologies and products that may emerge;
- our expectations related to the use of proceeds from our public offerings and other financing efforts;
- actual or anticipated variations in our operating results;
- market conditions in our industry;
- our ability to protect our intellectual property and other proprietary rights and technologies;
- our ability to retain and recruit key personnel;
- our ability to successfully enter into optimal strategic relationships with our subsidiaries and operating companies that we may form in the future; and

- the result of litigation proceedings or investigations that we currently face or may face in the future.

Forward-looking statements 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 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 and the documents that we have filed as exhibits to our filings with the Securities and Exchange Commission, or 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.

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 the historically unreliable and costly discovery and development process for new medicines is being replaced by the targeted engineering of biology at the genetic, molecular and cellular level. We believe that our therapies differentiate us from our competition through a focus on advanced multigenic construction, unique delivery mechanisms, and controllable expression. Our pipeline programs have the potential to help solve major outstanding technical and commercial challenges that continue to hinder the biopharmaceutical industry.

We believe that our array of technology platforms uniquely position 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, ActoBiotics, and AdenoVerse Immunotherapy, 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 currently are advancing multiple product candidates through clinical trials, including UltraCAR-T therapies PRGN-3005, which targets the Mucin 16 antigen, or MUC16, on the cell surface of ovarian and other peritoneal cancers, and PRGN-3006, which targets the CD33 antigen on the cell surface of acute myeloid leukemia, or AML, blasts, as well as AG013 and AG019, which are based on our ActoBiotics platform and are being investigated for the treatment of oral mucositis, or OM, and recent-onset type 1 diabetes mellitus, or T1D, respectively. In addition, we continue to rapidly advance earlier-stage preclinical programs across our core therapeutic areas.

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 selected programs quickly to "go" and "no go" decisions and value inflection points.
- **Strategic Partnerships.** Seek strategic partnerships to maximize value generation.

PRECIGEN'S VISION FOR PATIENTS

Develop life-saving and cost-conscious therapies utilizing our cutting-edge platform technologies for patients with unmet need



Our Strategy

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

- **Advancing our lead programs and seeking opportunities to maximize their value.** We are actively advancing our lead programs, including: PRGN-3005 and PRGN-3006, which are built on our UltraCAR-T platform; AG019, which is built on our ActoBiotics platform; and INXN-4001 non-viral triple effector plasmid DNA, which is built on our UltraVector platform. PRGN-3005 is in a Phase 1 clinical trial for advanced ovarian cancer patients and PRGN-3006 is in a Phase 1/1b clinical trial for patients with relapsed or refractory AML or high-risk MDS. The primary objective of the ongoing clinical studies is to determine the safety and maximum tolerated dose, or MTD, of PRGN-3005 and PRGN-3006. AG019 is currently being studied in a Phase 1b/2a multi-center study conducted in participants with clinical recent-onset T1D. INXN-4001 is being evaluated in a Phase 1 study to evaluate the safety of retrograde coronary sinus infusion of INXN-4001 in outpatient left ventricular assist device, or LVAD, recipients. 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 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.

In order to sharpen our focus on healthcare, solidify our capital position, and place our healthcare assets in the optimal position to succeed, in January 2020, we divested a number of our non-healthcare assets in two transactions to TS Biotechnology Holdings, LLC, or TS Biotechnology, a limited liability company managed by Third Security, LLC, or Third Security, which is a related party, and to Darling Ingredients, Inc., or Darling. These sales are referred to collectively herein as the Transactions. We also changed our company name to Precigen, Inc. See "Non-Healthcare Assets and Transition to our Core Healthcare Business Model" below.

Our Healthcare Subsidiaries

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

PGEN Therapeutics, Inc.

PGEN (formerly Precigen, Inc.) 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 operates as an innovation engine, progressing a preclinical and clinical pipeline of well-differentiated therapies toward clinical proof-of-concept and commercialization. Our most advanced programs within PGEN include two therapies built on our UltraCAR-T platform, PRGN-3005, which is in a Phase 1 clinical trial for the treatment of advanced ovarian cancer, and PRGN-3006, which is in a Phase 1/1b clinical trial for the treatment of relapsed or refractory AML and higher-risk MDS. In addition to our clinical programs, PGEN has a robust preclinical pipeline that includes PRGN-2009, an "off-the-shelf" therapy for human papillomavirus-positive, or HPV⁺, cancers developed using our AdenoVerse Immunotherapy platform, additional UltraCAR-T therapeutics for various cancers, additional "off-the-shelf" AdenoVerse Immunotherapeutics for infectious diseases, an AdenoVerse cytokine therapy for solid tumors, and PRGN-5001, a multifunctional therapeutic for solid tumors.

Precigen ActoBio, Inc.

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. Our ActoBiotics platform is a unique delivery platform precisely tailored for specific disease modification via local delivery directly to the relevant tissue. 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. ActoBio, both independently and through a collaboration, has a clinical pipeline and a portfolio of candidates available for clinical development across a number of potential indications. ActoBio's most advanced internal pipeline candidate, AG019, is currently in a Phase 1b/2a clinical trial for the treatment of recent onset T1D. Another clinical candidate from ActoBio's platform, AG013, is being developed by our partner Oragenics, Inc., or Oragenics, a Florida corporation, and is in a Phase 2 clinical trial for the treatment of OM.

Triple-Gene LLC

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 designed for constitutive expression of human S100A1, SDF-1a, and VEGF-165 genes to address multiple pathways of heart failure, is currently in a Phase 1 clinical trial.

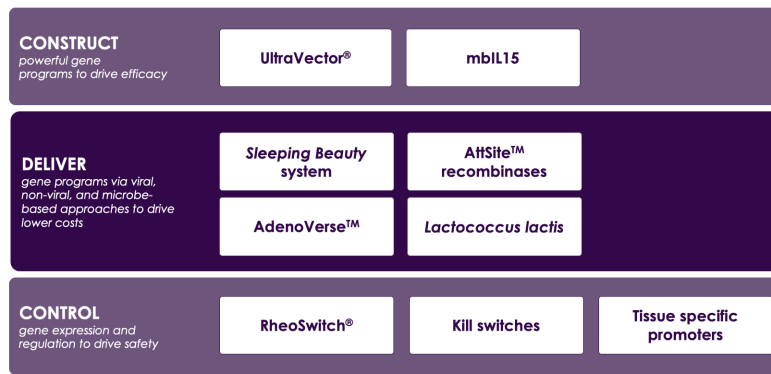
Exemplar Genetics, LLC

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.

Our Technology and Therapeutic Platforms

Our Technology Platforms

We leverage a diverse portfolio of proprietary technology platforms to accelerate research and development efforts to deliver the promise of precision medicine. Precigen's innovative technology platforms enable us to *construct* powerful, multigenic programs that we believe will drive efficacy, *deliver* multigenic constructs using viral, non-viral and microbe-based 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, gorilla adenoviral vectors, from our AdenoVerse library, and *L. lactis*. *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. *L. lactis* is a food-grade bacterium with a long history of safe use that we modify to deliver biologics at mucosal sites via oral administration.

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, 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, vededimex. 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 the safety profile of our cell therapies. 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, AdenoVerse, and ActoBiotics, to address multiple pathways of complex disorders with significant unmet medical needs and to realize our core promise of precision medicine.

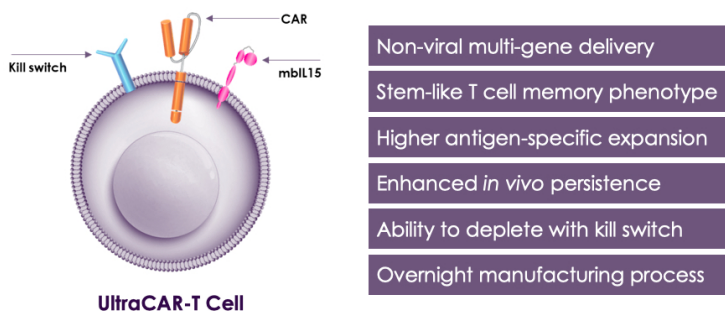
Our Therapeutic Platforms

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, conventional CAR-T cell therapies have faced a number of challenges in the treatment of solid tumors due to antigen heterogeneity, the suppressive nature of the tumor microenvironment and the 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 fundamentally 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.



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 our competition and reduces the developmental risk 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 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.

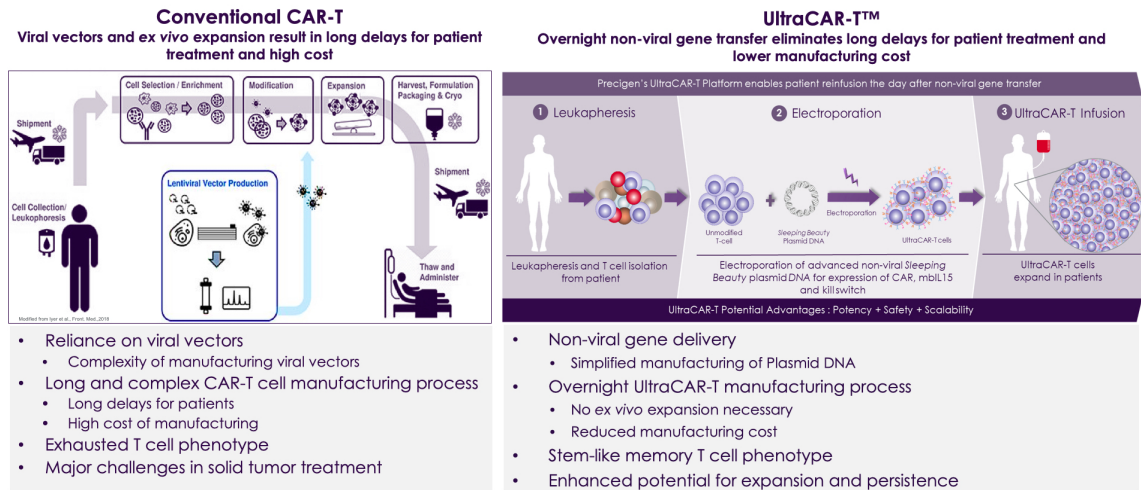
Enhanced persistence and elimination of ex vivo expansion step due to expression of mbIL15

The key driver of improved UltraCAR-T cell performance is our proprietary cytokine mbIL15. The expression of mbIL15 enhances *in vivo* expansion in the presence of tumor antigens and prevents 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 outlasts conventional CAR-T cells, which we believe is essential to successfully targeting solid tumors. This design allows us to eliminate the need for any 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 with the UltraCAR-T therapeutic platform is our decentralized and rapid proprietary manufacturing process, which allows us to manufacture overnight at a medical center's current good manufacturing practices, or cGMP, facility and reinfuse the patient the following day after gene transfer. The decentralized nature of this process allows us to scale beyond the confines of a dedicated facility. We are the first company to implement non-viral, decentralized, rapid 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. Our UltraCAR-T manufacturing process provides 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.



"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 for AdenoVerse Immunotherapies, which we believe is easily scalable for commercial supply. We believe that our proprietary gorilla adenovectors, part of the AdenoVerse technology, have superior performance characteristics as compared to current competition, including standard human adenovirus serotype 5, or Ad5, rare human adenovirus types and other non-human primate adenovirus types.

The key advantages of AdenoVerse 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% in the United States, with low seropositive titers. In comparison, the seroprevalence of Ad5 in the United States is estimated to be 58%, 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 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.

ActoBiotics®

Our ActoBiotics platform is a unique therapeutic platform precisely tailored for specific disease modification with the potential for superior efficacy and safety via oral or topical delivery of disease-modifying therapeutics directly to the relevant local mucosal sites. 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

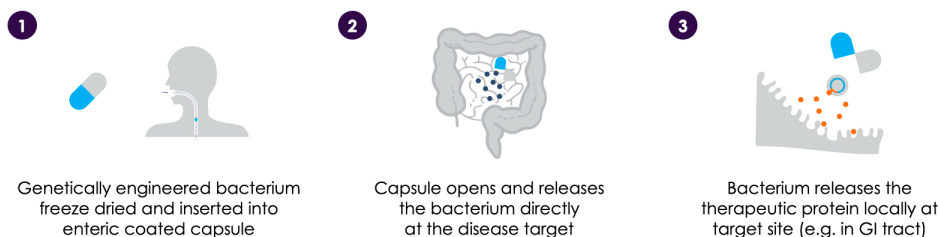
ActoBiotics combine the advantages of highly selective protein-based therapeutic agents with local delivery by the well-characterized and food-grade bacterium with *L. lactis*, which has a long history of safe use. ActoBiotics are generated by genetically modifying *L. lactis* via chromosomal integration 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 active ingredient, 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 pre-clinical 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.



Our Product Pipeline

We are leveraging our suite of technologies along with our internal research and development expertise to develop several preclinical and clinical stage programs.

	PRODUCT	PLATFORM	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PARTNER
PRECIGEN	AG019	ActoBiotics	Type 1 Diabetes						
	PRGN-3005	UltraCAR-T	Ovarian Cancer						
	PRGN-3006	UltraCAR-T	AML, MDS						
	INXN-4001	Non-viral UltraVector	Heart Failure						
PARTNERED	FCX-007	Fibroblast Cell Therapy	RDEB						
	AG013	ActoBiotics	Oral Mucositis						
	CGF164	Gene Therapy	Hearing Loss						
	FCX-013	Fibroblast Cell Therapy	Localized Scleroderma						

PRGN-3005

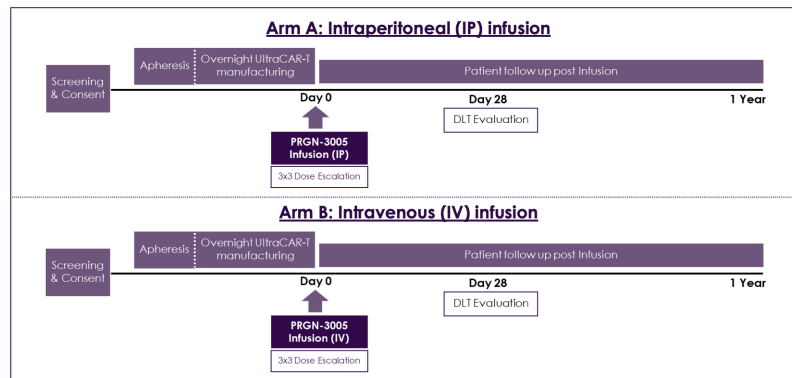
PRGN-3005 is a first-in-class, autologous CAR-T therapy that utilizes our UltraCAR-T platform to simultaneously co-express a CAR targeting MUC16, mbIL15, and kill switch genes. We have designed our CAR to improve signaling, and selected a specific anti-MUC16 binding domain and optimized its affinity to preferentially target PRGN-3005 to tumor cells.

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% 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, lung, and bladder cancer.

PRGN-3005 is in a Phase 1 clinical trial for the treatment of advanced ovarian cancer. Advanced ovarian cancer is often fatal, with Stage IV survival rates as low as 20%, 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 US 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. Administration of PRGN-3005 UltraCAR-T cells one day after non-viral gene transfer eliminated ovarian tumors in all treated mice. Furthermore, PRGN-3005 UltraCAR-T cells showed significantly superior expansion and persistence in ovarian tumor-bearing mice compared to conventional CAR-T cells.

We initiated a dual-arm, non-randomized, open-label Phase 1 clinical trial of PRGN-3005 in the second half of 2019 in patients with advanced, recurrent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer. 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. Patients in this investigator-initiated dose escalation trial receive either intraperitoneal, or IP (Arm A), or intravenous, or IV (Arm B), administration of PRGN-3005. The primary objectives of this trial are to assess the safety and MTD of PRGN-3005. For both routes of administration, PRGN-3005 will follow a 3x3 dose escalation pattern. We expect to enroll up to 41 patients total in this study.



In November 2019, we announced that we have successfully completed dosing of patients in the first dose level of the IP arm. Our consistent ability to successfully manufacture UltraCAR-T cells at a medical center confirms the validity of our rapid, decentralized approach to manufacturing. Moreover, we have observed encouraging preliminary findings of PRGN-3005 UltraCAR-T kinetics in patients. We expect to announce initial data from the IP arm in the second half of 2020.

PRGN-3006

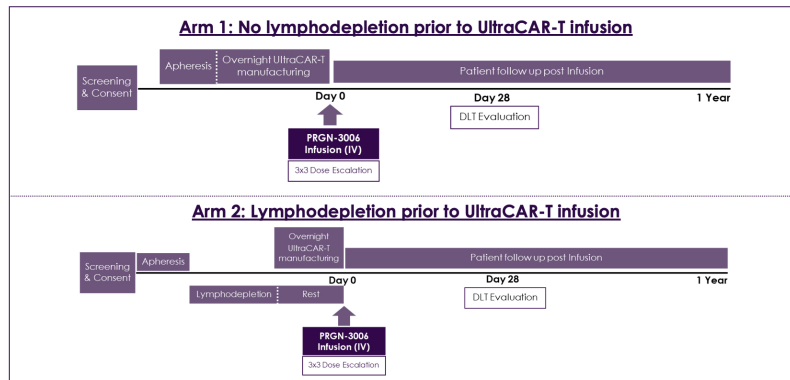
PRGN-3006 is a first-in-class autologous CAR-T therapy that utilizes our UltraCAR-T platform to co-express a CAR to target CD33, mbIL15 and a kill switch for better precision and control.

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% 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. Since 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 US annually. AML is a heterogeneous disease with 50-70% relapse rates and rapid progression. The prognosis for patients with AML is poor, with an average five-year survival rate of approximately 25%. 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 represents a significant 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 IFN γ , 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-TTM 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.

In 2019, we initiated a dual-arm, non-randomized, investigator-initiated Phase 1/1b clinical trial of PRGN-3006 delivered via intravenous infusion in patients with relapsed or refractory AML and higher-risk MDS. We are conducting this trial in collaboration with Moffitt Cancer Center, a pioneer in CAR-T clinical development. In the 3x3 dose escalation phase, patients will be treated in one of the two arms: Arm 1 will receive CAR-T cell infusion without prior lymphodepletion, and Arm 2 will receive lymphodepleting chemotherapy. The dose escalation phase of each arm will be followed by a dose expansion phase at the MTD. Because our UltraCAR-T cells have the potential for enhanced in vivo expansion and persistence due to expression of mbIL15, we are evaluating 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.



In November 2019, we announced that we have successfully completed dosing of patients in the first dose level of the "no lymphodepletion" arm (Arm 1). Our ability to successfully manufacture UltraCAR-T cells for patients at a second medical center in this trial has further validated our rapid, decentralized approach to manufacturing. PRGN-3006 was granted orphan drug designation for the treatment of AML in December 2019 by the U.S. Food and Drug Administration, or FDA.

We have observed encouraging preliminary findings of PRGN-3006 UltraCAR-T kinetics in patients. We are currently enrolling patients in the second cohort of the "no lymphodepletion" arm (Arm 1) and the first cohort of the "lymphodepletion" arm (Arm 2) of the trial, and expect to announce initial data from the trial in the second half of 2020.

AG019

AG019 is a first-in-class disease modifying antigen-specific immunotherapy for the prevention, delay, or reversal of 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 being studied in a Phase 1b/2a multi-center trial in participants with clinical recent-onset T1D with a residual functional mass of insulin-producing beta cells. The primary objective of this study, which we initiated in October 2018, is to assess the safety and tolerability of different doses of AG019 alone as well as AG019 in association with teplizumab, an anti-CD3 monoclonal antibody in development by Provention Bio, Inc. for the interception and prevention of clinical T1D, in both adolescent and adult patient groups. We have completed treatment in the open-label Phase 1b monotherapy portion of the trial, in which four cohorts consisting of adolescent or adult patients were treated with two or six AG019 capsules daily for eight weeks. Enrollment is ongoing in the randomized, double-blind Phase 2a combination portion. In this portion of the trial, patients will receive daily IV infusions of teplizumab during the first 12 days of AG019 treatment and two or six AG019 capsules daily for eight weeks. We expect to announce interim data from this trial in the third quarter of 2020.

INXN-4001

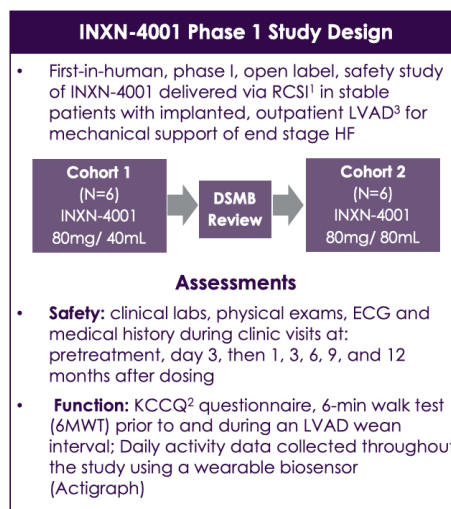
INXN-4001, a non-viral triple effector plasmid based on our UltraVector platform designed for the constitutive expression of human S100A1, SDF-1a, and VEGF-165, is engineered to address multiple pathways of heart failure. Utilizing a single plasmid comprising all three genes, instead of each individual 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% 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.

INXN-4001 is in a Phase 1 clinical trial, which is a first-in-human, open label study designed to evaluate the safety of retrograde coronary sinus infusion of INXN-4001 in outpatient LVAD recipients. Twelve stable patients with implanted LVAD for mechanical support of end stage heart failure were allocated into two cohorts of six subjects each to evaluate the safety of infusing the same amount of INXN-4001 (80mg) in two volumes (40mL and 80mL) at a rate of 20mL per minute. We have completed dosing of patients in this trial.



¹RCSI: Retrograde Coronary Sinus Infusion
²KCCQ: The Kansas City Cardiomyopathy Questionnaire
³LVAD: Left Ventricular Assist Device

The initial data shows evidence of improvement in cardiac function. We have observed beneficial trends in the distance walked during the Six Minute Walk Test and in the Left Ventricular Ejection Fraction heart function measure after six months post INXN-4001 treatment. There have been no treatment-related adverse events reported to date. We expect to have complete data for this Phase 1 study in 2020.

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 utilizing our "off-the-shelf" AdenoVerse immunotherapy, UltraCAR-T and ActoBiotics platforms that we expect to be in studies enabling Investigational New Drug applications, or INDs, or to have moved into Phase 1 clinical trials in 2020.

We are developing three product candidates utilizing our AdenoVerse Immunotherapy platform. Of these, PRGN-2009, an "off-the-shelf" immunotherapy for which we expect to initiate a Phase 1 clinical trial in 2020, is being developed for the treatment of

HPV⁺ cancers. HPV⁺ cancers represent a significant health burden in indications such as head and neck, cervical, vaginal and anal cancer. Our AdenoVerse platform allows us to optimize the HPV antigen design for improved immune response, which differentiates our therapy from the competition. Our preclinical research has shown that PRGN-2009 immunotherapy effectively controlled solid tumors in a murine model of HPV⁺ head and neck cancer. PRGN-2009 is designed to activate the immune system to recognize and target HPV⁺ solid tumors using a gorilla adenovector with a large payload capacity and the ability for repeat injections. PRGN-2009 is currently under development through a cooperative research and development arrangement, or CRADA, with Dr. Jeffrey Schlom, a world-renowned investigator in immuno-oncology, at the National Cancer Institute. This CRADA has allowed us to rapidly and cost-effectively complete preclinical work, and we expect it to have similar benefits for our forthcoming Phase 1 clinical trial. It also provides for potential expansion to other targets and combinations.

We are also developing immuno-oncology product candidates based on our Multifunctional Therapeutic platform. This platform allows us to simultaneously target multiple pathways to address senescence and trafficking of T lymphocytes in the tumor microenvironment. PRGN-5001 Multifunctional Therapeutic has exhibited the ability to enhance T cell activation and superior anti-tumor effects compared to anti-PD1 treatment in different humanized mouse models, including colorectal, lung, and cervical cancers, that do not respond well to anti-PD1 treatments. The preclinical data supports the potential for expansion to multiple targets. We plan to initiate IND-enabling studies for PRGN-5001 in 2020 and we are evaluating the optimal path forward for our Multifunctional Therapeutic platform, including ongoing partnership discussions.

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 plan to systematically evaluate data from our preclinical programs in order to make rapid "go" and "no go" decisions with respect to those candidates. Through this process, we will allocate resources to programs that we believe show the most promise and advance such programs to the clinic.

Partnered Programs

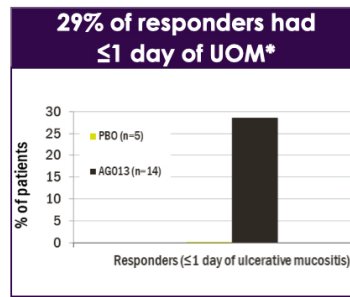
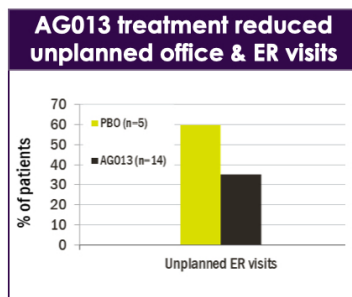
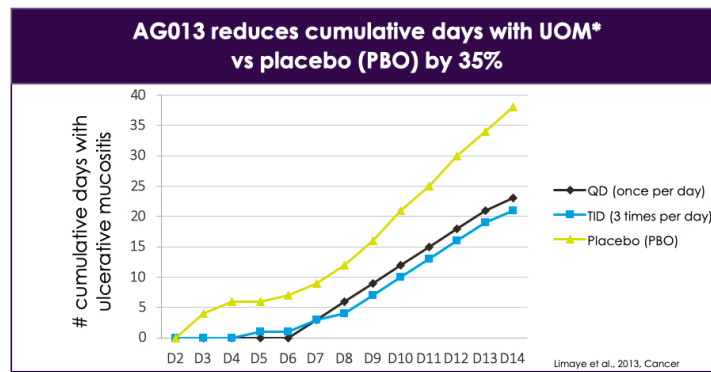
We also are engaged in a number of collaborations, pursuant to which our platforms are being used to advance additional product candidates.

AG013 (Oragenics, Inc.)

ActoBio is in collaboration with Oragenics for the continued development and commercialization of AG013 for use in the treatment of OM in humans through the administration of an effector via genetically modified bacteria. AG013 has been granted fast track designation by the FDA. AG013, built on the ActoBiotics platform, is a convenient and well-tolerated oral rinsing solution to deliver human Trefoil Factor 1, or hTFF1, via genetically modified *L. lactis*. The *L. lactis* is freeze dried and then mixed with a raspberry-flavored solution that the patient swishes after every meal. The swishing causes the delivery of hTFF1 to buccal mucosa, which is intended to prevent mucosal tissue damage and induce subsequent repair.

OM is a side effect of chemo- or radio-therapy in cancer patients caused by the breakdown of the mucosal lining and results in the formation of painful oral ulcers. This condition leads to nutritional deficits due to an inability to eat and drink. There are highly unmet medical needs for the prevention and treatment of OM, with no drug approved to prevent the condition in the broad cancer population and few treatments with confirmed efficacy available to manage OM. There are approximately 770,000 cancer patients annually in the United States that are at increased risk of developing OM.

AG013 was shown to be well-tolerated by head and neck cancer patients that were receiving induction chemotherapy in a completed Phase 1b single blind, placebo-controlled study in head and neck cancer patients receiving induction chemotherapy. The Phase 1b data showed that patients receiving AG013 experienced fewer days with ulcerative OM, or UOM, and fewer unscheduled office and emergency room visits as a result of UOM, as compared to patients that received the placebo. A total of 29% of patients treated with AG013 reported fewer than two days of UOM while all placebo-treated patients experienced more than two days of UOM. In addition, a 40% reduction in unscheduled office and emergency room visits compared to placebo was observed, as well as a 35% reduction in percentage of days with UOM compared to placebo.



* Ulcerative Oral Mucositis (UOM) : WHO score ≥ 2

AG013 is now in a Phase 2 clinical trial for the treatment of oral mucositis in patients with head and neck cancer. We expect interim data from this Phase 2 study in the first half of 2020. AG013 has been granted fast track designation by the FDA and orphan drug designation by the European Union. Pursuant to the collaboration with Oragenics, ActoBio is entitled to certain milestone payments and royalties related to the development and commercialization of AG013.

FCX-007 and FCX-013 (Castle Creek Pharma)

We have a collaboration with Fibrocell Sciences, Inc., which is now a wholly owned subsidiary of Castle Creek Pharmaceutical Holdings, Inc., to advance product candidates FCX-007, which initiated a pivotal Phase 3 clinical trial for the treatment of recessive dystrophic epidermolysis bullosa (RDEB) in July 2019, and FCX-013, which is currently enrolling the Phase 1 portion of its Phase 1/2 clinical trial for the treatment of localized scleroderma. FCX-007 and FCX-013 each have been granted Orphan Drug designation, Rare Pediatric Disease designation and Fast Track designation by the FDA. The FDA has also granted FCX-007 Regenerative Medicine Advanced Therapy designation. Pursuant to the collaboration, we license our technology platforms to Fibrocell for use in certain specified fields and in exchange we have received and are entitled to certain access fees, milestone payments, royalties, and sublicensing fees related to the development and commercialization FCX-007 and FCX-013.

CGF166 (Novartis AG)

We are party to a research collaboration and license agreement through a wholly owned subsidiary with Novartis Institutes for BioMedical Research, Inc., or Novartis, for the discovery and development of novel treatments for hearing loss and balance disorders. Under the terms of the agreement, our wholly owned subsidiary licensed world-wide rights to our preclinical hearing loss and balance disorders program to Novartis in exchange for an upfront payment and certain milestone payments related to the development and commercialization of certain licensed products. We are also entitled to tiered royalties on the annual net sales of the licensed products should any achieve commercialization. Currently, one of our product candidates, CGF166, is in a Phase 1/2 clinical trial for the treatment of hearing loss and balance disorders in collaboration with Novartis under this agreement.

Our Manufacturing Strategy

A core focus of our research and development program to date has been reducing risk, minimizing cost, and addressing drawbacks associated with conventional manufacturing approaches with the goal of improving safety and efficacy. As such, we have both developed therapeutic candidates that reduce manufacturing risk by eliminating the need for centralized manufacturing, and

strategically invested in internal manufacturing capabilities to de-risk our clinical production.

UltraCAR-T Manufacturing

Our development of rapid and successful overnight manufacturing of UltraCAR-T therapies at medical centers signifies a paradigm shift in CAR-T therapy by eliminating a multitude of manufacturing and timing risks associated with conventional CAR-T therapies. Our proprietary technologies and unique manufacturing approach rely on non-viral plasmid DNA and the elimination of ex vivo expansion, leading to reduced manufacturing time and cost. This manufacturing process has significant competitive advantages over conventional approaches, and our intent is for it to take place directly in numerous treatment centers, which can improve the accessibility of our therapies for patients. See "Our Therapeutic Platforms - UltraCAR-T" for more information.

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. This 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.

ActoBiotics Manufacturing

Our microbe-based therapeutic platform, ActoBiotics, can deliver protein-based therapeutic agents locally using well-characterized and safe food-grade bacterium *L. lactis*. 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 the active ingredient, followed by concentration and freeze-drying. This process provides a competitive advantage, we believe, because there is no need for the costly purification process required to produce conventional biologics.

See "Our Therapeutic Platforms - ActoBiotics" for more information.

Competition

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 payors 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. 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 Bristol-Myers Squibb and MaxCyte are developing CAR-T based treatments for ovarian cancer and Celyad, Mustang Bio, MolMed, Amgen (Gilead / Kite partnership), Cellectis S.A., and Allogene Therapeutics are also using CAR-T technology to develop product candidates for the treatment of AML.

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. 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.

For the treatment of AML using CAR-T therapies, we believe that Celyad, Mustang Bio, and MolMed have product candidates in the most advanced clinical trials. Celyad's product candidate is an NKG2D-based CAR-T approach that uses the OptimAb manufacturing process, which generates a higher frequency of less differentiated CAR-T cells. Celyad's product candidate exhibited enhanced anti-tumor activity in preclinical studies and is now being studied with and without lymphodepletion. Mustang Bio's product candidate is an anti-CD123 CAR-T cell therapy. CD123 is widely expressed on bone marrow cells of patients with myelodysplastic syndromes, as well as in hematologic malignancies, including AML, and Mustang Bio's MB-102 (CD123 CAR T) is a CAR-T cell therapy that is produced by engineering patient T cells to recognize and eliminate CD123-expressing tumors. MolMed is developing an anti-CD44v6 CAR-T cell therapy that involves isolating the patient's T cells and modifying them ex vivo with a viral vector. The T cells are engineered to express the CAR and the HSV-TK suicide gene already used in Zalmoxis®. The CAR facilitates the lymphocytes ability to recognize and kill the tumor cells, while the suicide gene allows for the elimination of the T lymphocytes in the case of a toxic reaction against the patient's healthy tissue. We believe that Amgen and Cellectis S.A.'s products are in Phase 1 clinical trials. Amgen is developing 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 an anti-CD123 CAR-T cell therapy, which utilizes gene editing, lentivector transduction and "Pulse Agile" electroporation technology. Finally, Allogene Therapeutics' anti-FLT3 CAR-T cell therapy, which we believe is in preclinical development for AML, is manufactured using healthy donor T-cells that are engineered to express a gene-edited CAR directed against FLT3, a receptor tyrosine kinase with high expression in AML stem cells and utilizes an off-switch activated by rituximab to enable CAR-T cell depletion via CDC and ADCC.

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, Gilead, Adaptimmune and GSK, Autolus Therapeutics, and Bellicum Pharmaceuticals. We also face competition from non-cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Incyte, Merck, 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.

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 Caladrius BioSciences, Midatech Pharma, and MerciaPharma.

Intellectual Property

As we advance technologies, correspondingly, 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. We seek patent protection in the United States and in other countries for our inventions and discoveries, and we develop and protect our key know-how and trade secrets relating to our platform technologies as well as to the product candidates we are developing with our subsidiaries and through our collaborations.

We seek patent protection for our platform technologies with a focus on our product pipeline, including but not limited to our (i) various switch technologies; (ii) gene delivery technologies; and (iii) our portfolio around various genetic componentry such

as specialized vectors containing these genetic componentry. 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.

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 candidates. 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 candidates. For instance, where we believe appropriate, we have also filed counterpart patents and patent applications in other jurisdictions, including Australia, Argentina, 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, 2019, we owned at least 55 issued United States patents and 55 pending United States patent applications relating to certain 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 technologies, methods and products as we and our collaborators deem appropriate. We divested of 20 issued United States patents and 23 pending United States patent applications as part of the Transactions.

We have strategic positioning with respect to our key technologies directed to: 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; our portfolio around various genetic componentry such as specialized vectors containing these genetic componentry and their use, with a last to expire patent in 2039. 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 each aspect 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 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, and as discussed below and in "Risk factors - Risks associated with our business strategy," 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 "Markets in which we and our collaborators are developing products 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, or GMMs, which impact us and our collaborators. Our and our collaborators' processes may contain GE organisms which, when used in industrial processes, are considered new chemicals under the Toxic Substances Control Act, or TSCA, 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

Government 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, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those being developed by 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 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 drug 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 the FDA's current Good Laboratory Practice regulations and standards, and other applicable requirements;
- 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 to assure that the facilities, methods and controls are adequate to preserve 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.

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. 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. Clinical trials involving recombinant DNA 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.

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

- *Phase 1.* The product candidate is introduced into 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, 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 ratio 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.

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, and may extend to requiring withdrawal of the product from the market.

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. 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, marketing applications generally must contain data to assess the safety and effectiveness of the biologic 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 post-marketing clinical trials designed to further assess a non-biologic drug's safety and effectiveness, or a biologic's safety, purity, and potency, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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 will typically 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.

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. 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 Federal Food, Drug, and Cosmetic Act; 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. 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 exclusive use 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 is 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 product candidates, 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 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.

Regulation of microbes and microbial products

The use of GMMs, such as our yeast and methanotroph strains, is subject to laws and regulations in many countries. In the United States, the EPA regulates the commercial use of many GMMs as well as potential products produced from GMMs. Various states within the United States could choose to regulate products made with GMMs as well. While the strain of genetically-modified yeast that we use, *S. cerevisiae*, is eligible for exemption from EPA review because it is generally recognized as safe, we must satisfy certain criteria to achieve this exemption, including, but not limited to, use of compliant containment structures and safety procedures. We expect to encounter GMM regulations in most if not all of the countries in that we may seek to make our products; however, the scope and nature of these regulations will likely vary from country to country. If we cannot meet the applicable requirements in countries in which we intend to produce our products using GMMs, then our business will be adversely affected.

Non-Healthcare Assets and Transition to Our Core Healthcare Business Model

Historically, we focused on programming biological systems for application across a variety of diverse end markets, including health, food, energy, and environment, but we have also consistently evolved the way in which we apply our synthetic biology technologies and the opportunities on which we have focused. In January 2020, we announced that we are increasing our focus on certain of our healthcare opportunities, which reflect our most-advanced platforms, and in connection therewith we divested a number of our non-healthcare assets and changed our name to Precigen, Inc. However, we continue to own our methane bioconversion business and our established bovine genetics company.

Prior to refocusing our business on healthcare, we sought to apply our synthetic biology technologies to a broad universe of markets. In order to operate in such a variety of markets, we built our business around collaborations, such as ECCs and JVs. Over time, we evolved away from entering into new collaborations and considered ways to reorganize our business to best leverage our

technology assets and focus on the opportunities that we believe are of the most immediate promise. Effective January 1, 2018, we transferred substantially all of our gene and cell therapy assets for human health to a newly-formed wholly owned subsidiary, PGEN, and we consolidated therapeutic applications of our proprietary ActoBiotics platform under ActoBio, another wholly owned subsidiary. In May 2019, we announced the alignment of our operations into two units focused on healthcare and bioengineering in order to better deploy resources, realize inherent synergies and position the company for growth with a core focus on healthcare.

In January 2020, we furthered our plans to enhance our focus on the healthcare industry when we sold a number of our bioengineering assets, or the TS Biotechnology Sale, to TS Biotechnology. 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 Chief Executive Officer of Third Security and owns 100 percent of the equity interests of Third Security. The assets divested in the TS Biotechnology Sale included our domain name dna.com and all of our equity interests in (1) Blue Marble AgBio LLC, or Blue Marble AgBio, a Delaware limited liability company, that we formed to hold our agricultural biotechnology assets, (2) ILH Holdings, Inc., or ILH Holdings, a Delaware corporation, which housed our yeast fermentation technology platform for the biologic production of active pharmaceutical ingredients and other fine chemicals, (3) Intrexon Produce Holdings, Inc., or IPHI, a Delaware corporation, which owns Okanagan Specialty Fruits, Inc., or Okanagan Specialty Fruits, the agricultural company developing non-browning apple without the use of any artificial additives, (4) Intrexon UK Holdings Inc., or Intrexon UK Holdings, a Delaware corporation, which owns Oxitec, Ltd., or Oxitec, the developer of an insect-based biological control system, (5) Oragenics, which is developing antibiotics against infectious disease and, in collaboration with ActoBio, treatments for oral mucositis, and (6) SH Parent, Inc., or SH Parent, a Delaware corporation, which held our ownership interests in Surterra Holdings, Inc., or Surterra, a cannabinoid-based wellness company. In addition, in January 2020, in a separate transaction, we sold our interest in EnviroFlight, LLC, or EnviroFlight, to Darling. See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report for a discussion of the Transactions and the discontinued operations.

Remaining Non-Healthcare Businesses

While our primary focus is in healthcare, after the Transactions we continue to have two non-healthcare businesses: our methane bioconversion business, MBP Titan, LLC, or MBP Titan, and our established bovine genetics company, Trans Ova Genetics, L.C., or Trans Ova.

MBP Titan

MBP Titan is our standalone subsidiary comprising our Methane Bioconversion Platform, or MBP, and our associated technologies, personnel, and facilities. Our MBP is designed to turn natural gas into more valuable and usable energy and chemical products through novel, highly engineered bacteria that utilize specific energy feedstocks. This technology can use pipeline grade natural gas, to synthesize commercial end products, such as isobutanol for gasoline blending, 2,3 Butanediol for conversion to synthetic rubber and 1,4 Butanediol for polyester. Traditional methods of feedstock conversion for fuel production and other materials are costly, wasteful and often come with significant environmental impact. The MBP production method has the potential to transform the generation of drop-in fuels, synthetic rubber, plastic material, and animal feed through less resource intensive and more sustainable approaches than conventional methods. In aggregate, the value of such fuel and chemical products and animal feed are significant, representing the potential of billions of dollars in estimated market opportunity.

We are currently assessing the appropriate next steps with respect to the future of our MBP platform, which could include a financing directly into MBP Titan, or other strategic alternatives. As part of this assessment, we are also considering the future of our joint ventures with Intrexon Energy Partners and Intrexon Energy Partners II.

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 and other significant collaborations between us and our JVs.

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 and Trans Ova are evaluating 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, 2019, Trans Ova had 229 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 in vitro fertilization processes, as well as housing livestock used in such processes. As of December 31, 2019, Trans Ova also leased or owned regional production facilities and land in California, Maryland, Missouri, New York, Oklahoma, South Dakota, Texas, and Washington for these purposes.

Competition: Non-Healthcare Assets

Energy Markets

MBP Titan differentiates itself through its use of cellular engineering experience and suite of technologies to develop environmentally-friendly products in the chemical and animal feed industries. While we believe this proprietary platform holds the potential to modernize the existing gas-to-liquids industry by generating important fuels and chemicals at a fraction of the cost of traditional conversion methods, any products MBP Titan develops will still compete with legacy technologies and approaches to fuel production. Many of MBP Titan's competitors in the energy market are significantly larger than MBP Titan and have significantly greater financial, technical and human resource capabilities. Further, MBP Titan is still developing our products and scaling them, while its competitors, who are utilizing more traditional methods, have the benefit of developed processes that are accepted by the market. In addition, there are others, including competitors with better financial, technical, and resources, and more experience, pursuing alternatives fuels as well as companies pursuing technologies based on the conversion of methanotrophs in the energy sector. MBP Titan's ability to compete successfully will depend on its ability to develop and produce products that can be scaled to reach the market in a timely manner and are environmentally superior to and/or are less expensive to produce than other products on the market.

Animal Genetics Market

We believe Trans Ova's focus on continuous research and use of applied science allow 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.

Energy and Chemical Regulation

The environmental regulations discussed above also govern the development, manufacture and marketing of energy and chemical products. Chemical products produced by us and our collaborators may be subject to government regulations in our target markets. In the United States, the EPA administers the requirements of the TSCA, which regulates the commercial registration, distribution and use of many chemicals. Before an entity can manufacture or distribute significant volumes of a chemical, it needs to determine whether that chemical is listed in the TSCA inventory. If the substance is listed, then manufacture or distribution can commence immediately. If not, then in most cases a "Chemical Abstracts Service" number registration and pre-manufacture notice must be filed with the EPA, which has 90 days to review the filing. A similar requirement exists in Europe under the REACH regulation. Additional regulations may apply to specific subsets of chemicals such as, for example, fuel products that are subject to regulation by various government agencies including, in the United States, the EPA and the California Air Resources Board.

Our Historic Operations

Until the closing of the Transactions, we operated under a strategy that allowed us to focus on our core expertise in synthetic biology while developing many different commercial product candidates via collaborations in a broad range of industries or end markets. We built our business primarily around the formation of ECCs, as well as certain research collaborations. Over time, our strategy has evolved away from ECC-type collaborations to relationships and structures that provided us with more control and ownership over the development process and commercialization path. In these new relationships and structures, we had more of the responsibility to fund the projects and execute on product candidate development. Eventually, we aligned our businesses into two units comprising our healthcare and bioengineering assets, a number of which we sold in early 2020. Some of the key businesses that we divested in connection with our focus on healthcare, include the following operating subsidiaries and JVs:

Okanagan Specialty Fruits, Inc.

Okanagan is the pioneering agricultural company behind the world's first non-browning apple without the use of any artificial

additives. Under our control, we worked with Okanagan to scale up its commercial supplies of non-browning apples and to develop new commercial tree fruit varieties intended to provide benefits to the entire supply chain, from growers to consumers. In 2020, we sold Okanagan in the TS Biotechnology Sale.

AquaBounty Technologies, Inc.

AquaBounty Technologies, Inc., or AquaBounty, is a company focused on improving productivity in commercial aquaculture, including the development of the AquAdvantage Salmon, an Atlantic salmon that has been genetically enhanced to reach market size in less time than conventionally farmed Atlantic salmon and approved by the FDA. Until October 2019, AquaBounty was a partially owned subsidiary of ours. In October 2019, we sold our ownership interests held in AquaBounty to an affiliate of Third Security.

EnviroFlight

In February 2016, we entered into a series of transactions involving a predecessor to EnviroFlight, or Old EnviroFlight, Darling, and a newly formed venture between us and Darling, EnviroFlight. This series of integrated transactions resulted in us acquiring substantially all of the assets of Old EnviroFlight and contemporaneously contributing all of these assets, with the exception of certain developed technology, and \$3 million of cash to EnviroFlight in exchange for a non-controlling, 50 percent membership interest in EnviroFlight. Our contributions to EnviroFlight included an exclusive license to the developed technology that was retained by us. Darling received the remaining 50 percent membership interest in EnviroFlight as consideration for terminating rights previously held in the developed technology with Old EnviroFlight. EnviroFlight was formed to generate high nutrition, low environmental impact animal and fish feed, as well as fertilizer products, from black soldier fly larvae. On January 2, 2020, we sold all of our interests in EnviroFlight to Darling.

Oxitec Limited

Oxitec is a pioneering company in biological insect control solutions. Oxitec is developing products that use genetic engineering to control insect pests that spread disease and damage crops. Among the applications of its platform, which uses advanced genetics and molecular biology, Oxitec has developed innovative solutions for controlling *Aedes aegypti*, a mosquito that is a known vector for the transmission of infectious disease including dengue fever, chikungunya, and Zika virus and, in conjunction with its collaborators, is pursuing solutions that target certain agricultural crop pests. Oxitec is pursuing regulatory and commercial approvals for its insect solutions in a number of countries, including the United States. In 2020, we sold Oxitec in the TS Biotechnology Sale.

Reportable Segments

Through March 31, 2019, we operated as a single operating segment. In April 2019, in our efforts to better deploy resources and realign our business, our chief operating decision maker, or CODM, began assessing the operating performance of and allocating our resources for several operating segments using Segment Adjusted EBITDA. As of December 31, 2019, taking into account the effect of the Transactions, our reportable segments are (i) PGEN Therapeutics, (ii) ActoBio, (iii) MBP Titan, and (iv) Trans Ova. These identified reportable segments met the quantitative thresholds to be reported separately for the year ended December 31, 2019. 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, 2019, we had 366 research and development employees. We incurred expenses of \$101.9 million, \$366.2 million and \$109.2 million in 2019, 2018, and 2017, respectively, on research and development activities for continuing operations. We anticipate that our research and development expenditures could increase as we focus on the healthcare industry and further advance our internally developed programs, including those we reacquired from former collaborators in 2018. As of December 31, 2019, our primary domestic research and development operations were located in laboratory facilities in Germantown, Maryland; South San Francisco, California; and Davis, California; and our primary international research and development operations were located in laboratory facilities in Budapest, Hungary; Ghent, Belgium; Campinas, Brazil; and Oxford, England. In connection with the Transactions, we no longer have research and development facilities in Davis, California; Budapest, Hungary; Campinas, Brazil; and Oxford, England and have reduced our research and development employees to 227 as of February 1, 2020.

Financial Information

Collaboration revenues, product revenues, service revenues and other revenues and operating income for each of the last three fiscal years, along with assets as of December 31, 2019 and 2018, 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.

Employees

As of December 31, 2019, we had 770 full-time and 87 part-time employees. As of February 1, 2020, after the closing of the Transactions, we had 601 full-time employees and 79 part-time employees, of which 210 full-time and 18 part-time employees supported healthcare and 391 full-time and 61 part-time employees supported our remaining non-healthcare assets. We consider our employee relations to be good. As we continue to streamline our operations and focus on healthcare, we believe the ratio of healthcare and non-healthcare employees will continue to change, with an expected decrease in the number of employees dedicated to supporting our remaining non-healthcare assets.

Corporate information

We are a Virginia corporation formed in 1998 and our principal executive offices are located at 20374 Seneca Meadows Parkway, Germantown, MD 20876, and our telephone number is (301) 556-9900.

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 \$322.3 million, \$509.3 million and \$117.0 million in 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of \$1.7 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 ECCs and license agreements, but revenues of these types will continue to

decrease as a result of our evolving business model. We no longer expect to receive reimbursement of costs incurred by us for new research and development services other than through existing ECCs, 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.

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, 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 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 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; 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 requires a significant amount of cash, and we may not have sufficient cash flows from our business to pay our substantial debt.

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, issued in July 2018, 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.

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, and AG019 in October 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, demonstration of effectiveness to 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 our clinical trials;
- acceptance of INDs for future product candidates;
- successful enrollment in and completion of clinical trials;
- successful 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;
- 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 payors;
- 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 payors.

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 through foreign agencies 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 and remains predominantly experimental. 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 they 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 payors. 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. 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.

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 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 biologic 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 and a communication plan to healthcare practitioners. 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 more narrow 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 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 contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing 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.

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 payors, 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 product candidates will depend, in part, on the acceptance of physicians, patients, and healthcare payors, 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 payors, 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 post-market 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 post-marketing 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.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may take adverse actions, which include, among other things, a range of sanctions from issuing a warning letter, monetary penalties, 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 payors, 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 payors, 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 payors 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 payor 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 payor, 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 payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors 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 payors 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 payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 payor 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 payors 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 U.S., federal and state legislatures, health agencies and third-party payors 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, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, 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 U.S. 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 payors, 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 payors 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 payors 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 purchase, lease or order, or 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, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal 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;
- HIPAA generally, which also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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 payors, 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.

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 MBP Titan and 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 U.S. 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, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, 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-U.S. 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 U.S. 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, U.S. 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. For the year ended December 31, 2019, we also recorded a noncash charge of \$29.8 million which arose from the impairment of goodwill, primarily related to a write down of the enterprise value of Trans Ova.

In January 2020, we announced and completed a sale of the majority of our bioengineering assets to TS Biotechnology. We simultaneously announced that Intrexon EF Holdings, Inc., our wholly owned subsidiary, sold its 50 percent membership interest in EnviroFlight. For the year ended December 31, 2019, we recorded a loss on discontinued operations of \$116.2 million related to the sale of these assets. 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, including ECCs and JVs, 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 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.

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 payors 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. 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 Bristol-Myers Squibb and MaxCyte are developing CAR-T based treatments for ovarian cancer and Celyad, Mustang Bio, MolMed, Amgen (Gilead/Kite partnership), 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, Gilead, Adaptimmune and GSK, Autolus Therapeutics, and Bellicum Pharmaceuticals. We also face competition from non-cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Incyte, Merck, and Roche.

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

While we believe the proprietary platform of our MBP Titan, our subsidiary developing environmentally-friendly products in the chemical and animal feed industries, holds the potential to modernize the existing gas-to-liquids industry, any products MBP Titan develops will still compete with incumbent technologies and approaches to fuel production, many of whom have the benefit of developed products that are accepted by the market. Many of MBP Titan's competitors in the energy market are significantly larger than MBP Titan and have significantly greater financial, technical, and human resource capabilities. MBP Titan's ability to compete successfully will depend on its ability to develop and produce products that can be scaled to reach the market in a timely manner and are environmentally superior to and/or are less expensive than other products on the market.

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 our Executive Chairman, Randal J. Kirk, 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, remains an employee under the new position of 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 could 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 our information systems, we cannot ensure that the coverage is adequate to compensate for any damages that may be incurred.

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.

We may encounter difficulties managing our growth, which could adversely affect our business.

Currently, we are working simultaneously on multiple projects targeting a handful of industries. We currently operate subsidiaries in the energy and animal genetics markets, and continue to increase our focus on our healthcare business. These diversified operations place increased demands on our limited resources and require us to substantially expand the capabilities of our administrative and operational resources and to attract, train, manage, and retain qualified management, technicians, scientists, and other personnel. If our operations expand domestically and internationally, we will need to continue to manage multiple locations and additional relationships with various customers, collaborators, suppliers, and other third parties. Our ability to manage our operations, growth, and various projects effectively will require us to make additional investments in our infrastructure to continue to improve our operational, financial and management controls, and our reporting systems and procedures and to attract and retain sufficient numbers of talented employees, which we may be unable to do effectively. As a result, we may be unable to manage our expenses in the future, which may negatively impact our gross margins or operating margins in any particular quarter. In addition, we may not be able to successfully improve our management information and control systems, including our internal control over financial reporting, to a level necessary to manage our growth.

Certain of our subsidiaries, including MBP Titan and Trans Ova, operate in industries that are not a part of our core business, and require additional resources and capital.

We anticipate incurring significant costs associated with advancing our production opportunities through MBP Titan and Trans Ova. We may never succeed in advancing our non-healthcare assets and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. 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 our non-healthcare assets in order to focus on our core healthcare business. The failure of our subsidiaries, including MBP Titan and 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. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Convertible Notes, then our diluted earnings per share would be adversely affected.

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. Because of the inherent unpredictability in the future

performance of the investments requiring Level 3 valuations, we may be required to adjust the value of certain assets, which could adversely affect our financial position.

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

As of December 31, 2019, we had net operating loss carryforwards of approximately \$568.8 million for United States federal income tax purposes available to offset future taxable income, including \$316.1 million generated after 2017, United States capital loss carryforwards of \$111.6 million, and United States federal and state research and development tax credits of \$9.6 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 by 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, 2019, we had utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, 2019, 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, 2019, our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately \$72.8 million, most of which do not expire.

The Tax Cuts and Jobs Act of 2017, or 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 candidates. 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.

We seek patent protection for our platform technologies with a focus on our product pipeline, including but not limited to our (i) various switch technologies; (ii) gene delivery technologies; and (iii) our portfolio around various genetic componentry such as specialized vectors containing these genetic componentry. In addition, we seek patents covering specific collaborator's products. We have also filed counterpart patents and patent applications in other jurisdictions, including Australia, Argentina, 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, 2018 through February 15, 2020, our common stock has traded as high as \$20.16 per share and as low as \$3.85 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.

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 should rely on 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 on two occasions distributed equity securities to our shareholders as a special stock dividend: 17,830,305 shares of ZIOPHARM Oncology, Inc., or ZIOPHARM, common stock were distributed in June 2015 and 1,776,557 shares of our former subsidiary, AquaBounty's, common stock were distributed in January 2017. However, 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.

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.

As of December 31, 2019, our executive officers and directors owned approximately 48 percent of our voting common stock, including shares subject to outstanding options; restricted stock units, or RSUs; and warrants. As a result, these shareholders, acting together, 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 bioengineering 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, 18, and 23" appearing elsewhere in this Annual Report for a

discussion of such transactions. Mr. Kirk serves as the Senior Managing Director and Chief Executive Officer 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.

As of December 31, 2019, Randal J. Kirk controlled approximately 46 percent of our common stock and may be able to control or significantly influence shareholder votes and other corporate actions, which may result in Mr. Kirk taking actions contrary to the desires of our 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, 2019, while Mr. Kirk is no longer our Chief Executive Officer, he is our current Executive Chairman, and Mr. Kirk and shareholders affiliated with him beneficially owned approximately 46 percent of our voting 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. The interests of Mr. Kirk may not always coincide with the interests of other shareholders, and he may take actions that advance his personal interests and are contrary to the desires of our other shareholders.

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, 2019, there were 9,022,282 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, 2019, there were 1,781,982 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, 2019, we had 8,991,369 of shares available for grant under the 2013 Omnibus Incentive Plan and 4,087,444 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.

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.

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 continuing operations as of December 31, 2019:

Location	Square Footage
Germantown, Maryland (PGEN Therapeutics segment)	61,048
South San Francisco, California (MBP Titan segment)	55,609
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 281,000 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 in vitro fertilization processes, as well as housing livestock used in such processes. We also lease or own regional production facilities and land in California, Maryland, Missouri, New York, Oklahoma, South Dakota, Texas, and Washington for these purposes.

We lease an additional 31,000 square feet of administrative offices in South San Francisco, California; West Palm Beach, Florida; Germantown, Maryland; and Blacksburg, Virginia. The terms of our leases range from one to ten years. 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

We may become subject to other claims, assessments, and governmental investigations from time to time in the ordinary course of business. 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, 2020, we had 292 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

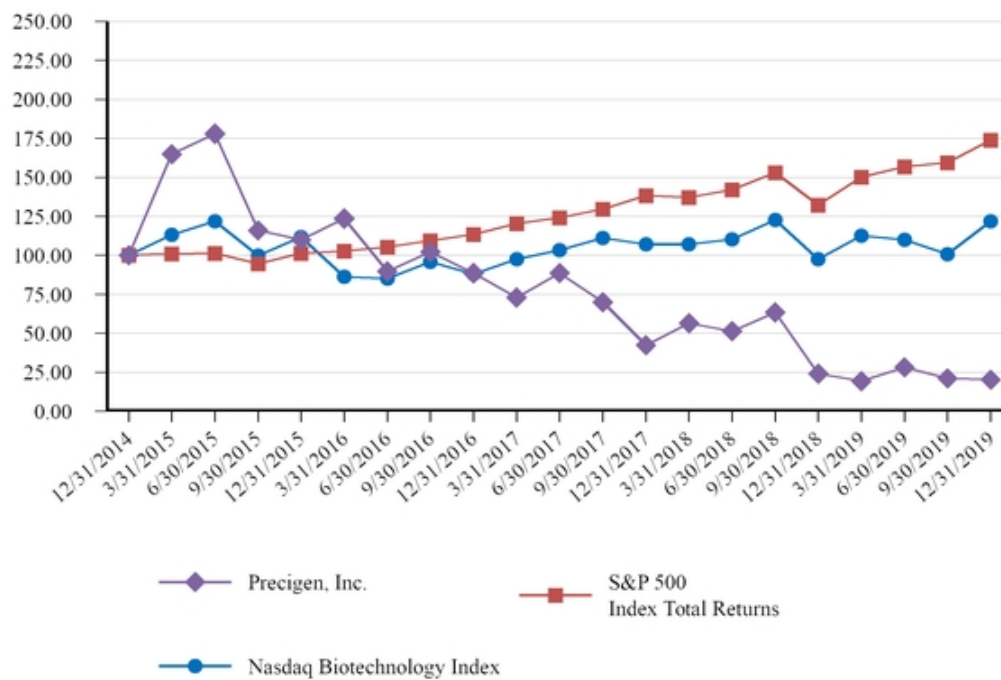
Information about our equity compensation plans is incorporated herein by reference to [Item 12 of Part III](#) of this Annual Report.

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, 2014 through December 31, 2019 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, 2014 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.

**Comparison of 60 Month Cumulative Total Return
Assumes Initial Investments of \$100
December 2019**



Company / Index	Base Period				
	12/31/2014	3/31/2015	6/30/2015	9/30/2015	12/31/2015
Precigen, Inc.	\$ 100.00	\$ 164.80	\$ 177.87	\$ 115.91	\$ 109.89
S&P 500 Index	100.00	100.95	101.23	94.71	101.38
Nasdaq Biotechnology Index	100.00	113.27	121.79	99.96	111.77

Company / Index	3/31/2016	6/30/2016	9/30/2016	12/31/2016	3/31/2017	6/30/2017	9/30/2017	12/31/2017
	Precigen, Inc.	\$ 123.53	\$ 89.70	\$ 102.13	\$ 88.57	\$ 72.98	\$ 88.70	\$ 70.00
S&P 500 Index	102.75	105.27	109.33	113.51	120.40	124.12	129.69	138.30
Nasdaq Biotechnology Index	86.19	85.22	95.87	87.91	97.43	103.18	111.16	106.95

Company / Index	3/31/2018	6/30/2018	9/30/2018	12/31/2018	3/31/2019	6/30/2019	9/30/2019	12/31/2019
	Precigen, Inc.	\$ 56.45	\$ 51.33	\$ 63.41	\$ 24.08	\$ 19.37	\$ 28.20	\$ 21.06
S&P 500 Index	137.25	141.97	152.91	132.24	150.29	156.76	159.42	173.88
Nasdaq Biotechnology Index	107.01	110.31	122.66	97.47	112.62	110.09	100.59	121.94

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

(a) Sales of Unregistered Securities

From January 1, 2019 through December 31, 2019, we issued 1,606,062 unregistered shares of our common stock as payment under the services agreement entered into and effective as of November 1, 2015, as amended, by and between us and Third Security as previously discussed in our Current Report on Form 8-K filed on April 22, 2019.

We issued the above referenced shares of common stock in reliance on exemptions from registration under Section 4(a)(2) of the Securities Act.

(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, 2019 and 2018, and for the years ended December 31, 2019, 2018 and 2017, 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, 2017, 2016, and 2015, and for the years ended December 31, 2016 and 2015, 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,				
	2019	2018	2017	2016	2015
(In thousands, except share and per share amounts)					
Statements of Operations Data:					
Collaboration and licensing revenues	\$ 14,059	\$ 69,540	\$ 134,624	\$ 97,160	\$ 77,242
Product revenues	23,780	28,486	33,585	36,958	41,879
Service revenues	51,803	52,419	50,611	43,049	42,923
Total revenues (1)	90,722	151,178	219,463	177,607	162,635
Total operating expenses	294,934	554,675	315,373	274,734	303,329
Operating loss	(204,212)	(403,497)	(95,910)	(97,127)	(140,694)
Loss from continuing operations	(207,757)	(414,317)	(80,439)	(154,158)	(88,848)
Net loss attributable to noncontrolling interests	1,592	5,370	9,802	3,662	3,501
Net loss from continuing operations attributable to Precigen	(206,165)	(408,947)	(70,637)	(150,496)	(85,347)
Net loss from continuing operations attributable to Precigen per share, basic and diluted	\$ (1.34)	\$ (3.16)	\$ (0.59)	\$ (1.28)	\$ (0.77)
Weighted average shares outstanding, basic and diluted	154,138,774	129,521,731	119,998,826	117,983,836	111,066,352

	December 31,				
	2019	2018	2017	2016	2015
(In thousands)					
Balance Sheet Data:					
Cash and cash equivalents	\$ 65,793	\$ 96,876	\$ 59,251	\$ 60,217	\$ 126,658
Short-term and long-term investments	9,260	119,614	6,273	180,595	207,975
Total assets (2)	455,763	716,177	846,851	949,068	982,046
Deferred revenue, current and non-current (1)	53,833	57,816	226,343	298,842	184,825
Long-term debt (3)	217,991	211,695	8,037	7,948	8,528
Other liabilities (4)	112,228	67,944	65,926	73,030	83,807
Total Precigen shareholders' equity	71,711	362,855	533,631	560,237	694,078
Noncontrolling interests	—	15,867	12,914	9,011	10,808
Total equity	71,711	378,722	546,545	569,248	704,886

- (1) Revenues and deferred revenue in 2019 and 2018 are accounted for under Accounting Standards Codification, or 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 long-lived assets recognized in 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 and \$15,629 of deferred consideration as of December 31, 2016 and 2015, respectively.

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. Outside of collaboration and license fee payments and sales of products and services, which vary over time, we have not generated significant revenues, including revenues or royalties from product sales by us or our collaborators. Certain of our consolidated subsidiaries require regulatory approval and/or commercial scale-up before they may commence significant product sales and operating profits.

In April 2019, we initiated efforts to better deploy resources, realize inherent synergies, and position us for growth with a core focus on healthcare and initiated plans to achieve this through various corporate activities, including partnering, potential asset sales, and operating cost reductions. In conjunction with these efforts, our CODM began assessing the operating performance of, and allocated resources for, our operating segments using Segment Adjusted EBITDA as defined below.

In January 2020, we furthered our plans to enhance our focus on the healthcare industry when we sold a number of our bioengineering assets in the TS Biotechnology Sale to TS Biotechnology. The assets divested in the TS Biotechnology Sale included our domain name dna.com and all of our equity interests in (1) Blue Marble AgBio, a Delaware limited liability company, that we formed to hold our agricultural biotechnology assets, (2) ILH Holdings, a Delaware corporation, which housed our yeast fermentation technology platform for the biologic production of active pharmaceutical ingredients and other fine chemicals, (3) IPHI, a Delaware corporation, which owns Okanagan Specialty Fruits, the agricultural company developing non-browning apples without the use of any artificial additives, (4) Intrexon UK Holdings, a Delaware corporation, which owns Oxitec, the developer of an insect-based biological control system, (5) Oragenics, a Florida corporation, which is developing antibiotics against infectious disease and, in collaboration with ActoBio, treatments for oral mucositis, and (6) SH Parent, a Delaware corporation, which held our ownership interests in Surterra, a cannabinoid-based wellness company. In addition, in January 2020, in a separate transaction, we sold our interest in EnviroFlight to Darling, referred to collectively with the TS Biotechnology Sale as the Transactions.

Beginning in the fourth quarter of 2019, we determined that assets, liabilities and operations sold in the Transactions collectively met the criteria for discontinued operations. As such, the assets, liabilities, and operations related to the Transactions are reclassified and presented as discontinued operations for all periods.

See "Notes to the Consolidated Financial Statements - Note 3" appearing elsewhere in this Annual Report for a discussion of the Transactions and the 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 our 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 expect to cancel collaboration agreements or we may 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 in-process research and development expense, depending on the circumstances.

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. 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. We expect our collaboration revenues will continue to decrease in the near term as the number of collaborations to which we are party declines and as we fulfill our obligations under any remaining ECCs. Our revenues will also depend upon our ability to maintain or improve the volume and pricing of Trans Ova'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 allocated expenses for rent and maintenance of facilities and other operating costs.

We currently have no individually significant research and development projects, and our research and development expenses primarily relate to either the costs incurred to expand or otherwise improve our technologies, the costs incurred to develop our own products and services, or the costs incurred to develop a specific application of our technologies in support of current partners. Research and development expenses, including costs for preclinical and clinical development, incurred for programs we support pursuant to an ECC agreement are typically reimbursed by the partner at cost, and all other research and development programs may be terminated or otherwise deferred at our discretion. The amount of our 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 the progression of these programs into pre-clinical or clinical stages. We believe these increases will likely include increased costs related to the hiring of additional personnel in research and development functions, 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, and expenses associated with obtaining and maintaining our intellectual property.

SG&A expenses may fluctuate in the future depending on the number and nature of transactions we may undertake with certain of our operations and subsidiaries. These fluctuations could be related to personnel, legal fees, outside consultants, and other professional services.

Other income (expense), net

We have historically held equity securities and preferred stock of private and publicly traded companies, including investments received and/or purchased from certain collaborators. We evaluate whether to elect the fair value option on an individual investment basis. We elected the fair value option to account for our equity securities and preferred stock held in publicly traded companies. These equity securities and preferred stock are recorded at fair value at each reporting date. Unrealized appreciation (depreciation) resulting from fair value adjustments are reported as other income (expense) in the consolidated statements of operations. We account for our investments in private companies using either the equity method or the measurement alternative method for equity securities without readily determinable fair values, which represents cost and any adjustments for impairment or observable price changes in certain transactions. See "Notes to the Consolidated Financial Statements - Note 2" appearing elsewhere in this Annual Report. We expect minimal gains (losses) on our securities portfolio in future periods as we expect to finish liquidating our portfolio in early 2020.

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 issued in July 2018.

Interest income consists of interest earned on our cash and cash equivalents and short-term and long-term investments. Dividend income historically consisted of the monthly preferred stock dividends received from our investments in preferred stock, virtually all of which has been liquidated as of December 31, 2019.

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 and start-up entities backed by Harvest Intrexon Enterprise Fund I, LP, or Harvest, 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.

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 impairment of goodwill and other long-lived assets, (vi) equity in net loss of affiliates, and

(vii) 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.

Results of operations

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,		Dollar Change	Percent Change
	2019	2018		
(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	101,879	366,248	(264,369)	(72.2)%
Selling, general and administrative	100,844	125,751	(24,907)	(19.8)%
Impairment loss	30,810	—	30,810	N/A
Total operating expenses	294,934	554,675	(259,741)	(46.8)%
Operating loss	(204,212)	(403,497)	199,285	(49.4)%
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	(208,687)	(429,742)	221,055	(51.4)%
Income tax benefit	930	15,425	(14,495)	(94.0)%
Loss from continuing operations	(207,757)	(414,317)	206,560	(49.9)%
Loss from discontinued operations, net of income tax benefit (2)	(116,159)	(100,389)	(15,770)	15.7 %
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) The results of operations in the table above include the operations related to the Transactions, as well as adjustments to those businesses as a result of the Transactions, in loss from discontinued operations, net of income tax benefit. The increase in the loss from discontinued operations in 2019 is due to additional impairment losses recorded related to the Transactions. 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)
Fibrocell Science, 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 Exotech Bio, Inc.; AD Skincare, Inc.; and Thrive Agrobotics, 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 \$264.4 million, or 72 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 \$24.9 million, or 20 percent, from the year ended December 31, 2018. Salaries, benefits and other personnel costs decreased \$14.9 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 \$6.1 million primarily due to fewer legal fees associated with Trans Ova.

Impairment loss

Impairment loss for the year ended December 31, 2019 of \$30.8 million arose primarily from a goodwill impairment charge related to Trans Ova. As a result of our annual goodwill impairment test in the fourth quarter, we determined that it was more-likely-than-not that the fair value of Trans Ova was less than its carrying value. As a result, we performed a quantitative analysis and recorded a \$29.6 million impairment charge.

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 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	\$ (30,166)	\$ (32,841)	\$ 2,675	8.1 %
ActoBio	(13,662)	(12,797)	(865)	(6.8)%
MBP Titan	(36,718)	(29,403)	(7,315)	(24.9)%
Trans Ova	(6,337)	(5,730)	(607)	(10.6)%
All Other	(5,952)	(10,708)	4,756	44.4 %
Unallocated corporate costs	47,577	84,536	(36,959)	(43.7)%

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

[Table of Contents](#)

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)%
MBP Titan	3,813	9,927	(6,114)	(61.6)%
Trans Ova	68,672	75,178	(6,506)	(8.7)%
All Other	16,227	30,213	(13,986)	(46.3)%

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.

MBP Titan

Research and development services performed on our partnered programs have declined in the current period as we focus more resources on our unpartnered platform, resulting in a decline in both Segment Adjusted EBITDA and revenues for this segment.

Trans Ova

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

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.

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017, together with the changes in those items in dollars and as a percentage:

	Year Ended December 31,		Dollar Change	Percent Change
	2018	2017		
	(In thousands)			
Revenues (1)				
Collaboration and licensing revenues (2)	\$ 69,540	\$ 134,624	\$ (65,084)	(48.3)%
Product revenues	28,486	33,585	(5,099)	(15.2)%
Service revenues	52,419	50,611	1,808	3.6 %
Other revenues	733	643	90	14.0 %
Total revenues	151,178	219,463	(68,285)	(31.1)%
Operating expenses				
Cost of products	35,087	33,236	1,851	5.6 %
Cost of services	27,589	28,456	(867)	(3.0)%
Research and development	366,248	109,176	257,072	>200%
Selling, general and administrative	125,751	130,682	(4,931)	(3.8)%
Impairment loss	—	13,823	(13,823)	(100.0)%
Total operating expenses	554,675	315,373	239,302	75.9 %
Operating loss	(403,497)	(95,910)	(307,587)	>200%
Total other income (expense), net	(17,259)	29,979	(47,238)	(157.6)%
Equity in loss of affiliates	(8,986)	(12,436)	3,450	(27.7)%
Loss from continuing operations before income taxes	(429,742)	(78,367)	(351,375)	>200%
Income tax benefit (expense)	15,425	(2,072)	17,497	>200%
Loss from continuing operations	(414,317)	(80,439)	(333,878)	>200%
Loss from discontinued operations, net of income tax benefit (3)	(100,389)	(46,381)	(54,008)	116.4 %
Net loss	(514,706)	(126,820)	(387,886)	>200%
Net loss attributable to noncontrolling interests	5,370	9,802	(4,432)	(45.2)%
Net loss attributable to Precigen	\$ (509,336)	\$ (117,018)	\$ (392,318)	>200%

- (1) Revenues in 2018 are accounted for under ASC 606 and revenues in 2017 are accounted for under 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.
- (2) Including \$55,573 and \$122,485 from related parties for the years ended December 31, 2018 and 2017, respectively.
- (3) The results of operations in the table above include the operations related to the Transactions in loss from discontinued operations, net of income tax benefit. The increase in the loss from discontinued operations in 2018 is due to additional impairment losses recorded at Oxitec. 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, 2018 and 2017, together with the changes in those items.

	Year Ended December 31,		Dollar Change
	2018	2017	
	(In thousands)		
ZIOPHARM Oncology, Inc.	\$ 16,298	\$ 69,812	\$ (53,514)
Ares Trading S.A.	11,175	10,738	437
Oragenics, Inc.	1,353	1,469	(116)
Intrexon T1D Partners, LLC	2,502	5,968	(3,466)
Intrexon Energy Partners, LLC	6,929	10,665	(3,736)
Intrexon Energy Partners II, LLC	2,998	3,672	(674)
Fibrocell Science, Inc.	1,394	7,344	(5,950)
OvaXon, LLC	—	1,966	(1,966)
S & I Ophthalmic, LLC	—	755	(755)
Harvest start-up entities (1)	14,447	15,232	(785)
Other	12,444	7,003	5,441
Total	\$ 69,540	\$ 134,624	\$ (65,084)

- (1) For the years ended December 31, 2018 and 2017, revenue recognized from collaborations with Harvest start-up entities include Genten Therapeutics, Inc.; CRS Bio, Inc.; Exotech Bio, Inc.; AD Skincare, Inc.; and Thrive Agrobotics, Inc. For the year ended December 31, 2017, revenues recognized from collaborations with Harvest start-up entities also include Relieve Genetics, Inc.

Collaboration and licensing revenues decreased \$65.1 million, or 48 percent, from the year ended December 31, 2017 due to (i) the mutual termination in 2017 of our second ECC with ZIOPHARM for the treatment of graft-versus-host disease, (ii) a decrease in research and development services for certain of our ECCs as we redeployed certain resources towards supporting prospective new platforms and partnering opportunities and began to focus more on the further development of relationships and structures that provide us with more control and ownership over the development process and commercialization path, including programs where we reacquired the previously licensed technology rights in 2018, and (iii) a decrease in research and development services we perform for collaborators upon the transition of program execution to our collaborators.

Product revenues and gross margin

Product revenue decreased \$5.1 million, or 15 percent, from the year ended December 31, 2017. The decrease in product revenues was primarily due to lower milk prices which in turn resulted in lower customer demand for live calves, cows previously used in production, and cloned products. Gross margin on products declined in the current period as a result of the lower product sales and increased operating costs associated with new product offerings and cloned products.

Service revenues and gross margin

Service revenue increased \$1.8 million, or 4 percent, over the year ended December 31, 2017. The increase in service revenues and gross margin thereon relates to pricing changes and an increase in the number of embryos produced per bovine in vitro fertilization cycle performed due to improved production results.

Research and development expenses

Research and development expenses increased \$257.1 million, or 236 percent, over the year ended December 31, 2017. Current period 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 \$4.9 million, or 4 percent, from the year ended December 31, 2017. Legal and professional fees decreased \$6.2 million primarily due to (i) decreased legal fees associated with ongoing litigation and (ii) decreased fees incurred for regulatory and other consultants.

Impairment loss

Impairment loss for the year ended December 31, 2017 of \$13.8 million resulted from our annual test for goodwill and indefinite-lived intangible asset impairment in the fourth quarter. Based on the price per share received by AquaBounty in its then-recent underwritten public offering, we determined that it was more likely than not that the fair value of our AquaBounty reporting unit was less than the carrying value and recorded a \$13.0 million impairment charge representing the estimated excess of carrying value over fair value of this reporting unit.

Total other income (expense), net

Total other income (expense), net, decreased \$47.2 million, or 158 percent, from the year ended December 31, 2017. This decrease was primarily attributable to losses on our investment in ZIOPHARM preferred stock prior to returning this investment to ZIOPHARM in October 2018, as well as an increase in interest expense related to the 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, 2018 and 2017, 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
	2018	2017		
(In thousands)				
Segment Adjusted EBITDA:				
PGEN Therapeutics	\$ (32,841)	\$ (5,655)	\$ (27,186)	<(200)%
ActoBio	(12,797)	(2,656)	(10,141)	<(200)%
MBP Titan	(29,403)	(32,251)	2,848	8.8%
Trans Ova	(5,730)	1,020	(6,750)	<(200)%
All Other	(10,708)	(1,102)	(9,606)	<(200)%
Unallocated corporate costs	84,536	53,197	31,339	58.9%

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

[Table of Contents](#)

The following table summarizes revenues from external customers for the years ended December 31, 2018 and 2017, for each of our reportable segments and for All Other segments combined.

	Year Ended December 31,		Dollar Change	Percent Change
	2018	2017		
	(In thousands)			
PGEN Therapeutics	\$ 29,021	\$ 53,184	\$ (24,163)	(45.4)%
ActoBio	6,684	12,929	(6,245)	(48.3)%
MBP Titan	9,927	14,336	(4,409)	(30.8)%
Trans Ova	75,178	79,783	(4,605)	(5.8)%
All Other	30,213	59,174	(28,961)	(48.9)%

PGEN Therapeutics

Revenues for PGEN Therapeutics declined from 2017 to 2018 due to a reduction in the level of services requested by our collaborators during the first half of the year and declined further in late 2018 upon the reacquisition of rights previously licensed to certain collaborators. The decline in Segment Adjusted EBITDA resulted from both the decline in revenues and also the increased costs of funding our own internal programs beginning in 2018.

ActoBio

The decrease in ActoBio's Segment Adjusted EBITDA and revenues is due to the Company reacquisition of rights previously licensed during 2018 to certain collaborators, including T1D and certain of the Harvest start-up entities. The result of which eliminated or substantially reduced revenues generated from those collaborations.

MBP Titan

Research and development services performed on our partnered programs have declined in 2018 as we focused more resources on our unpartnered platform, resulting in a decline in both Segment Adjusted EBITDA and revenues for this segment. The decline in Segment Adjusted EBITDA in 2018 was partially offset by a reduction in capital expenditure investments at MBP Titan's facility.

Trans Ova

The decrease in Trans Ova's Segment Adjusted EBITDA was primarily attributable to lower product revenues and margins thereon due to lower customer demand, as well as the cost of capital expenditure investments in Progentus' breeding herd and facility improvements in the 2018.

All Other

The Segment Adjusted EBITDA and revenues of All Other decreased due to the terminations of ECCs with certain collaborators.

Unallocated Corporate Costs

Unallocated corporate costs increased primarily due to a decline in the unrealized and realized appreciation (depreciation) in our securities portfolio of \$38.4 million primarily from unrealized losses on our ZIOPHARM preferred stock, which was partially offset with decreases in professional fees due to decreased fees incurred for regulatory and other consultants.

Liquidity and capital resources*Sources of liquidity*

We have incurred losses from operations since our inception, and as of December 31, 2019, we had an accumulated deficit of \$1.7 billion. From our inception through December 31, 2019, 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, 2019, we had cash and cash equivalents of \$65.8 million and short-term

investments of \$9.3 million. 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, reimbursement of research and development services performed by us, and from strategic transactions involving our subsidiaries. In January 2020, we also received proceeds of \$65.2 million from the Transactions and an additional \$35.0 million from the sale of our common stock in a private placement.

Cash flows

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

	Year Ended December 31,		
	2019	2018	2017
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$ (135,927)	\$ (124,240)	\$ (103,720)
Investing activities	86,851	(151,213)	104,332
Financing activities	8,138	309,795	4,284
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(810)	295	1,055
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (41,748)</u>	<u>\$ 34,637</u>	<u>\$ 5,951</u>

Cash flows from operating activities:

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.

In 2017, our net loss was \$126.8 million, which includes the following significant noncash expenses totaling \$114.9 million from both continuing and discontinued operations: (i) \$41.6 million of stock-based compensation expense, (ii) \$31.1 million of depreciation and amortization expense, (iii) \$16.8 million of impairment losses, (iv) \$14.3 million of equity in net loss of affiliates, and (v) \$11.1 million of shares issued as payment for services. These expenses were partially offset by \$16.8 million of noncash dividend income. Additionally, we had a \$74.6 million net increase in our operating assets and liabilities primarily as a result of the recognition of previously deferred revenue.

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.

Our 2018 cash outflows from operations increased \$20.5 million over the year ended December 31, 2017 primarily due to a decrease in revenues from research and development services for certain of our collaborations as we redeployed certain resources towards supporting prospective new platforms and partnering opportunities and began to focus more on the further

development of relationships and structures that provide us with more control and ownership over the development process and commercialization path.

Cash flows from investing activities:

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.

During 2017, we received proceeds of \$174.5 million from the maturity of short-term investments, and we used \$46.7 million for purchases of property, plant and equipment; \$14.2 million for the purchase of a land-based aquaculture facility by AquaBounty; and \$11.2 million for investments in our JVs.

Cash flows from financing activities:

During 2019, we received \$6.6 million net proceeds from public offerings through our consolidated subsidiary, AquaBounty, which we deconsolidated in April 2019.

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.

During 2017, we received \$13.7 million proceeds from a private placement of our common stock with an affiliate of Third Security and paid \$8.7 million of deferred consideration to former shareholders of acquired businesses.

Future capital requirements

We believe our existing liquid assets, including the cash received from the Transactions and the private placement in January 2020, 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;
- the timing of 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 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; and
- the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes.

Until such time, if ever, as we can regularly generate positive operating cash flows, we plan to finance our cash needs through a combination of equity offerings, debt financings, government, or other third-party funding, strategic alliances, sales of assets, and licensing arrangements. 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.

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, 2019 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	\$ 37,361	\$ 7,071	\$ 14,445	\$ 11,565	\$ 4,280
Convertible debt (1)	256,211	31,211	25,000	200,000	—
Cash interest payable on convertible debt	28,000	10,500	14,000	3,500	—
Long-term debt, excluding convertible debt	4,221	460	669	724	2,368
Contingent consideration	585	585	—	—	—
Total	<u>\$ 326,378</u>	<u>\$ 49,827</u>	<u>\$ 54,114</u>	<u>\$ 215,789</u>	<u>\$ 6,648</u>

(1) Of the \$256.2 million convertible debt, \$200.0 million may be converted into Precigen common stock, and \$56.2 million may be converted into either Precigen common stock or the stock of certain of our subsidiaries. See "Notes to the Consolidated Financial Statements - Note 12" appearing elsewhere in this Annual Report for further discussion of these instruments.

In addition to the obligations in the table above, as of December 31, 2019 we also have the following significant contractual obligations from continuing operations 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, 2019, 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, 2019, we also had research and development commitments with third parties totaling \$15.4 million that had not yet been incurred.

Net operating losses

As of December 31, 2019, we had net operating loss carryforwards of approximately \$568.8 million for United States federal income tax purposes available to offset future taxable income, including \$316.1 million generated after 2017, United States capital loss carryforwards of \$111.6 million, and United States federal and state research and development tax credits of approximately \$9.6 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 by 2024. Our foreign subsidiaries included in continuing operations have foreign loss carryforwards of approximately \$72.8 million, most of which do not expire. Excluding certain deferred tax liabilities totaling \$2.8 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, 2019, Precigen has utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, 2019, 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, other than purchase commitments as mentioned above, 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 (for the years ended December 31, 2019 and 2018)

Effective January 1, 2018, we apply ASC 606. Under ASC 606, 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 \$14.1 million and \$69.5 million of collaboration and licensing revenues in the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, we have \$50.6 million and \$54.3 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 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. 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 \$68.7 million and \$75.2 million of these product and service revenues from Trans Ova for the years ended December 31, 2019 and 2018, respectively.

Revenue recognition (for the year ended December 31, 2017)

Collaboration and licensing revenues

We have historically generated collaboration and licensing revenue through agreements with collaborators and licensing agreements whereby the collaborators or the licensees 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.

Our collaborations and licensing agreements typically contain multiple elements, or deliverables, including technology licenses, research and development services, and in certain cases manufacturing services. We identify the deliverables within the agreements and evaluate which deliverables represent separate units of accounting. Analyzing the agreements to identify deliverables requires the use of judgment. A deliverable is considered a separate unit of accounting when the deliverable has value to the collaborator or licensee on a standalone basis based on the consideration of the relevant facts and circumstances for each agreement.

Consideration received is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. When available, the relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of the selling price or third-party evidence of the selling price, if VSOE does not exist. If neither VSOE nor third-party evidence of the selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. We recognize the revenue allocated to each unit of accounting as we deliver the related goods or services. If we determine that certain deliverables should be treated as a single unit of accounting, then the revenue is recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. As we cannot reasonably estimate our performance obligations related to our collaborators or licensees, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations, which is reevaluated each reporting period.

The terms of our agreements may provide for milestone payments upon achievement of certain defined events. We apply the Milestone Method for recognizing milestone payments. Under the Milestone Method, we recognize consideration that is

contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
- The consideration relates solely to past performance; and
- The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

In the event that a milestone is not considered substantive, we recognize the milestone consideration as revenue using the same method applied to the upfront payments.

Research and development services are a deliverable satisfied by us in accordance with the terms of the collaboration and licensing agreements and we consider these services to be inseparable from the license to the core technology; therefore, reimbursements of services performed are recognized as revenue. Because reimbursement (i) is contingent upon performance of the services by us, (ii) does not include a profit component, and (iii) does not relate to any future deliverable, the revenue is recognized during the period in which the related services are performed and collection of such amounts is reasonably assured. Payments received for manufacturing services will be recognized when the earnings process related to the manufactured materials has been completed. Royalties to be received under the agreements will be recognized as earned.

From time to time, we and certain collaborators may cancel the agreements, relieving us of any further performance obligations under the agreement. When no further performance obligations are required of us under an agreement, we recognize the remaining balance of deferred revenue.

We recognized \$134.6 million of collaboration and licensing revenues in the year ended December 31, 2017.

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 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. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) services have been rendered or delivery has occurred such that risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collection from the customer is reasonably assured. We recognized \$78.8 million of these product and service revenues from Trans Ova for the year ended December 31, 2017.

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 year ended December 31, 2019, we recorded \$30.8 million of impairment charges from continuing operations to write down the values of goodwill and other long-lived assets. See additional discussion regarding this impairment 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, stock price 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 \$75.1 million and \$216.5 million as of December 31, 2019 and 2018, 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 a number of countries, including 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-68 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, 2019. 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, 2019, 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, 2019. 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, 2019.

Deloitte & Touche LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2019, 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, 2019 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 2020 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Shareholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 as of and for the Year Ended December 31, 2019

Report of Independent Registered Public Accounting Firm as of and for the Two Years Ended December 31, 2018

Consolidated Balance Sheets as of December 31, 2019 and 2018

Consolidated Statements of Operations for the Years Ended December 31, 2019, 2018, and 2017

Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2019, 2018, and 2017

Consolidated Statements of Shareholders' and Total Equity for the Years Ended December 31, 2019, 2018 and 2017

Consolidated Statements of Cash Flows for the Years Ended December 31, 2019, 2018, and 2017

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
1.1*	Controlled Equity OfferingSM Sales Agreement between the Company and Cantor Fitzgerald & Co., dated November 11, 2015 (6)
2.1*	Agreement and Plan of Merger, dated as of January 24, 2017, by and among the Company, GenVec and Intrexon GV Holding, Inc. (8)
3.1*	Amended and Restated Articles of Incorporation (20)
3.2*	Amended and Restated Bylaws (20)
4.1*	Specimen certificate evidencing shares of common stock (1)
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. (12)

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. (12)
4.5	Description of Securities
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 (7)
10.2F†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, effective as of June 28, 2017 (9)
10.2G†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 7, 2018 (11)
10.2H†*	Amendment to the Amended and Restated 2013 Omnibus Incentive Plan of the Company, as amended, effective as of June 12, 2019 (16)
10.2I†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Restricted Stock Unit Agreement, by and between the Company and Randal J. Kirk, effective as of April 1, 2019 (15)
10.2J†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Officers (10)
10.2K†*	2013 Amended and Restated Omnibus Incentive Plan of the Company, as amended, Form of Restricted Stock Unit Agreement for Directors (10)
10.3*	2019 Incentive Plan of the Company for Non-Employee Service Providers, effective as of June 12, 2019 (16)
10.4†*	Form of Continuing Employment Agreement (15)
10.5†*	Second Amended and Restated Employment Agreement, dated as of August 31, 2006, between the Company and Thomas D. Reed (1)
10.6†*	Employment Agreement, dated January 1, 2020, by and between the Company and Helen Sabzevari, Ph.D. (19)
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*	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)
10.11*	Registration Rights 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)
10.12#*	Exclusive License Agreement, dated October 5, 2018, by and between Precigen, Inc. and ZIOPHARM Oncology, Inc. (13)
10.13†*	Annual Executive Incentive Plan of the Company, adopted as of April 29, 2015 (5)
10.14*	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 (12)

- 10.15#* [Securities Purchase, Assignment and Assumption Agreement, dated December 19, 2018, by and between the Company, ARES TRADING S.A. and Precigen, Inc.](#) (14)
- 10.16#* [Convertible Note issued to ARES TRADING S.A., dated December 28, 2018](#) (14)
- 10.17* [Stock Purchase Agreement, dated October 29, 2019, by and between the Company and TS AquaCulture](#) (17)
- 10.18* [Stock and Asset Purchase Agreement, dated January 1, 2020, by and between the Company and TS Biotechnology Holdings, LLC](#) (18)
- 10.19* [Subscription Agreement, dated January 1, 2020, by and between the Company and TS Biotechnology Holdings, LLC](#) (18)
- 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 Randal J. Kirk, Executive Chairman \(Principal Executive Officer\) 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 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](#)
- 31.3 [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 Randal J. Kirk, Executive Chairman \(Principal Executive Officer\) 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 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](#)
- 32.3** [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, 2019, 2018 and 2017, 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, 2019 and 2018, (ii) the Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017, (iii) the Consolidated Statements of Shareholders' and Total Equity for the years ended December 31, 2019, 2018 and 2017, (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017 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 November 12, 2015.
- (7) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2016.

- (8) Amendment No. 2 to the Registration Statement on Form S-4, filed with the Securities and Exchange Commission on May 11, 2017.
- (9) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 30, 2017.
- (10) Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2018.
- (11) Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 8, 2018.
- (12) Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 3, 2018.
- (13) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 8, 2018.
- (14) Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2019.
- (15) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 9, 2019.
- (16) Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 9, 2019.
- (17) Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 31, 2019.
- (18) Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 2, 2020.
- (19) Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 7, 2020.
- (20) Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 4, 2020.

** Furnished herewith

† Indicates management contract or compensatory plan.

Portions of the exhibit (indicated by asterisks) have been omitted as permitted by the Securities and Exchange Commission.

(c) Financial Statement Schedules

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

Item 16. Form 10-K Summary

None.

Index to the Financial Statements and Schedules

	Page(s)
Consolidated Financial Statements of Precigen, Inc. and Subsidiaries	F-2
Reports of Independent Registered Public Accounting Firm as of and for the Year Ended December 31, 2019	F-3
Report of Independent Registered Public Accounting Firm as of and for the Two Years Ended December 31, 2018	F-7
Consolidated Balance Sheets as of December 31, 2019 and 2018	F-8
Consolidated Statements of Operations for the Years Ended December 31, 2019, 2018, and 2017	F-10
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2019, 2018, and 2017	F-11
Consolidated Statements of Shareholders' and Total Equity for the Years Ended December 31, 2019, 2018, and 2017	F-12
Consolidated Statements of Cash Flows for the Years Ended December 31, 2019, 2018, and 2017	F-15
Notes to the Consolidated Financial Statements	F-18

Precigen, Inc. and Subsidiaries
Consolidated Financial Statements
December 31, 2019, 2018 and 2017

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 sheet of Precigen, Inc. (formerly Intrexon Corporation) and subsidiaries (the "Company") as of December 31, 2019, the related consolidated statements of operations, comprehensive loss, shareholders' and total equity, and cash flows, for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, 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, 2019, 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 2, 2020, 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 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 the 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 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition - Collaboration and Licensing Revenues - Refer to Notes 2 and 6 to the financial statements

Critical Audit Matter Description

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. 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. Options to acquire additional services are considered to determine if they constitute material rights. 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. For the year ended December 31, 2019, the Company's total revenue from continuing operations was \$90.7 million, of which \$14.1 million relates to collaboration and licensing revenues.

[Table of Contents](#)

Given the judgments necessary to estimate total contract costs and revenue for the performance obligation used to recognize revenue for certain collaboration and licensing contracts, auditing such estimates required extensive audit effort due to the complexity of collaboration and licensing contracts and the high degree of auditor judgment applied when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's estimates of total contract costs and revenue for the performance obligation used to recognize revenue for certain collaboration and licensing contracts included the following, among others:

- We tested the operating effectiveness of controls over contract revenue, including those over the estimates of total contract costs and revenue for performance obligations.
- We selected a sample of collaboration and licensing contracts and performed the following:
 - Evaluated whether the contracts were properly included in management's calculation of contract revenue based on the terms and conditions of each contract, including whether transfer of control to the customer occurred as progress was made toward fulfilling the performance obligation.
 - Compared the transaction price to the consideration expected to be received based on current rights and obligations under the contracts and any modifications that were agreed upon with the customers.
 - Tested management's identification of the distinct performance obligation(s) by evaluating whether the underlying technology license, services, or both were highly interdependent and interrelated.
 - Evaluated management's determination of the contractual term and the appropriateness of management's method to measure its progress over that term.
 - Tested the accuracy and completeness of the total contract costs incurred to date for the performance obligation.
 - Evaluated the estimates of total contract costs and revenue for the performance obligation by:
 - Comparing costs incurred to date to the costs management estimated to be incurred to date.
 - Evaluating management's ability to achieve the estimates of total contract costs by performing corroborating inquiries with the Company's project managers and financial analysts, and comparing the estimates to management's work plans and cost estimates.
 - We evaluated management's ability to estimate total contract costs accurately by comparing actual costs to management's historical estimates for performance obligations that have been fulfilled.
 - Tested the mathematical accuracy of management's calculation of revenue for the performance obligation.

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 \$63.8 million as of December 31, 2019. 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. 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 the carrying amount. As a result, the Company compared the carrying amount of the Trans Ova reporting unit to the fair value as of the measurement date and determined the carrying amount exceeded the fair value, resulting in a \$29.6 million goodwill impairment charge.

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 operations to changes in these estimates, performing audit procedures to evaluate the

[Table of Contents](#)

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 and external information.
- 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 2, 2020

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. (formerly Intrexon Corporation) and subsidiaries (the "Company") as of December 31, 2019, 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, 2019, 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, 2019, of the Company and our report dated March 2, 2020, 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 2, 2020

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 balance sheet of Precigen, Inc. (formerly known as Intrexon Corporation) and its subsidiaries (the "Company") as of December 31, 2018, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' and total equity and cash flows for each of the two years in the period 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 financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for each of the two years in the period 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.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for revenues from contracts with customers in 2018.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina

March 1, 2019, except for the effects of discontinued operations discussed in Note 3 and the change in composition of reportable segments discussed in Note 20, as to which the date is March 2, 2020.

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

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2019 and 2018

(Amounts in thousands, except share data)	2019	2018
Assets		
Current assets		
Cash and cash equivalents	\$ 65,793	\$ 96,876
Restricted cash	—	6,987
Short-term investments	9,260	119,614
Equity securities	—	384
Receivables		
Trade, net	20,650	21,179
Related parties, net	600	4,129
Other	4,978	1,257
Inventory	16,097	20,575
Prepaid expenses and other	6,444	5,327
Current assets held for sale	110,821	9,155
Total current assets	234,643	285,483
Equity securities, noncurrent	—	640
Property, plant and equipment, net	60,969	86,896
Intangible assets, net	68,346	88,962
Goodwill	63,754	93,627
Investments in affiliates	1,461	2,139
Right-of-use assets	25,228	—
Other assets	1,362	2,069
Noncurrent assets held for sale	—	156,361
Total assets	\$ 455,763	\$ 716,177

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

Precigen, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2019 and 2018

(Amounts in thousands, except share data)	2019	2018
Liabilities and Total Equity		
Current liabilities		
Accounts payable	\$ 5,917	\$ 11,973
Accrued compensation and benefits	14,091	9,955
Other accrued liabilities	12,049	19,005
Deferred revenue, including \$877 and \$6,502 from related parties as of December 31, 2019 and 2018, respectively	5,697	11,088
Lines of credit	1,922	466
Current portion of long-term debt, including \$31,211 and \$0 to related parties as of December 31, 2019 and 2018, respectively	31,670	479
Current portion of lease liabilities	4,182	—
Related party payables	51	256
Current liabilities held for sale	47,333	8,340
Total current liabilities	122,912	61,562
Long-term debt, net of current portion, including \$25,000 and \$55,290 to related parties as of December 31, 2019 and 2018, respectively	186,321	211,216
Deferred revenue, net of current portion, including \$30,182 and \$44,772 from related parties as of December 31, 2019 and 2018, respectively	48,136	46,728
Lease liabilities, net of current portion	23,849	—
Deferred tax liabilities	2,834	3,856
Other long-term liabilities	—	3,135
Long-term liabilities held for sale	—	10,958
Total liabilities	384,052	337,455
Commitments and contingencies (Note 17)		
Total equity		
Common stock, no par value, 400,000,000 shares and 200,000,000 shares authorized as of December 31, 2019 and 2018, respectively; and 163,274,880 shares and 160,020,466 shares issued and outstanding as of December 31, 2019 and 2018, respectively	—	—
Additional paid-in capital	1,752,048	1,722,012
Accumulated deficit	(1,652,869)	(1,330,545)
Accumulated other comprehensive loss	(27,468)	(28,612)
Total Precigen shareholders' equity	71,711	362,855
Noncontrolling interests	—	15,867
Total equity	71,711	378,722
Total liabilities and total equity	\$ 455,763	\$ 716,177

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

Precigen, Inc. and Subsidiaries
Consolidated Statements of Operations
Years Ended December 31, 2019, 2018 and 2017

(Amounts in thousands, except share and per share data)	2019	2018	2017
Revenues			
Collaboration and licensing revenues, including \$11,832, \$55,573, and \$122,485 from related parties in 2019, 2018, and 2017, respectively	\$ 14,059	\$ 69,540	\$ 134,624
Product revenues	23,780	28,486	33,585
Service revenues	51,803	52,419	50,611
Other revenues	1,080	733	643
Total revenues	<u>90,722</u>	<u>151,178</u>	<u>219,463</u>
Operating Expenses			
Cost of products	31,930	35,087	33,236
Cost of services	29,471	27,589	28,456
Research and development	101,879	366,248	109,176
Selling, general and administrative	100,844	125,751	130,682
Impairment loss	30,810	—	13,823
Total operating expenses	<u>294,934</u>	<u>554,675</u>	<u>315,373</u>
Operating loss	<u>(204,212)</u>	<u>(403,497)</u>	<u>(95,910)</u>
Other Income (Expense), Net			
Unrealized and realized appreciation (depreciation) in fair value of equity securities and preferred stock, net	8,291	(28,273)	10,130
Interest expense	(17,666)	(8,473)	(584)
Interest and dividend income	3,871	19,017	19,431
Other income, net	3,445	470	1,002
Total other income (expense), net	<u>(2,059)</u>	<u>(17,259)</u>	<u>29,979</u>
Equity in net loss of affiliates	<u>(2,416)</u>	<u>(8,986)</u>	<u>(12,436)</u>
Loss from continuing operations before income taxes	<u>(208,687)</u>	<u>(429,742)</u>	<u>(78,367)</u>
Income tax benefit (expense)	930	15,425	(2,072)
Loss from continuing operations	<u>(207,757)</u>	<u>(414,317)</u>	<u>(80,439)</u>
Loss from discontinued operations, net of income tax benefit	<u>(116,159)</u>	<u>(100,389)</u>	<u>(46,381)</u>
Net loss	<u>\$ (323,916)</u>	<u>\$ (514,706)</u>	<u>\$ (126,820)</u>
Net loss attributable to the noncontrolling interests	1,592	5,370	9,802
Net loss attributable to Precigen	<u>\$ (322,324)</u>	<u>\$ (509,336)</u>	<u>\$ (117,018)</u>
Amounts Attributable to Precigen			
Net loss from continuing operations attributable to Precigen	<u>\$ (206,165)</u>	<u>\$ (408,947)</u>	<u>\$ (70,637)</u>
Net loss from discontinued operations attributable to Precigen	<u>(116,159)</u>	<u>(100,389)</u>	<u>(46,381)</u>
Net loss attributable to Precigen	<u>\$ (322,324)</u>	<u>\$ (509,336)</u>	<u>\$ (117,018)</u>
Net Loss per Share			
Net loss from continuing operations attributable to Precigen per share, basic and diluted	<u>\$ (1.34)</u>	<u>\$ (3.16)</u>	<u>\$ (0.59)</u>
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	<u>(0.75)</u>	<u>(0.77)</u>	<u>(0.39)</u>
Net loss attributable to Precigen per share, basic and diluted	<u>\$ (2.09)</u>	<u>\$ (3.93)</u>	<u>\$ (0.98)</u>
Weighted average shares outstanding, basic and diluted	<u>154,138,774</u>	<u>129,521,731</u>	<u>119,998,826</u>

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, 2019, 2018 and 2017

(Amounts in thousands)	2019	2018	2017
Net loss	\$ (323,916)	\$ (514,706)	\$ (126,820)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments	68	(59)	87
Gain (loss) on foreign currency translation adjustments	1,087	(13,073)	20,599
Comprehensive loss	(322,761)	(527,838)	(106,134)
Comprehensive loss attributable to the noncontrolling interests	1,581	5,548	9,764
Comprehensive loss attributable to Precigen	\$ (321,180)	\$ (522,290)	\$ (96,370)

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, 2019, 2018 and 2017

(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, 2016	118,688,770	\$ —	\$1,325,780	\$ (36,202)	\$ (729,341)	\$ 560,237	\$ 9,011	\$ 569,248
Cumulative effect of adoption of ASU 2016-09	—	—	1,461	—	(1,461)	—	—	—
Stock-based compensation expense	—	—	41,525	—	—	41,525	51	41,576
Exercises of stock options and warrants	149,429	—	952	—	—	952	28	980
Shares issued as payment for services	654,456	—	11,118	—	—	11,118	—	11,118
Shares issued in private placement	1,207,980	—	13,686	—	—	13,686	—	13,686
Shares and warrants issued in business combination	684,240	—	16,997	—	—	16,997	—	16,997
Acquisitions of noncontrolling interests	221,743	—	5,082	—	—	5,082	(5,995)	(913)
Shares issued as payment of deferred consideration	480,422	—	—	—	—	—	—	—
Adjustments for noncontrolling interests	—	—	2,789	—	—	2,789	(2,802)	(13)
Noncash dividend	—	—	(22,385)	—	—	(22,385)	22,385	—
Net loss	—	—	—	—	(117,018)	(117,018)	(9,802)	(126,820)
Other comprehensive income	—	—	—	20,648	—	20,648	38	20,686
Balances at December 31, 2017	<u>122,087,040</u>	<u>\$ —</u>	<u>\$1,397,005</u>	<u>\$ (15,554)</u>	<u>\$ (847,820)</u>	<u>\$ 533,631</u>	<u>\$ 12,914</u>	<u>\$ 546,545</u>

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, 2019, 2018 and 2017

(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	<u>160,020,466</u>	<u>\$ —</u>	<u>\$1,722,012</u>	<u>\$ (28,612)</u>	<u>\$(1,330,545)</u>	<u>\$ 362,855</u>	<u>\$ 15,867</u>	<u>\$ 378,722</u>

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, 2019, 2018 and 2017

(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, 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	<u>163,274,880</u>	<u>\$ —</u>	<u>\$1,752,048</u>	<u>\$ (27,468)</u>	<u>\$(1,652,869)</u>	<u>\$ 71,711</u>	<u>\$ —</u>	<u>\$ 71,711</u>

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, 2019, 2018 and 2017

(Amounts in thousands)	2019	2018	2017
Cash flows from operating activities			
Net loss	\$ (323,916)	\$ (514,706)	\$ (126,820)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	24,896	33,112	31,145
Loss on abandonment and disposals of assets, net	3,071	20,928	3,124
Impairment loss	120,489	60,504	16,773
Reacquisition of in-process research and development	—	236,748	—
Unrealized and realized (appreciation) depreciation on equity securities and preferred stock, net	(7,833)	30,200	(2,586)
Noncash dividend income	(48)	(14,841)	(16,756)
Amortization of premiums (discounts) on investments, net	(1,005)	(771)	411
Equity in net loss of affiliates	6,730	11,608	14,283
Stock-based compensation expense	18,950	36,296	41,576
Shares issued as payment for services	10,446	10,695	11,118
Provision for bad debts	3,242	1,779	1,217
Accretion of debt discount and amortization of deferred financing costs	9,459	4,378	—
Deferred income taxes	(3,674)	(21,278)	(2,528)
Other noncash items	837	1,093	(517)
Changes in operating assets and liabilities:			
Receivables:			
Trade	(262)	(2,698)	740
Related parties	967	11,003	631
Other	(656)	(542)	661
Inventory	4,100	(478)	663
Prepaid expenses and other	(2,262)	1,006	492
Other assets	333	652	(1,017)
Accounts payable	(5,349)	4,680	(3,402)
Accrued compensation and benefits	5,186	4,385	(1,466)
Other accrued liabilities	(5,516)	356	3,007
Deferred revenue	7,423	(38,578)	(75,337)
Deferred consideration	—	—	(313)
Lease liabilities	(995)	—	—
Related party payables	45	(52)	(147)
Other long-term liabilities	(585)	281	1,328
Net cash used in operating activities	(135,927)	(124,240)	(103,720)

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, 2019, 2018 and 2017

(Amounts in thousands)	2019	2018	2017
Cash flows from investing activities			
Purchases of investments	(55,073)	(178,681)	—
Sales and maturities of investments	166,495	65,975	174,542
Purchases of preferred stock and warrants	—	—	(1,161)
Proceeds from sales of equity securities	23,456	217	235
Acquisitions of businesses, net of cash received	—	(920)	2,054
Investments in affiliates	(3,713)	(16,582)	(11,189)
Decrease in cash from deconsolidation of subsidiary	(7,244)	—	—
Return of investment in affiliate	125	2,598	—
Cash received (paid) in asset acquisitions	—	15,500	(14,219)
Purchases of property, plant and equipment	(37,883)	(41,587)	(46,666)
Proceeds from sale of assets	688	2,267	1,636
Issuances of notes receivable	—	—	(2,400)
Proceeds from repayment of notes receivable	—	—	1,500
Net cash provided by (used in) investing activities	86,851	(151,213)	104,332
Cash flows from financing activities			
Proceeds from issuance of shares in a private placement	—	—	13,686
Proceeds from issuance of shares and warrants in public offerings, net of issuance costs	6,611	87,990	—
Acquisitions of noncontrolling interests	—	—	(913)
Advances from lines of credit	11,757	4,561	5,906
Repayments of advances from lines of credit	(10,301)	(4,328)	(6,493)
Proceeds from long-term debt, net of issuance costs	376	219,859	325
Payments of long-term debt	(618)	(623)	(519)
Payments of deferred consideration for acquisitions	—	—	(8,678)
Proceeds from stock option and warrant exercises	313	2,336	980
Payment of stock issuance costs	—	—	(10)
Net cash provided by financing activities	8,138	309,795	4,284
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(810)	295	1,055
Net increase (decrease) in cash, cash equivalents, and restricted cash	(41,748)	34,637	5,951
Cash, cash equivalents, and restricted cash			
Beginning of year	110,182	75,545	69,594
End of year	\$ 68,434	\$ 110,182	\$ 75,545

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, 2019, 2018 and 2017

(Amounts in thousands)	2019	2018	2017
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	\$ 3,751	\$ 3,868	\$ 617
Cash paid during the period for income taxes	50	216	566
Significant noncash activities			
Stock received as consideration for collaboration agreements	\$ 4,530	\$ —	\$ —
Receivables converted to preferred stock	—	—	3,385
Stock and warrants issued in business combinations	—	—	16,997
Stock issued to acquire noncontrolling interests	—	—	5,082
Stock issued for reacquired in-process research and development	—	159,323	—
Long-term debt issued to a related party in an asset acquisition	—	30,000	—
Noncash dividend to shareholders	—	—	22,385
Purchases of property and equipment included in accounts payable and other accrued liabilities	694	2,267	2,257
Purchases of equipment financed through debt	—	234	—
Receivable recorded in anticipation of dissolution of affiliate	—	—	2,598

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of December 31, 2019 and 2018 as shown above:

	2019	2018
Cash and cash equivalents	\$ 65,793	\$ 96,876
Restricted cash	—	6,987
Cash and cash equivalents included in current assets held for sale	2,223	5,892
Restricted cash included in other assets	418	427
Cash, cash equivalents, and restricted cash	<u>\$ 68,434</u>	<u>\$ 110,182</u>

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"), formerly known as Intrexon Corporation, 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. Precigen also continues to advance its methane bioconversion business and its established bovine genetics company. There have been no commercialized products derived either directly by Precigen or through its collaborations or joint ventures ("JVs") to date.

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

Precigen ActoBio, Inc. ("ActoBio"), formerly known as ActoBio Therapeutics, Inc., 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 ("Exemplar") is committed to enabling the study of life-threatening human diseases through the development of miniswine 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.

Effective October 1, 2019, Precigen transferred substantially all of its proprietary methane bioconversion platform assets to a new wholly owned subsidiary, MBP Titan LLC ("MBP Titan"), with primary operations in California. MBP Titan's proprietary methane bioconversion platform is designed to turn 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, MBP Titan was an operating division within Precigen. There was no impact to the accompanying consolidated financial statements resulting from the transfer of these assets.

Trans Ova Genetics, L.C. ("Trans Ova"), Progentus, L.C. ("Progentus"), and ViaGen, L.C. ("ViaGen"), providers of advanced 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, New York, Oklahoma, Texas, and Washington.

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. After remeasuring its retained interest in AquaBounty, Precigen recorded 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. The deconsolidation resulted in the derecognition of the carrying amount of \$38,682 in net assets that are no longer reported in the accompanying consolidated balance sheet during the year ended December 31, 2019. See Notes 10, 11, and 12 for additional discussion of material impacts to the accompanying consolidated balance sheet as of December 31, 2019. After deconsolidating the entity in April 2019, Precigen accounted for these equity securities using the fair value option. In October 2019, 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 (depreciation) 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 bioengineering assets and operations, which are presented as discontinued operations for all periods presented. See Notes 3 and 23 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, 2019, as well as amounts secured subsequent to December 31, 2019 and before the issuance of these consolidated financial statements, 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, 2019, the Company incurred a net loss attributable to Precigen of \$322,324 and, as of December 31, 2019, has an accumulated deficit of \$1,652,869. 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 nonhealthcare businesses, obtain regulatory approval of its products, successfully commercialize its products, generate revenue, meet its obligations and, ultimately, attain profitable operations.

Upon the original issuance of the Company's financial statements as of and 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 be 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 the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated.

Revenue Recognition (For the Years Ended December 31, 2019 and 2018)

Effective January 1, 2018, the Company applies Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, 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 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. 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.

Revenue Recognition (For the Year Ended December 31, 2017)

Collaboration and licensing revenues

The Company historically generated collaboration and licensing revenue through agreements with collaborators 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 Company's collaboration and licensing agreements typically contain multiple elements, or deliverables, including technology licenses, research and development services, and in certain cases manufacturing services. The Company identifies the deliverables within the agreements and evaluates which deliverables represent separate units of accounting. Analyzing the agreements to identify deliverables requires the use of judgment. A deliverable is considered a separate unit of accounting when the deliverable has value to the collaborator or licensee on a standalone basis based on the consideration of the relevant facts and circumstances for each agreement.

Consideration received is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. When available, the relative selling price for each deliverable is determined using vendor specific objective evidence ("VSOE") of the selling price or third-party evidence of the selling price, if VSOE does not exist. If neither VSOE nor third-party evidence of the selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. The Company recognizes the revenue allocated to each unit of accounting as the Company delivers the related goods or services. If the Company determines that certain deliverables should be treated as a single unit of accounting, then the revenue is recognized using either a proportional performance or straight-line method, depending on whether the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. As the Company cannot reasonably estimate its performance

obligations related to its collaborators or licensees, the Company recognizes revenue on a straight-line basis over the period it expects to complete its performance obligations, which is reevaluated each reporting period.

The terms of the Company's agreements may provide for milestone payments upon achievement of certain defined events. The Company applies the Milestone Method for recognizing milestone payments. Under the Milestone Method, the Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- (1) The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
- (2) The consideration relates solely to past performance; and
- (3) The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

In the event that a milestone is not considered substantive, the Company recognizes the milestone consideration as revenue using the same method applied to upfront payments.

Research and development services are a deliverable satisfied by the Company in accordance with the terms of the collaboration and licensing agreements and the Company considers these services to be inseparable from the license to the core technology; therefore, reimbursements of services performed are recognized as revenue. Because reimbursement (i) is contingent upon performance of the services by the Company, (ii) does not include a profit component, and (iii) does not relate to any future deliverable, the revenue is recognized during the period in which the related services are performed and collection of such amounts is reasonably assured. Payments received for manufacturing services will be recognized when the earnings process related to the manufactured materials has been completed. Royalties to be received under the agreements will be recognized as earned.

From time to time, the Company and certain collaborators may cancel their agreements, relieving the Company of any further performance obligations under the agreement. When no further performance obligations are required of the Company under an agreement, the Company recognizes the remaining balance of deferred 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. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) services have been rendered or delivery has occurred such that risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collection from the customer is reasonably assured.

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, 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, 2019 and 2018, the Company had research and development commitments from continuing operations with third parties that had not yet been incurred totaling \$15,369 and \$11,801, 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, 2019 and 2018, the Company had cash equivalent investments in highly liquid money market accounts at major financial institutions of \$47,238 and \$40,155, respectively.

Restricted Cash

Restricted cash represented funds deposited with the United States Treasury, as required by a court decision resulting from litigation against Trans Ova (Note 17).

Short-term and Long-term Investments

As of December 31, 2019, 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 has 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. In June 2019, in connection with its collaboration agreement with Surterra Holdings, Inc. ("Surterra"), the Company received common shares of Surterra's parent company, SH Parent, Inc. ("SH Parent") and accounted for these common shares using the measurement alternative method. As of December 31, 2019, there have been no adjustments for impairment or observable price changes for the SH Parent common shares and these shares have been reclassified to current assets held for sale as of December 31, 2019, and were subsequently sold in January 2020 (Note 3). Equity securities that the Company did not intend to sell within one year were classified as noncurrent in the consolidated balance sheets. 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, 2019, there were no gross unrealized losses on the Company's short-term investments. 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 JVs and for its investments 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 Note 4 and to certain of the Company's JVs in Note 5.

Effective in April 2019, the Company accounted for its investment in AquaBounty, using the fair value option until the Company sold the investment in October 2019. See Note 1 for additional discussion regarding AquaBounty.

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, 2019 and 2018, the Company determined that certain of its collaborators and JVs as well as Harvest were VIEs. The Company was not the primary beneficiary for these entities since it did not have the power to direct the activities that most significantly impact the economic performance of the VIEs. The Company's aggregate investment balances of these VIEs as of December 31, 2019 and 2018, were \$1,461 and \$3,341, 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 the significant JVs.

Accounts Receivables

Accounts receivables consist of credit extended to the Company's customers in the normal course of business and are reported net of an allowance for doubtful accounts. The Company reviews its customer accounts on a periodic basis and records bad debt expense for specific amounts the Company evaluates as uncollectible. Past due status is determined based upon contractual terms. Amounts are written off at the point when collection attempts have been exhausted. Management estimates uncollectible amounts considering such factors as current economic conditions and historic and anticipated customer performance. This estimate can fluctuate due to changes in economic, industry, or specific customer conditions that may require adjustment to the allowance recorded by the Company. Management has included amounts believed to be uncollectible in the allowance for doubtful accounts.

The following table shows the activity in the allowance for doubtful receivable accounts from continuing operations for the years ended December 31, 2019, 2018, and 2017:

	2019	2018	2017
Beginning balance	\$ 4,991	\$ 4,631	\$ 3,703
Charged to operating expenses	3,384	1,627	1,217
Write offs of accounts receivable, net of recoveries	(862)	(1,267)	(289)
Ending balance	<u>\$ 7,513</u>	<u>\$ 4,991</u>	<u>\$ 4,631</u>

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 generally 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	1-10
Equipment	1-9
Breeding stock	1-4
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 adopted ASC Topic 842, *Leases* ("ASC 842"), effective January 1, 2019. Under ASC 842, 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 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 performs 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). If the fair value of the reporting unit is less than its carrying amount, an indication of goodwill impairment exists for the reporting unit and 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. In April 2019, as a result of the Company's change in segments (Notes 2 and 20), one of the Company's prior reporting units was separated into various reporting units. Accordingly, the Company performed a relative fair value allocation of certain of its goodwill to the applicable reporting units and reviewed the reallocated goodwill for impairment.

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 year ended December 31, 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. Indefinite-lived intangible assets consist of in-process research and development technologies acquired in mergers or acquisitions and were recorded at fair value at the dates of the respective acquisitions.

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.

Indefinite-lived intangible assets, including in-process research and development, are tested for impairment annually, or more frequently if events or circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of their fair value to carrying value, without consideration of any recoverability test. The Company monitors the progression of its in-process research and development, as the likelihood of success is contingent upon commercial development or regulatory approval.

See Notes 3 and 10 for additional discussion of impairment of long-lived assets for the three years ended December 31, 2019.

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 is 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 represents the value of the conversion option and is 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 are 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 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 allocated to additional paid-in capital are 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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law and significantly revised United States corporate income tax law by, among other things, reducing the corporate income tax rate to 21% effective January 1, 2018, eliminating the corporate alternative minimum tax and implementing a modified territorial tax system that includes a one-time transition tax on deemed repatriated earnings from foreign subsidiaries. The United States Securities and Exchange Commission ("SEC") Staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed, including computations, in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company recognized provisional tax impacts related to revaluation of most of the Company's domestic deferred tax assets, the impact of revaluation of those deferred tax assets on the Company's valuation allowance and elimination of the corporate alternative minimum tax, and included those amounts in the consolidated financial statements for the year ended December 31, 2017. The Company completed its accounting for the Tax Act in the fourth quarter of 2018, and there were no significant adjustments to the previously recorded provisional amounts.

In addition, the Tax Act implemented a new minimum tax on global intangible low-taxed income ("GILTI"). A company can elect an accounting policy to account for GILTI in either of the following ways:

- As a period charge in the future period in which the tax arises; or
- As part of deferred taxes related to the investment or subsidiary.

The Company elected to account for GILTI as a period charge in the period in which the tax arises. There was no impact to the accompanying consolidated financial statements as of and for the years ended December 31, 2019 and 2018.

See Note 13 for additional discussion of the Tax Act.

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. Since Precigen does not have sufficient history to estimate the expected volatility of its common stock price, expected volatility is based on a blended approach that utilizes the volatility of Precigen's common stock and the volatility of peer public entities that are similar in size and industry. Precigen estimates the expected term of all options based on previous history of exercises. 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, 2019, 2018 and 2017 are set forth in the table below:

	2019	2018	2017
Valuation assumptions			
Expected dividend yield	0%	0%	0%
Expected volatility	58%—64%	55%—59%	57%—60%
Expected term (years)	6.25	6.25	6.25
Risk-free interest rate	1.53%—2.58%	2.33%—3.06%	1.89%—2.27%

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 realigned its business in April 2019, and as a result, its chief operating decision maker ("CODM") now regularly reviews disaggregated financial information for various operating segments. As of December 31, 2019, the Company's reportable segments were (i) PGEN Therapeutics; (ii) ActoBio; (iii) MBP Titan; and (iv) Trans Ova. 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 each of these reportable segments. 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, 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. The Company's segment presentation has been recast to retrospectively reflect the change from one reportable segment to multiple reportable segments. 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

The Company adopted ASC 842 on January 1, 2019 using the modified retrospective method as of the adoption date without restating prior periods. In addition, the Company elected to use the package of practical expedients which allowed the Company to not have to reassess whether expired or existing contracts contain leases under the new definition of a lease or the lease classification for expired or existing leases under ASC Topic 840. As a result of the adoption of ASC 842, the Company recorded ROU Assets and lease liabilities of \$30,000 and \$32,300, respectively, as of January 1, 2019 for continuing operations. The difference between the ROU Assets and lease liabilities primarily represents the balance of deferred rent as of December 31, 2018 that resulted from historical straight-lining of operating leases expense, which was reclassified upon adoption to reduce the measurement of the ROU Assets. There was no impact to accumulated deficit.

In June 2018, the FASB issued Accounting Standards Update ("ASU") 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). The provisions of ASU 2018-07 expand the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted this standard effective January 1, 2019, and there was no material impact to the accompanying consolidated financial statements.

Recently Issued 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 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 guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's 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 guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's 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 guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's 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 guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

3. Discontinued Operations

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 bioengineering 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 held in Oragenics, Inc. ("Oragenics") and SH Parent that were directly related to the subsidiaries sold:

- Intrexon Produce Holdings, Inc. is the parent company of the Company's non-browning apple subsidiaries, Okanagan Specialty Fruits, Inc. and Fruit Orchard Holdings, Inc. (collectively referred herein as "Okanagan");
- Intrexon UK Holdings, Inc. is the parent company of Oxitec Limited and subsidiaries, which is a pioneering company in biological insect solutions (referred to herein as "Oxitec");
- ILH Holdings, Inc. includes the Company's fine chemicals operations that were focused primarily on microbial production of therapeutic compounds ("Fine Chemicals"); and
- Blue Marble AgBio LLC which was formed in January 2020 and includes the Company's agriculture biotechnology assets and operations which were previously a division within Precigen ("AgBio").

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 represent 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. As of December 31, 2019, the Company has estimated \$942 of selling costs related to the Transactions.

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

	December 31, 2019		
	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	<u>\$ 98,621</u>	<u>\$ 12,200</u>	<u>\$ 110,821</u>
Liabilities			
Deferred revenue, current (1)	\$ 8,723	\$ —	\$ 8,723
Operating 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
Operating lease liabilities, net of current portion	12,623	—	12,623
Other long-term liabilities	1,019	—	1,019
Total liabilities held for sale	<u>\$ 47,292</u>	<u>\$ 41</u>	<u>\$ 47,333</u>

(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.

	December 31, 2018		
	TS Biotechnology Sale	EnviroFlight Sale	Total
Assets			
Cash and cash equivalents	\$ 5,892	\$ —	\$ 5,892
Other current assets	3,263	—	3,263
Property, plant and equipment, net	41,978	—	41,978
Intangible assets, net	31,782	8,547	40,329
Investments in affiliates	—	16,720	16,720
Goodwill	55,958	—	55,958
Other noncurrent assets	1,376	—	1,376
Total assets held for sale	<u>\$ 140,249</u>	<u>\$ 25,267</u>	<u>\$ 165,516</u>
Liabilities			
Deferred revenue, current (1)	\$ 4,466	\$ —	\$ 4,466
Other current liabilities	3,874	—	3,874
Deferred revenue, net of current portion (2)	7,482	—	7,482
Other long-term liabilities	3,476	—	3,476
Total liabilities held for sale	<u>\$ 19,298</u>	<u>\$ —</u>	<u>\$ 19,298</u>

(1) Includes deferred revenue, current, from related parties of \$443.

(2) Includes deferred revenue, net of current portion, from related parties of \$7,455.

The following tables present the financial results of discontinued operations:

	Year Ended December 31, 2019		
	TS Biotechnology Sale	EnviroFlight Sale	Total
Revenue (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	<u>\$ (101,051)</u>	<u>\$ (15,108)</u>	<u>\$ (116,159)</u>

(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
Revenue (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.

Year Ended December 31, 2017

	TS Biotechnology		
	Sale	EnviroFlight Sale	Total
Revenue (1)	\$ 11,518	\$ —	\$ 11,518
Operating expenses (2)	53,028	470	53,498
Operating loss	(41,510)	(470)	(41,980)
Other expense, net	(7,506)	—	(7,506)
Equity in net loss of affiliates	—	(1,847)	(1,847)
Loss before income taxes	(49,016)	(2,317)	(51,333)
Income tax benefit	4,952	—	4,952
Loss from discontinued operations	\$ (44,064)	\$ (2,317)	\$ (46,381)

(1) Includes revenue recognized from related parties of \$8,185.

(2) Includes an impairment charge of \$2,950 recorded as part of its annual impairment assessment of indefinite-lived intangible assets.

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

	Year Ended December 31,		
	2019	2018	2017
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	\$ 5,107	\$ 9,007	\$ 9,536
Impairment loss	89,679	60,504	2,950
Unrealized and realized depreciation on equity securities and preferred stock, net	458	1,927	7,544
Equity in net loss of EnviroFlight	4,314	2,622	1,847
Stock-based compensation expense	2,507	3,872	4,683
Deferred income taxes	(2,710)	(5,703)	(4,575)
Cash flows from investing activities			
Investments in EnviroFlight	(2,000)	(12,250)	(4,750)
Purchases of property, plant and equipment	(23,326)	(21,191)	(13,455)

Also see Note 23 below.

Equity Method Investments

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

The Company accounted for its equity securities held in Oragenics, one of its collaborators and a related party, using the fair value option. Oragenics 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	2018
Current assets	\$ 703	\$ 5,119
Noncurrent assets	30,549	29,326
Total assets	31,252	34,445
Current liabilities	2,352	1,005
Non-current liabilities	88	—
Total liabilities	2,440	1,005
Net assets	\$ 28,812	\$ 33,440

	Year Ended December 31,		
	2019	2018	2017
Revenues	\$ 510	\$ 268	\$ 254
Operating expenses	9,159	12,709	10,671
Operating loss	(8,649)	(12,441)	(10,417)
Other, net	21	39	(8)
Net loss	\$ (8,628)	\$ (12,402)	\$ (10,425)

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

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.

GenVec Acquisition

In June 2017, pursuant to an Agreement and Plan of Merger (the "GenVec Merger Agreement"), the Company acquired 100% of the outstanding shares of GenVec, Inc. ("GenVec"), a clinical-stage company and pioneer in the development of AdenoVerse gene delivery technology. Pursuant to the GenVec Merger Agreement, the former shareholders of GenVec received an aggregate of 684,240 shares of the Company's common stock and have the right to receive contingent consideration equal to 50% of any milestone or royalty payments received under one of GenVec's collaboration agreements, provided such payments are received within three years after the closing of the transaction. The Company also assumed warrants held by certain former shareholders of GenVec. The results of GenVec's operations subsequent to the acquisition date have been included in the consolidated financial statements.

The fair value of the total consideration transferred was \$17,582. The acquisition date fair value of each class of consideration transferred is presented below:

Common shares	\$	15,616
Warrants		1,381
Contingent consideration		585
	\$	<u>17,582</u>

[Table of Contents](#)

The fair value of the shares of the Company's common stock issued was based on the quoted closing price of the Company's common stock immediately prior to the closing of the acquisition. The fair value of the warrants assumed was estimated using the Black-Scholes option-pricing model. The fair value of the contingent consideration was determined using a probability weighted discounted cash flows model and is considered a freestanding financial instrument and recorded at fair value each reporting period. The estimated fair value of assets acquired and liabilities assumed at the acquisition date is shown below:

Cash and cash equivalents	\$	2,054
Short-term investments		542
Trade receivables		75
Other receivables		97
Prepaid expenses and other		227
Property and equipment		250
Intangible assets		14,000
Other noncurrent assets		58
Total assets acquired		17,303
Accounts payable		2,158
Accrued compensation and benefits		1,226
Other accrued expenses		856
Other long-term liabilities		92
Deferred tax liabilities		239
Total liabilities assumed		4,571
Net assets acquired		12,732
Goodwill		4,850
Total consideration	\$	17,582

The acquired intangible assets include developed technology, the fair value of which was determined using the multi-period excess earning method, which is a variation of the income approach that converts future cash flows to single discounted present value amounts. The intangible assets are being amortized over a useful life of eleven years. Goodwill, which is not deductible for tax purposes, represents the assembled workforce and the anticipated buyer-specific synergies arising from the combination of the Company's and GenVec's technology.

Acquisition-related costs totaling \$507 are included in selling, general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2017.

Unaudited Condensed Pro Forma Financial Information

GenVec's results of operations subsequent to the acquisition are included in the consolidated statements of operations. The following unaudited condensed pro forma financial information for the year ended December 31, 2017, is presented as if the acquisition had been consummated on January 1, 2016:

	Year Ended December 31, 2017
	Pro Forma
Revenues	\$ 219,695
Loss from continuing operations before income taxes	(85,633)
Net loss	(134,275)
Net loss attributable to the noncontrolling interests	9,802
Net loss attributable to Precigen	(124,473)

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, 2019, 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 \$(423) and \$(656) as of December 31, 2019 and 2018, 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.

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, 2019, 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 \$(50) as of December 31, 2019 and 2018, 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.

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.

6. Collaboration and Licensing Revenue

The Company's collaborations and licensing agreements 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 either majority-owned subsidiaries or equity method investments, or other qualitative factors. Collaboration and licensing revenues generated from consolidated subsidiaries are eliminated in consolidation. Amounts for periods subsequent to January 1, 2018 reflect revenue recognition under ASC 606.

The following table summarizes the amounts recorded as revenue from continuing operations in the consolidated statements of operations for each significant counterparty to a collaboration or licensing agreement for the years ended December 31, 2019, 2018 and 2017.

	Year Ended December 31,		
	2019	2018	2017
ZIOPHARM Oncology, Inc.	\$ 2,171	\$ 16,298	\$ 69,812
Ares Trading S.A.	—	11,175	10,738
Orogenics, Inc.	(564)	1,353	1,469
Intrexon T1D Partners, LLC	—	2,502	5,968
Intrexon Energy Partners, LLC	2,596	6,929	10,665
Intrexon Energy Partners II, LLC	1,217	2,998	3,672
Fibrocell Science, Inc.	3,713	1,394	7,344
OvaXon, LLC	—	—	1,966
S & I Ophthalmic, LLC	—	—	755
Harvest start-up entities (1)	4,862	14,447	15,232
Other	64	12,444	7,003
Total	\$ 14,059	\$ 69,540	\$ 134,624

- (1) For the years ended December 31, 2019, 2018, and 2017, revenue recognized from collaborations with Harvest start-up entities include Exotech Bio, Inc.; AD Skincare, Inc.; and Thrive Agrobiotics, Inc. For the years ended December 31, 2018 and 2017, revenue recognized from collaborations with Harvest start-up entities also include Genten Therapeutics

and CRS Bio. For the year ended December 31, 2017, revenue recognized from collaborations with Harvest start-up entities also include Relieve Genetics.

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. Upon execution of the ECC, the Company received 3,636,926 shares of ZIOPHARM's common stock valued at \$17,457 as upfront consideration. In addition to the promises discussed above, the Company transferred two clinical product candidates to ZIOPHARM for which \$1,115 of the upfront consideration was allocated and recognized as collaboration revenue in 2011. The remaining \$16,342 of upfront consideration was allocated to a single performance obligation as discussed above. The Company was entitled to additional shares of common stock at the date of the dosing of the first patient in a Phase II clinical trial of a product candidate created, produced or developed by ZIOPHARM using the Company's technology ("ZIOPHARM Milestone"). In October 2012, the ZIOPHARM Milestone was achieved and the Company received 3,636,926 shares of ZIOPHARM's common stock valued at \$18,330 as milestone consideration. Upon adoption of ASC 606, the Company recorded a cumulative catch-up adjustment of \$873 related to milestone consideration. The Company allocated the ZIOPHARM Milestone to the two performance obligations and recognized those in a manner similar to the discussion above. The Company received reimbursement payments for research and development services provided and manufacturing services for Company materials provided to ZIOPHARM 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 September 2015, the Company entered into its second ECC with ZIOPHARM ("ZIOPHARM ECC 2"). Pursuant to the ECC, ZIOPHARM received a license to the Company's technology platform to develop and commercialize novel biotherapeutics for the treatment of patients with graft-versus-host disease. Upon execution of ZIOPHARM ECC 2, the Company received a technology access fee of \$10,000. 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 ZIOPHARM during the ECC. In December 2017, the Company and ZIOPHARM mutually agreed to terminate ZIOPHARM ECC2 and accordingly, the Company recognized the remaining balance of the deferred revenue associated with ZIOPHARM ECC2 totaling \$28,943.

In June 2016, the Company amended each of its two existing collaboration agreements with ZIOPHARM and as a result the rate of the royalty that the Company is entitled to receive on certain products commercialized pursuant to the agreements was reduced from 50% to 20%. As consideration for execution of the amendments, ZIOPHARM issued the Company 100,000 shares of ZIOPHARM's Series 1 Preferred Stock valued at \$120,000. 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. Upon adoption of ASC 606, the Company recognized a cumulative catch-up adjustment of \$32,422 as a result of the contract modification requiring a cumulative catch-up under ASC 606 versus prospective recognition under previous revenue recognition accounting standards. 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, sublicenseable 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 products in various jurisdictions, totaling up to an additional \$52,500 for each of four exclusively licensed products, 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 is a contract modification under ASC 606 that represents the termination of the original agreement and the creation of a new agreement as the remaining rights, obligations, and services to be exchanged, which are limited to the Transition Services, are 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 are only related to the Transition Services and no other obligations under the ECC remain, a portion of the previously deferred revenue from the ECC should be 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 includes 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 represents a separate collaboration agreement under the scope of ASC 808, *Collaborative Arrangements*, ("ASC 808") and will not be 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 Collaborations

In June 2015, the Company entered into an ECC with Oragenics. 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 maturing on or before December 31, 2015 as upfront consideration. Prior to the maturity date, Oragenics had the right to convert the promissory note into shares of Oragenics' common stock, subject to its shareholders' approval. In December 2015, Oragenics converted the promissory note into 338,100 shares of Oragenics' common stock. These shares were sold in the TS Biotechnology Sale (Note 3). Following an amendment in November 2017, the Company is entitled to up to \$37,500 of potential one-time payments for development and commercial milestones under the ECC. The Company receives 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. Oragenics will pay the Company royalties as a percentage in the low-teens of net sales derived from the sale of products developed from the ECC, as defined in the agreement.

Oragenics is responsible for funding the further development of products under the ECC towards the goal of commercialization, conducting preclinical and clinical development of product candidates, as well as for other aspects of commercialization or manufacturing of the product candidates. The term of the ECC commenced in June 2015 and may be

terminated by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Oragenics upon 90 days written notice to the Company.

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 Collaboration

In September 2016, the Company entered into an ECC with Genten Therapeutics, an affiliate of Harvest and a related party. Genten Therapeutics was formed for the purpose of entering into the ECC and developing and commercializing products using the Company's technology for expression of gluten peptides, alone or in combination with immunomodulatory cytokines, to reestablish immune tolerance for patients with celiac disease. Upon execution of the ECC, the Company received a technology access fee in the form of a \$1,500 cash payment and equity in Genten Therapeutics valued at \$3,000 as upfront consideration. The Company received reimbursement payments for research and development services provided pursuant to the ECC. In September 2018, the Company completed an asset acquisition with Harvest, resulting in the Company owning 100% of the equity interests of Genten Therapeutics including all rights under the ECC (Note 4).

CRS Bio Collaboration

In September 2016, the Company entered into an ECC with CRS Bio, an affiliate of Harvest and a related party. CRS Bio was formed for the purpose of entering into the ECC and developing and commercializing products through targeted delivery of antibodies for treatment of chronic rhinosinusitis with and without nasal polyps, by utilizing the Company's technology to block inflammatory mediators in the nasal passage, leading to improved breathing and, importantly, patients' quality of life. Upon execution of the ECC, the Company received a technology access fee in the form of equity in CRS Bio valued at \$2,100. The Company received reimbursement payments for research and development services provided pursuant to the ECC. In September 2018, the Company completed an asset acquisition with Harvest, resulting in the Company owning 100% of the equity interests of CRS Bio including all rights under the ECC (Note 4).

Relieve Genetics Collaboration

In March 2016, the Company entered into an ECC with Relieve Genetics, an affiliate of Harvest and a related party. Relieve Genetics was formed for the purpose of entering into the ECC and developing and commercializing products using a viral vector expressing interleukin-10 for the treatment of chronic neuropathic pain resultant from cancer in humans. Upon execution of the ECC, the Company received a technology access fee in the form of equity in Relieve Genetics valued at \$4,333 as upfront consideration. The Company received reimbursement payments for research and development services provided pursuant to the ECC. In September 2018, the Company completed an asset acquisition with Harvest, resulting in the Company owning 100% of the equity interests of Relieve Genetics including all rights under the ECC (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.

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.

Exotech Bio Collaboration

In March 2016, the Company entered into an ECC with Exotech Bio, Inc. ("Exotech Bio"), an affiliate of Harvest and a related party. Exotech Bio was formed for the purpose of entering into the ECC and developing and commercializing products using exosomes carrying a RNA payload designed to kill, suppress, or render immune-visible a cancer cell. Upon execution of the ECC, the Company received a technology access fee in the form of equity in Exotech Bio valued at \$5,000 as upfront consideration. In June 2018, the Company and Exotech Bio amended the ECC, which resulted in the expansion of the defined field of use and the Company's ownership in Exotech Bio increasing to 49%. The amendment also eliminated potential future milestone payments and royalties for which the Company was previously entitled. The Company receives reimbursement payments for research and development services provided pursuant to the ECC. The ECC may be terminated by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Exotech Bio upon 90 days written notice to the Company.

AD Skincare Collaboration

In June 2016, the Company entered into an ECC with AD Skincare, Inc. ("AD Skincare"), an affiliate of Harvest and a related party. AD Skincare was formed for the purpose of entering into the ECC and developing an advanced topical delivery system to improve the efficacy of biologically active ingredients aimed at improving signs of aging human skin. Upon execution of the ECC, the Company received a technology access fee in the form of equity in AD Skincare valued at \$4,333 as upfront consideration. The Company is also entitled to up to \$2,000 of potential payments for substantive and non-substantive development milestones for each product developed under the ECC, as well as up to \$17,000 in one-time commercial milestones. The Company receives reimbursement payments for research and development services provided pursuant to the ECC. AD Skincare will pay the Company royalties as a percentage in the low double-digits on the quarterly net sales of products developed under the ECC, as defined in the agreement. AD Skincare is responsible for the development and commercialization of the product candidates. The term of the ECC commenced in June 2016 and continues until terminated pursuant to the ECC agreement. The ECC may be terminated by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by AD Skincare upon 90 days written notice to the Company.

Fibrocell Science Collaborations

In October 2012, the Company entered into an ECC ("Fibrocell ECC 1") with Fibrocell Science, Inc. ("Fibrocell"), a then publicly traded cell and gene therapy company focused on diseases affecting the skin and connective tissue and a related party until the acquisition of Fibrocell by a third party as discussed below. Pursuant to Fibrocell ECC 1, at the transaction effective date, Fibrocell 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. Upon execution of Fibrocell ECC 1, the Company received a technology access fee of 87,835 shares of Fibrocell's common stock valued at \$7,576 as upfront consideration. The Company receives reimbursement payments for research and development services provided pursuant to the agreement during Fibrocell ECC 1 and manufacturing services for Company materials provided to Fibrocell during Fibrocell ECC 1. On a quarterly basis, Fibrocell will pay the Company royalties of 7% of net sales up to \$25,000 and 14% of net sales above \$25,000 on each product developed from Fibrocell ECC 1, as defined in the agreement. If Fibrocell uses the Company's technology platform to improve the production of a current or new Fibrocell product not developed from Fibrocell ECC 1, Fibrocell will pay the Company quarterly royalties equal to 33% of the cost of goods sold savings generated by the improvement, as defined in the agreement.

Fibrocell is responsible for conducting preclinical and clinical development of product candidates associated with Fibrocell ECC 1, as well as for other aspects of commercialization and manufacturing of the product candidates. The term of the ECC commenced in October 2012 and continues until terminated pursuant to the ECC agreement. The ECC may be terminated by

either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Fibrocell upon 90 days written notice to the Company.

In June 2013, the Company and Fibrocell entered into an amendment to the Fibrocell ECC 1. The amendment expanded the field of use defined in the ECC agreement. Under the terms of the amendment to the Fibrocell ECC 1, the Company received 82,919 shares of Fibrocell's common stock valued at \$7,612 as a supplemental technology access fee.

In April 2019, Fibrocell entered into a collaboration agreement with a Castle Creek Pharmaceuticals, LLC to develop and commercialize a product in the field of the Fibrocell ECC 1. Pursuant to the terms of the Fibrocell ECC 1, the Company is entitled to 50% of sublicensing fees and accordingly, received \$3,750 during the year ended December 31, 2019.

In December 2015, the Company entered into a second ECC with Fibrocell ("Fibrocell ECC 2"). Pursuant to the ECC, at the transaction effective date, Fibrocell 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. Upon execution of the ECC, the Company received a technology access fee of \$10,000. The Company is also entitled to (i) up to \$30,000 of potential one-time payments for certain development and regulatory milestones for the first product developed under Fibrocell ECC 2, (ii) up to \$30,000 of potential payments for certain regulatory milestones for each additional product developed under Fibrocell ECC 2, and (iii) up to \$22,500 of potential payments for certain sales milestones for each product developed under Fibrocell ECC 2. The Company receives reimbursement payments for research and development services provided pursuant to the agreement during the ECC and manufacturing services for Company materials provided to Fibrocell during the ECC. Fibrocell will pay the Company royalties as a percentage in the low double-digits of net sales derived from the sale of products developed from Fibrocell ECC 2, as defined in the agreement.

Fibrocell is responsible for conducting preclinical and clinical development of product candidates associated with Fibrocell ECC 2, as well as for other aspects of commercialization and manufacturing of the product candidates. The term of the ECC commenced in December 2015 and continues until terminated pursuant to the ECC agreement. The ECC may be terminated by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Fibrocell upon 90 days written notice to the Company.

In December 2019, Fibrocell was acquired by Castle Creek Pharmaceutical Holdings, Inc. ("Castle Creek"), a privately held company focused on developing medicine for rare genetic disorders. See Note 18 for further discussion of the impact of the Castle Creek acquisition on the Company's investments in Fibrocell.

Thrive Agrobiotics Collaboration

In September 2015, the Company entered into an ECC with Thrive Agrobiotics, Inc. ("Thrive Agrobiotics"), an affiliate of Harvest and a related party. Thrive Agrobiotics was formed for the purpose of entering into the ECC and developing and commercializing products to improve the overall growth and feed efficiency in piglets. Upon execution of the ECC, the Company received a technology access fee in the form of equity in Thrive Agrobiotics valued at \$1,667 as upfront consideration. The Company is also entitled to up to \$5,500 of potential payments for development and commercial milestones for each product developed under the ECC. The Company receives reimbursement payments for research and development services provided pursuant to the agreement during the ECC. Thrive Agrobiotics will pay the Company royalties as a percentage in the lower-double digits on the quarterly gross profits of product sales from products developed under the ECC, as defined in the agreement. Thrive Agrobiotics is responsible for the development and commercialization of the product candidates. The term of the ECC commenced in September 2015 and continues until terminated pursuant to the ECC agreement. The ECC may be terminated by either party in the event of certain material breaches defined in the agreement and may be terminated voluntarily by Thrive Agrobiotics upon 90 days written notice to the Company.

Deferred Revenue

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

	December 31,	
	2019	2018
Collaboration and licensing agreements	\$ 50,593	\$ 54,323
Prepaid product and service revenues	2,805	2,933
Other	435	560
Total	<u>\$ 53,833</u>	<u>\$ 57,816</u>
Current portion of deferred revenue	<u>\$ 5,697</u>	<u>\$ 11,088</u>
Long-term portion of deferred revenue	48,136	46,728
Total	<u>\$ 53,833</u>	<u>\$ 57,816</u>

The following table summarizes the remaining balance of deferred revenue from continuing operations associated with upfront and milestone payments for each significant counterparty to a collaboration or licensing agreement as of December 31, 2019 and 2018, including the estimated remaining performance period as of December 31, 2019.

	Average Remaining Performance Period (Years)	December 31,	
		2019	2018
ZIOPHARM Oncology, Inc.	0.0	\$ —	\$ 1,214
Oragenics, Inc.	4.4	2,864	1,785
Intrexon Energy Partners, LLC	4.2	8,362	10,267
Intrexon Energy Partners II, LLC	4.9	12,843	14,060
Fibrocell Science, Inc.	4.9	17,697	17,519
Harvest start-up entities (1)	5.2	6,993	7,644
Other	2.8	1,834	1,834
Total		<u>\$ 50,593</u>	<u>\$ 54,323</u>

(1) As of December 31, 2019 and 2018, the balance of deferred revenue for collaborations with Harvest start-up entities includes Exotech Bio, AD Skincare, and Thrive Agrobotics.

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, 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	<u>\$ 9,253</u>	<u>\$ 7</u>	<u>\$ —</u>	<u>\$ 9,260</u>

The following table summarizes the amortized cost, gross unrealized gains and losses, and fair value of available-for-sale investments as of December 31, 2018:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
United States government debt securities	\$ 119,401	\$ —	\$ (61)	\$ 119,340
Certificates of deposit	274	—	—	274
Total	\$ 119,675	\$ —	\$ (61)	\$ 119,614

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, 2019, 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 as of December 31, 2018 were primarily a result of unfavorable changes in interest rates subsequent to the initial purchase of these investments, and there were none as of December 31, 2019.

As of December 31, 2018, the Company did not consider any of its debt security investments to be other-than-temporarily impaired. When evaluating its debt security investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer, the Company's ability and intent to hold the security and whether it is more likely than not that it will be required to sell the investment before recovery of its cost basis.

8. Fair Value Measurements

The carrying amount of cash and cash equivalents, restricted cash, 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, 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 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, 2018:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2018
Assets				
United States government debt securities	\$ —	\$ 119,340	\$ —	\$ 119,340
Equity securities	950	74	—	1,024
Other	—	394	191	585
Total	<u>\$ 950</u>	<u>\$ 119,808</u>	<u>\$ 191</u>	<u>\$ 120,949</u>

The method used to estimate the fair value of the Level 1 assets in the tables above is based on observable market data as these equity securities are publicly-traded. 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. The methods used to estimate the fair value of the Level 2 equity securities in the tables above are based on the quoted market price of the publicly-traded security, adjusted for adjusted for a discount for lack of marketability. The Company owned preferred stock in certain of its collaborators, and these investments were classified as Level 3 within the fair value hierarchy. See Note 18 for additional discussion of these investments in preferred stock.

The following table summarizes the changes in the Level 3 investments during the years ended December 31, 2019 and 2018.

	2019	2018
Beginning balance	\$ 191	\$ 161,225
Retained interest in deconsolidated subsidiary	14,239	—
Dividend income from investments in preferred stock	48	14,841
Net unrealized appreciation (depreciation) in the fair value of the investments in equity securities and preferred stock	7,446	(17,499)
Return of preferred stock	—	(158,376)
Proceeds from sale of equity securities	(21,587)	—
Proceeds to be received from preferred stock	(337)	—
Ending balance	<u>\$ —</u>	<u>\$ 191</u>

There were no transfers of assets between levels of the fair value hierarchy during the year ended December 31, 2019.

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 \$126,000 and \$141,000 as of December 31, 2019 and 2018, respectively, and is based on the recent third-party trades of the instrument as of the balance sheet dates. 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 \$157,560 and \$148,101 as of December 31, 2019 and 2018, respectively.

The Company's contingent consideration liabilities (Note 4) are measured on a recurring basis and were \$585 as of December 31, 2019 and 2018. These fair value measurements were based on significant inputs not observable in the market and thus represented a Level 3 measurement. A significant change in unobservable inputs could result in a significant impact on the fair value of the Company's contingent consideration liabilities. The contingent consideration liabilities are remeasured to fair

value at each reporting date until the contingencies are resolved, and those changes in fair value are recognized in earnings. There were no changes in the fair value of the Level 3 liabilities during the years ended December 31, 2019 and 2018.

9. Inventory

Inventory from continuing operations consists of the following:

	December 31,	
	2019	2018
Supplies, embryos and other production materials	\$ 2,282	\$ 3,857
Work in process	3,702	4,391
Livestock	7,553	10,167
Feed	2,560	2,160
Total inventory	\$ 16,097	\$ 20,575

10. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following:

	December 31,	
	2019	2018
Land and land improvements	\$ 9,814	\$ 10,001
Buildings and building improvements	11,765	20,099
Furniture and fixtures	1,315	1,812
Equipment	54,448	63,947
Leasehold improvements	12,821	14,219
Breeding stock	5,191	4,582
Computer hardware and software	9,434	10,789
Construction and other assets in progress	5,313	10,497
	110,101	135,946
Less: Accumulated depreciation and amortization	(49,132)	(49,050)
Property, plant and equipment, net	\$ 60,969	\$ 86,896

The deconsolidation of AquaBounty (Note 1) in April 2019 resulted in the reduction of \$24,186 of property, plant and equipment, net on the accompanying consolidated balance sheet during the year ended December 31, 2019.

During the year ended December 31, 2019, the Company recorded \$448 of property, plant and equipment impairment losses in conjunction with the closing of two of its operating units during the third quarter of 2019.

Depreciation expense was \$11,869, \$12,439 and \$10,137 for the years ended December 31, 2019, 2018 and 2017, respectively.

11. Goodwill and Intangible Assets, Net

The changes in the carrying amount of goodwill for the years ended December 31, 2019 and 2018, are as follows:

	2019	2018
Beginning of year	\$ 93,627	\$ 93,751
Impairment	(29,820)	—
Foreign currency translation adjustments	(53)	(124)
End of year	\$ 63,754	\$ 93,627

The Company had \$43,643 and \$13,823 of cumulative impairment losses as of December 31, 2019 and 2018, respectively.

[Table of Contents](#)

For the year ended December 31, 2019, the Company recorded \$29,820 of goodwill impairment charges. 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 charges in conjunction with the closing of two of its reporting units in 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, 2019:

	Weighted Average Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	15.8	\$ 90,659	\$ (26,619)	\$ 64,040
Customer relationships	6.5	10,700	(8,440)	2,260
Trademarks	8.4	5,900	(3,854)	2,046
Total		<u>\$ 107,259</u>	<u>\$ (38,913)</u>	<u>\$ 68,346</u>

Intangible assets consist of the following as of December 31, 2018:

	Gross Carrying Amount	Accumulated Amortization	Net
Patents, developed technologies and know-how	\$ 106,042	\$ (23,674)	\$ 82,368
Customer relationships	10,700	(7,565)	3,135
Trademarks	6,800	(3,341)	3,459
Total	<u>\$ 123,542</u>	<u>\$ (34,580)</u>	<u>\$ 88,962</u>

In the fourth quarter of 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; however, because the Company made a decision to abandon the assets, it recorded the charge to research and development expense.

The deconsolidation of AquaBounty (Note 1) in April 2019 resulted in the reduction of \$11,567 of net intangible assets, primarily related to patents, developed technologies, and know-how, on the accompanying consolidated balance sheet during the year ended December 31, 2019.

Amortization expense was \$7,920, \$11,666 and \$11,472 for the years ended December 31, 2019, 2018 and 2017, respectively. Estimated aggregate amortization expense for definite lived intangible assets is expected to be as follows:

2020	\$ 7,501
2021	7,313
2022	6,518
2023	5,350
2024	5,066
Thereafter	36,598
Total	<u>\$ 68,346</u>

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, 2020. The line of credit bears interest at the greater of 2.95% above the London Interbank Offered Rate or 3.00%, and the actual rate was 4.76% as of December 31, 2019. As of December 31, 2019, there was an outstanding balance of \$1,695. The amount available under the line of credit is based on eligible accounts receivable and inventory up to the maximum principal amount, and was \$3,235 as of December 31, 2019. 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. Trans Ova was in compliance with these covenants as of December 31, 2019.

Exemplar has a \$700 revolving line of credit with American State Bank that matures on October 31, 2020. The line of credit bears interest at 5.50% per annum. As of December 31, 2019, there was an outstanding balance of \$227.

Long-Term Debt

Long-term debt consists of the following:

	December 31,	
	2019	2018
Convertible debt	\$ 213,771	\$ 203,391
Notes payable	4,089	4,551
Other	131	3,753
Long-term debt	217,991	211,695
Less current portion	31,670	479
Long-term debt, less current portion	\$ 186,321	\$ 211,216

The deconsolidation of AquaBounty (Note 1) in April 2019 resulted in the reduction of \$4,030 of long-term debt on the accompanying consolidated balance sheet during the year ended December 31, 2019.

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, unless earlier repurchased or converted. 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;

[Table of Contents](#)

- 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, 2019. 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, 2019, the outstanding principal balance on the Convertible Notes was \$200,000 and the carrying value of long-term debt was \$157,560. 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, 2019, the unamortized long-term debt discount and debt issuance costs totaled \$42,440.

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

	Year Ended December 31,	
	2019	2018
Cash interest expense	\$ 7,000	\$ 3,462
Non-cash interest expense	9,459	4,378
Total interest expense	\$ 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, 2019.

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 have a maturity date of September 6, 2020, accrue interest at 3.0% compounded annually ("accrued PIK interest"), are convertible into shares of ActoBio common stock at any time by the holder, and are automatically convertible in shares of ActoBio common stock upon the closing of certain financing events as defined in the ActoBio Notes. If the ActoBio Notes have not been converted to ActoBio common stock by the maturity date, ActoBio can pay the principal and accrued PIK interest in cash or with shares of Precigen common stock at its election. There are no embedded features that are required to be separated from the debt host and accounted for separately, so the ActoBio Notes were recorded at \$30,000. Interest expense was \$921 and \$290 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the carrying value of the ActoBio Notes, including accrued interest, was \$31,211.

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 has a maturity date of June 28, 2021 and will be converted to Precigen common stock on the first trading day following maturity if not otherwise converted prior to that date. Prior to maturity, Ares Trading may convert the Merck Note, at their election, into (i) Precigen common stock at any time, (ii) Precigen common stock upon the Company's closing of qualified financing as defined in the agreement, (iii) PGEN Therapeutics equity upon PGEN Therapeutics closing a qualified financing as defined in the agreement, and (iv) PGEN Therapeutics common stock upon the closing of a qualified initial public offering ("IPO") of PGEN Therapeutics common stock. In the event of a conversion upon a qualified IPO, the conversion price will be 90% of the IPO price. There is no stated interest rate on the Merck Note. However, in the event Ares Trading elects to convert the Merck Note into PGEN Therapeutics equity, the Merck Note accrues interest at a rate of 5% per year ("PIK interest") and will be converted with the outstanding principal. The Company determined that the potential PIK interest and IPO conversion discount represented embedded derivatives requiring bifurcation from the debt host but had no significant value as of December 31, 2019.

Notes Payable

Trans Ova has a note payable to American State Bank that matures in April 2033 and had an outstanding principal balance of \$4,077 as of December 31, 2019. 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 are as follows:

2020	\$	31,670
2021		25,328
2022		341
2023		200,355
2024		369
Thereafter		2,368
Total	\$	<u>260,431</u>

13. Income Taxes

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

	Year Ended December 31,		
	2019	2018	2017
Domestic	\$ (205,413)	\$ (428,410)	\$ (24,965)
Foreign	(3,274)	(1,332)	(53,402)
Loss from continuing operations before income taxes	<u>\$ (208,687)</u>	<u>\$ (429,742)</u>	<u>\$ (78,367)</u>

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

	Year Ended December 31,		
	2019	2018	2017
United States federal income taxes:			
Current	\$ —	\$ (31)	\$ 27
Deferred	(561)	(11,855)	(523)
Foreign income taxes:			
Current	34	68	(4)
Deferred	(230)	635	2,308
State income taxes:			
Current	—	113	—
Deferred	(173)	(4,355)	264
Income tax expense (benefit) from continuing operations	<u>\$ (930)</u>	<u>\$ (15,425)</u>	<u>\$ 2,072</u>

Income tax expense (benefit) from continuing operations for the years ended December 31, 2019, 2018 and 2017 differed from amounts computed by applying the applicable United States federal corporate income tax rate of 21% for 2019 and 2018, and 34% for 2017, to loss before income taxes as a result of the following:

	2019	2018	2017
Computed statutory income tax benefit from continuing operations	\$ (43,824)	\$ (90,246)	\$ (26,645)
State and provincial income tax benefit, net of federal income taxes	(7,298)	(23,347)	(1,888)
Nondeductible stock based compensation	10,303	4,696	3,391
Nondeductible officer compensation	595	294	476
Gain on dividend distribution of AquaBounty common stock	—	—	3,965
Impairment of goodwill	273	—	4,700
Research and development tax incentives	(1,772)	(185)	(359)
Acquisition and internal restructuring transaction costs	260	52	354
Provisional impact of the Tax Act	—	—	85,288
Enacted changes in foreign tax rates and foreign tax reforms	—	—	2,021
Reacquired in-process research and development	—	2,696	—
Change in deferred state tax rate	—	8,666	—
United States-foreign rate differential	(76)	215	410
Other, net	(72)	(3,517)	(189)
	<u>(41,611)</u>	<u>(100,676)</u>	<u>71,524</u>
Change in valuation allowance for deferred tax assets	40,681	85,251	(69,452)
Total income tax expense (benefit) from continuing operations	<u>\$ (930)</u>	<u>\$ (15,425)</u>	<u>\$ 2,072</u>

The tax effects of temporary differences that comprise the deferred tax assets and liabilities included in continuing operations as of December 31, 2019 and 2018, are as follows:

	2019	2018
Deferred tax assets		
Allowance for doubtful accounts	\$ 2,140	\$ 1,490
Inventory	415	614
Equity securities and investments in affiliates	11,933	30,241
Property, plant and equipment	1,830	—
Intangible assets	85,308	78,858
Accrued liabilities	3,385	4,412
Lease liabilities	10,035	—
Stock-based compensation	19,389	28,885
Deferred revenue	14,876	16,297
Research and development tax credits	9,686	10,558
Investments in subsidiaries included in discontinued operations	8,592	—
Net operating and capital loss carryforwards	196,663	129,291
Total deferred tax assets	364,252	300,646
Less: Valuation allowance	349,008	292,217
Net deferred tax assets	15,244	8,429
Deferred tax liabilities		
Property, plant and equipment	—	149
Right-of-use assets	8,091	—
Intangible assets	—	—
Long-term debt	9,987	12,136
Total deferred tax liabilities	18,078	12,285
Net deferred tax liabilities included in continuing operations	\$ (2,834)	\$ (3,856)

Activity within the valuation allowance for deferred tax assets included in continuing operations during the years ended December 31, 2019, 2018 and 2017 was as follows:

	2019	2018	2017
Valuation allowance at beginning of year	\$ 292,217	\$ 211,078	\$ 253,549
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	40,681	107,284	17,735
Discontinued operations treated as asset sales	10,585	3,832	6,940
Adoption of ASC 842	512	—	—
Adoption of ASC 606	—	(7,477)	—
Adoption of ASU 2016-09	—	—	17,843
Provisional impact of the Tax Act	—	—	(87,473)
Equity component of long-term debt	—	(13,367)	—
Change in deferred state tax rate	—	(8,666)	—
Changes in foreign tax rates and foreign tax reforms	—	—	1,494
Foreign currency translation adjustment	(75)	(885)	990
Valuation allowance at end of year	\$ 349,008	\$ 292,217	\$ 211,078

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, 2019, all such limited losses applicable to Precigen, other than losses inherited via acquisition, have been fully utilized. As of December 31, 2019, approximately \$42,100 of the Company's domestic net operating losses were inherited via acquisition, including \$13,376 acquired via the acquisition of GenVec, and are limited based on the value of the target at the time of the transaction.

As of December 31, 2019, the Company has net operating loss carryforwards for United States federal income tax purposes of approximately \$568,800 available to offset future taxable income, including approximately \$316,100 generated after 2017, United States capital loss carryforwards of approximately \$111,600, and federal and state research and development tax credits of approximately \$9,600, 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 by 2024. The Company's foreign subsidiaries included in continuing operations have foreign loss carryforwards of approximately \$72,800, most of which do not expire.

As of December 31, 2019, the Company's direct foreign subsidiaries included in continuing operations had accumulated deficits of approximately \$14,900. Future distributions of accumulated earnings of the Company's direct foreign subsidiaries may be subject to United States income and foreign withholding taxes.

In the year ended December 31, 2017, the Company recorded a net provisional income tax benefit of \$2,185 upon enactment of the Tax Act, which is comprised of several items. Amounts related to the remeasurement of most of the Company's domestic deferred tax assets as a result of the United States corporate rate change to 21% as part of the Tax Act are \$87,473, which was fully offset by a reduction in the Company's valuation allowance. The Company's net United States deferred tax liability that is not offset by a valuation allowance was similarly written down, and the Company recorded a provisional deferred tax benefit of \$1,730. The Company also recorded a provisional current tax benefit of \$455 related to the expected refundability of accumulated corporate alternative minimum tax credits. The Company provisionally estimated its transition tax exposure to be zero, as any accumulated earnings in foreign subsidiaries are offset by accumulated deficits in other foreign subsidiaries. The Company completed its accounting for the Tax Act in the fourth quarter of 2018, and there were no significant adjustments to the previously recorded provisional amounts.

Additionally, in December 2017, Belgium enacted significant tax reform measures, the most significant of which to the Company is the limitation on the utilization of accumulated losses in years after 2017. After that date, loss carryforwards can only be used to offset 70% of taxable income that exceeds a certain threshold. As a result, the Company recorded adjustments to its net deferred tax assets and valuation allowances. These adjustments resulted in a net deferred tax liability of \$2,307, which was recorded as a component of deferred tax expense for the year ended December 31, 2017.

The Company and its subsidiaries do not have material unrecognized tax benefits as of December 31, 2019. 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

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.

In December 2017, the Company entered into a securities purchase agreement with an affiliate of Third Security for the private placement of 1,207,980 shares of the Company's common stock for gross proceeds of \$13,686.

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.

In January 2017, in conjunction with the listing by AquaBounty of their common stock on the Nasdaq Stock Market, Precigen purchased \$25,000 of additional AquaBounty common stock and subsequently distributed shares of AquaBounty common stock as a dividend to Precigen shareholders.

Dividends to Shareholders

In January 2017, the Company distributed to its shareholders 1,776,557 shares of AquaBounty common stock valued at \$22,385. The distribution constituted a dividend to shareholders of record as of January 9, 2017. In connection with the distribution and pursuant to the terms of the Company's equity incentive plans, the conversion terms of all outstanding options for shares of the Company's common stock as of January 9, 2017 were adjusted to reflect the value of the distribution with respect to shares of the Company's common stock by decreasing the exercise prices and increasing the number outstanding options. This adjustment resulted in 46,766 additional outstanding options at a weighted average exercise price of \$31.11.

Components of Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss are as follows:

	December 31,	
	2019	2018
Unrealized gain (loss) on investments	\$ 7	\$ (61)
Loss on foreign currency translation adjustments	(27,475)	(28,551)
Total accumulated other comprehensive loss	\$ (27,468)	\$ (28,612)

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,		
	2019	2018	2017
Cost of products	\$ 20	\$ 78	\$ 116
Cost of services	220	237	322
Research and development	4,784	6,850	7,654
Selling, general and administrative	11,419	25,259	28,801
Discontinued operations	2,507	3,872	4,683
Total	<u>\$ 18,950</u>	<u>\$ 36,296</u>	<u>\$ 41,576</u>

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, 2019, there were 378,409 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, 2019, there were 25,000,000 shares authorized for issuance under the 2013 Plan, of which 8,643,873 stock options and 1,781,982 RSUs were outstanding and 8,991,369 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, 2019, there were 5,000,000 shares authorized for issuance under the 2019 Plan, of which no awards were outstanding and 4,087,444 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, 2016	11,640,383	\$ 31.25	8.21
Granted	3,920,950	21.47	
Adjustment due to dividend (Note 14)	46,766	31.11	
Exercised	(149,429)	(6.37)	
Forfeited	(3,797,105)	(28.37)	
Expired	(278,818)	(33.18)	
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
Exercisable at December 31, 2019	6,264,194	24.89	5.20

Total unrecognized compensation costs related to unvested awards as of December 31, 2019 were \$16,057, and are expected to be recognized over a weighted-average period of approximately two years.

The weighted average grant date fair value of options granted during 2019, 2018 and 2017 was \$3.79, \$7.94 and \$12.19, respectively. The aggregate intrinsic value of options exercised during 2019, 2018 and 2017 was \$66, \$356 and \$2,429, 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, 2019:

Range of Exercise Prices	Options Outstanding				Options Exercisable			
	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

The following table summarizes additional information about stock options outstanding as of December 31, 2018:

Range of Exercise Prices	Options Outstanding				Options Exercisable			
	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 — \$ 19.52	1,973,818	\$ 13.70	7.54	\$ 169	833,007	\$ 12.80	4.85	\$ 169
\$19.85 — \$ 20.94	1,914,763	20.93	7.99	—	500,263	20.92	7.67	—
\$21.00 — \$ 27.08	2,057,126	23.29	7.26	—	1,248,370	23.01	6.69	—
\$27.10 — \$ 29.56	2,666,109	29.19	5.28	—	2,593,151	29.20	5.23	—
\$29.58 — \$ 65.08	2,481,247	47.24	6.59	—	1,827,728	47.65	6.54	—
	<u>11,093,063</u>	<u>\$ 27.95</u>	<u>6.81</u>	<u>\$ 169</u>	<u>7,002,519</u>	<u>\$ 30.37</u>	<u>5.97</u>	<u>\$ 169</u>

RSU activity was a 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	<u>1,781,982</u>	<u>8.71</u>	<u>1.24</u>

Total unrecognized compensation costs related to unvested RSU awards as of December 31, 2019 were \$10,795 and are expected to be recognized over a weighted-average period of approximately two 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, receives a base salary of \$200 per month 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 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, which is subject to renewal annually by the compensation committee of the board of directors of the Company, expired March 31, 2019. In April 2019, the Company entered into a new RSU agreement through March 31, 2020, pursuant to which the base salary and lock-up terms remained unchanged and the number of fully-vested shares of Precigen common stock paid monthly was subsequently calculated 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. 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 \$1,868, \$1,956, and \$1,908 for the years ended December 31, 2019, 2018 and 2017, respectively.

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

[Table of Contents](#)

term of the lease. The Company's leases have remaining terms of one to ten 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. In these leases, 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 Company's finance leases are not material.

The components of lease costs from continuing operations were as follows:

	Year Ended December 31, 2019
Operating lease costs	\$ 7,260
Short-term lease costs	2,042
Variable lease costs	2,076
Lease costs	<u>\$ 11,378</u>

As of December 31, 2019, maturities of lease liabilities, excluding short-term leases, for continuing operations were as follows:

2020	\$ 7,071
2021	7,449
2022	6,996
2023	5,831
2024	5,734
Thereafter	4,280
Total	<u>37,361</u>
Present value adjustment	(9,330)
Total	<u>\$ 28,031</u>
Current portion of operating lease liabilities	\$ 4,182
Long-term portion of operating lease liabilities	23,849
Total	<u>\$ 28,031</u>

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

	December 31, 2019
Weighted average remaining lease term (years)	5.24
Weighted average discount rate	10.96%
Supplemental Cash Flows Information	
Cash paid for operating lease liabilities	\$ 7,294
Operating lease right-of-use assets added in exchange for new lease liabilities	1,137

At December 31, 2018, future minimum lease payments under operating leases for continuing operations having initial or remaining noncancelable lease terms in excess of one year were as follows:

	Year Ended December 31, 2019
2019	\$ 6,889
2020	7,384
2021	7,246
2022	6,815
2023	5,747
Thereafter	11,734
Total	<u>\$ 45,815</u>

17. Commitments and Contingencies

Contingencies

In March 2012, Trans Ova was named as a defendant in a licensing and patent infringement suit brought by XY, LLC ("XY") alleging that certain of Trans Ova's sale of semen-sorting products and services breached a 2004 licensing agreement and infringed on patents related to semen sorting that XY allegedly owned. Trans Ova filed a number of counterclaims in the case. The matter proceeded to a jury trial in the United States District Court for the District of Colorado in January 2016. The jury determined that XY and Trans Ova had each breached the licensing agreement and that Trans Ova had infringed XY's patents. In April 2016, the court issued its post-trial order, awarding \$528 in damages to Trans Ova and \$6,066 in damages to XY. The order also provided Trans Ova with the ability to continue to practice XY's technology, subject to an ongoing royalty obligation of 12.5% of gross proceeds on Trans Ova's standard sorted semen products, plus a 2% enhancement on those products utilizing "reverse-sorted semen", or semen that is frozen before being sorted. In addition, the court assigned a \$5.00 minimum royalty for a straw of sexed semen. Both parties appealed the district court's order. In May 2018, the Court of Appeals for the Federal Circuit denied Trans Ova's appeal of its claims for antitrust, breach of contract and patent invalidity (except as to one patent, for which the Federal Circuit affirmed invalidity in a separate, same-day ruling in a third-party case). The Federal Circuit remanded the district court's calculation of the ongoing royalty and instructed the district court to re-calculate the ongoing royalty in light of post-verdict economic factors. In March 2019, the district court clarified the royalty base and reset the royalty rates consistent with the Federal Circuit's opinion. The district court increased the royalty rate on Trans Ova's standard sorted semen products to 18.75%. For the reverse-sort enhancement, however, it applied a weighted, blended royalty of 12.63% to Trans Ova's entire in vitro fertilization service cycle that utilizes reverse-sorted semen. The district court also changed the minimum royalty for a straw of sexed semen to \$6.25 for a 2-million cell straw (prorated appropriately for straws of higher cell counts), and assigned a minimum royalty for a sexed embryo at \$6.25 per embryo. The new royalty rates were made retroactive to February 2016 (the end date of the trial).

Since the inception of the 2004 licensing agreement, Trans Ova has remitted payments to XY pursuant to the terms of that agreement, or pursuant to the terms of the district court's April 2016 post-trial order and its March 2019 post-remand order, and has recorded these payments in cost of services in the consolidated statements of operations for the respective periods. For the period from inception of the 2004 licensing agreement through the district court's April 2016 order, aggregate royalty and license payments were \$3,170, of which \$2,759 had not yet been deposited by XY. In 2016, the Company recorded the expense

of \$4,228, representing the excess of the net damages awarded to XY, including prejudgment interest, over the liability previously recorded by Trans Ova for uncashed checks previously remitted to XY. In August 2016, Trans Ova deposited the net damages amount, including prejudgment interest, into the district court's registry, to be held until the appeals process was complete and final judgment amounts were determined. These amounts were included in restricted cash and other accrued liabilities on the accompanying consolidated balance sheet as of December 31, 2018. After the appeal, the district court subsequently released the funds held in its registry to XY in January 2019. As for post-trial damages, Trans Ova continued to remit payment to XY every quarter based on the original ongoing royalty rates set by the district court, though XY refused to cash those checks.

Under the district court's March 2019 post-remand order clarifying the royalty base and resetting the royalty rates, Trans Ova recalculated royalties owed from February 2016 through the first quarter of 2019, plus any applicable pre- and post-judgment interest, and remitted that payment, totaling \$5,801, to XY in May 2019. In June 2019, XY deposited the \$5,801 into the district court's registry while the parties resolve two separate disputes over the appropriate calculation of royalties. In the first dispute, XY filed a motion claiming over \$1,000 in additional back royalties. Trans Ova contested XY's motion. On February 6, 2020, the district court denied XY's motion without prejudice, holding that XY failed to satisfy its obligation under the court's local rules to meaningfully confer with Trans Ova before filing its motion. The district court held that, if XY chooses to re-file its motion, it must include a substantial certificate of conferral demonstrating that it seriously and in good faith tried to resolve its disputes with Trans Ova. In the second dispute, Trans Ova moved for partial relief from judgment after XY's last patent covering standard sorting expired in December 2019. Trans Ova is seeking an appropriate reduction in its royalty obligation in light of the fact that XY's only non-expired patents are limited to reverse sorting. Trans Ova's motion is pending before the court.

During the year ended December 31, 2019, the Company recorded additional royalty expense of \$383 based on the recalculation of royalties owed XY from February 2016 through December 2018. This amount is included in selling, general and administrative expenses on the accompanying consolidated statement of operations.

In December 2016, XY filed a complaint for patent infringement, trade secret misappropriation, and various state law claims against Trans Ova in the United States District Court for the Western District of Texas in Waco, Texas. Since the claims in the 2016 complaint directly relate to the parties' other litigation, Trans Ova filed and was granted a motion to transfer the case to Colorado district court. That court subsequently dismissed nine of the complaint's twelve counts, including all five non-patent counts and four patent counts. The court subsequently dismissed a fifth patent count after ruling that the patent was invalid, leaving only two patent counts left in the case. In February 2019, a Wisconsin district court invalidated one of the two remaining patents, which XY had asserted against another competitor. That ruling prompted the Colorado district court to stay the two remaining patent counts and enter final judgment against XY's ten other dismissed counts. The 2016 litigation is administratively closed, pending XY's appeal to the Federal Circuit, wherein XY is appealing the district court's dismissal of four of its patent causes of action. XY is not appealing one of the five dismissed patent counts or any of the dismissed non-patent causes of action. The Federal Circuit hearing is scheduled for March 5, 2020. Separately, after initially appealing the Wisconsin court's invalidation of the sixth patent, XY subsequently withdrew its appeal.

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 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 has produced documents to, and met with, the staff of the SEC and is voluntarily cooperating with their investigation. In November 2019, the staff of the SEC informed the Company that its investigative work was largely completed. The Company and the staff of the SEC are currently in discussions, and there can be no assurance regarding the ultimate outcome of the investigation.

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, strategic collaborations. The Company has had, and has, disagreements and disputes with certain collaborators and JV partners, including Harvest, the IEP Investors, and the IEP II Investors. While the Company believes it has the right to payment with respect to work performed for all of 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, 2019. These disagreements and disputes may result

in litigation, unfavorable settlements or concessions by the Company, adverse regulatory action, or management distraction, any of which could harm the Company's business or results of operations.

The Company may become subject to other claims, assessments and governmental investigations from time to time in the ordinary course of business. 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, 2019, 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 and Chairman of the board of directors is also the Senior Managing Director and CEO of Third Security and owns 100% of the equity interests of Third Security. In November 2015, the independent members of Precigen's board of directors, with the recommendation of the audit committee of the board of directors, approved the execution of 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. The Services Agreement provided for a term of one year, could be terminated by the Company at any time, and could be extended only by agreement of the parties, including approval of a majority of the independent members of Precigen's board of directors. The independent members of Precigen's board of directors, with the recommendation of the audit committee of the board of directors, subsequently approved extensions of the Services Agreement through January 1, 2020 at which point it was not further extended. 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 approximates \$800 per month. Through 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. Through May 2019, the payments made by the Company under the Services Agreement constitute, in the aggregate, an award under the 2013 Plan and are subject to the terms of the 2013 Plan. Following the effectiveness of the 2019 Plan in June 2019, subsequent payments made by the Company under the Services Agreement constitute, in the aggregate, an award under the 2019 Plan and are subject to the terms of the 2019 Plan (Note 15). For the years ended December 31, 2019, 2018 and 2017, the Company issued 1,606,062 shares, 696,033 shares, and 500,650 shares, respectively, with values of \$8,233, \$8,324, and \$8,704, respectively, to Third Security as payment for services pursuant to the Services Agreement. The Services Agreement was not extended and was allowed to expire on January 1, 2020. In addition to the foregoing Services Agreement, the Company reimburses Third Security for certain out-of-pocket expenses incurred on the Company's behalf, and the total expenses incurred by the Company under this arrangement was \$26, \$47, and \$409 for the years ended December 31, 2019, 2018 and 2017, 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.

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 \$89, \$89, and \$43 for the years ended December 31, 2019, 2018 and 2017, respectively.

See Notes 1, 3, and 23 regarding additional transactions with affiliates of Third Security.

Transactions with ECC Parties

Entities controlled by Third Security are considered related parties and are disclosed below. The Company also disclosed entity relationships below where it holds more than a de minimis equity interest, including equity securities received as upfront or milestone consideration, and that also are party to a collaboration with the Company.

In June 2016, the Company received 100,000 shares of Series 1 Preferred Stock (the "Preferred Shares") of ZIOPHARM, with a per share stated value of \$1,200, as consideration for amending their two previously existing ECC agreements (Note 6). The Company received a monthly dividend, paid in additional Preferred Shares, equal to \$12.00 per Preferred Share held per month divided by the stated value of the Preferred Shares. The Company elected the fair value option to account for the Preferred Shares whereby the value of the Preferred Shares was adjusted to fair value as of each reporting date and unrealized gains and losses were reported in the consolidated statements of operations. 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 years ended December 31, 2018 and 2017, the Company recognized \$14,793 and \$16,717 of dividend income in the accompanying consolidated statements of operations, respectively. Following the transaction in October 2018, ZIOPHARM is no longer considered a related party.

In March 2017, Fibrocell sold Series A Convertible Preferred Stock (the "Convertible Preferred Shares") convertible into shares of Fibrocell common stock and warrants to purchase shares of Fibrocell common stock to certain institutional and accredited investors, including the Company and affiliates of Third Security. The Company paid \$1,161 in exchange for 1,161 Convertible Preferred Shares and warrants to acquire 99,769 shares of Fibrocell common stock. The Convertible Preferred Shares accrued dividends at 4% per annum, compounded quarterly, increasing the stated value of the shares. The Company also holds a promissory note which was convertible into shares of Fibrocell common stock ("convertible note") and warrants to purchase shares of Fibrocell common stock. The Company elected the fair value option to account for these investments whereby the values of investments were adjusted to fair value as of each reporting date and unrealized gains and losses were reported in the consolidated statements of operations. As of December 31, 2018, the fair value of the Company's investment in Fibrocell preferred stock totaled \$191, and the value of the convertible note and warrants totaled \$120, all of which are included in other assets on the accompanying consolidated balance sheet. The Company also owned common shares of Fibrocell previously acquired through collaborations and other transactions, and the fair value of these common shares was \$640 as of December 31, 2018. In December 2019, Fibrocell was acquired by Castle Creek, and as a result, the Company received \$1,280 in December 2019 for its common shares 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 other 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 income (expense), net, in the accompanying consolidated statement of operations for the year ended December 31, 2019. Subsequent to the acquisition by Castle Creek, Fibrocell is no longer a related party.

During 2018, the Company mutually terminated each of its ECC agreements with Histogenics Corporation ("Histogenics"), OvaScience, Inc., and Synthetic Biologics, Inc. ("Synthetic Biologics"). Upon termination of these ECCs, the Company recognized the remaining deferred revenue totaling \$11,877.

In December 2017, the Company purchased certain property and equipment comprising the pilot plant production facility for its energy programs for \$2,812 from Intrexon Energy Partners. The Company intends to use the pilot plant to support the collaborations with Intrexon Energy Partners and Intrexon Energy Partners II and its own research programs.

Other Related Parties

In June 2015, the Company entered into an agreement with Harvest, an investment fund sponsored by Harvest Capital Strategies, LLC, and a related party based on ownership in the fund by affiliates of Third Security. Harvest was established to invest in life science research and development start-up opportunities that the Company offered to Harvest with exclusive rights of first-look and first negotiation. Based on this agreement, Harvest established six new collaboration entities, each of which entered into an ECC with the Company in a designated field. The terms of such ECCs were negotiated between the Company and Harvest. As consideration for providing exclusive rights of first-look and first negotiation for start-up opportunities, the Company received a portion of the management fee collected by the fund sponsor of Harvest. These fees are included in other income in the accompanying consolidated statement of operations and totaled \$1,839 for the year ended December 31, 2017. In September 2017, the commitment period for Harvest was terminated and, as a result, the agreement with Harvest terminated. The termination of the agreement had no effect on the existing collaborations with Harvest-controlled entities. See Note 4 for further discussion of the asset acquisition of certain Harvest entities.

19. Net Loss per Share

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

	2019	2018	2017
Historical net loss per share:			
Numerator:			
Net loss from continuing operations attributable to Precigen	\$ (206,165)	\$ (408,947)	\$ (70,637)
Net loss from discontinued operations attributable to Precigen	(116,159)	(100,389)	(46,381)
Net loss attributable to Precigen	<u>\$ (322,324)</u>	<u>\$ (509,336)</u>	<u>\$ (117,018)</u>
Denominator:			
Weighted average shares outstanding, basic and diluted	<u>154,138,774</u>	<u>129,521,731</u>	<u>119,998,826</u>
Net loss per share:			
Net loss from continuing operations attributable to Precigen per share, basic and diluted	\$ (1.34)	\$ (3.16)	\$ (0.59)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	(0.75)	(0.77)	(0.39)
Net loss attributable to Precigen per share, basic and diluted	<u>\$ (2.09)</u>	<u>\$ (3.93)</u>	<u>\$ (0.98)</u>

The following potentially dilutive securities as of December 31, 2019, 2018, and 2017, 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,		
	2019	2018	2017
Convertible debt	21,323,068	18,955,668	—
Options	9,022,282	11,093,063	11,382,747
Restricted stock units	1,781,982	970,341	—
Warrants	133,264	133,264	133,264
Total	<u>32,260,596</u>	<u>31,152,336</u>	<u>11,516,011</u>

20. Segments

Through March 31, 2019, the Company was a single operating segment. In April 2019, the Company initiated efforts to better deploy resources, realize inherent synergies, and position the Company for growth with a core focus on healthcare and initiated plans to achieve this through various corporate activities, ultimately resulting in the closing of the Transactions in January 2020 (Note 3). Beginning in the second quarter of 2019, the Company's CODM assessed the operating performance of and allocated 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 impairment of goodwill and other long-lived assets, (vi) equity in net loss of affiliates, and (vii) recognition of previously deferred revenue associated with upfront and milestone payments as well as cash outflows from capital expenditures and investments in affiliates.

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 CODM now regularly reviews disaggregated financial information for each of the Company's operating segments. The Company's segment presentation has been recast to retrospectively reflect the change from one reportable segment to the newly identified reportable segments, including goodwill and also excludes consideration of all of the businesses included in the Transactions (Note 3).

For the year ended December 31, 2019, the Company's reportable segments are (i) PGEN Therapeutics, (ii) ActoBio, (iii) MBP Titan, and (iv) Trans Ova. These identified reportable segments met the quantitative thresholds for the year ended December 31, 2019, to be reported separately. See Note 1 for a description of each of these reportable segments. The All Other category as reported below reflects Precigen's other operating segments that do not meet the quantitative thresholds to report separately. The Company has also recast 2018 and 2017 segment information on the same basis as the 2019 presentation.

Information by reportable segment was as follows:

	PGEN Therapeutics	ActoBio	MBP Titan	Trans Ova	All Other	Total
Goodwill						
Balances at December 31, 2017	\$ —	\$ —	\$ —	\$ 46,236	\$ 47,515	\$ 93,751
Reallocations from changes to reporting units	15,232	1,788	—	—	(17,020)	—
Foreign currency translation adjustments	—	—	—	—	(124)	(124)
Balances at December 31, 2018	15,232	1,788	—	46,236	30,371	93,627
Reallocations from changes to reporting units	—	—	9,635	—	(9,635)	—
Impairments	—	—	—	(29,642)	(178)	(29,820)
Foreign currency translation adjustments	—	(53)	—	—	—	(53)
Balances at December 31, 2019	\$ 15,232	\$ 1,735	\$ 9,635	\$ 16,594	\$ 20,558	\$ 63,754

Year Ended December 31, 2019

	PGEN Therapeutics	ActoBio	MBP Titan	Trans Ova	All Other	Total
Revenues from external customers	\$ 2,227	\$ (364)	\$ 3,813	\$ 68,672	\$ 16,227	\$ 90,575
Intersegment revenues	11,341	498	96	1,361	1,270	14,566
Total segment revenues	\$ 13,568	\$ 134	\$ 3,909	\$ 70,033	\$ 17,497	\$ 105,141
Segment Adjusted EBITDA	\$ (30,166)	\$ (13,662)	\$ (36,718)	\$ (6,337)	\$ (5,952)	\$ (92,835)

Year Ended December 31, 2018

	PGEN Therapeutics	ActoBio	MBP Titan	Trans Ova	All Other	Total
Revenues from external customers	\$ 29,021	\$ 6,684	\$ 9,927	\$ 75,178	\$ 30,213	\$ 151,023
Intersegment revenues	617	840	9	558	255	2,279
Total segment revenues	\$ 29,638	\$ 7,524	\$ 9,936	\$ 75,736	\$ 30,468	\$ 153,302
Segment Adjusted EBITDA	\$ (32,841)	\$ (12,797)	\$ (29,403)	\$ (5,730)	\$ (10,708)	\$ (91,479)

Year Ended December 31, 2017

	PGEN Therapeutics	ActoBio	MBP Titan	Trans Ova	All Other	Total
Revenues from external customers	\$ 53,184	\$ 12,929	\$ 14,336	\$ 79,783	\$ 59,174	\$ 219,406
Intersegment revenues	—	1,183	—	243	630	2,056
Total segment revenues	\$ 53,184	\$ 14,112	\$ 14,336	\$ 80,026	\$ 59,804	\$ 221,462
Segment Adjusted EBITDA	\$ (5,655)	\$ (2,656)	\$ (32,251)	\$ 1,020	\$ (1,102)	\$ (40,644)

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

	Year Ended December 31,		
	2019	2018	2017
Total segment revenues from reportable segments	\$ 87,644	\$ 122,834	\$ 161,658
Other revenues, including from other operating segments	18,602	30,914	59,861
Elimination of intersegment revenues	(15,524)	(2,570)	(2,056)
Total consolidated revenues	<u>\$ 90,722</u>	<u>\$ 151,178</u>	<u>\$ 219,463</u>

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

	Year Ended December 31,		
	2019	2018	2017
Segment Adjusted EBITDA for reportable segments	\$ (86,883)	\$ (80,771)	\$ (39,542)
All Other Segment Adjusted EBITDA	(5,952)	(10,708)	(1,102)
Remove cash paid for capital expenditures and investments in affiliates	15,339	19,906	31,701
Add recognition of previously deferred revenue associated with upfront and milestone payments	17,843	39,446	68,539
Other expenses:			
Interest expense	(17,666)	(8,473)	(584)
Depreciation and amortization	(19,789)	(24,105)	(21,609)
Impairment loss	(30,810)	—	(13,823)
Reacquisition of in-process research and development	—	(236,748)	—
Stock-based compensation expense	(16,443)	(32,424)	(36,893)
Equity in net loss of affiliates	(2,416)	(8,986)	(12,436)
Other	67	—	—
Unallocated corporate costs	(47,577)	(84,536)	(53,197)
Eliminations	(14,400)	(2,343)	579
Consolidated net loss from continuing operations before income taxes	<u>\$ (208,687)</u>	<u>\$ (429,742)</u>	<u>\$ (78,367)</u>

As of December 31, 2019 and 2018, the Company had \$6,724 and \$10,011, respectively, of long-lived assets in foreign countries from continuing operations. The Company recognized revenues from continuing operations derived in foreign countries totaling \$1,401, \$6,255, and \$13,771 for the years ended December 31, 2019, 2018 and 2017, 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, 2019	June 30, 2019	September 30, 2019	December 31, 2019 (1)
Total revenues	\$ 22,585	\$ 32,836	\$ 18,299	\$ 17,002
Operating loss	(50,216)	(31,373)	(44,637)	(77,986)
Loss from continuing operations	(52,900)	(32,305)	(49,054)	(73,498)
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	\$ (0.34)	\$ (0.21)	\$ (0.32)	\$ (0.47)
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).

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018 (1)
Total revenues	\$ 37,160	\$ 42,771	\$ 30,055	\$ 41,192
Operating loss	(42,241)	(34,807)	(58,330)	(268,119)
Loss from continuing operations	(37,103)	(52,120)	(50,507)	(274,587)
Net loss attributable to Precigen	(46,165)	(65,382)	(57,324)	(340,465)
Net loss from continuing operations attributable to Precigen per share, basic and diluted	\$ (0.28)	\$ (0.39)	\$ (0.38)	\$ (2.08)
Net loss attributable to Precigen per share, basic and diluted	\$ (0.36)	\$ (0.51)	\$ (0.44)	\$ (2.59)

- (1) During the fourth quarter of 2018, the Company reacquired certain in-process research and development from ZIOPHARM, Ares Trading, and Intrexon T1D Partners, all of which were immediately expensed (Notes 5 and 6). The Company also recorded a loss on abandonment of certain of its intangible assets (Note 11). The Company also recognized the remaining balance of deferred revenue associated with Histogenics and Synthetic Biologics upon the mutual termination of the ECCs with these entities (Note 18).

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 for continuing operations were \$1,427, \$1,662 and \$1,545 in 2019, 2018 and 2017, respectively.

23. Subsequent Events

In January 2020, the Company completed the Transactions discussed in Note 3. 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 February 2020, the Company and Fibrocell mutually agreed to terminate Fibrocell ECC 2. The Company is considering the impact of this termination on its 2020 financial results.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of the date of the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of Precigen, Inc. ("we" and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended is our common stock, no par value.

DESCRIPTION OF COMMON STOCK

The following description summarizes information about our common stock. This information does not purport to be complete and is subject to, and qualified in its entirety by reference to, the terms of our amended and restated articles of incorporation and amended and restated bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of Virginia law, the state in which we are incorporated.

Authorized Common Stock

We have the authority to issue 400,000,000 shares of our common stock, no par value per share.

Rights

Shares of our common stock have the following rights, preferences, and privileges:

Voting rights; Dividends; Liquidation. Holders of our common stock are entitled to:

- Cast one vote on all matters submitted to a vote of our shareholders, including the election of directors. Holders of our common stock do not have cumulative voting rights in the election of directors;
- receive dividends if and when dividends are declared by our board of directors out of assets legally available for the payment of dividends, subject to preferential rights of outstanding shares of preferred stock, if any;
- in the event of our liquidation, dissolution or winding up, whether voluntary or involuntary, after payment of our debts and other liabilities and making provision for the holders of outstanding shares of preferred stock, if any, to share equally and ratably in the remainder of our assets.

Rights and preferences

The common stock has no preemptive, redemption, conversion, or subscription rights and is not subject to sinking fund provisions. The rights, powers, preferences, and privileges of holders of common stock are subject to, and may be impaired by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our board has the authority to designate and issue from time to time one or more series of preferred stock without shareholder approval. Our board may fix and determine the preferences, limitations and relative rights of each series of preferred stock issued. Because our board has the power to establish the preferences and rights of each series of preferred stock, it may afford the holders of any series of preferred stock preferences and rights, voting or otherwise, senior to the rights of holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of common stock until our board determines the specific rights of the holders of preferred stock. However, the effects might include:

- restricting dividends on our common stock;
- diluting the voting power of our common stock;
- impairing liquidation rights of our common stock; or

- delaying or preventing a change in control of us without further action by our shareholders.

Anti-takeover Effects of Provisions of our Charter and Bylaws and of Virginia Law

Our amended and restated articles of incorporation, bylaws, and Virginia law contain provisions that may have the effect of impeding the acquisition of control of us by means of a tender offer, a proxy contest, open market purchases, or otherwise in a transaction not approved by our board of directors. These provisions are designed to reduce, or have the effect of reducing, our vulnerability to coercive takeover practices and inadequate takeover bids. The existence of these provisions could limit the price that investors might otherwise pay in the future for shares of common stock. In addition, these provisions make it more difficult for our shareholders to remove our board of directors or management, should they choose to do so.

Articles of Incorporation and Bylaws

Undesignated Preferred stock

Our amended and restated articles of incorporation authorize our board to establish one or more series of preferred stock and to determine, with respect to any series of preferred stock, the preferences, rights, and other terms of such series. See “Preferred stock” above for additional information. Under this authority, our board could create and issue a series of preferred stock with rights, preferences or restrictions that have the effect of discriminating against an existing or prospective holder of our capital stock as a result of such holder beneficially owning or commencing a tender offer for a substantial amount of our common stock. One of the effects of authorized but unissued and unreserved shares of preferred stock may be to render it more difficult for, or to discourage an attempt by, a potential acquiror to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without any action by our shareholders.

Qualification and election of directors

Our bylaws provide that to be eligible to be a nominee for election to our board of directors, a person must submit a written questionnaire regarding his or her background and qualifications and must agree to other representations as set forth in our bylaws. In addition, we have adopted a director resignation policy. Our bylaws provide that, in uncontested director elections (i.e., an election where the number of nominees is not greater than the number of directors to be elected), a nominee for director will be elected to the board of directors if the votes cast for such nominee’s election exceed the votes cast against such nominee’s election. However, directors will be elected by a plurality of the votes cast at any meeting of the shareholders for which (i) the Secretary receives a notice that a shareholder has nominated a person for election to the board of directors in compliance with the advance notice requirements for shareholder nominees for director set forth in the bylaws, and (ii) such nomination has not been withdrawn by such shareholder on or prior to the 10th day preceding the date we first mail the notice of meeting for such meeting to the shareholders (i.e., if there is a contested director election). If directors are to be elected by a plurality of the votes cast, the shareholders may withhold votes, but will not be permitted to vote against a nominee. Our Corporate Governance Guidelines provide that any nominee for director in an uncontested election who receives a greater number of shareholder votes cast against his or her election than votes for his or her election must promptly tender his or her resignation to the board of directors for consideration. The Nominating and Governance Committee will then evaluate the best interests of the company and will recommend to the board of directors whether to accept or reject the tendered resignation. Following the board of directors’ receipt of this recommendation and determination as to whether to accept the resignation, we will disclose the board of directors’ decision and an explanation of how the decision was reached.

Board vacancies; removal

Our amended and restated articles of incorporation provide that any vacancy occurring on our board of directors may be filled by a majority of directors then in office, even if less than a quorum.

Special meetings of shareholders

Our bylaws provide that a special meeting may be called by a vote of shareholders representing in the aggregate not less than 25 percent of the total number of shares of stock entitled to vote on the matter to be brought before the proposed special meeting, and that shareholders may only conduct business at special meetings of shareholders that was specified in the notice of the meeting.

Advance notification of shareholder nominations and proposals

Our bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of persons for election as directors, other than nominations made by or at the direction of our board.

Exclusive forum provision

Our bylaws provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the Eastern District of Virginia, Alexandria Division, or in the event that court lacks subject matter jurisdiction to hear such action, the Circuit Court of the County of Fairfax, Virginia, will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action for breach of duty to the Company or our shareholders by any current or former officer or other employee or agent or director of the Company, (iii) any action against the Company or any current or former officer or other employee or agent or director of the Company arising pursuant to any provision of the Virginia Stock Corporation Act (as it may be amended from time to time) or our articles of incorporation or our bylaws (as either may be amended from time to time), or (iv) any action against the Company or any current or former officer or other employee or agent or director of the Company governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated bylaws. It is possible that a court of law could rule that the choice of forum provision contained in our bylaws is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Virginia Anti-takeover Statutes

Affiliated transactions statute

Virginia law contains provisions governing affiliated transactions. In general, these provisions prohibit a Virginia corporation from engaging in affiliated transactions with any holder of more than 10 percent of any class of its outstanding voting shares, or an interested shareholder, for a period of three years following the date that such person became an interested shareholder unless:

- a majority of (but not fewer than two) disinterested directors of the corporation and the holders of two-thirds of the voting shares, other than the shares beneficially owned by the interested shareholder, approve the affiliated transaction; or
- before or on the date the person became an interested shareholder, a majority of disinterested directors approved the transaction that resulted in the shareholder becoming an interested shareholder.

Affiliated transactions subject to this approval requirement include mergers, share exchanges, material dispositions of corporate assets not in the ordinary course of business, any dissolution of the corporation proposed by or on behalf of an interested shareholder or any reclassification, including reverse stock splits, recapitalizations or mergers of the corporation with its subsidiaries, which increases the percentage of voting shares owned beneficially by an interested shareholder by more than five percent.

Virginia law permits a corporation to exempt itself from this statutory provision by placing a statement to that effect in its articles of incorporation. Our amended and restated articles of incorporation do not specifically address the Virginia statute regarding affiliated transactions; therefore, we are subject to this provision.

Control share acquisitions statute

Virginia law also contains provisions relating to control share acquisitions, which are transactions causing the voting strength of any person acquiring beneficial ownership of shares of a Virginia public corporation to meet or exceed certain threshold percentages (20 percent, 33 $\frac{1}{3}$ percent or 50 percent) of the total votes entitled to be cast for the election of directors. Shares acquired in a control share acquisition have no voting rights unless:

- the voting rights are granted by a majority vote of all outstanding shares entitled to vote in the election of directors, other than those held by the acquiring person or any officer or employee director of the corporation; or
- the articles of incorporation or bylaws of the corporation provide that these Virginia law provisions do not apply to acquisitions of its shares.

The acquiring person may require that a special meeting of the shareholders be held within 50 days of the corporation's receipt of the acquiring person's request to consider the grant of voting rights to the shares acquired in the control share acquisition. If voting rights are not granted and the corporation's articles of incorporation or bylaws permit, the acquiring person's shares may be repurchased by the corporation, at its option, at a price per share equal to the acquiring person's cost. Virginia law grants dissenters' rights to any shareholder who objects to a control share acquisition that is approved by a vote of disinterested shareholders and that gives the acquiring person control of a majority of the corporation's voting shares.

Our amended and restated articles of incorporation provide that the statutory provisions governing control share acquisitions do not apply to our Company; therefore, we are not subject to this provision.

Authorized but Unissued Shares

The authorized but unissued shares of common stock and preferred stock are available for future issuance without shareholder approval, subject to any limitations imposed by the Nasdaq Stock Market LLC listing rules. These additional shares may be used for a variety of corporate finance transactions, acquisitions, and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger, or otherwise.

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 EF Holdings, 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 (<i>besloten vennootschap met beperkte aansprakelijkheid</i>)	Belgium
ER Cell LLC	Russia
Intrexon ActoBiotics NV (<i>naamloze vennootschap</i>)	Belgium
Precigen BioInformatics Germany GmbH	Germany

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-220326 on Form S-3 and Registration Statement Nos. 333-190614, 333-196840, 333-205642, 333-213065, 333-219874, 333-226821, 333-233209, and 333-233211 on Form S-8 of our reports dated March 2, 2020, relating to the financial statements of Precigen, Inc. (formerly Intrexon Corporation) 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, 2019.

/s/ Deloitte & Touche LLP

Baltimore, Maryland

March 2, 2020

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, 333-233211, and 333-233209) and Form S-3 (No. 333-220326) of Precigen, Inc. (formerly known as Intrexon Corporation) of our report dated March 1, 2019, except for the effects of discontinued operations discussed in Note 3 and the change in composition of reportable segments discussed in Note 20, as to which the date is March 2, 2020, relating to the consolidated financial statements which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina

March 2, 2020

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

I, Randal J. Kirk, 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 2, 2020

/s/ RANDAL J. KIRK

Randal J. Kirk
Executive Chairman
(Principal Executive Officer)

**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 2, 2020

/s/ HELEN SABZEVARI

Helen Sabzevari
Chief Executive Officer
(Principal Executive Officer)

**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 2, 2020

/s/ RICK L. STERLING

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

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

I, Randal J. Kirk, Executive Chairman 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, 2019 (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 2, 2020

/s/ RANDAL J. KIRK

Randal J. Kirk

Executive Chairman

(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.

**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, 2019 (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 2, 2020

/s/ HELEN SABZEVARI

Helen Sabzevari

Chief Executive Officer

(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.

**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 Intrexon Corporation (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, 2019 (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 2, 2020

/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.