

REPLIGEN CORP
Form 10-K
February 23, 2017
Table of Contents

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, 2016

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 000-14656

REPLIGEN CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of	04-2729386 (I.R.S. Employer
incorporation or organization) 41 Seyon Street, Bldg. 1, Suite 100	Identification No.) 02453
Waltham, MA (Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code: (781) 250-0111	

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, \$0.01 Par Value Per Share	The NASDAQ Stock Market LLC
Securities registered pursuant to Section 12(g) of the Act: None	

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

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

Indicate by checkmark 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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No .

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Edgar Filing: REPLIGEN CORP - Form 10-K

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, was \$915,057,854.

The number of shares of the registrant's common stock outstanding as of February 17, 2017 was 33,845,474.

Documents Incorporated By Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2016. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents**Table of Contents**

	PAGE
<u>Forward-looking Statements</u>	1
<u>PART I</u>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	12
Item 1B. <u>Unresolved Staff Comments</u>	24
Item 2. <u>Properties</u>	25
Item 3. <u>Legal Proceedings</u>	25
Item 4. <u>Mine Safety Disclosures</u>	25
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	26
Item 6. <u>Selected Consolidated Financial Data</u>	28
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
Item 8. <u>Financial Statements and Supplementary Data</u>	43
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	43
Item 9A. <u>Controls and Procedures</u>	43
Item 9B. <u>Other Information</u>	47
<u>PART III</u>	48
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	49
Item 16. <u>10-K Summary</u>	53
<u>SIGNATURES</u>	54

Table of Contents

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). The forward-looking statements in this Annual Report on Form 10-K do not constitute guarantees of future performance. Investors are cautioned that statements in this Annual Report on Form 10-K that are not strictly historical statements, including, without limitation, statements regarding current or future financial performance, potential impairment of future earnings, management s strategy, plans and objectives for future operations or acquisitions, product development and sales, product candidate research and development, selling, general and administrative expenditures, intellectual property, development and manufacturing plans, availability of materials, and product and adequacy of capital resources and financing plans constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, the risks identified under the caption Risk Factors and other risks detailed in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission. We assume no obligation to update any forward-looking information contained in this Annual Report on Form 10-K, except as required by law.

Table of Contents**PART I****ITEM 1. BUSINESS**

The following discussion of our business contains forward-looking statements that involve risks and uncertainties. When used in this report, the words intend, anticipate, believe, estimate, plan and expect and similar expressions as they relate to us are included to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements and are a result of certain factors, including those set forth under Risk Factors and elsewhere in this Annual Report on Form 10-K.

Overview

Repligen (Repligen , the Company , we or our) is a bioprocessing-focused, global life sciences company bringing over 30 years of expertise and innovation to our customers. Our mission is to inspire advances in bioprocessing as a trusted partner in the production of biologic drugs that improve human health worldwide. Focused on cost and process efficiencies, we deliver innovative technologies that help set new standards in the way biologic drugs are manufactured. We develop and market a broad range of high-value products and flexible solutions that address critical steps in the production of biologic drugs principally antibody-based therapeutics, recombinant proteins and vaccines while ensuring that the highest drug quality and safety standards are upheld.

Since our strategic decision in 2012 to focus fully on building our bioprocessing business, we have expanded and diversified our portfolio beyond our legacy Protein A affinity ligands business to include a number of technology leading bioprocessing products that we sell direct to biopharmaceutical companies and CDMOs (contract development and manufacturing organizations) worldwide. Our dedicated team of professionals has substantial experience in biomanufacturing and works proactively with industry leaders and customers to develop innovative solutions that address pressure points in the bioproduction process.

Our bioprocessing products drive process efficiency, cost and yield improvements. In upstream processes, our XCell ATF filtration devices and protein cell culture supplements are used in clinical and commercial-stage manufacturing to improve biologic drug yields. In downstream processes, our Protein A ligands are a critical component of Protein A resins used to purify over 50 antibody-based drugs on the market and more than 350 in clinical development. Also in downstream processes, our OPUS pre-packed chromatography columns (PPCs) are used in the purification of clinical-stage biologics, and our Sius tangential flow filtration (TFF) cassettes are used to concentrate clinical and commercial-stage biologic drugs.

We manufacture and supply Protein A ligands through long-term agreements with major life sciences companies such as GE Healthcare and MilliporeSigma, who in turn produce and sell Protein A resins to end users (biopharmaceutical companies and CDMOs). We manufacture and supply our cell culture supplements through a distribution agreement with MilliporeSigma.

We market our chromatography and filtration products globally through a direct commercial organization in the United States and Europe with a combination of direct sales and distributors in Asia. Since 2014, we have invested in expanding our global commercial organization adding 30 sales, marketing, product management, service and applications personnel to form a 37-person commercial team. Our commercial and R&D teams have a track record of successfully launching new products and applications, as well as building new markets for acquired technologies. For example, since acquiring the XCell ATF business in 2014, we have rapidly expanded its market penetration through increased customer interaction, new products and expanded applications that increase flexibility and convenience

while streamlining biomanufacturing workflow for our customers.

Our portfolio of bioprocessing products has expanded from our legacy Protein A line since 2011 through strategic acquisitions and internal product development. We have focused on building a portfolio of technology-leading products that we sell directly to end users. In 2016, we added the Sius TFF filtration line through our

Table of Contents

purchase of TangenX Technology Corporation (the TangenX Acquisition), and we added a lab-scale pre-packed chromatography column line through our purchase of Atoll GmbH (the Atoll Acquisition). In 2014, we acquired the XCell ATF filtration line from Refine Technologies LLC (the Refine Acquisition). In 2011, we added to our Protein A ligands business and added cell culture growth factors through our acquisition of Novozymes Biopharma Sweden AG (the Novozymes Acquisition). Internally, we develop and market our process-scale OPUS pre-packed chromatography columns. Also through internal innovation, we have extended both our OPUS and XCell ATF product lines, to include more size options and technology features to benefit our customers. For example in 2016 we introduced a resin recovery feature on our largest OPUS columns (OPUS R) and we launched a single-use (disposable) alternative to our stainless steel XCell ATF Systems.

Many of our products are early in their adoption cycle, and together with the expansion of our commercial organization and strategic acquisitions, have contributed to product revenue expansion from \$41.8 million in 2012, to \$104.5 million in 2016. While all product franchises have grown, our diversification strategy has resulted in our direct product sales accounting for approximately 52% of our bioprocessing revenue in 2016, compared to approximately 20% in 2012. To meet increased demand for our products, we have increased and continue to increase the volume and scale of manufacturing at our two manufacturing facilities in the United States and Sweden and plan to expand manufacturing capacity at our newly acquired manufacturing facilities in the United States and Germany.

Customers use our products to produce initial quantities of drug for clinical studies, then scale-up to larger volumes as the drug progresses to commercial production following regulatory approval. Detailed specifications for a drug's manufacturing process are included in applications that must be approved by regulators, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, throughout the clinical trial process and prior to final commercial approval. As a result, products that become part of the manufacturing specifications of a late-stage clinical or commercial process can be very sticky due to the costs and uncertainties associated with displacing them.

We were incorporated in May 1981 under the laws of the State of Delaware. Our principal executive offices are located at 41 Seyon Street, Waltham, Massachusetts 02453 and our telephone number is (781) 250-0111.

Our Market Opportunity

The global biologics drug market is estimated to be over \$200 billion. This market includes therapeutic antibodies, recombinant proteins and vaccines. Antibody-based biologics alone accounted for approximately \$90 billion of global biopharma revenue and represented a majority of the top 10 best-selling drugs across the pharmaceutical industry in 2016. Industry sources project the biologics market to grow at a rate of 8%-10% annually over the next five years, driven by strength in the monoclonal antibody (mAb) class of biologics, as evidenced by the rate of new approvals, expanded labels for marketed antibodies and the emergence of biosimilar versions of originator mAbs. For example, in 2016, a record ten antibodies (seven originator and three biosimilar antibodies) were approved by the FDA to treat a diverse range of diseases.

There are currently more than 300 mAbs in various stages of clinical development addressing a wide range of medical conditions including asthma, migraines and Alzheimer's disease.

In addition to investments in the discovery and development of novel biologic drugs, there has been substantial investment in follow-on products (biosimilars) by generic and specialty pharmaceutical as well as large biopharmaceutical companies. We believe development of follow-on products is accelerating as the first major mAbs begin to come off patent in the European Union and United States. For example, there are at least 12 companies attempting to market the first Humira® (adalimumab) biosimilar, for which patent protection expired in the United States at the end of 2016. Also, due to the high cost of biologic drugs, many countries in the developing and emerging

markets have been aggressively investing in biomanufacturing capabilities to supply

Table of Contents

lower cost alternatives or biosimilars for the local markets. We believe they are focused on innovative technologies that offer greater manufacturing flexibility, production yields and lower-costs through improved process efficiencies.

The Biologics Manufacturing Process

Manufacturing biologic drugs requires three fundamental steps. First, upstream manufacturing involves the production of the biologic by living cells that are grown in a bioreactor under controlled conditions. These cells, or factories, are highly sensitive to the conditions under which they grow, including the composition of the cell culture media and the growth factors used to stimulate increased cell growth and protein production, or titre. In the second, downstream step, the biologic must be separated and purified, typically through various filtration and chromatography steps. In the third stage of the process, the purified biologic drug is formulated, quality controlled and packaged into its final injectable form.

Biologics are generally high value therapies. Given the inherent complexities of the process and drug product, we have observed that manufacturers are seeking and investing in innovative technologies that address pressure points in the production process in order to improve yields. We see that manufacturers are also seeking technologies that reduce costs as the biologic drug moves through clinical stages and into commercial processes by adopting single-use technologies as well as other products that confer more flexibility and efficiency.

Our Strategy

We are focused on the development, production and commercialization of differentiated, technology-leading solutions or products that address pressure points in the biologics manufacturing process and deliver substantial value to our customers. We are committed to supporting our customers with strong customer service and applications expertise.

We intend to build on our recent history of developing market leading solutions and delivering strong financial performance through the following strategies.

Continued innovation. We plan to capitalize on our internal technological expertise to develop products that address unmet needs in upstream and downstream bioprocessing. We intend to invest further in our core ligands business while developing platform and derivative products to support our growth factor, XCell ATF System and OPUS franchises.

Platforming our products. A key strategy for accelerating market adoption of our products is delivery of enabling technologies that become the standard, or platform, technology in markets where we compete. We focus our efforts on winning early-stage technology evaluations through direct interaction with the key biomanufacturing decision makers in process development labs. This strategy is designed to establish both early adoption of our enabling technologies at key accounts and accelerate the implementation of our products as platform products, thereby strengthening our competitive advantage and contributing to long-term growth.

Targeted acquisitions. We will selectively pursue acquisitions of innovative technologies and products. We intend to leverage our balance sheet to acquire technologies and products that improve our overall financial performance by improving our competitiveness and/or moving us into adjacent markets with common

commercial call points.

Geographical expansion. We intend to expand our commercial presence by continuing to build out our global sales, marketing, field applications and services infrastructure.

Operational efficiency. We seek to expand operating margins through capacity utilization and process optimization strategies designed to increase our manufacturing yields. We plan to invest in systems to support our global operations, optimizing resources across our global footprint to maximize productivity.

Table of Contents**Our Products*****Protein Products******Protein A***

We are the leading provider of Protein A ligands, an essential component of Protein A chromatography resins (media) used in the purification of virtually all mAb-based drugs on the market (more than 50) or in development (more than 300). We manufacture multiple forms of Protein A ligands under long term supply agreements for major life sciences companies including GE Healthcare and MilliporeSigma, who in turn sell their Protein A chromatography media to end users (biopharmaceutical manufacturers). We have two manufacturing sites, one in Lund, Sweden and another in Waltham, MA, collectively supporting overall global demand for our Protein A ligands. On February 22, 2016, we amended our long term supply agreements with GE Healthcare to, among other things, extend the terms of the supply agreement relating to our Lund, Sweden facility through 2019. The supply agreement relating to our Waltham, MA facility runs through 2021. We also extended a long term supply agreement with MilliporeSigma for Protein A ligands through 2023. This dual manufacturing capability gives us strong business continuity and reduces overall supply risk for our major customers.

Protein A chromatography media is considered the industry standard for purification of antibody-based therapeutics (primarily mAbs, and also including bi-specific antibodies and antibody drug conjugates), due to the ability of Protein A to selectively bind to or capture antibodies from crude protein mixtures. Protein A media is packed into chromatography columns as the standard first step in a purification process. As a result of Protein A's high affinity for antibodies, the product is highly purified and concentrated within this first capture step before moving to polishing steps. The global Protein A media market that we supply generates annual revenues of \$350-\$400 million. We expect continued growth for our Protein A ligands as new drugs are approved and biosimilar manufacturing accelerates.

Cell Culture Growth Factors

Most biopharmaceuticals are produced through a mammalian cell fermentation process. In order to stimulate increased cell growth and maximize overall yield from a bioreactor, manufacturers often add growth factors, such as insulin, to the cell culture fermentation media. As part of the Novozymes Acquisition, we acquired several cell culture growth factor additives. Among those products is LONG[®]R3 IGF-1, our insulin-like growth factor that has been shown to be 100 times more biologically potent than insulin (the industry standard), thereby increasing recombinant protein production in cell culture fermentation applications. LONG[®]R3 IGF-1 is currently used in the manufacture of several commercial biopharmaceutical products and is sold through a distribution partnership with MilliporeSigma. Our goal over the last few years with MilliporeSigma has been to focus on pipeline development and work with customers already familiar with the product to more broadly adopt LONG[®]R3 IGF-1 as a platform product.

We estimate that the current market for cell culture growth factors is \$75-\$80 million. We are gaining share of this market as customers displace insulin with LONG[®]R3 IGF-1.

Chromatography Products

Our chromatography portfolio includes a number of products used in the downstream purification and quality control of biological drugs. The main driver of growth in this portfolio is our OPUS pre-packed chromatography (PPC) column line. Our other products include Protein A chromatography resins used in a small number of commercial drug processes and ELISA test kits used by quality control departments to detect and measure the presence of leached Protein A and/or growth factor in the final product. In April 2016, we acquired the OPUS PD (formerly MediaScout)

PPC manufacturing business through our acquisition of Atoll GmbH, expanding our chromatography portfolio into high throughput process development screening, viral validation studies and scale down validation of chromatography processes.

Table of Contents

Chromatography columns, packed with chromatography media, are used in biomanufacturing to purify the biological drugs once separated, typically using filtration technology, from the contents of a bioreactor. For late-stage clinical and large commercial processes, stainless steel columns are standard, and are packed in-house by the biomanufacturer. For clinical stage manufacturing, biomanufacturers value the quick turnover, cost savings and convenience of using pre-packed columns such as OPUS versus traditional glass columns.

OPUS columns are pre-packed with purification media and are an efficient plug-and-play solution for our customers, and represent a growing area of our business. As biomanufacturers have become acutely focused on improving the drug development process, they are moving towards flexible manufacturing and disposable solutions such as OPUS. In recent years, we have observed customers moving away from in-house solutions (self-packed glass columns). They are starting to adopt the OPUS ready-to-use format due to convenience, flexibility and consistent product performance. OPUS columns save labor time, reduce overall costs and improve overall manufacturing efficiency, allowing biomanufacturers to reassign resources to higher value-add processes.

Our OPUS line is distinctly open platform, providing desirable opportunities for customization. For example, most biopharmaceutical manufacturers utilize three different chromatography media in a given process, and our flexible columns are designed to meet these needs. We differentiate ourselves in the pre-packed column space by packing any brand of chromatography media in OPUS to any bed height, ensuring the most convenient and efficient process for end users. The plug-and-play nature of our OPUS columns make them ideal for purification of antibodies and recombinant proteins. With the launch of OPUS 45cm diameter columns in 2014 and 60cm columns in 2015, we have further differentiated ourselves from our competitors who offer a limited number of column diameter and resin (media) options. By offering these larger columns, we are making inroads in the glass column market which customers typically self-pack. To address customer feedback and further enhance our product offering, we developed and launched in October 2016, OPUS R, which are OPUS pre-packed columns with an innovative side port for recovering chromatography resin from inside the column. This allows our customers to re-use the unpacked resin in other applications. The unpacking port feature will be available in the first quarter of 2017 on our largest production-scale OPUS columns; we refer to these as our OPUS 45R and OPUS 60R columns.

Pre-packed chromatography columns are at the early stages of adoption; we estimate that currently, we and our competitors collectively capture approximately 30% of a \$165 million addressable market. As our sales force expands and we increase the number of call points, we are seeing more multi-site adoption of our OPUS pre-packed columns, including increased use by contract manufacturers and large pharma companies, where quick turnover of multiple production runs is critical to profitability.

Filtration Products***Sius Filtration Products***

We acquired the Sius line of tangential flow filtration (TFF) cassettes and hardware as part of our acquisition of TangenX Technology in December 2016. The acquisition of this product line complements our OPUS line of pre-packed chromatography columns used in downstream purification of biologics, and extends our filtration portfolio beyond our upstream XCell ATF offering.

TFF is a rapid and efficient method for separation and purification of biomolecules that is widely used in laboratory, process development and process scale applications in biopharmaceutical manufacturing. Sius is an innovative single-use TFF line of cassettes and hardware for lab-scale through process-scale biopharmaceutical manufacturing. Single-use Sius TFF cassettes with enclosed flat sheet membranes are designed to provide a high performing membrane at significantly lower cost compared to reusable TFF products. Each disposable cassette is delivered

pre-sanitized, integrity tested and ready to be equilibrated and used for tangential flow diafiltration and ultrafiltration processing. Internal studies demonstrate that utilizing Sius TFF in downstream processing provides

Table of Contents

equivalent or higher performance while reducing filter costs, labor and buffer usage, eliminating non-value added steps of cleaning and flushing required in alternative TFF products. Sius TFF cassettes are interchangeable with filter hardware from multiple manufacturers, simplifying customer trial and adoption of Sius products.

The market for TFF cassettes in downstream purification is estimated at \$200 million. The Sius TFF products have started to move into this market over the last few years as more customers opt for the convenience of single-use solutions. We expect this business to grow rapidly over the next few years as the technology gets adopted and we drive a greater number of evaluations through our larger commercial organization.

XCell ATF

The XCell ATF System is a technologically advanced filtration device used in upstream processes to continuously remove cellular metabolic waste products during the course of a fermentation run, freeing healthy cells to continue producing the biologic drug of interest. XCell ATF was designed to both increase the density of cells in a bioreactor and extend the production run. By continuously removing waste products from the fermentor, the XCell ATF System routinely increases cell densities to 2- or 3-times the levels achieved by standard batch fermentation. As a result, product yield is increased, which improves facility utilization and can reduce the size of a bioreactor required to manufacture a given volume of biologic drug product. This is important to biomanufacturers who seek to maximize output from their existing facilities.

XCell ATF Systems consist of either a stainless steel or plastic housing that contains a hollow-fiber filter, plus an associated pump and controller. We sell the XCell ATF System in a variety of sizes (ATF 2, ATF 4, ATF 6, ATF 10) suitable for use in laboratory and scale-up all the way to production bioreactors as large as 2,000 liters. XCell ATF Systems are used in the production of several FDA-approved mAbs.

Following our acquisition of the XCell ATF System from Refine Technology in 2014, we integrated the production of XCell ATF into our operations in Waltham, MA. We also invested in and developed the single-use version of XCell ATF, which we launched in October 2016. The XCell ATF device is now available as the original stainless steel configuration (steel housing and replaceable filters) in all sizes, or as a single-use device (disposable housing/filter combination) in select sizes (ATF 2 su, ATF 6 su). The availability of XCell ATF in a single-use format eliminates the pre-use workflow associated with autoclaving, leading to an 80% reduction in implementation time. We expect these advancements will enable our customers to accelerate evaluations, eliminate autoclaving, simplify implementation time and lower initial overall cost of ownership.

We estimate that the current market for cell retention devices is approximately \$125-150 million. Within this market, we expect continued growth for our XCell ATF portfolio over the next several years, as biologics manufacturing accelerates globally and as large pharmaceutical customers who have evaluated the system adopt the technology as platform.

Research and Development

Our research activities are focused on developing new bioprocessing products. Specifically, we plan to focus these efforts on our expanding our product portfolio and applications for our OPUS PPC, XCell ATF and Sius TFF products, and developing next generation Protein A ligands. Research and development expenses totaled approximately \$7.4 million, \$5.7 million and \$5.6 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Sales and Marketing

Our sales and marketing strategy supports our objective of establishing Repligen as a leading provider of products and services, addressing upstream, downstream and quality control needs of bioprocessing customers in the biotechnology and biopharmaceutical industries. Through our products and brands, including Protein A,

Table of Contents

LONG®R3 IGF-1, OPUS, XCell ATF and Sius TFF, we provide premier offerings and services to our bioprocessing customers. We are committed to being a partner of choice for our customers with distributor and supply agreements in place for our growth factor and Protein A products with GE Healthcare and MilliporeSigma. On February 22, 2016, we amended our long term supply agreements with GE Healthcare to, among other things, extend the terms of the supply agreement relating to our Lund, Sweden facility through 2019. The GE Healthcare supply agreement relating to our Waltham, MA facility runs through 2021. We also extended a long term supply agreement for Protein A with MilliporeSigma through 2023.

We have invested in our commercial organization and now have 37 sales, marketing, product management and service individuals providing service and support to our expanding customer base. Our global sales organization has both distributor and direct sales personnel, depending on the market and application area. We will continue to expand our commercial organization to support increasing demand for our products. Our commercial organization also helps us identify market opportunities, including potential new technologies that we can license and develop into new products.

Segment and Geographic Areas

We have one reportable segment. Segment and geographical information is contained in Note 2 of the notes to our consolidated financial statements as of and for the years ended December 31, 2016, 2015, and 2014.

Significant Customers and Geographic Reporting

Customers for our bioprocessing products include major life science companies, contract manufacturing organizations, biopharmaceutical companies, diagnostics companies and laboratory researchers.

The following table represents the Company's total revenue by geographic area (based on the location of the customer):

	Years ended December 31,		
	2016	2015	2014
Sweden	29%	37%	38%
United States	39%	28%	33%
United Kingdom	7%	17%	20%
Other	25%	18%	9%
Total	100%	100%	100%

GE Healthcare, our largest bioprocessing customer, accounted for 29%, 37% and 38% of total revenues in the fiscal years ended December 31, 2016, 2015 and 2014, respectively. MilliporeSigma, our second largest bioprocessing customer, accounted for 28%, 29% and 33% of total revenues in the fiscal years ended December 31, 2016, 2015 and 2014, respectively.

Employees

As of February 17, 2016, we had 236 employees. Of those employees, 29 were engaged in engineering and research and development, 130 in manufacturing, 37 in sales and marketing and 40 in administrative functions. Each of our employees has signed a confidentiality agreement. None of our U.S. employees are covered by collective bargaining

agreements. We have two collective bargaining agreements that cover our 61 employees in Sweden, comprising approximately 26% of our total workforce. We renewed these collective bargaining agreements during 2016, and the new collective bargaining agreements expire on March 31, 2017. We consider our employee relations to be satisfactory.

Table of Contents**Patents, Licenses and Proprietary Rights**

We consider patents to be an important element in the protection of our competitive and proprietary position and actively, and selectively, pursue patent protection in the United States and in major countries abroad. As further described below, we own or have exclusive rights to a number of U.S. patents and U.S. pending patent applications as well as corresponding foreign patents and patent applications. The expiration of key patents owned or licensed by us or the failure of patents to issue on pending patent applications could create increased competition, with potential adverse effects on our business prospects.

Other forms of market protection, including trade secrets and know-how, are also considered important elements of our proprietary strategy. Our policy is to require each of our employees, consultants, business partners and major customers to execute confidentiality agreements upon the commencement of an employment, consulting, business relationship, or product related audit with us. These agreements provide that all confidential information developed or made known to the other party during the course of the relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements generally provide that all inventions conceived by the individual in the course of rendering services to Repligen shall be our exclusive property and must be assigned to Repligen.

Protein A

We have developed proprietary technology, trade secrets, and know-how relating to the manufacture of recombinant Protein A at a scale and quality standard that is consistent with the requirements of the biopharmaceutical industry. In addition, in April 2010, we were granted U.S. Patent No. 7,691,608, Nucleic Acids Encoding Recombinant Protein A, which claims an isolated nucleic acid molecule that encodes a Protein A molecule with an amino acid sequence identical to that of the natural Protein A molecule, which has long been commercialized for bioprocessing applications. This U.S. patent, with the term adjustment that was granted, will remain in effect until June 2028. Foreign equivalents of this patent have been issued in Sweden, Netherlands, Great Britain, France, Germany and Canada. The claims of U.S. Patent No. 7,691,608 cover compositions of matter including isolated nucleic acids, expression vectors, bacterial cells that include the nucleic acids, as well as methods of producing truncated Protein A polypeptides, methods of producing affinity chromatography resins, and methods of purifying proteins.

OPUS

In January 2012, we filed a provisional patent application with the U.S. Patent and Trademark Office (USPTO) which covers certain unique features of our OPUS pre-packed columns. Pending claims that relate to these unique features cover methods of making and loading these chromatography columns and the columns themselves. The ease and flexibility of column packing, bed height adjustment and cleaning of these new columns is improved over existing pre-packed column designs. In January 2013, we filed an international patent cooperation treaty (PCT) application as well as a utility application with the USPTO on the basis of the provisional application. The OPUS pre-packed column patent application is pending in the United States, Europe, Hong Kong, India, and Japan, and patents have been granted in Australia and Canada.

XCell ATF Systems

As part of the Refine Acquisition, we acquired the exclusive rights to an issued U.S. patent (US 6,544,424) covering the Alternating Tangential Flow (ATF) System and a process related to the filtration of biologic fluids from a bioreactor through hollow fiber filters by the action of a diaphragm pump which creates alternating tangential flow through the filter. The patent expires in 2020. Another patent has been issued in the U.S. covering improvements on

the original ATF design that include a screen filter module (US 9,050,547). This family of patents and applications has issued or is pending in Brazil, China, Europe (issued in Germany, France and Great Britain), India, Korea and Sweden. Other additional improvements on the original ATF systems and methods are

Table of Contents

covered by patents and patent applications pending in one or more of the U.S., Canada, China, Europe, Hong Kong, India, Japan, and Korea. These patents and patent applications expire between 2029 and 2033.

Spinal Muscular Atrophy

In 2009, we entered into an exclusive license agreement with a non-profit organization, FSMA, now called CureSMA, for worldwide rights to patent applications related to compositions and methods for the treatment of spinal muscular atrophy (SMA). FSMA had funded the development of these compounds and identified a novel enzyme target (DcpS) that these compounds inhibit. In 2011, we were granted U.S. Patent Nos. 7,888,366 (the 366 patent) and 7,985,755 (the 755 patent), both entitled 2,4 Diaminoquinazolines for Spinal Muscular Atrophy, with allowed composition claims that cover both the genus and the species of the chemical structures of the lead clinical candidates. The expiration date of the 366 patent is in 2028 with potential for patent term extension. The expiration date of the 755 patent is in 2027 with potential for patent term extension. U.S. Patent No. 9,067,897, which is a continuation of the 366 patent, was issued in 2015 and expires in 2027. Foreign equivalents of these U.S. patents have been issued and/or are pending in Australia, Canada, Europe, Hong Kong, Japan, and New Zealand.

Pursuant to the License Agreement, we licensed all of our intellectual property related to SMA to Pfizer and Pfizer assumed responsibility for maintaining existing intellectual property and prosecuting new intellectual property relating to this program. On January 26, 2015, Pfizer issued to us a notice of its termination of the License Agreement for convenience, effective as of April 26, 2015. On March 17, 2016, we entered into a Termination Agreement with CureSMA through which we returned all patent rights and transferred all related data and materials back to CureSMA.

Histone Deacetylase Inhibitors

In 2007, we entered into an exclusive license agreement with The Scripps Research Institute for worldwide rights to a patent application claiming compounds and methods for treating Friedreich s ataxia with inhibitors of histone deacetylase. We extended this original work and filed additional patent applications which claim both methods and compositions for treating Friedreich s ataxia. On January 21, 2014, we out-licensed all of our intellectual property related to HDAC to BioMarin, and BioMarin has assumed responsibility for maintaining existing intellectual property and prosecuting new intellectual property relating to this program. Our out-licensed HDACi portfolio included patent applications in the United States as well as patent applications in Europe, Canada, Japan and Australia. Patents, if any, that are granted in the U.S. based on these patent applications are expected to expire from 2029 to 2032.

Licensing Agreements*HDAC Agreement with BioMarin*

On January 21, 2014, we out-licensed our HDACi portfolio, which includes the Friedreich s ataxia program, to BioMarin Pharmaceuticals Inc. Friedreich s ataxia is an inherited disease that causes progressive damage to the nervous system resulting in symptoms ranging from impaired walking and speech problems to heart disease. Pursuant to the terms of the agreement, BioMarin agrees to use commercially reasonable efforts to commercialize HDACi portfolio product until the later of (i) the expiration of the last-to-expire valid claim of an issued and unexpired patent or pending patent application claiming a compound included in the agreement or (ii) 10 years. Under the terms of the agreement, Repligen received an upfront payment of \$2 million in January 2014 from BioMarin and we have the potential to receive up to \$160 million in future milestone payments for BioMarin s development, regulatory approval and commercial sale of portfolio compounds included in the agreement. These potential milestone payments are approximately 37% related to clinical development and 63% related to initial commercial sales in specific geographies. In addition, Repligen is eligible to receive royalties on sales of qualified products developed. The royalty

rates are tiered and begin in the mid-single-digits for the first

Table of Contents

HDACi portfolio product and for the first non-HDACi portfolio product with lesser amounts for any backup products developed under the agreement. Repligen's receipt of these royalties is subject to customary offsets and deductions. There are no refund provisions in this agreement. Royalties under this agreement are paid on a country-by-country basis during the period beginning on the first commercial sale of a compound in such country, until the later of: (i) the expiration of exclusivity period granted by a governmental authority to prevent the entry of generic product into such country; (ii) the expiration of the last-to-expire valid claim of an issued and unexpired patent or pending patent application claiming such compound in such country; or (iii) ten years following the first commercial sale of such HDACi portfolio product in any country. Royalty payments on products derived from the compounds included in the agreement are calculated by multiplying net sales of such product for the calendar year by an applicable royalty rate based on incremental net sale amounts. We have no further obligations to BioMarin.

RG1068

Our clinical development portfolio previously included RG1068, a synthetic human hormone we had developed as a novel imaging agent for the improved detection of pancreatic duct abnormalities in combination with magnetic resonance imaging in patients with pancreatitis and potentially other pancreatic diseases. On December 23, 2014, Innovate Biopharmaceuticals, Inc. (Innovate) acquired our RG1068 program for a nominal amount. Innovate is solely responsible for future development and commercialization of RG1068. If Innovate gains marketing approval and successfully commercializes RG1068, Repligen is eligible to receive royalties through the latter of ten years after the first commercial sale or the entry of a generic equivalent into the U.S. market.

Competition

Our bioprocessing products compete on the basis of quality, performance, cost effectiveness, and application suitability with numerous established technologies. Additional products using new technologies that may be competitive with our products may also be introduced. Many of the companies selling or developing competitive products, which in some cases includes GE Healthcare and MilliporeSigma, our two largest customers, have greater financial and human resources, research and development, manufacturing and marketing experience than we do. They may succeed in developing products that are more effective or less costly than any that we may develop. These competitors may also prove to be more successful in their production, marketing and commercialization activities. We cannot be certain that the research, development and commercialization efforts of our competitors will not render any of our existing or potential products obsolete.

Manufacturing

We manufacture seven commercial forms of Protein A, including native Protein A for life sciences companies including GE Healthcare and MilliporeSigma under long-term supply agreements which expire between 2019 and 2023. Native Protein A is manufactured in Lund, Sweden, while the recombinant forms are manufactured in both Waltham, Massachusetts and Lund, Sweden. We currently manufacture our growth factor products in Lund, Sweden; our OPUS chromatography columns and XCell ATF System products in Waltham, Massachusetts; our OPUS PD columns in Weingarten, Germany; and our Sius TFF products in Shrewsbury, Massachusetts.

We generally purchase raw materials from more than one commercially established company and believe that the necessary raw materials are currently commercially available in sufficient quantities necessary to meet market demand. However, there are only a limited number of suppliers of materials related to the XCell ATF System products, one of which is the primary supplier of materials used for consumable XCell ATF System products.

We utilize our own facilities in Waltham, Massachusetts and Lund, Sweden as well as third party contract manufacturing organizations to carry out certain fermentation and recovery operations, while the purification, immobilization, packaging and quality control testing of our bioprocessing products are conducted at our facilities. Our facilities located in Waltham, Massachusetts; Lund, Sweden; and Weingarten, Germany are

Table of Contents

ISO 9001 certified and maintain formal quality systems to maintain process control, traceability, and product conformance. We practice continuous improvement initiatives based on routine internal audits as well as external feedback and audits performed by our partners and customers. In addition, we maintain a business continuity management system which focuses on key areas such as contingency planning, security stocks and off-site storage of raw materials and finished goods to ensure continuous supply of our products.

Available Information

We maintain a website with the address www.repligen.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the Securities and Exchange Commission. Our Code of Business Conduct and Ethics is also available free of charge through our website.

In addition, the public may read and copy any materials that we file with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. Also, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov.

ITEM 1A. RISK FACTORS

Investors should carefully consider the risk factors described below before making an investment decision.

If any of the events described in the following risk factors occur, our business, financial condition or results of operations could be materially harmed. In that case the trading price of our common stock could decline, and investors may lose all or part of their investment. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial may also become important factors that affect Repligen.

This Annual Report on Form 10-K 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 on Form 10-K.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration.

The bioprocessing market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants.

Many of our competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Many of these competitors have:

significantly greater name recognition;

larger and more established distribution networks;

additional lines of products and the ability to bundle products to offer higher discounts or other incentives to gain a competitive advantage;

greater experience in conducting research and development, manufacturing, clinical trials, marketing, obtaining regulatory approval and entering into collaboration or other strategic partnership arrangements;
and

Table of Contents

greater financial and human resources for product development, sales and marketing and patent litigation. Our current competitors or other companies may at any time develop additional products that compete with our products. If an existing or future competitor develops products that compete with or are superior to our products, our revenue may decline. In addition, some of our competitors may compete by lowering the price of their products. If prices were to fall, we may not be able to improve our gross margins or sales growth sufficiently to maintain and grow our profitability.

We depend on, and expect to continue to depend on, a limited number of customers for a high percentage of our revenues.

The loss of, or a significant reduction in orders from, any of these customers, including following any termination or failure to renew a long-term supply contract, would significantly reduce our revenues and harm our results of operations. If a large customer purchases fewer of our products, defers orders or fails to place additional orders with us, our revenue could decline, and our operating results may not meet market expectations. In addition, if those customers order our products, but fail to pay on time or at all, our liquidity and operating results could be materially and adversely affected. Furthermore, if any of our current or future products compete with those of any of our largest customers, these customers may place fewer orders with us or cease placing orders with us, which would negatively affect our revenues and operating results.

If we are unable to expand our product portfolio, our ability to generate revenue could be adversely affected.

In connection with the Company's decision to focus our efforts on the growth of our core bioprocessing business, we are increasingly seeking to develop and commercialize our own portfolio of products. Our future financial performance will depend, in part, on our ability to successfully develop and acquire additional bioprocessing products. There is no guarantee that we will be able to successfully acquire or develop additional bioprocessing products, and the Company's financial performance will likely suffer if we are unable to do so.

If intangible assets and goodwill that we recorded in connection with our acquisitions become impaired, we could have to take significant charges against earnings.

In connection with the accounting for the Novozymes Acquisition, the Refine Acquisition, the Atoll Acquisition and the TangenX Acquisition, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the acquired product lines, and goodwill. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of intangible assets and goodwill has been impaired. Intangible assets and goodwill will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of intangible assets and goodwill will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Our exposure to political, economic and other risks that arise from operating a multinational business has and may continue to increase.

Our operations and sales outside of the United States have increased as a result of the Novozymes Acquisition, the Refine Acquisition and the Atoll Acquisition and the continued expansion of our commercial organization. Risks related to these increased foreign operations include:

fluctuations in foreign currency exchange rates;

changes in general economic and political conditions in countries where we operate, particularly as a result of ongoing economic instability within the European Union and other foreign jurisdictions;

Table of Contents

being subject to complex and restrictive employment and labor laws and regulations, as well as union and works council restrictions;

changes in tax laws or rulings in the United States or other foreign jurisdictions that may have an adverse impact on our effective tax rate;

being subject to burdensome foreign laws and regulations, including regulations that may place an increased tax burden on our operations;

being subject to longer payment cycles from customers and experiencing greater difficulties in timely accounts receivable collections; and

required compliance with a variety of foreign laws and regulations.

Our business success depends in part on our ability to anticipate and effectively manage these and other. We cannot assure you that these and other related factors will not materially adversely affect our international operations or business as a whole.

We may be unable to manage efficiently having become a larger and more geographically diverse organization.

Our acquisitions of Novozymes, Refine, Atoll and TangenX, the continued expansion of our commercial sales operations, and our organic growth have increased the scope and complexity of our business. We will face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Our inability to manage successfully the geographically more diverse (including from a cultural perspective) and substantially larger combined organization could materially adversely affect our operating results and, as a result, the market price of our common stock.

Our business is subject to a number of environmental risks.

Our manufacturing business involves the controlled use of hazardous materials and chemicals and is therefore subject to numerous environmental and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. In addition to these hazardous materials and chemicals, our facility in Sweden also uses Staphylococcus aureus and toxins produced by Staphylococcus aureus in some of its manufacturing processes. Staphylococcus aureus and the toxins it produces, particularly enterotoxins, can cause severe illness in humans. The costs of compliance with environmental and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental, safety laws or regulations and the cost of compliance with any resulting order or fine could adversely affect our operations.

Our acquisitions expose us to risks that could adversely affect our business, and we may not achieve the anticipated benefits of acquisitions of businesses or technologies.

In addition to our acquisitions of Novozymes, Refine, Atoll and TangenX, and as a part of our growth strategy, we may make selected acquisitions of complementary products and/or businesses. Any acquisition involves numerous risks and operational, financial, and managerial challenges, including the following, any of which could adversely

affect our business, financial condition, or results of operations:

difficulties in integrating new operations, technologies, products, and personnel;

problems maintaining uniform procedures, controls and policies with respect to our financial accounting systems;

lack of synergies or the inability to realize expected synergies and cost-savings;

difficulties in managing geographically dispersed operations;

Table of Contents

underperformance of any acquired technology, product, or business relative to our expectations and the price we paid;

negative near-term impacts on financial results after an acquisition, including acquisition-related earnings charges;

the potential loss of key employees, customers, and strategic partners of acquired companies;

claims by terminated employees and shareholders of acquired companies or other third parties related to the transaction;

the assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash;

the issuance of equity securities to finance or as consideration for any acquisitions would dilute the ownership of our stockholders;

the issuance of equity securities to finance or as consideration for any acquisitions may not be an option if the price of our common stock is low or volatile which could preclude us from completing any such acquisitions;

any collaboration, strategic alliance and licensing arrangement may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us;

diversion of management's attention and company resources from existing operations of the business;

inconsistencies in standards, controls, procedures, and policies;

the impairment of intangible assets as a result of technological advancements, or worse-than-expected performance of acquired companies; and

assumption of, or exposure to, historical liabilities of the acquired business, including unknown contingent or similar liabilities that are difficult to identify or accurately quantify.

In addition, the successful integration of acquired businesses requires significant efforts and expense across all operational areas, including sales and marketing, research and development, manufacturing, finance, legal, and information technologies. There can be no assurance that any of the acquisitions we may make will be successful or will be, or will remain, profitable. Our failure to successfully address the foregoing risks may prevent us from

achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our debt.

We incurred significant indebtedness in the amount of \$115.0 million in aggregate principal with additional accrued interest under our 2.125% Convertible Senior Notes due 2021 (the Notes). Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, 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. In addition, in the event of a fundamental change or a default under the Notes, the holders and/or the trustee under the indentures governing the Notes may accelerate the payment obligations or trigger the holders' repurchase rights under the Notes. 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, including the Notes.

Table of Contents

If a make-whole fundamental change, such as an acquisition of our company, occurs prior to the maturity of the Notes, under certain circumstances, the conversion rate for the Notes will increase such that additional shares of our common stock will be issued upon conversion of the Notes in connection with such make-whole fundamental change. The increase in the conversion rate will be determined based on the date on which the make-whole fundamental change occurs or becomes effective and the price paid (or deemed paid) per share of our common stock in such transaction. Upon conversion of the 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 Notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or notes being converted. Our failure to repurchase Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. 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 notes or make cash payments upon conversions thereof.

In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;

limit our flexibility in planning for, or reacting to, changes in our business and our industry;

place us at a disadvantage compared to our competitors who have less debt; and

limit our ability to borrow additional amounts for working capital and other general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products, services and technologies.

Any of these factors could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

Future strategic transactions or acquisitions may require us to seek additional financing, which we may not be able to secure on favorable terms, if at all.

We plan to continue a strategy of growth and development for our bioprocessing business, and we actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. In order to complete such strategic transactions, we may need to seek additional financing to fund these investments and acquisitions. Should we need to do so, we may not be able to secure such financing, or obtain such financing on favorable terms because of the volatile nature of the biotechnology marketplace. In addition, future acquisitions may require the issuance or sale of additional equity or debt securities, which may result in additional dilution to our stockholders.

We rely on a limited number of suppliers or, for certain of our products, one supplier, and we may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our financial condition, results of operations and reputation.

There are only a limited number of suppliers of materials related to the XCell ATF System products. An interruption in operations of the business related to these products could occur if we encounter delays or difficulties in securing these materials, or if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect the business related to these products and our financial condition, results of operations and reputation.

Table of Contents

For example, we believe that only a small number of suppliers are currently qualified to supply materials for the XCell ATF System. The use of materials furnished by these replacement suppliers would require us to alter our operations related to the XCell ATF System. Transitioning to a new supplier for our products would be time consuming and expensive, may result in interruptions in our operations, could affect the performance specifications of our product lines or could require that we revalidate the materials. There can be no assurance that we will be able to secure alternative materials, and bring such materials on line and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the materials required for our products, our business related to these products and our financial condition, results of operations and reputation could be adversely affected.

We have limited sales and as we evolve from a company dependent on others to commercialize our products to a company selling directly to end users, we may encounter difficulties in expanding our product portfolio and our commercial marketing capabilities.

We have a small sales force and, prior to 2016 we generated most of our revenues through sales of bioprocessing products to a limited number of life sciences companies, such as GE Healthcare, MilliporeSigma and through other individual distributors. However, due in part to our recent strategic acquisitions, an increasing amount of our revenue is attributable to our commercialization of bioprocessing products that we sell directly to end-users such as biopharmaceutical companies and contract manufacturing organizations. This has required and will continue to require us to invest additional resources in our sales and marketing capabilities. We may not be able to attract and retain additional sales and marketing professionals, and the cost of building the sales and marketing function may not generate our anticipated revenue growth. In addition, our sales and marketing efforts may be unsuccessful. Our failure to manage these risks may have a negative impact on our financial condition, or results of operations and may cause our stock price to decline.

If we are unable to obtain or maintain our intellectual property, we may not be able to succeed commercially.

We endeavor to obtain and maintain patent and trade secret protection for our products and processes when available in order to protect them from unauthorized use and to produce a financial return consistent with the significant time and expense required to bring our products to market. Our success will depend, in part, on our ability to:

obtain and maintain patent protection for our products and manufacturing processes;

preserve our trade secrets;

operate without infringing the proprietary rights of third parties; and

secure any necessary licenses from others on acceptable terms.

We cannot be sure that any patent applications relating to our products that we will file in the future or that any currently pending applications will issue on a timely basis, if ever. Since patent applications in the United States filed prior to November 2000 are maintained in secrecy until patents issue and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file patent applications

for such inventions. Even if patents are issued, the degree of protection afforded by such patents will depend upon the:

scope of the patent claims;

validity and enforceability of the claims obtained in such patents; and

our willingness and financial ability to enforce and/or defend them.

Table of Contents

The patent position of life sciences companies is often highly uncertain and usually involves complex legal and scientific questions. Patents which may be granted to us in certain foreign countries may be subject to opposition proceedings brought by third parties or result in suits by us, which may be costly and result in adverse consequences for us.

In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to us or our licensors, to protect trade secrets, know-how or other intellectual property rights we own or to determine the scope and validity of the proprietary rights of third parties. Such litigation could result in substantial cost to us and diversion of our resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on our business, financial condition and results of operations.

If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which would result in substantial costs to us.

While one of our U.S. patents covering recombinant Protein A had its term adjusted to expire in 2028, our other U.S. patents covering recombinant Protein A have expired, and as a result, we may face increased competition, which could harm our results of operations, financial condition, cash flow and future prospects.

Other companies could begin manufacturing and selling native or some of the commercial forms of recombinant Protein A in the U.S. and may directly compete with us on certain Protein A products. This may induce us to sell Protein A at lower prices and may erode our market share, which could adversely affect our results of operations, financial condition, cash flow and future prospects.

Our freedom to develop our products may be challenged by others, and we may have to engage in litigation to determine the scope and validity of competitors' patents and proprietary rights, which, if we do not prevail, could harm our business, results of operations, financial condition, cash flow and future prospects.

There has been substantial litigation and other proceedings regarding the complex patent and other intellectual property rights in the life sciences industry. We have been a party to, and in the future may become a party to, patent litigation or other proceedings regarding intellectual property rights.

Other types of situations in which we may become involved in patent litigation or other intellectual property proceedings include:

We may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or services do not infringe such third parties' patents.

We may initiate litigation or other proceedings against third parties to seek to enforce our patents against infringement.

If our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention.

If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such claims.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved in a way that is unfavorable to us, we or our collaborative or strategic partners

Table of Contents

may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. The failure to obtain any required license on commercially acceptable terms or at all may harm our business, results of operations, financial condition, cash flow and future prospects.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time, attention and resources.

We may become involved in litigation or other proceedings with collaborative partners, which may be time consuming, costly and could result in delays in our development and commercialization efforts.

In connection with the Company's decision to focus its efforts on the growth of its core bioprocessing business, we sought development and commercialization partnerships for our remaining portfolio of clinical stage assets. Any disputes with such partners, such as BioMarin, that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and with terms that are no less favorable to us than the current terms of the arrangements, our business, results of operations, financial condition, cash flow and future prospects may be harmed.

If we are unable to continue to hire and retain skilled personnel, then we will have trouble developing and marketing our products.

Our success depends largely upon the continued service of our management and scientific staff and our ability to attract retain and motivate highly skilled technical, scientific, management and marketing personnel. We also face significant competition in the hiring and retention of such personnel from other companies, research and academic institutions, government and other organizations who have superior funding and resources. The loss of key personnel or our inability to hire and retain skilled personnel could materially adversely affect our product development efforts and our business.

The market may not be receptive to our new bioprocessing products upon their introduction.

We expect a portion of our future revenue growth to come from introducing new bioprocessing products, including line extensions and new features for our OPUS disposable chromatography columns, our XCell ATF System, our Sius TFF product line, and our growth factors. For example, in 2016, we introduced a resin recovery port on our largest OPUS columns, and we launched single-use versions of XCell ATF Systems. The commercial success of all of our products will depend upon their acceptance by the life science and biopharmaceutical industries. Many of the bioprocessing products that we are developing are based upon new technologies or approaches. As a result, there can be no assurance that these new products, even if successfully developed and introduced, will be accepted by customers. If customers do not adopt our new products and technologies, our results of operations may suffer and, as a result, the market price of our common stock may decline.

If our new products do not achieve sufficient market acceptance, our results of operations and competitive position could suffer.

There can be no assurance that unforeseen problems will not occur with respect to the development, performance or market acceptance of new products or that we will otherwise be able to successfully develop and market new products. Failure of our new products to gain market acceptance or our failure to successfully develop and market new products could reduce our margins, which would have an adverse effect on our business, financial condition and

results of operations.

Table of Contents

If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, we could experience lost revenue, delayed or reduced market acceptance of our products, increased costs and damage to our reputation.

Our success depends on the market's confidence that we can provide reliable, high-quality bioprocessing products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products and technologies may be impaired if our products fail to perform as expected. Although our products are tested prior to shipment, defects or errors could nonetheless occur in our products. Furthermore, the Protein A that we manufacture is subsequently incorporated into products that are sold by other life sciences companies and we have no control over the manufacture and production of those products. In the future, if our products experience, or are perceived to experience, a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also narrow the scope of the use of our products, which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any lingering concerns in our target market regarding our technology or any manufacturing defects or performance errors in our products could continue to result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

If we are unable to manufacture our products in sufficient quantities and in a timely manner, our operating results will be harmed, our ability to generate revenue could be diminished and our gross margin may be negatively impacted.

Our revenues and other operating results will depend in large part on our ability to manufacture and assemble our products in sufficient quantities and in a timely manner. Any interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter. Manufacturing problems can and do arise, and as demand for our products increases, any such problems could have an increasingly significant impact on our operating results. While we have not generally experienced problems with, or delays in, our production capabilities that resulted in delays in our ability to ship finished products, there can be no assurance that we will not encounter such problems in the future. We may not be able to quickly ship products and recognize anticipated revenues for a given period if we experience significant delays in the manufacturing process. In addition, we must maintain sufficient production capacity in order to meet anticipated customer demand, which carries fixed costs that we may not be able to offset if orders slow, which would adversely affect our operating margins. If we are unable to manufacture our products consistently, in sufficient quantities, and on a timely basis, our bioprocessing revenue, gross margins and our other operating results will be materially and adversely affected.

Our operating results may fluctuate significantly, our customers' future purchases are difficult to predict and any failure to meet financial expectations may result in a decline in our stock price.

Our quarterly operating results may fluctuate in the future as a result of many factors such as the impact of seasonal spending patterns, changes in overall spending levels in the life sciences industry, the inability of some of our customers to consummate anticipated purchases of our products due to changes in end-user demand, and other unpredictable factors that may affect ordering patterns. Because our revenue and operating results are difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indicator of our future performance. Additionally, if revenue declines in a quarter, whether due to a delay in recognizing expected revenue, adverse economic conditions or otherwise, our results of operations will be harmed because many of our expenses are relatively fixed. In particular, a large portion of our manufacturing costs, our research and development, sales and marketing and general and administrative expenses are not significantly affected by variations in revenue. If our quarterly operating results fail to meet investor expectations, the price of our common stock may decline.

Table of Contents

Our future revenues pursuant to our asset purchase agreement with BioMarin regarding the HDACi program depends significantly on BioMarin's development and commercialization activities, over which we have no control. If BioMarin is unable or determines not to further develop or commercialize the HDACi program, or experiences significant delays in doing so, we may see a delay in receiving any potential milestone or royalty payments or fail to receive any additional financial benefits from the program.

We entered into an asset purchase agreement with BioMarin on January 21, 2014, related to the histone deacetylase inhibitor (HDACi) portfolio, which includes the Friedreich's ataxia program. We are dependent on BioMarin for the future success of this development program. We have no control over the conduct and timing of development efforts with respect to the HDACi program. BioMarin's failure to devote sufficient financial and other resources to the development plan may result in the delayed or unsuccessful development of the program, which could lead to the non-payment or delay in payment of milestones under the asset purchase agreement and may preclude or delay commercialization of any product under the HDACi program and any royalties we could receive on future commercial sales. Our future financial results may be harmed if BioMarin does not commercialize the HDACi program successfully or on a timely basis prior to the achievement of any milestones or the payment of any royalties to us.

Health care reform measures could adversely affect our business.

The efforts of governmental and third-party payors to contain or reduce the costs of health care may adversely affect the business and financial condition of pharmaceutical and biotechnology companies, including us. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The U.S. Congress passed the America Affordable Health Choices Act of 2009 and the Patient Protection and Affordable Care Act. This Act and other federal and state proposals and health care reforms could limit the prices that can be charged for the products we develop and may limit our commercial opportunity. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act (the MMA) changed the way Medicare covers and pays for pharmaceutical products. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. Efforts by the government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunities and result in a decrease in the price of our common stock or limit our ability to raise capital.

The recent presidential and congressional elections may lead to amendments or repeals of all or portions of existing health care reform legislation, including the Affordable Care Act. Changes in existing health care reform measures may result in uncertainty with respect to legislation, regulation and government policy that could significantly impact our business and the life sciences industry.

We compete with life science, pharmaceutical and biotechnology companies who are capable of developing new approaches that could make our products and technology obsolete.

The market for therapeutic and commercial products is intensely competitive, rapidly evolving and subject to rapid technological change. Life science, pharmaceutical and biotechnology companies may have substantially greater financial, manufacturing, marketing, and research and development resources than we have. New approaches by these competitors may make our products and technologies obsolete or noncompetitive.

Table of Contents

We may become subject to litigation, which could result in substantial costs and divert management's attention and resources from our business.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. Litigation is subject to inherent risks and uncertainties that may cause actual results to differ materially from our expectations. If we receive an adverse judgment in any litigation, we could be required to pay substantial damages. With or without merit, litigation can be complex, can extend for a protracted period of time, can be very expensive and the expense can be unpredictable. Litigation initiated by us could also result in counter-claims against us, which could increase the costs associated with the litigation and result in our payment of damages or other judgments against us. In addition, litigation, and any related publicity, may divert the efforts and attention of some of our management and key personnel, which would adversely affect our business.

We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

We are subject to the Foreign Corrupt Practice Act (the "FCPA") and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute for the purpose of obtaining or retaining business. We have operations, agreements with third parties and make sales in jurisdictions outside of the U.S., which may experience corruption. Our activities in jurisdictions outside of the U.S. create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents or distributors, because these parties are not always subject to our control. These risks have increased following our recent acquisitions of overseas operations and facilities. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents or distributors of our Company may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the government may seek to hold us liable for successor liability FCPA violations committed by any companies in which we invest or that we acquire.

Our stock price could be volatile, which could cause shareholders to lose part or all of their investment.

The market price of our common stock, like that of the common stock of many other companies with similar market capitalizations, is highly volatile. In addition, the stock market has experienced extreme price and volume fluctuations. This volatility has significantly affected the market prices of securities of many life sciences, biotechnology and pharmaceutical companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

Anti-takeover provisions in our charter documents, certain of our contracts with third parties, and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and by-laws may delay or prevent an acquisition of us or a change in our management. These provisions include the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some

stockholders. Additionally, certain of our contracts with third parties allow for

Table of Contents

termination upon specified change of control transactions. Anti-takeover provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management, and anti-takeover or change of control contract termination rights may frustrate or prevent any attempts by a third party to acquire or attempt to acquire the Company.

Changes in accounting standards and subjective assumptions, estimates, and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition.

Generally accepted accounting principles and related accounting pronouncements, implementation guidelines, and interpretations with regard to a wide range of matters that are relevant to our business, such as revenue recognition, asset impairment and fair value determinations, inventories, business combinations and intangible asset valuations, leases, and litigation, are highly complex and involve many subjective assumptions, estimates, and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates, or judgments could significantly change our reported or expected financial performance or financial condition.

Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates.

We conduct a large portion of our business in international markets. For the fiscal year ended December 31, 2016, 40% of our revenues and 22% of our costs and expenses were denominated in foreign currencies, primarily the Swedish Krona, the British pound sterling, and the Euro. We are exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U.S. Dollar, which could increase the value of our expenses and decrease the value of our revenue when measured in U.S. Dollars. As a result, our results of operation may be influenced by the effects of future exchange rate fluctuations and such effects may have an adverse impact on our common stock price.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and it is possible that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. We have completed a number of financings since our inception which may have resulted in a change in control as defined by Section 382, or could result in a change in control in the future.

If we identify a material weaknesses in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

Table of Contents

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. For example, in 2012, we updated our internal controls to include our operations in Sweden. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The NASDAQ Stock Market or other regulatory authorities.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report financial results or prevent fraud.

Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We must annually evaluate our internal procedures to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires management and our independent registered public accounting firm to assess the effectiveness of internal control over financial reporting.

We have recently implemented several significant ERP modules and expect to implement additional ERP modules in the future. The implementation of the ERP system represents a change in our internal control over financial reporting. Although we continue to monitor and assess our internal controls in the new ERP system environment as changes are made and new modules are implemented, and have taken additional steps to modify and enhance the design and effectiveness of our internal control over financial reporting, there is a risk that deficiencies may occur that could constitute significant deficiencies or in the aggregate a material weakness.

If we fail to remedy any deficiencies or maintain the adequacy of our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties or shareholder litigation. In addition, failure to maintain adequate internal controls could result in financial statements that do not accurately reflect our operating results or financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

Table of Contents**ITEM 2. PROPERTIES**

We lease office and manufacturing properties as detailed below:

Location	Square Feet	Principal Use	Lease Expiration
Waltham, Massachusetts	76,000	Corporate headquarters, manufacturing, research and development, marketing and administration offices	May 31, 2023
Waltham, Massachusetts	2,500	Manufacturing operations	Month-to-month
Shrewsbury, Massachusetts	12,000	Manufacturing operations	December 31, 2018
Lund, Sweden	45,000	Manufacturing and administrative operations	December 31, 2021
Weingarten, Germany	7,300	Manufacturing and administrative operations	Month-to-month

During the fiscal year ended December 31, 2016, we incurred total rental costs for all facilities of approximately \$2,664,000.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock is traded on the Nasdaq Global Market under the symbol RGEN. The quarterly high and low sales prices for our common stock are shown in the following tables.

	Year Ended December 31, 2016	
	High	Low
First Quarter	\$ 28.85	\$ 20.07
Second Quarter	\$ 28.97	\$ 21.11
Third Quarter	\$ 33.79	\$ 25.93
Fourth Quarter	\$ 34.06	\$ 26.16

	Year Ended December 31, 2015	
	High	Low
First Quarter	\$ 34.15	\$ 19.53
Second Quarter	\$ 42.48	\$ 28.88
Third Quarter	\$ 42.22	\$ 27.25
Fourth Quarter	\$ 36.00	\$ 21.69

Stockholders and Dividends

As of February 17, 2017, there were 412 stockholders of record of our common stock. We have not paid any dividends since our inception and do not intend to pay any dividends on our common stock in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations. Any future determination as to the payment of dividends will be at the sole discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors our Board of Directors deems relevant.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2016 regarding shares of Common Stock that may be issued under the Company's equity compensation plans, consisting of the 2001 Stock Plan, the 1992 Repligen Corporation Stock Option Plan and the current 2012 Stock Option and Incentive Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average price of outstanding options	Number of securities remaining available for future issuance under equity compensation
----------------------	---	--	---

			plans (excluding securities reflected in first column)⁽²⁾
Equity compensation plans approved by security holders	1,236,586 ⁽¹⁾	\$ 16.88 ⁽²⁾	1,821,576
Equity compensation plans not approved by security holders	N/A	\$ N/A	N/A
Total	1,236,586	\$ 16.88	1,821,576

- (1) Includes 882,748 shares of Common Stock issuable upon the exercise of outstanding options and 353,838 shares of Common Stock issuable upon the vesting of restricted stock units. No shares of restricted stock are outstanding.
- (2) Since restricted stock units do not have any exercise price, such units are not included in the weighted average exercise price calculation.

Issuer Purchases of Equity Securities

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million shares of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately

Table of Contents

negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We did not repurchase any shares of common stock during the year ended December 31, 2016. In prior years, we repurchased a total of 592,827 shares, leaving 657,173 shares remaining under this authorization.

The graph below matches Repligen Corporation's cumulative 5-year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index, the NASDAQ Pharmaceutical index, and the NASDAQ Biotechnology index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2011 to December 31, 2016.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Repligen Corporation, the NASDAQ Composite Index,
the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index

*\$100 invested on 12/31/11 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

The information contained in the performance graph shall not be deemed to be soliciting material or to be filed with the Securities and Exchange Commission, and such information shall not be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that Repligen specifically incorporates it by reference into such filing.

Recent Sales of Unregistered Securities and Equity Purchases by the Company

In April 2016, in connection with the Atoll acquisition, we issued and contributed 538,700 shares of our common stock to our wholly-owned subsidiary, Repligen Sweden AB, to enable Repligen Sweden AB to fulfill its obligation to deliver the aforementioned shares under the share purchase agreement we entered into with Repligen Sweden AB and the seller of Atoll GmbH. This issuance was intended to be exempt from the registration requirements pursuant to Section 4(2) of the Securities Act of 1933 and Rule 506(b) promulgated under Regulation D.

Table of Contents**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The following selected consolidated financial data are derived from the audited financial statements of Repligen. The selected financial data set forth below should be read in conjunction with our financial statements and the related notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report, our Annual Reports on Form 10-K for the fiscal years ended December 31, 2016, 2015, 2014, 2013 and 2012.

(In thousands, except per share data)	2016	2015 ⁽¹⁾	2014	2013	2012
Revenue:					
Product revenue	\$ 104,441	\$ 83,537	\$ 60,431	\$ 47,482	\$ 41,834
Royalty and other revenue	100		3,117	20,687	20,433
Total revenue	104,541	83,537	63,548	68,169	62,267
Operating expenses:					
Cost of product revenue	47,117	35,251	28,022	22,481	24,957
Cost of royalty and other revenue				2,682	2,213
Research and development	7,355	5,740	5,609	7,341	10,490
Selling, general and administrative	30,853	24,699	17,154	12,701	13,227
Contingent consideration fair value adjustments	3,242	4,083	2,072	91	611
Gain on bargain purchase					(314)
Total operating expenses	88,567	69,773	52,857	45,296	51,184
Income (loss) from operations	15,974	13,764	10,691	22,873	11,083
Investment income	346	136	309	301	219
Interest expense	(3,768)	(32)	(50)	(50)	(57)
Other income (expense)	(860)	(445)	188	(110)	26
Income (loss) before income taxes	11,692	13,423	11,138	23,014	11,271
Income tax (benefit) provision	11	4,078	2,968	6,921	(2,885)
Net income (loss)	\$ 11,681	\$ 9,345	\$ 8,170	\$ 16,093	\$ 14,156
Earnings (loss) per share:					
Basic	\$ 0.35	\$ 0.28	\$ 0.25	\$ 0.51	\$ 0.46
Diluted	\$ 0.34	\$ 0.28	\$ 0.25	\$ 0.50	\$ 0.45
Weighted average shares outstanding:					
Basic	33,573	32,882	32,498	31,667	30,914
Diluted	34,099	33,577	33,264	32,407	31,253
	2016	2015	2014	2013	2012

Balance Sheet Data:

Edgar Filing: REPLIGEN CORP - Form 10-K

Cash and marketable securities ⁽²⁾	\$ 141,780	\$ 73,407	\$ 62,003	\$ 73,842	\$ 49,970
Working capital	163,078	84,471	70,264	75,049	55,457
Total assets	288,913	146,237	128,293	118,645	97,010
Long-term obligations	99,074	4,708	5,879	3,458	2,133
Accumulated deficit	(59,861)	(71,542)	(80,887)	(89,057)	(105,151)
Stockholders' equity	168,764	122,748	111,732	103,886	84,125

(1) Includes the full year impact of the Refine Acquisition on June 2, 2014.

(2) Excludes restricted cash of \$450,000 as of December 31, 2016, 2015 and 2014 and \$200,000 as of December 31, 2013 and 2012 related to our headquarters lease arrangement.

Table of Contents**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

Repligen (Repligen , the Company , we or our) is a bioprocessing-focused, global life sciences company bringing over 30 years of expertise and innovation to our customers. Our mission is to inspire advances in bioprocessing as a trusted partner in the production of biologic drugs that improve human health worldwide. Focused on cost and process efficiencies, we deliver innovative technologies that help set new standards in the way biologic drugs are manufactured. We develop and market a broad range of high-value products and flexible solutions that address critical steps in the production of biologic drugs—principally antibody-based therapeutics, recombinant proteins and vaccines while ensuring that the highest drug quality and safety standards are upheld.

Since our strategic decision in 2012 to focus fully on building our bioprocessing business, we have expanded and diversified our portfolio beyond our legacy Protein A affinity ligands business to include a number of technology leading bioprocessing products that we sell direct to biopharmaceutical companies and CDMOs (contract development and manufacturing organizations) worldwide. Our dedicated team of professionals has substantial experience in biomanufacturing and works proactively with industry leaders and customers to develop innovative solutions that address pressure points in the bioproduction process.

Our bioprocessing products drive process efficiency, cost and yield improvements. In upstream processes, our XCell ATF filtration devices and protein cell culture supplements are used in clinical and commercial-stage manufacturing to improve biologic drug yields. In downstream processes, our Protein A ligands are a critical component of Protein A resins used to purify over 50 antibody-based drugs on the market and more than 350 in clinical development. Also in downstream processes, our OPUS pre-packed chromatography columns (PPCs) are used in the purification of clinical-stage biologics, and our Sius TFF filtration cassettes are used to concentrate clinical and commercial-stage biologic drugs.

We manufacture and supply Protein A ligands through long-term agreements with major life sciences companies, such as GE Healthcare and MilliporeSigma, who in turn produce and sell Protein A resins to end users (biopharmaceutical companies and CDMOs). We manufacture and supply our cell culture supplements through a distribution agreement with MilliporeSigma.

We market our chromatography and filtration products globally through a direct commercial organization in the United States and Europe with a combination of direct sales and distributors in Asia. Since 2014, we have invested in expanding our global commercial organization adding 30 sales, marketing, product management, service and applications personnel to form a 37-person commercial team. Our commercial and R&D teams have a track record of successfully launching new products and applications, as well as building new markets for acquired technologies. For example, since acquiring the XCell ATF business in 2014, we have rapidly expanded its market penetration through increased customer interaction, new products and expanded applications that increase flexibility and convenience while streamlining biomanufacturing workflow for our customers.

Our portfolio of bioprocessing products has expanded from our legacy Protein A line since 2011 through strategic acquisitions and internal product development. We have focused on building a portfolio of technology-leading products that we sell directly to end users. In 2016, we added the Sius TFF filtration line through our purchase of TangenX Technology Corporation (TangenX), and we added a lab-scale pre-packed chromatography column line through our purchase of Atoll GmbH. In 2014, we acquired the XCell ATF filtration line from Refine Technologies LLC. In 2011, we added to our Protein A ligands business and added cell culture growth factors through our acquisition of Novozymes Biopharma Sweden AG. Internally, we developed and market our process-scale OPUS pre-packed chromatography columns. Also through internal innovation, we have extended both our OPUS and XCell ATF product lines, to include more size options and technology features to benefit our customers. For example in

2016 we introduced a resin recovery feature on our largest OPUS columns (OPUS R) and we launched a single-use (disposable) alternative to our stainless steel XCell ATF Systems.

Table of Contents

Many of our products are early in their adoption cycle and, together with the expansion of our commercial organization and strategic acquisitions, have contributed to product revenue expansion from \$41.8 million in 2012 to \$104.5 million in 2016. While all product franchises have grown, our diversification strategy has resulted in our direct product sales accounting for approximately 50% of our bioprocessing revenue in 2016, compared to approximately 20% in 2012. To meet increased demand for our products, we have increased and continue to increase the volume and scale of manufacturing at our two manufacturing facilities in the United States and Sweden and plan to expand manufacturing capacity at our newly acquired manufacturing facilities in the United States and Germany.

Customers use our products to produce initial quantities of drug for clinical studies, then scale-up to larger volumes as the drug progresses to commercial production following regulatory approval. Detailed specifications for a drug's manufacturing process are included in applications that must be approved by regulators, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, throughout the clinical trial process and prior to final commercial approval. As a result, products that become part of the manufacturing specifications of a late-stage clinical or commercial process can be very sticky due to the costs and uncertainties associated with displacing them.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

While our significant accounting policies are more fully described in the notes to our financial statements, we have identified the policies and estimates below as being critical to our business operations and the understanding of our results of operations. The impact of and any associated risks related to these policies on our business operations are discussed throughout Management's Discussion and Analysis of Financial Condition, including in the Results of Operations section, where such policies affect our reported and expected financial results.

Revenue recognition***Product Sales***

We generate revenue from the sale of bioprocessing products, equipment devices, and related consumables used with these equipment devices to customers in the life science and biopharmaceutical industries. On product sales to end customers, revenue is recognized, net of discounts, when both the title and risk of loss have transferred to the customer, as determined by the shipping terms provided there are no uncertainties regarding acceptance, and all obligations have been completed. Generally, our product arrangements for equipment sales are multiple element arrangements, and may include services, such as installation and training, and multiple products, such as consumables and spare parts. In accordance with ASC 605-25, based on terms and conditions of the product arrangements, the Company believes that these services and undelivered products can be accounted for separately from the delivered product element as the delivered products have value to our customers on a standalone basis. Accordingly, revenue for services not yet performed at the time of product shipment are deferred and recognized as such services are performed. The relative selling price of any undelivered products is also deferred at the time of shipment and recognized as revenue when these products are delivered. For product sales to distributors, the Company recognizes revenue for both equipment and consumables upon delivery to the distributors unless direct shipment to the end user is requested. In this case, revenue is recognized upon delivery to the end user's location. In general, distributors are responsible for shipment to the end customer along with installation, training and acceptance of the equipment by the end customer. Shipments to distributors are not contingent upon resale of the product. We have a few longstanding customers who comprise the majority of revenue and have excellent payment histories and therefore we do not require collateral. We have had no significant write-offs of uncollectible invoices in the periods presented.

At the time of sale, we also evaluate the need to accrue for warranty and sales returns. The supply agreements we have with our customers and related purchase orders identify the terms and conditions of each sale and the price of the

goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for

Table of Contents

quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales return, warranty or other issues is largely diminished. Furthermore, there is no customer right of return in our sales agreements. Sales returns and warranty issues are infrequent and have not had a material impact on our financial statements historically.

Shipping and handling fees are recorded as a component of product revenue, with the associated costs recorded as a component of cost of product revenue.

Pfizer License Agreement

In December 2012, we entered into an exclusive worldwide licensing agreement (the License Agreement) with Pfizer, Inc. (Pfizer) to advance the SMA program, which is led by RG3039 and also includes backup compounds and enabling technologies. Under the terms of the License Agreement, we received \$5 million from Pfizer as an upfront payment on January 22, 2013, a \$1 million milestone payment on September 4, 2013 and a \$1 million milestone payment on December 28, 2014. On January 26, 2015, Pfizer sent us a termination notice, and the License Agreement expired on April 25, 2015. On March 17, 2016, we terminated our licensing agreement with CureSMA and returned all patent rights and related data and materials to CureSMA.

BioMarin License Agreement

On January 21, 2014, we out-licensed our histone deacetylase inhibitor (HDACi) portfolio, which includes the Friedreich's ataxia program, to BioMarin Pharmaceuticals Inc. (BioMarin). Under the terms of the agreement, we received an upfront payment of \$2 million in January 2014 from BioMarin and a \$125,675 payment in September 2014 upon tech transfer, and we have the potential to receive up to \$160 million in future milestone payments for the development, regulatory approval and commercial sale of portfolio compounds included in the agreement. In addition, we are eligible to receive royalties on sales of qualified products developed.

Inventories

Inventories relate to our bioprocessing business. We value inventory at cost or, if lower, fair market value, using the first-in, first-out method. We review our inventory at least quarterly and record a provision for excess and obsolete inventory based on our estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in-process and finished products. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to 12 months. We write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements to cost of product revenue. Manufacturing of bioprocessing finished goods is done to order and tested for quality specifications prior to shipment.

A change in the estimated timing or amount of demand for our products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of inventory and reported operating results. During all periods presented in the accompanying consolidated financial statements, there have been no material adjustments related to a revised estimate of inventory valuations.

Business combinations

Amounts paid for acquisitions are allocated to the assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that

use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. The fair value of contingent consideration includes estimates and judgments made by management regarding the probability that future contingent payments will be made, the extent of royalties to be earned in excess of the defined minimum

Table of Contents

royalties, etc. Management updates these estimates and the related fair value of contingent consideration at each reporting period based on the estimated probability of achieving the earnout targets and applying a discount rate that captures the risk associated with the expected contingent payments. To the extent our estimates change in the future regarding the likelihood of achieving these targets we may need to record material adjustments to our accrued contingent consideration. Changes in the fair value of contingent consideration are recorded in our consolidated statement of operations. We have accrued approximately \$6.1 million as of December 31, 2016 related to sales targets as part of the Refine Acquisition and the Atoll Acquisition.

We use the income approach to determine the fair value of certain identifiable intangible assets including customer relationships and developed technology. This approach determines fair value by estimating after-tax cash flows attributable to these assets over their respective useful lives and then discounting these after-tax cash flows back to a present value. We base our assumptions on estimates of future cash flows, expected growth rates, expected trends in technology, etc. We base the discount rates used to arrive at a present value as of the date of acquisition on the time value of money and certain industry-specific risk factors. We believe the estimated purchased customer relationships, developed technologies, trademark / tradename, patents, and in process research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets.

Intangible assets and goodwill***Intangible Assets***

We amortize our intangible assets that have finite lives using the straight-line method. Amortization is recorded over the estimated useful lives ranging from 2 to 20 years. We review our intangible assets subject to amortization to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Further, we also review our indefinite-lived intangible assets not subject to amortization to determine if any adverse conditions exist or a change in circumstances occurred that would indicate an impairment. If the carrying value of an asset exceeds its estimated undiscounted cash flows, we will write-down the carrying value of the intangible asset to its fair value in the period identified. In assessing fair value, we must make assumptions regarding estimated future cash flows and discount rates. If these estimates or related assumptions change in the future, we may be required to record impairment charges. We generally calculate fair value as the present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

Goodwill

We test goodwill for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator. Our annual impairment test date is the last day of our fiscal year, December 31, 2016. The Company performed its annual impairment test over the Company's one reporting unit and concluded that goodwill was not impaired.

Accrued liabilities

We estimate accrued liabilities by identifying services performed on our behalf, estimating the level of service performed and determining the associated cost incurred for such service as of each balance sheet date. For example, we would accrue for professional and consulting fees incurred with law firms, audit and accounting

Table of Contents

service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred or tracking costs incurred by service providers under fixed fee arrangements.

We have processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that we do not identify certain costs that have begun to be incurred or we under or over-estimate the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services often require the exercise of judgment. We make these judgments based upon the facts and circumstances known at the date of the financial statements.

A change in the estimated cost or volume of services provided could result in additional accrued liabilities. Any significant unanticipated changes in such estimates could have a significant impact on our accrued liabilities and reported operating results. There have been no material adjustments to our accrued liabilities in any of the periods presented in the accompanying financial statements.

Stock-based compensation

We use the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date.

The expected term of options granted represents the period of time for which the options are expected to be outstanding and is derived from our historical stock option exercise experience and option expiration data. For purposes of estimating the expected term, we have aggregated all individual option awards into one group, as we do not expect substantial differences in exercise behavior among our employees. The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determined the expected volatility based upon the historical volatility of our common stock over a period commensurate with the option's expected term. The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date. We have never declared or paid any cash dividends on any of our capital stock and do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

We recognize compensation expense on awards that vest based on service conditions on a straight-line basis over the requisite service period based upon the number of options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted by an amount of estimated forfeitures. Forfeitures represent only the unvested portion of a surrendered option. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical data, we have calculated an 8% annual forfeiture rate for non-executive level employees, a 3% annual forfeiture rate for executive level employees, and a 0% forfeiture rate for non-employee members of the Board of Directors, which we believe are reasonable assumptions to estimate forfeitures. However, the estimation of forfeitures requires significant judgment and, to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

For the fiscal years ended December 31, 2016, 2015 and 2014, we recorded stock-based compensation expense of approximately \$4,595,000, \$3,598,000 and \$1,766,000, respectively, for share-based awards granted under all of the Company's stock plans.

As of December 31, 2016, there was \$9,555,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.97 years. We expect 719,579 unvested options and restricted stock units to vest over the next five years.

Table of Contents**Income Taxes**

Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We account for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate our tax position on a quarterly basis. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the accompanying consolidated financial statements and the related footnotes thereto.

Revenues

Total revenues for fiscal years 2016, 2015, and 2014 were comprised of the following:

	Years ended December 31,			% Change	
	2016	2015	2014	2016 vs. 2015	2015 vs. 2014
	(in thousands, except percentages)				
Product revenues	\$ 104,441	\$ 83,537	\$ 60,431	25%	38%
Royalty and other revenue	100		3,117	100%	(100%)
Total revenue	\$ 104,541	\$ 83,537	\$ 63,548	25%	31%

Product revenues

Historically, the majority of our bioprocessing products are sold to customers who incorporate our products into their proprietary antibody purification processes for monoclonal antibodies. These customers then sell their products directly to the pharmaceutical industry. Increasingly, we are selling our products directly to the pharmaceutical industry and its contract manufacturers. These direct sales increased to approximately 52% of our revenue during fiscal 2016. Sales of our bioprocessing products can be impacted by the timing of large-scale production orders and the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

Product revenues were comprised of the following (in thousands):

	December 31, 2016	December 31, 2015	December 31, 2014
Protein products	\$ 54,716	\$ 52,938	\$ 43,674
Filtration products	19,774 ⁽²⁾	15,676	6,739 ⁽¹⁾
Chromatography products	29,520 ⁽³⁾	14,613	9,811

Edgar Filing: REPLIGEN CORP - Form 10-K

Other	431	310	207
Total product revenues	\$ 104,441	\$ 83,537	\$ 60,431

- (1) 2014 revenue for filtration products includes revenue related to the Refine Acquisition from June 2, 2014 through December 31, 2014.
- (2) 2016 revenue for filtration products includes revenue related to the TangenX Acquisition from December 14, 2016 through December 31, 2016.

Table of Contents

(3) 2016 revenue for chromatography products includes revenue related to the Atoll Acquisition from April 1, 2016 through December 31, 2016.

Revenue from protein products includes our Protein A ligands and cell culture growth factors. Revenue from filtration products includes our XCell ATF Systems and consumables and Sius filtration products. Revenue from chromatography products includes our OPUS and OPUS PD chromatography columns, chromatography resins and ELISA test kits. Other revenue primarily consists of freight revenues.

For fiscal 2016, bioprocessing product sales increased by \$20,904,000 or 25% as compared to fiscal 2015, due largely to increased volumes in our Filtration and Chromatography products, as well as from revenues generated from the Atoll Acquisition. We sell our various bioprocessing products at different price points. The mix of products sold varies and impacts the fluctuations in total product revenue and cost of product revenues from period to period.

For fiscal 2015, bioprocessing product sales increased by \$23,106,000 or 38% as compared to fiscal 2014, due largely to increased volumes in our Protein, Chromatography and Filtration products. We sell our various bioprocessing products at different price points. The mix of products sold varies and impacts the fluctuations in total product revenue and cost of product revenues from period to period.

Royalty revenues

We recognized \$2,126,000 of revenue for fiscal 2014 from the out-license of our HDACi portfolio to BioMarin on January 21, 2014. We also recognized \$1,000,000 of revenue for fiscal 2014 from the out-license of our Spinal Muscular Atrophy program to Pfizer on December 28, 2012. We did not recognize any such revenue in fiscal 2015 and 2016, and we do not expect to recognize any research and license revenue or to receive any incremental funding for our therapeutic development programs going forward.

Costs and operating expenses

Total costs and operating expenses for fiscal years 2016, 2015, and 2014 were comprised of the following:

	Years ended December 31,			% Change	
	2016	2015	2014	2016 vs. 2015	2015 vs. 2014
	(in thousands, except percentages)				
Cost of product revenue	\$ 47,117	\$ 35,251	\$ 28,022	34%	26%
Research and development	7,355	5,740	5,609	28%	2%
Selling, general and administrative	30,853	24,699	17,154	25%	44%
Contingent consideration fair value adjustments	3,242	4,083	2,072	(21%)	97%
Total costs and operating expenses	\$ 88,567	\$ 69,773	\$ 52,857	27%	32%

Cost of product revenue

For fiscal 2016, cost of product revenue increased \$11,866,000 or 34% as compared to fiscal 2015. This increase is primarily due to the increase in product revenues noted above. For fiscal 2015, cost of product revenue increased \$7,229,000 or 26% as compared to fiscal 2014. This increase is primarily due to the increased product revenue noted

above.

Gross margins were 55%, 58%, and 54% for fiscal 2016, 2015, and 2014, respectively. During fiscal 2016, gross margins decreased slightly compared to fiscal 2015 due to product mix and increased investments in operations to support growing demands for the bioprocessing products that we manufacture. During fiscal 2015, gross margins increased slightly compared to fiscal 2014 due to increased capacity utilization and product mix.

Table of Contents*Research and development expenses*

During fiscal 2016, 2015 and 2014, research and development expenses were related to bioprocessing products which included personnel, supplies and other research expenses. In August 2012, we announced a strategic focus on our Bioprocessing business and a simultaneous effort to find partners, out-licensing opportunities or other funding arrangements with external parties to reduce or eliminate the net expenditures on research and development activities for our therapeutic programs. In January 2013, we announced that we entered into an outlicensing agreement with Pfizer, Inc. for our Spinal Muscular Atrophy program, under an arrangement that would provide \$5.0 million up front and up to \$65.0 million in milestone payments, plus royalties. On January 26, 2015, Pfizer notified us that they were terminating this arrangement for convenience effective as of April 26, 2015. In January 2014, we announced that we entered into an outlicensing agreement with BioMarin Pharmaceutical Inc. for our Friedreich's ataxia portfolio, under an arrangement that would provide \$2.0 million up front and up to \$160.0 million in future milestones, plus royalties.

Due to the small size of the Company and the fact that these various programs share personnel and fixed costs, we do not track all of our expenses or allocate any fixed costs by program, and therefore, have not provided an estimate of historical costs incurred by project. In addition to the legacy product research and development, the current single-use XCell ATF project incurs expenses related to product development, sterilization, validation testing, and other research related expenses.

For fiscal 2016, research and development expenses increased by \$1,615,000 or 28% as compared to fiscal 2015. This increase is related to the increased expenditures related to the development of our single use XCell ATF products, our OPUS resin recovery port, and other new products in development. Expenditures in 2016 included personnel, supplies and other external development expenses.

For fiscal 2015, research and development expenses increased by \$131,000 or 2% as compared to fiscal 2014. This increase is primarily related to the timing of expenditures, including personnel, supplies and other development expenses related to our new products in development.

We expect our research and development expenses in the year ending December 31, 2017, which relate to bioprocessing product development, to increase moderately.

Selling, general and administrative expenses

Selling, general and administrative (SG&A) expenses include the costs associated with selling our commercial products and costs required to support our marketing efforts, including legal, accounting, patent, shareholder services, amortization of intangible assets and other administrative functions.

For fiscal 2016, SG&A costs increased by \$6,154,000 or 25% as compared to fiscal 2015. This increase is primarily due to the continuing buildout of our administrative infrastructure to support future growth, the continuing expansion of our customer-facing activities to drive sales of our bioprocessing products, costs related to the Atoll Acquisition and TangenX Acquisition and expenses incurred by Repligen GmbH (formerly Atoll) post-acquisition.

For fiscal 2015, SG&A costs increased by \$7,545,000 or 44% as compared to fiscal 2014. This increase is primarily due to higher administrative expenses related to the implementation of an inventory accounting software package, the buildout of our administrative infrastructure to support future growth and the expansion of our customer-facing activities to drive sales of our bioprocessing products. This increase is partially offset by \$818,000 of closing and transition costs incurred in 2014 related to the Refine Acquisition.

Contingent Consideration

For fiscal 2016, our contingent consideration liability decreased approximately \$669,000 compared to fiscal 2015. In fiscal 2016, we recorded contingent consideration expense related primarily to the Refine Acquisition

Table of Contents

and the Atoll Acquisition. Contingent consideration related to the Refine Acquisition in 2016 is based on actual 2016 XCell ATF sales and any receipts related to the resolution, withdrawal or settlement of certain patent disputes with a third party to be paid to the former shareholders of Refine. Contingent consideration related to Atoll is based on actual 2016 sales growth compared to 2015 sales. The decrease is attributable to recording Refine contingent consideration fair value adjustments related to projected 2015 and 2016 XCell ATF sales in the previous year, while in 2016 we only recorded fair value adjustments related to 2016 sales. This decrease is partially offset by contingent consideration expense related to the Atoll Acquisition. Because the contingent consideration periods related to the BioFlash, Refine and Atoll acquisitions all concluded in 2016, we do not expect to incur contingent consideration expense in 2017.

For fiscal 2015, our contingent consideration liability increased approximately \$2,943,000 compared to fiscal 2014. The contingent consideration for this period stems from the BioFlash and Refine acquisitions. The increase is primarily attributed to a \$4,048,000 increase in the fair value of the contingent consideration stemming from the Refine acquisition, partially offset by payments of approximately \$1,139,000 to Refine and BioFlash. The contingent consideration related to BioFlash is valued using management's estimates of royalties to be paid to the former shareholders of BioFlash based on sales of the acquired assets. The contingent consideration related to the Refine Acquisition is valued using management's estimates of expected future milestone payments based on forecasted sales of the acquired assets and portion of any receipts that might be received in connection with the resolution, withdrawal or settlement of certain patent disputes with a third party to be paid to the former shareholders of Refine.

Investment income

Investment income includes income earned on invested cash balances. Investment income for fiscal 2016, 2015, and 2014 was \$346,000, \$136,000, and \$309,000, respectively. The increase of \$210,000 or 154% for fiscal 2016 was primarily due to higher invested funds following the issuance of our convertible senior notes during 2016 compared to 2015. The decrease of \$173,000 or 56% for fiscal 2015 was primarily due to lower invested funds during 2015 compared to 2014. We expect investment income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

Provision for income taxes

The provision for income taxes for the year ended December 31, 2016 totaled \$11,000. Our current tax provision of \$4,077,000 primarily relates to a foreign tax provision of \$4,027,000. Our deferred tax benefit of (\$4,066,000) is due to a reduction of the valuation allowance on our deferred tax assets in the amount of \$8,535,000 resulting from taxable temporary differences generated from the TangenX Acquisition and the issuance of our convertible senior notes, partially offset by an increase in deferred tax liabilities related to tax amortization of indefinite lived intangibles and the conversion option on our convertible senior notes.

The provision for income taxes for the year ended December 31, 2015 totaled \$4,078,000. Our current tax provision of \$3,745,000 primarily relates to a foreign tax provision of \$3,507,000 and \$315,000 related to the resolution of our uncertain tax position for historic research and development credits and certain state apportionment matters. Our deferred tax provision of \$333,000 is primarily due to an increase in deferred tax liabilities related to tax amortization of indefinite lived intangibles.

In June 2015, we received a final assessment from the Massachusetts Department of Revenue (DOR) regarding an examination for the years ended March 31, 2010 and 2011 and the nine months ended December 31, 2011. This examination related to the qualification of Research and Development tax credits. The final settlement resulted in a payment to the DOR of approximately \$141,000.

In December 2015, we reached a negotiated settlement with the DOR regarding an appeal of an assessment made in 2013 for the years ended March 31, 2008 and 2009. The primary issues in the appeal related to the sourcing of intellectual property settlements and the qualification of Research and Development tax credits. The final settlement resulted in a payment to the DOR of approximately \$1,012,000.

Table of Contents**Non-GAAP Financial Measures**

We provide non-GAAP adjusted income from operations, non-GAAP adjusted net income and adjusted EBITDA as supplemental measures to GAAP measures regarding our operating performance. These financial measures exclude the impact of certain acquisition related items and, therefore, have not been calculated in accordance with GAAP. A detailed explanation and a reconciliation of each non-GAAP financial measures to its most comparable GAAP financial measures are described below.

We include this financial information because we believe these measures provide a more accurate comparison of our financial results between periods and more accurately reflect how management reviews its financial results. We excluded the impact of certain acquisition related items because we believe that the resulting charges do not accurately reflect the performance of our ongoing operations for the period in which such charges are incurred.

Non-GAAP Adjusted Income from Operations

Non-GAAP adjusted income from operations is measured by taking income from operations as reported in accordance with GAAP and excluding acquisition costs and contingent consideration expenses booked through our consolidated statements of comprehensive income. The following is a reconciliation of income from operations in accordance with GAAP to non-GAAP adjusted income from operations for the years ended December 31, 2016 and 2015 (in thousands):

	Year ended December 31,	
	2016	2015
GAAP income from operations	\$ 15,974	\$ 13,764
Non-GAAP adjustments to net income:		
Acquisition costs	2,214	
Contingent consideration fair value adjustments	3,242	4,083
Non-GAAP adjusted income from operations	\$ 21,430	\$ 17,847

Non-GAAP Adjusted Net Income

Non-GAAP adjusted net income is measured by taking net income as reported in accordance with GAAP and excluding acquisition costs, contingent consideration expenses, non-cash interest expense and tax benefits recorded in conjunction with the TangenX Acquisition booked through our consolidated statements of comprehensive income. The following is a reconciliation of net income in accordance with GAAP to non-GAAP adjusted net income for the years ended December 31, 2016 and 2015:

	Year Ended December 31,			
	2016		2015	
	Amount	Fully Diluted	Amount	Fully Diluted
	(in thousands)	Earnings	(in thousands)	Earnings
		per Share		per Share
GAAP net income	\$ 11,681	\$ 0.34	\$ 9,345	\$ 0.28

Edgar Filing: REPLIGEN CORP - Form 10-K

Non-GAAP adjustments to net income:

Acquisition costs	2,214	0.07		
Contingent consideration fair value adjustments	3,242	0.10	4,083	0.12
Non-cash interest expense	2,274	0.07		
Net tax benefit from Atoll and TangenX acquisitions	(4,269)	(0.13)		
Non-GAAP adjusted net income	\$ 15,142	\$ 0.44	\$ 13,428	\$ 0.40

Note that earnings per share amounts may not add due to rounding.

Table of Contents*Adjusted EBITDA*

Adjusted EBITDA is measured by taking net income as reported in accordance with GAAP, excluding investment income, interest expense, taxes, depreciation and amortization, and excluding acquisition costs and contingent consideration expenses booked through our consolidated statements of comprehensive income. The following is a reconciliation of net income in accordance with GAAP to adjusted EBITDA for years ended December 31, 2016 and 2015 (in thousands):

	Year ended December 31,	
	2016	2015
GAAP net income	\$ 11,681	\$ 9,345
Non-GAAP EBITDA adjustments to net income:		
Investment income	(346)	(136)
Interest expense	3,768	32
Tax provision	11	4,078
Depreciation	3,269	2,996
Amortization	2,052	1,600
 EBITDA	 20,435	 17,915
Other non-GAAP adjustments:		
Acquisition costs	2,214	
Contingent consideration fair value adjustments	3,242	4,083
 Adjusted EBITDA	 \$ 25,891	 \$ 21,998

Liquidity and capital resources

We have financed our operations primarily through revenues derived from product sales, research grants, proceeds and royalties from license arrangements, and the issuance of senior convertible notes in May 2016. Our revenue for the foreseeable future will primarily be limited to our bioprocessing product revenue.

At December 31, 2016, we had cash and marketable securities of \$141,780,000 compared to \$73,407,000 at December 31, 2015. In fiscal 2016 we utilized \$8,767,000 of cash (net of cash received) in the Atoll Acquisition and \$35,847,000 of cash (net of cash received) in the TangenX Acquisition. A deposit for leased office space of \$450,000 is classified as restricted cash and is not included in cash and marketable securities totals for December 31, 2016 or December 31, 2015.

On April 1, 2016, pursuant to the terms of a Share Purchase Agreement dated as of March 31, 2016, Repligen Sweden AB, our wholly-owned subsidiary, acquired Atoll from UV-Cap GmbH & Co. KG (the Seller). Under the terms of the Share Purchase Agreement, Repligen Sweden paid to the Seller in consideration for all of the equity interests in Atoll a purchase price of 7.8 million (\$8.8 million) in cash (net of cash received) and 538,700 shares of our common stock. The Share Purchase Agreement includes a future contingent payment by Repligen Sweden to the Seller consisting of 1.0 million (\$1.1 million) in cash if Atoll's revenue increases by a specified amount from calendar year 2015 to calendar year 2016.

On May 24, 2016, we received net proceeds of \$111,070,000 from the issuance of our 2.125% Convertible Senior Notes due 2021 (the Notes). The Notes bear interest at the rate of 2.125% per annum, payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2016.

The Notes will mature on June 1, 2021, unless earlier repurchased, redeemed or converted in accordance with their terms. Prior to March 1, 2021, the Notes will be convertible at the option of holders of the Notes only upon satisfaction of certain conditions and during certain periods, and thereafter, the Notes will be convertible at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. Upon conversion, holders of the Notes will receive shares of the Company s common stock, cash or a combination thereof, at the Company s election.

Table of Contents

The Company will not have the right to redeem the Notes prior to June 5, 2019, but may redeem the Notes, at its option, in whole or in part, on any business day on or after June 5, 2019 and prior to the maturity date if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides written notice of redemption. The redemption price will be equal to 100% of the principal amount of the principal amount of Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

On December 14, 2016, pursuant to the terms of a Share Purchase Agreement dated as of December 14, 2016, we acquired TangenX Technology Corporation (TangenX), from Novasep SAS and John Connors. Under the terms of the Share Purchase Agreement, we paid \$35.9 million in cash (net of cash received) in consideration for all of the equity interests in TangenX.

Cash flows**(In thousands)**

	Year ended December 31, 2016	Increase / (Decrease)	Year ended December 31, 2015	Increase / (Decrease)	Year ended December 31, 2014
Cash provided by (used in)					
Operating activities	\$ 7,521	\$ (7,532)	\$ 15,053	\$ (3,348)	\$ 18,401
Investing activities	(49,194)	(53,985)	4,791	24,583	(19,792)
Financing activities	112,113	111,346	767	(913)	1,680
Operating activities					

For fiscal 2016, our operating activities provided cash of \$7,521,000 reflecting net income of \$11,681,000 and non-cash charges totaling \$11,345,000 comprised mainly of depreciation, amortization, stock-based compensation charges, deferred tax benefits and the revaluation of contingent consideration. Increases in accounts receivable and inventories consumed \$9,385,000 of cash. Decreases in accounts payable and accrued liabilities consumed \$5,840,000 of cash.

For fiscal 2015, our operating activities provided cash of \$15,053,000 reflecting net income of \$9,345,000 and non-cash charges totaling \$12,158,000 including depreciation, amortization, stock-based compensation charges, deferred tax changes and the revaluation of contingent consideration. Increases in accounts payable and long-term liabilities provided an additional \$5,139,000 of cash. Increases in accounts receivable, inventories and prepaid expenses and other current assets consumed \$10,155,000 of cash. Decreases in accrued liabilities consumed \$1,592,000 of cash.

For fiscal 2014, our operating activities provided cash of \$18,401,000 reflecting net income of \$8,170,000 and non-cash charges totaling \$8,188,000 including depreciation, amortization, stock-based compensation charges, deferred tax asset valuation allowance changes and the revaluation of contingent consideration. Decreases in royalties and other receivables and increases in accounts payable provided an additional \$6,557,000 and \$2,288,000 of cash. Increases in accounts receivable, inventories and prepaid expenses and other current assets consumed \$3,277,000 of cash. Decreases in accrued liabilities and long term liabilities consumed \$3,525,000 of cash.

Investing activities

Edgar Filing: REPLIGEN CORP - Form 10-K

For fiscal 2016, our investing activities consumed \$49,194,000 of cash. We used \$8,767,000 in cash (net of cash received) for the Atoll Acquisition and \$35,847,000 (net of cash received) for the TangenX Acquisition. Fixed asset additions consumed \$4,325,000, as we increased the manufacturing capacity of our facilities in the United States and Sweden. Net purchases of marketable securities consumed \$300,000 of cash in fiscal 2016.

In fiscal 2015, our investing activities provided \$4,791,000 of cash, comprised of \$7,419,000 of net redemptions of marketable securities, offset by \$2,628,000 of fixed asset additions.

Table of Contents

In fiscal 2014, our investing activities consumed \$19,792,000 of cash, comprised of \$21,236,000 for the Refine Acquisition, \$5,602,000 of fixed asset additions as we completed the second phase of our Waltham facility expansion and a \$250,000 increase in restricted cash related to our amended lease for our Waltham facility, partially offset by \$7,296,000 of net redemptions of marketable securities.

Financing activities

In May 2016, we received net proceeds of \$111,070,000 from the issuance of our senior convertible notes. Exercises of stock options provided cash receipts of \$1,841,000, \$866,000 and \$1,680,000 in fiscal 2016, 2015 and 2014, respectively. Cash payments to Refine and BioFlash in 2016 totaled \$4,105,000, of which \$798,000 related to the fair value of these liabilities as of the respective acquisition dates and is included as part of financing activities. Payments to Refine in 2015 related to achieving 2014 sales goals totaled \$1,000,000, of which \$99,000 related to the fair value of this liability as of the acquisition date and is included as part of financing activities. The remaining amounts are included as an offset to our cash provided by operating activities.

Off-balance sheet arrangements

We do not have any special purpose entities or off-balance sheet financing arrangements.

Contractual obligations

As of December 31, 2016, we had the following fixed obligations and commitments (in thousands):

	Total	Payments Due By Period				More than 5 Years
		Less than 1 Year	1 Year	3 Years	3 5 Years	
Operating lease obligations	\$ 14,304	\$ 2,523	\$ 5,075	\$ 4,970	\$ 1,736	
Purchase obligations ⁽¹⁾	10,008	10,008				
Contingent consideration ⁽²⁾	6,119	6,119				
Total	\$ 30,431	\$ 18,650	\$ 5,075	\$ 4,970	\$ 1,736	

(1) Primarily represents purchase orders for the procurement of raw material for manufacturing.

(2) Represents the amount of contingent consideration relating to acquisitions. These amounts are recorded in accrued expenses on our consolidated balance sheets. We have contingent consideration for an earnout pertaining to the Refine Acquisition and for an earnout pertaining to the Atoll Acquisition.

Capital requirements

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

the expansion of our bioprocessing business;

the ability to sustain sales and profits of our bioprocessing products;

our ability to acquire additional bioprocessing products;

our ability to realize value from our outlicensed early stage CNS programs and the RG1068 program;

the scope of and progress made in our research and development activities;

the extent of any share repurchase activity; and

the success of any proposed financing efforts.

Table of Contents

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash balances are adequate to meet our cash needs for at least the next 24 months. We expect operating expenses in the year ending December 31, 2017 to increase as we continue to expand our bioprocessing business. We expect to incur continued spending related to the development and expansion of our bioprocessing product lines and expansion of our commercial capabilities for the foreseeable future. Our future capital requirements may include, but are not limited to, purchases of property, plant and equipment, the acquisition of additional bioprocessing products and technologies to complement our existing manufacturing capabilities, and continued investment in our intellectual property portfolio.

We plan to continue to invest in our bioprocessing business and in key research and development activities associated with the development of new bioprocessing products. We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio. We continue to seek to acquire such potential assets that may offer us the best opportunity to create value for our shareholders. In order to acquire such assets, we may need to seek additional financing to fund these investments. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of any such acquisition-related financing needs or lower demand for our products, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt funding. The sale of equity and convertible debt securities may result in dilution to our stockholders, and those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, if at all.

Net operating loss carryforwards

At December 31, 2016, we had net operating loss carryforwards of approximately \$48,550,000 and business tax credits carryforwards of approximately \$2,187,000 available to reduce future federal income taxes, if any. The net operating loss and business tax credits carryforwards will continue to expire at various dates through December 2036. Net operating loss carryforwards and available tax credits are subject to review and possible adjustment by the Internal Revenue Service, state and foreign jurisdictions and may be limited in the event of certain changes in the ownership interest of significant stockholders.

Foreign earnings

At December 31, 2016, we have not provided for U.S. income taxes or foreign withholding taxes on outside basis differences of foreign subsidiaries of approximately \$43,679,000 as we have the ability and intent to indefinitely reinvest the undistributed earnings of Repligen Sweden, Repligen GmbH and Repligen Singapore Pte. Ltd., and there are no needs for such earnings in the U.S. that would contradict our plan to indefinitely reinvest.

Effects of inflation

Our assets are primarily monetary, consisting of cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

We have investments in commercial paper, U.S. Government and agency securities as well as corporate bonds and other debt securities. As a result, we are exposed to potential loss from market risks that may occur as a result of changes in interest rates, changes in credit quality of the issuer or otherwise.

We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines. A hypothetical 100 basis point increase in interest rates would result in an approximate \$64,000 decrease in the fair value of our investments as of December 31, 2016. We believe, however, that the conservative nature of our investments mitigates our interest rate exposure, and our investment policy limits the amount of our credit exposure to any one issue, issuer (with the exception of U.S. agency obligations) and type of instrument. We do not expect any material loss from our marketable security investments and therefore believe that our potential interest rate exposure is limited.

Foreign exchange risk

Transactions by our subsidiary, Repligen Sweden, may be denominated in Swedish krona, British pound sterling, U.S. dollars, or in Euros while the entity's functional currency is the Swedish krona. Transactions by our subsidiary, Repligen GmbH, may be denominated in Euros or U.S. dollars while the entity's functional currency is the Euro. Certain sales transactions related to XCell ATF System products are denominated in foreign currencies. Exchange gains or losses resulting from the translation between the transactional currency and the functional currency of Repligen Sweden, Repligen GmbH and XCell ATF System product sales are included in our consolidated statements of operations. The functional currency of the Company is U.S. dollars. Fluctuations in exchange rates may adversely affect our results of operations, financial position and cash flows. We currently do not seek to hedge this exposure to fluctuations in exchange rates.

Although a majority of our contracts are denominated in U.S. dollars, 40% and 33% of total revenues during fiscal 2016 and 2015, respectively, were denominated in foreign currencies while 22% and 23% of our costs and expenses during fiscal 2016 and 2015, respectively, were denominated in foreign currencies, primarily operating expenses associated with cost of revenue, sales and marketing and general and administrative. In addition, 26% and 43% of our consolidated tangible assets were subject to foreign currency exchange fluctuations as of each of December 31, 2016 and 2015, respectively, while 2% and 21% of our consolidated liabilities were exposed to foreign currency exchange fluctuations as of each of December 31, 2016 and 2015, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and supplementary data required by Item 8 are set forth at the pages indicated in Item 15(a) below and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures.

The Company's management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act and as required by paragraph (b) of Rules 13a-15 or

Table of Contents

15d-15 under the Exchange Act) as of the end of the period covered by this report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

(b) Report of Management on Internal Control Over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

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

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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO).

Management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Atoll GmbH acquired on April 1, 2016 or TangenX Technology Corporation acquired on December 14, 2016, which are included in the December 31, 2016 consolidated financial statements of Repligen Corporation and constituted \$70,569,000 of total assets as of December 31, 2016 and \$3,543,000 of revenues for the year then ended.

Subject to the foregoing, based on this assessment, our management concluded that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria. Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2016.

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

Table of Contents

(c) Attestation Report of the Independent Registered Public Accounting Firm.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Repligen Corporation:

We have audited Repligen Corporation's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Repligen Corporation'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 Report of Management 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

As indicated in the accompanying 10-K, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Atoll GmbH acquired on April 1, 2016 or TangenX Technology Corporation acquired on December 14, 2016, which are included in the December 31, 2016 consolidated financial statements of Repligen Corporation and constituted \$70,569,000 of total assets as of December 31, 2016 and \$3,543,000 of revenues for the year then ended. Our audit of internal control over financial reporting of Repligen Corporation also did not include an evaluation of the internal control over financial reporting of Atoll GmbH or TangenX Technology Corporation.

In our opinion, Repligen Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Repligen Corporation as of December 31, 2016 and 2015, and

Table of Contents

the related consolidated statements of operations and comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2016 of Repligen Corporation and our report dated February 22, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 23, 2017

Table of Contents

(d) Changes in Internal Control Over Financial Reporting

We acquired Atoll in April 2016 and TangenX in December 2016. The financial results of Atoll and TangenX are included in our consolidated financial statements as of December 31, 2016 and for the year then ended and represented approximately \$70,569,000 of our total assets as of December 31, 2016 and \$3,543,000 of revenues for the year ended December 31, 2016. As these acquisitions occurred during 2016, the scope of our assessment of our internal control over financial reporting does not include Atoll and TangenX. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from our scope in the year of acquisition.

Except as otherwise described above, there have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

Pursuant to General Instructions G to Form 10-K, the information required for Part III, Items 10, 11, 12, 13 and 14, is incorporated herein by reference from the Company's proxy statement for the 2017 Annual Meeting of Stockholders.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

(a) (1) *Financial Statements:*

The financial statements required by this item are submitted in a separate section beginning on page 42 of this Report, as follows:

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	56
<u>Consolidated Balance Sheets as of December 31, 2016 and December 31, 2015</u>	57
<u>Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2016, 2015 and 2014</u>	58
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2016, 2015 and 2014</u>	59
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2016, 2015 and 2014</u>	60
<u>Notes to Consolidated Financial Statements</u>	61

(a) (2) *Financial Statement Schedules:*

None.

Table of Contents(a) (3) *Exhibits:*

The Exhibits which are filed as part of this Annual Report or which are incorporated by reference are set forth in the Exhibit Index hereto.

EXHIBIT INDEX

Exhibit Number	Document Description
3.1	Restated Certificate of Incorporation dated June 30, 1992, as amended September 17, 1999 and May 16, 2014 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
3.2	Amended and Restated Bylaws (filed as Exhibit 3.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference) (SEC File No. 000-14656).
3.3	Amendment No. 1 to the Amended and Restated Bylaws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on December 20, 2011 and incorporated herein by reference).
3.4	Amendment No. 2 to the Amended and Restated Bylaws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on May 25, 2012 and incorporated herein by reference).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
4.2	Base Indenture, dated as of May 24, 2016, by and between Repligen Corporation and Wilmington Trust, National Association (filed as Exhibit 4.1 to Repligen Corporation's Current Report on 8-K filed on May 24, 2016).
4.3	First Supplemental Indenture, dated as of May 24, 2016, by and between Repligen Corporation and Wilmington Trust, National Association (filed as Exhibit 4.2 to Repligen Corporation's Current Report on 8-K filed on May 24, 2016).
4.4	Form of 2.125% Convertible Senior Note due 2012 (included in Exhibit 4.2).
10.1*	Employment Agreement, dated March 14, 1996, between Repligen Corporation and Walter C. Herlihy (filed as Exhibit 10.3 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
10.2*	Employment Agreement, dated March 14, 1996, between Repligen Corporation and James R. Rusche (filed as Exhibit 10.4 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
10.3*	Repligen Executive Incentive Compensation Plan (filed as Exhibit 10.1 to Repligen Corporation's Current Report on form 8-K filed on December 14, 2005 and incorporated herein by reference).
10.4*	The Amended 1992 Repligen Corporation Stock Option Plan, as amended (filed as Exhibit 4.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000

and incorporated herein by reference) (SEC File No. 000-14656).

10.5*

The Second Amended and Restated 2001 Repligen Corporation Stock Plan (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on September 18, 2008 and incorporated herein by reference).

Table of Contents

Exhibit Number	Document Description
10.6.1*	The Amended and Restated 2001 Repligen Corporation Stock Option Plan, Form of Incentive Stock Option Agreement (filed as Exhibit 10.14 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2005 and incorporated herein by reference).
10.6.2*	The Amended and Restated 2001 Repligen Corporation Stock Plan, Form of Restricted Stock Agreement (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on January 9, 2006 and incorporated herein by reference).
10.7	Lease Between Repligen Corporation as Tenant and West Seyon LLC as Landlord, 35 Seyon Street, Waltham, MA (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2001 and incorporated herein by reference) (SEC File No. 000-14656).
10.8#	License Agreement by and between The Scripps Research Institute and Repligen Corporation dated April 6, 2007 (filed as Exhibit 10.18 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2007 and incorporated herein by reference).
10.9#	Strategic Supplier Alliance Agreement dated January 28, 2010 by and between Repligen Corporation and GE Healthcare Bio-Sciences AB (filed as Exhibit 10.17 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2010 and incorporated herein by reference).
10.10+	Strategic Supplier Alliance Agreement, by and between GE Healthcare Bio-Sciences AB and Repligen Corporation, dated as of January 28, 2010, as amended on February 23, 2016 (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.11+	Strategic Supplier Alliance Agreement – Contract Manufacturing, by and between GE Healthcare Bio-Sciences AB and Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB), dated as of July 7, 2011, as amended on February 23, 2016 (filed as Exhibit 10.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.12	First Amendment to Lease, dated July 5, 2011, by and between Repligen Corporation and TC Saracen, LLC (filed as Exhibit 10.1 to Repligen's Current Report on Form 8-K filed on July 8, 2011 and incorporated herein by reference).
10.13	Lease Between Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB) as Tenant and i-parken i Lund AB as Landlord, St. Lars Vag 47, 220 09 Lund, Sweden (filed as Exhibit 10.18 to Repligen Corporation's Transition Report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.14#	Amendment No. 1 to Strategic Supplier Alliance Agreement, by and between GE Healthcare Bio-Sciences AB and Repligen Corporation, dated as of October 27, 2011 (filed as Exhibit 10.19 to Repligen Corporation's Transition Report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.15#	Strategic Supplier Alliance Agreement – Contract Manufacturing, by and between GE Healthcare Bio-Sciences AB and Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB), dated as of July 7, 2011 (filed as Exhibit 10.20 to Repligen Corporation's Transition Report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.16#	Amendment to Strategic Supply Alliance Agreement, by and between GE Healthcare Bio-Sciences AB and Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB), dated as of

Edgar Filing: REPLIGEN CORP - Form 10-K

October 27, 2011 (filed as Exhibit 10.21 to Repligen Corporation's Transition Report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).

Table of Contents

Exhibit Number	Document Description
10.17*	Repligen Corporation Amended and Restated 2012 Stock Option and Incentive Plan (filed as Exhibit 99.1 to Repligen Corporation's Form S-8 filed on June 2, 2014 and incorporated herein by reference).
10.18*	Repligen Corporation Non-Employee Directors' Deferred Compensation Plan. (filed as Exhibit 10.16 to Repligen Corporation's Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated by reference)
10.19#	Asset Purchase Agreement, dated January 21, 2014, by and between Repligen Corporation and BioMarin Pharmaceutical Inc. (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and incorporated herein by reference).
10.20#	Asset Purchase Agreement, dated as of June 2, 2014, by and among Repligen Corporation, Refine Technology, LLC, Jerry Shevitz, certain members of Refine Technology, LLC, Refine Technology Sales LLC, and Refine Technology Sales Asia Pte. Ltd. (filed as Exhibit 10.3 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 and incorporated herein by reference).
10.21	Stock Purchase Agreement, dated December 14, 2016, by and among Repligen Corporation, Novasep Process SAS and John Connors (filed as Exhibit 2.1 to Repligen Corporation's Current Report on Form 8-K filed on December 15, 2016 and incorporated herein by reference).
10.22	Fourth Amendment to Lease, dated March 26, 2014, by and between Repligen Corporation and Centerpoint Acquisitions LLC (filed as Exhibit 10.3 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and incorporated by reference herein).
10.23*	Letter Agreement, dated as of April 7, 2014, by and between Repligen Corporation and Tony J. Hunt (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on May 6, 2014 and incorporated herein by reference).
10.24*	Letter Agreement, dated as of June 10, 2014, by and between Repligen Corporation and Jon K. Snodgres (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on July 15, 2014 and incorporated herein by reference).
10.25*	Transitional Services and Separation Agreement, dated as of January 22, 2015, by and between Repligen Corporation and Walter C. Herlihy, Jr. (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on January 23, 2015 and incorporated herein by reference).
10.26*	Employment Agreement, dated as of February 26, 2015, by and between Repligen Corporation and Tony J. Hunt (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K/A filed on March 2, 2015 and incorporated herein by reference).
10.27*	Amended and Restated Transitional Services and Separation Agreement, dated August 31, 2016, by and between Repligen and James R. Rusche, Ph.D. (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on September 2, 2016).
10.28*	Repligen Corporation Amended and Restated Non-Employee Directors' Compensation Policy (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 and incorporated herein by reference).
10.29	Form of Indemnification Agreement (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on May 12, 2016).

- 21.1+ Subsidiaries of the Registrant.
- 23.1+ Consent of Ernst & Young LLP.

Table of Contents

Exhibit Number	Document Description
24.1+	Power of Attorney (included on signature page).
31.1+	Rule 13a-14(a)/15d-14(a) Certification.
31.2+	Rule 13a-14(a)/15d-14(a) Certification.
32.1+	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Repligen Corporation on Form 10-K for the fiscal year ended December 31, 2016, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Statements of Operations and Comprehensive Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statement of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

Confidential treatment obtained as to certain portions.

* Management contract or compensatory plan or arrangement.

+ Filed herewith.

The exhibits listed above are not contained in the copy of the Annual Report on Form 10-K distributed to stockholders. Upon the request of any stockholder entitled to vote at the 2015 annual meeting, the Registrant will furnish that person without charge a copy of any exhibits listed above. Requests should be addressed to Repligen Corporation, 41 Seyon Street, Waltham, MA 02453.

ITEM 16. 10-K SUMMARY

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

Table of Contents**SIGNATURES**

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

REPLIGEN CORPORATION

Date: February 23, 2017

By: /s/ TONY J. HUNT
Tony J. Hunt

President and Chief Executive Officer**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below hereby makes, constitutes and appoints Tony J. Hunt and Jon K. Snodgres with full power to act without the other, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign any or all amendments to this Form 10-K, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents of any of them, or any substitute or substitutes, lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ TONY J. HUNT Tony J. Hunt	President, Chief Executive Officer and Director (Principal executive officer)	February 23, 2017
/s/ JON K. SNODGRES Jon K. Snodgres	Chief Financial Officer (Principal financial and accounting officer)	February 23, 2017
/s/ KAREN DAWES Karen Dawes	Chairperson of the Board	February 23, 2017
/s/ NICOLAS M. BARTHELEMY Nicolas M. Barthelemy	Director	February 23, 2017

/s/ GLENN L. COOPER Director February 23, 2017

Glenn L. Cooper, M.D.

/s/ JOHN G. COX Director February 23, 2017

John G. Cox

/s/ GLENN P. MUIR Director February 23, 2017

Glenn P. Muir

/s/ THOMAS F. RYAN, JR. Director February 23, 2017

Thomas F. Ryan, Jr.

Table of Contents

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	56
<u>Consolidated Balance Sheets as of December 31, 2016 and December 31, 2015</u>	57
<u>Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2016, 2015 and 2014</u>	58
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2016, 2015 and 2014</u>	59
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2016, 2015 and 2014</u>	60
<u>Notes to Consolidated Financial Statements</u>	61

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Repligen Corporation:

We have audited the accompanying consolidated balance sheets of Repligen Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Repligen Corporation at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Repligen Corporation's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 23, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 23, 2017

Table of Contents

REPLIGEN CORPORATION
CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 122,233	\$ 54,092
Marketable securities	19,547	17,682
Accounts receivable, less reserve for doubtful accounts of \$23 and \$31, respectively	15,194	11,300
Royalties and other receivables	839	82
Inventories, net	24,696	17,998
Prepaid expenses and other current assets	1,644	2,098
Total current assets	184,153	103,252
Property, plant and equipment, net	14,956	13,801
Long-term marketable securities		1,633
Intangible assets, net	29,806	12,755
Goodwill	59,548	14,346
Restricted cash	450	450
Total assets	\$ 288,913	\$ 146,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,061	\$ 6,724
Accrued liabilities	16,014	12,057
Total current liabilities	21,075	18,781
Convertible senior notes, net	95,272	
Other long-term liabilities	3,802	4,708
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, no shares issued or outstanding		
Common stock, \$.01 par value, 80,000,000 shares authorized, 33,844,074 shares at December 31, 2016 and 32,949,353 shares at December 31, 2015 issued and outstanding	338	329
Additional paid-in capital	242,036	202,527
Accumulated other comprehensive loss	(13,749)	(8,566)
Accumulated deficit	(59,861)	(71,542)
Total stockholders' equity	168,764	122,748
Total liabilities and stockholders' equity	\$ 288,913	\$ 146,237

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

Table of Contents**REPLIGEN CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME**

(in thousands, except share and per share data)

	Years ended December 31,		
	2016	2015	2014
Revenue:			
Product revenue	\$ 104,441	\$ 83,537	\$ 60,431
Royalty and other revenue	100		3,117
Total revenue	104,541	83,537	63,548
Operating expenses:			
Cost of product revenue	47,117	35,251	28,022
Cost of royalty and other revenue			
Research and development	7,355	5,740	5,609
Selling, general and administrative	30,853	24,699	17,154
Contingent consideration fair value adjustments	3,242	4,083	2,072
Total operating expenses	88,567	69,773	52,857
Income from operations	15,974	13,764	10,691
Investment income	346	136	309
Interest expense	(3,768)	(32)	(50)
Other income (expense)	(860)	(445)	188
Income before income taxes	11,692	13,423	11,138
Income tax provision	11	4,078	2,968
Net income	\$ 11,681	\$ 9,345	\$ 8,170
Earnings per share:			
Basic	\$ 0.35	\$ 0.28	\$ 0.25
Diluted	\$ 0.34	\$ 0.28	\$ 0.25
Weighted average shares outstanding:			
Basic	33,572,883	32,881,940	32,497,657
Diluted	34,098,898	33,577,091	33,263,667
Other comprehensive income:			
Unrealized gain (loss) on investments	6	22	(28)
Foreign currency translation loss	(5,189)	(2,815)	(7,743)
Comprehensive income	\$ 6,498	\$ 6,552	\$ 399

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

Table of Contents

REPLIGEN CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share data)	Common Stock		Accumulated Other Additional Comprehensive		Accumulated	Stockholders
	Number of Shares	Amount	in Capital	Income (Loss)	Deficit	Equity
Balance, December 31, 2013	31,195,041	\$ 312	\$ 187,051	\$ 1,911	\$ (105,150)	\$ 84,124
Net income					8,170	8,170
Unrealized loss on investments				(28)		(28)
Foreign currency translation adjustment				(7,743)		(7,743)
Share-based compensation expense			1,766			1,766
Shares issued in acquisition	215,285	2	3,998			4,000
Exercise of stock options and vesting of restricted stock	633,348	7	1,674			1,681
Balance, December 31, 2014	32,774,374	\$ 328	\$ 198,064	\$ (5,773)	\$ (80,887)	\$ 111,732
Net income					9,345	9,345
Unrealized gain on investments				22		22
Foreign currency translation adjustment, net				(2,815)		(2,815)
Share-based compensation expense			3,598			3,598
Exercise of stock options and vesting of restricted stock	174,979	1	865			866
Balance, December 31, 2015	32,949,353	\$ 329	\$ 202,527	\$ (8,566)	\$ (71,542)	\$ 122,748
Net income					11,681	11,681
Unrealized gain on investments				6		6
Shares issued in acquisition	538,700	5	14,130			14,135
Payment of contingent consideration in stock	34,803		875			875
Conversion option of convertible notes, net of issuance costs of \$639,000			18,072			18,072
Foreign currency translation adjustment, net				(5,189)		(5,189)
Share-based compensation expense			4,595			4,595
Exercise of stock options and vesting of restricted stock	321,218	4	1,837			1,841
Balance, December 31, 2016	33,844,074	\$ 338	\$ 242,036	\$ (13,749)	\$ (59,861)	\$ 168,764

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

Table of Contents

REPLIGEN CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net income:	\$ 11,681	\$ 9,345	\$ 8,170
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	5,334	4,594	4,020
Non-cash interest expense	2,274		
Stock-based compensation expense	4,595	3,598	1,766
Deferred tax expense (benefit)	(4,092)	(118)	295
Loss on revaluation of contingent consideration	3,242	4,083	2,072
Gain on sale of fixed assets	(15)		
Loss on disposal of assets	7	1	35
Changes in assets and liabilities:			
Accounts receivable	(3,222)	(3,729)	(1,597)
Royalties and other receivables	(652)	158	6,557
Inventories	(6,163)	(6,149)	(860)
Prepaid expenses and other current assets	612	(277)	(820)
Accounts payable	(1,802)	3,024	2,288
Accrued liabilities	(4,038)	(1,592)	(2,489)
Long-term liabilities	(240)	2,115	(1,036)
Net cash provided by operating activities	7,521	15,053	18,401
Cash flows from investing activities:			
Purchases of marketable securities	(23,700)	(20,168)	(27,508)
Redemptions of marketable securities	23,400	27,587	34,804
Acquisition of assets of Atoll GmbH, net of cash acquired	(8,767)		
Acquisition of assets of TangenX Technology Corporation, net of cash acquired	(35,847)		
Acquisition of assets of Refine Technology, LLC			(21,236)
Increase of restricted cash			(250)
Proceeds from sale of fixed assets	45		
Purchases of property, plant and equipment	(4,325)	(2,628)	(5,602)
Net cash provided by (used in) investing activities	(49,194)	4,791	(19,792)
Cash flows from financing activities:			
Proceeds from issuance of senior convertible notes, net of issuance costs	111,070		
Exercise of stock options	1,841	866	1,680
Payments of contingent consideration	(798)	(99)	

Edgar Filing: REPLIGEN CORP - Form 10-K

Net cash provided by financing activities	112,113	767	1,680
Effect of exchange rate changes on cash and cash equivalents	(2,299)	(1,882)	(4,756)
Net increase (decrease) in cash and cash equivalents	68,141	18,729	(4,467)
Cash and cash equivalents, beginning of period	54,092	35,363	39,830
Cash and cash equivalents, end of period	\$ 122,233	\$ 54,092	\$ 35,363
Supplemental information:			
Income taxes paid	\$ 3,993	\$ 4,948	\$ 2,547
Payment of contingent consideration in common stock	\$ 875	\$	\$
Common stock tendered for acquisition of Atoll GmbH	\$ 14,135	\$	\$

	Years ended December 31,		
	2016	2015	2014
Business Acquisitions:			
Fair value of tangible assets acquired	1,420		1,175
Fair value of accounts receivable	1,267		1,647
Fair value of other assets	183		184
Liabilities assumed	(3,662)		(365)
Fair value of stock issued	(14,135)		(4,000)
Cost in excess of fair value of assets acquired (Goodwill)	46,505		13,199
Acquired identifiable intangible assets	19,829		9,100
Deferred tax liabilities, net	(5,841)		
In-process research and development			1,600
	45,566		22,540
Less accrued contingent consideration	(952)		(1,370)
Working capital adjustment, reflected in other receivables as of December 31, 2014			66
Net cash paid for business acquisitions	44,614		21,236

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

Table of Contents

REPLIGEN CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Business

Repligen Corporation (NASDAQ:RGEN) is a bioprocessing company focused on the development, manufacture and commercialization of highly innovative products used to improve the interconnected phases of the biological drug manufacturing process. The Company's portfolio includes protein products (Protein A affinity ligands, cell culture growth factors), chromatography products (OPUS pre-packed columns, chromatography resins, ELISA kits), and filtration products (XCell ATF Systems, Sius TFF cassettes). The Company's bioprocessing products are sold to major life sciences companies, biopharmaceutical development companies and contract manufacturing organizations worldwide. The Protein A ligands and growth factor products that the Company manufactures are components of chromatography resins and cell culture media, respectively

The Company is the leading manufacturer of Protein A ligands, a critical component of Protein A resins that are the industry standard for downstream separation and purification of monoclonal antibody-based therapeutics. The Company's growth factors are used in upstream processes to accelerate cell growth and productivity in a bioreactor. The Company's innovative line of OPUS chromatography columns, used in downstream processes for bench-scale through clinical-scale purification needs, are delivered pre-packed with its customers' choice of resin and volume. The Company's XCell ATF Systems, available in stainless steel and single-use configurations, continuously eliminate waste from a bioreactor, to accelerate and increase productivity in upstream processes. Single-use Sius TFF cassettes and hardware are used for biologic drug concentration in downstream processes. Repligen's corporate headquarters are in Waltham, Massachusetts (USA) and its manufacturing facilities are located in Waltham, Massachusetts; Shrewsbury, Massachusetts; Lund, Sweden; and Weingarten, Germany.

The Company is subject to a number of risks typically associated with companies in the biotechnology industry. These risks principally include the Company's dependence on key customers, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with the FDA and other governmental regulations and approval requirements, as well as the ability to grow the Company's business and obtain adequate funding to finance this growth.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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.

Significant estimates and assumptions by management affect the Company's revenue recognition for multiple element arrangements, allowance for doubtful accounts, the net realizable value of inventory, estimated fair value of cost method investments, valuations and purchase price allocations related to business combinations, expected future cash flows including growth rates, discount rates, terminal values and other assumptions and estimates used to evaluate the recoverability of long-lived assets, estimated fair values of intangible assets and goodwill, amortization methods and

periods, warranty reserves, certain accrued expenses, stock-based compensation, fair value estimates of contingent consideration, contingent liabilities, tax reserves and recoverability of the Company's net deferred tax assets and related valuation allowance.

Although the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances.

Table of Contents***Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Repligen Sweden AB, Repligen GmbH, TangenX Technology Corporation and Repligen Singapore Pte. Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency

The Company translates the assets and liabilities of its foreign subsidiary at rates in effect at the end of the reporting period. Revenues and expenses are translated at average rates in effect during the reporting period. Translation adjustments, including adjustments related to the Company's intercompany loan with Repligen Sweden and Repligen Sweden's intercompany loan with Repligen GmbH, are remeasured at each period end and included in accumulated other comprehensive income.

Revenue Recognition***Product Sales***

The Company's revenue recognition policy is to recognize revenues from product sales and services in accordance with ASC 605, Revenue Recognition. These standards require that revenues are recognized when persuasive evidence of an arrangement exists, product delivery, including customer acceptance, has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Determination of whether these criteria have been met are based on management's judgments primarily regarding the fixed nature of the fee charged for the product delivered and the collectability of those fees. The Company has a few longstanding customers who comprise the majority of revenue and have excellent payment histories and therefore the Company does not require collateral. The Company has had no significant write-offs of uncollectible invoices in the periods presented. When more than one element such as equipment, consumables, and services are contained in a single arrangement, the Company allocates revenue between the elements based on each element's relative selling price, provided that each element meets the criteria for treatment as a separate unit of accounting. An item is considered a separate unit of accounting if it has value to the customer on a stand-alone basis. The selling price of the undelivered elements is determined by the price charged when the element is sold separately, or in cases when the item is not sold separately, by third-party evidence of selling price or management's best estimate of selling price.

The Company's product revenues are from the sale of bioprocessing products, equipment devices, and related consumables used with these equipment devices to customers in the life science and biopharmaceutical industries. On product sales to end customers, revenue is recognized, net of discounts, when both the title and risk of loss have transferred to the customer, as determined by the shipping terms provided there are no uncertainties regarding acceptance, and all obligations have been completed. Generally, our product arrangements for equipment sales are multiple element arrangements, and may include services, such as installation and training, and multiple products, such as consumables and spare parts. In accordance with ASC 605-25, based on terms and conditions of the product arrangements, the Company believes that these services and undelivered products can be accounted for separately from the delivered product element as the delivered products have value to our customers on a standalone basis. Accordingly, revenue for services not yet performed at the time of product shipment are deferred and recognized as such services are performed. The relative selling price of any undelivered products is also deferred at the time of shipment and recognized as revenue when these products are delivered. For product sales to distributors, the Company recognizes revenue for both equipment and consumables upon delivery to the distributor unless direct shipment to the end user is requested. In this case, revenue is recognized upon delivery to the end user's location. In general, distributors are responsible for shipment to the end customer along with installation, training and acceptance of the

equipment by the end customer. Sales to distributors are not contingent upon resale of the product.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and the related purchase orders identify the terms and conditions

Table of Contents

of each sale and the price of the goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales return, warranty or other issues is largely diminished. Furthermore, there is no customer right of return in our sales agreements. Sales returns and warranty issues are infrequent and have not had a material impact on the Company's financial statements historically.

Shipping and handling fees are recorded as a component of product revenue, with the associated costs recorded as a component of cost of product revenue.

The Scripps Research Institute

On April 6, 2007, the Company entered into an exclusive worldwide commercial license agreement (Scripps License Agreement) with The Scripps Research Institute (Scripps). Pursuant to the License Agreement, the Company obtained a license to use, commercialize and sublicense certain patented technology and improvements thereon, owned or licensed by Scripps, relating to compounds that may have utility in treating Friedreich's ataxia, an inherited neurodegenerative disease.

Pursuant to the Scripps License Agreement, the Company agreed to pay Scripps an initial license fee of \$300,000, certain royalty and sublicense fees and, in the event that the Company achieved specified developmental and commercial milestones, certain additional milestone payments. Total future milestone payments, if all milestones had been achieved, would have been approximately \$4,300,000. In addition, the Company issued Scripps and certain of its designees 87,464 shares of the Company's common stock, which had a value of \$300,000 on the date of issuance.

In connection with the Scripps License Agreement, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. No expense was recorded related to these warrants through December 31, 2014, as the vesting of these warrants was contingent upon certain performance conditions that were not satisfied. During the year ending December 31, 2014, the warrant's seven-year term expired.

As of January 2014, all rights and obligations have been transferred to BioMarin.

Sale of Intellectual Property to BioMarin

In January 2014, the Company entered into an asset purchase agreement (the Asset Purchase Agreement) with BioMarin Pharmaceutical Inc. (BioMarin) to sell Repligen's histone deacetylase inhibitor (HDACi) portfolio. Pursuant to the terms of the Asset Purchase Agreement, the Company received \$2 million from BioMarin as an upfront payment on January 30, 2014 and a \$125,675 payment on September 3, 2014 upon completion of the Technology Transfer. The Company is entitled to receive up to \$160 million in potential future milestone payments for the development, regulatory approval and commercial sale of portfolio compounds included in the agreement. These potential milestone payments are approximately 37% related to clinical development and 63% related to initial commercial sales in specific geographies. In addition, Repligen is eligible to receive royalties on sales of therapeutic products originating from the HDACi portfolio. The royalty rates are tiered and begin in the mid-single-digits for the first HDACi portfolio product and for the first non-HDACi portfolio product with lesser amounts for any backup products developed under the Asset Purchase Agreement. Repligen's receipt of these royalties is subject to customary offsets and deductions. There are no refund provisions in this agreement. The Company recognized \$2.1 million of revenue in the fiscal year ended December 31, 2014 related to the transfer of the HDACi technology under the Asset Purchase Agreement. Any milestones earned upon specified clinical development or commercial sales events or future royalty payments, under the Asset Purchase Agreement will be recognized as revenue when they are earned.

Table of Contents

Activities under this agreement were evaluated in accordance with ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Company identified the following deliverables in the BioMarin agreement:

The assignment by Repligen to BioMarin of the Repligen Technology (Repligen Know-How and Repligen Patents) and the Scripps Agreement (the Transferred Assets);

The transfer of certain notebooks, data, documents, biological materials (if any) and other such documents in our possession that might be useful to further development of the program (the Technology Transfer). Two criteria must be met in order for a deliverable to be considered a separate unit of accounting. The first criterion requires that the delivered item or items have value to the customer on a stand-alone basis. The second criterion, which relates to evaluating a general right of return, is not applicable because such a provision does not exist in the Asset Purchase Agreement. The deliverables outlined above were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in this determination included, among other things, BioMarin's right under the agreement to assign the Transferred Assets, whether any other vendors sell the items separately and if BioMarin could use the delivered item for its intended purpose without the receipt of the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the multiple-element arrangements guidance addresses how to allocate the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price.

The Company identified the arrangement consideration to allocate among the units of accounting as the \$2.0 million non-refundable up-front payment and the \$125,675 payment to be received upon completion of the Technology Transfer. The Company excluded the potential milestone payments provided for in the Asset Purchase Agreement from the arrangement consideration as they were not considered fixed or determinable at the time the Asset Purchase Agreement was signed. Because Repligen had not sold these items on a standalone basis previously, Repligen had no vendor-specific objective evidence of selling price. Furthermore, Repligen did not have detailed third-party evidence of selling price, and as a result we used our best estimate of selling price for each item. In determining these prices, Repligen considered what Repligen would be willing to sell the items for on a standalone basis, what the market would bear for such items and what another party might charge for these items.

The up-front arrangement consideration allocated to the Transferred Assets was recognized upon execution of the Asset Purchase Agreement as the risks and rewards associated with the Transferred Assets transferred at that time. The Company used a discounted cash flow analysis to determine the value of the Transferred Assets. Key assumptions in the analysis included: the estimated market size for a compound targeted at Friedreich's ataxia, the estimated remaining costs of development and time to commercialization, and the probability of successfully developing and commercializing the program. Based on this analysis, the Company allocated \$2,115,000 to the value of the Transferred Assets. However, as the recognized revenue is limited to the non-contingent consideration received, the Company recognized \$2,000,000, the amount of the up-front payment, as revenue in the three months ended March 31, 2014.

The estimated selling price of the Technology Transfer items was approximately \$300,000 resulting in consideration allocation of approximately \$11,000. However, as this item was not delivered prior to March 31, 2014, the Company did not recognize any revenue related to the Technology Transfer in the three months ended March 31, 2014. Repligen

received the payment and recognized \$125,675 of other revenues in September 2014 upon completion of the Technology Transfer.

The Company believes that a change in the key assumptions used to determine best estimate of selling price for each of the deliverables would not have a significant effect on the allocation of arrangement consideration.

Table of Contents

In addition to the \$2.1 million up-front payment, the Company is also eligible to receive up to \$160 million in potential milestone payments from BioMarin comprised of:

Up to \$60 million related to the achievement of specified clinical and regulatory milestone events; and

Up to \$100 million related to the achievement of specified commercial sales events, specifically the first commercial sale in specific territories.

The Company evaluated the potential milestones in accordance with ASC 605-28, which allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This evaluation included an assessment of the risks that must be overcome to achieve the respective milestone as well as whether the achievement of the milestone was due in part to our initial clinical work, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestones that are not considered substantive are recognized as earned if there are no remaining performance obligations or over the remaining period of performance, assuming all other revenue recognition criteria are met.

The Company believes that the \$60 million of specified clinical and regulatory milestone payments are substantive. Therefore, any such milestones achieved will be recognized as revenue when earned.

Any milestones achieved upon specified commercial sales events or future royalty payments are considered contingent revenue under the Asset Purchase Agreement, and will be recognized as revenue when they are earned as there are no undelivered elements remaining and no continuing performance obligations under the arrangement.

Sale of SecreFlo

On December 23, 2014, the Company sold its synthetic human secretin line, SecreFlo, to Innovate Biopharmaceuticals, Inc., or Innovate, pursuant to an asset purchase agreement. Under the terms of the agreement, Repligen received a nominal upfront payment and is eligible to receive royalties on net sales of qualified products for a period beginning on the first commercial sale of such product through the earlier of the expiration of the regulatory exclusivity period for the product or 10 years from its first commercial sale.

Pfizer License Agreement

In December 2012, the Company entered into an exclusive worldwide licensing agreement (the License Agreement) with Pfizer Inc. (Pfizer) to advance the spinal muscular atrophy program, or SMA program. Pursuant to the terms of the License Agreement, the Company received \$5 million from Pfizer as an upfront payment on January 22, 2013, a \$1 million milestone payment on September 4, 2013 and a \$1 million milestone payment on December 28, 2014. On January 26, 2015, Pfizer notified the Company that they were terminating the License Agreement for convenience, effective as of April 26, 2015.

Therapeutics Licensing Agreements

Activities under licensing agreements are evaluated in accordance with ASC 605-25 to determine if they represent a multiple element revenue arrangement. The Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate units of accounting if the following two criteria are met:

The delivered item or items have value to the customer on a stand-alone basis.

If there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within our control.

Table of Contents

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the Company allocates the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price. Revenue is recognized for each unit of accounting when the appropriate revenue recognition criteria are met.

Future milestone payments, if any, under a license agreement will be recognized under the provisions of ASC 605-28, which the Company adopted on January 1, 2011. The Company has elected to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is substantive if:

It can only be achieved based in whole or in part on either (1) the Company's performance or (2) on the occurrence of a specific outcome resulting from the Company's performance;

There is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and

It would result in additional payments being due to the entity.

The commercial milestone payments and royalty payments received under license agreements, if any, will be recognized as revenue when they are earned.

There have been no material changes to the Company's initial estimates related to revenue recognition in any periods presented in the accompanying consolidated financial statements.

Risks and Uncertainties

The Company evaluates its operations periodically to determine if any risks and uncertainties exist that could impact its operations in the near term. The Company does not believe that there are any significant risks which have not already been disclosed in the consolidated financial statements. A loss of certain suppliers could temporarily disrupt operations, although alternate sources of supply exist for these items. The Company has mitigated these risks by working closely with key suppliers, identifying alternate sources and developing contingency plans.

Cash, Cash Equivalents and Marketable Securities

At December 31, 2016, the Company's investments included money market funds and short-term marketable securities. At December 31, 2015, the Company's investments included money market funds as well as short-term and long-term marketable securities. Short-term marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are securities with maturities of greater than one year at the original date of purchase. The average remaining contractual maturity of marketable securities at December 31, 2016 is approximately 3.9 months.

Investments in debt securities consisted of the following at December 31, 2016 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	\$ 807	\$	\$	\$ 807
Corporate and other debt securities	18,745	2	(7)	18,740
Total	\$ 19,552	\$ 2	\$ (7)	\$ 19,547

Table of Contents

There were no long-term marketable securities as of December 31, 2016.

At December 31, 2016, the Company's investments included fifteen debt securities in unrealized loss positions with a total unrealized loss of approximately \$7,000 and a total fair market value of approximately \$9,758,000. All investments with gross unrealized losses have been in unrealized loss positions for less than 12 months. The unrealized losses were caused primarily by current economic and market conditions. There was no change in the credit risk of the securities. The Company does not intend to sell any investments in an unrealized loss position, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases. There were no realized gains or losses on the investments for the fiscal years ended December 31, 2016, 2015 and 2014.

Investments in debt securities consisted of the following at December 31, 2015 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	\$ 7,029	\$	\$ (6)	\$ 7,023
Corporate and other debt securities	10,659	7	(7)	10,659
	17,688	7	(13)	17,682
Long-term marketable securities:				
U.S. Government and agency securities	838		(2)	836
Corporate and other debt securities	800		(3)	797
	1,638		(5)	1,633
Total	\$ 19,326	\$ 7	\$ (18)	\$ 19,315

The contractual maturities of debt securities at December 31, 2016 were as follows (in thousands):

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 19,552	\$ 19,547
	\$ 19,552	\$ 19,547

Fair Value Measurement

In determining the fair value of its assets and liabilities, the Company uses various valuation approaches. The Company employs a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the

inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

Table of Contents

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The Company's fixed income investments are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2016.

The following fair value hierarchy table presents information about each major category of the Company's assets measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for			
	identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	\$ 81,819	\$	\$	\$ 81,819
U.S. Government and agency securities	808			808
Corporate and other debt securities		18,740		18,740
Total	\$ 82,627	\$ 18,740	\$	\$ 101,367
Liabilities:				
Contingent consideration short-term			6,119	6,119
Total	\$	\$	\$ 6,119	\$ 6,119

As of December 31, 2016, the Company has no other assets or liabilities for which fair value measurement is either required or has been elected to be applied, other than the liabilities for contingent consideration recorded in connection with the Refine and Atoll business combinations. The Company entered into a settlement agreement and remitted all remaining contingent consideration to BioFlash Partners, LLC (BioFlash) in the third quarter of 2016. The contingent consideration related to Refine is valued based on actual 2016 XCell ATF sales. The contingent consideration related to Atoll is valued based on achieving 2016 sales growth metrics. These valuations are Level 3

valuations, as the primary inputs are unobservable.

Changes in the fair value of contingent consideration in the year ended December 31, 2016 are primarily attributable to contingent consideration recorded at the date of the Atoll Acquisition in the amount of 836,000 (approximately \$928,000), an increase to the expected 2016 Refine milestone payment of \$3,048,000, an increase to the expected 2016 Atoll milestone payment of 164,000 (approximately \$182,000), a \$4,350,000 milestone payment to Refine, a \$130,000 minimum royalty payment made to BioFlash, and a final settlement payment of \$500,000 to BioFlash, of which \$301,000 was previously accrued as contingent consideration and \$199,000 was recorded to selling, general and administrative expenses.

Table of Contents

The following table provides a rollforward of the fair value of contingent consideration (in thousands):

Balance at December 31, 2015	\$ 6,788
Additions	928
Payments	(4,781)
Foreign currency translation adjustments	(58)
Changes in fair value	3,242
Balance at December 31, 2016	\$ 6,119

The following table provides quantitative information associated with the fair value measurement of the Company's contingent consideration related to Refine using Level 3 inputs (in thousands):

	Fixed Earn-out	Variable Earn-out	Accrued Balance
2016	4,250	1,300	5,067

The significant unobservable input used in the fair value measurement of Refine's contingent consideration is actual 2016 revenues. The fair value of the 2016 contingent payment was increased by \$3,048,000 during the year as forecasted revenues increased.

As of December 31, 2016, the fair value of Atoll's contingent consideration is 1,000,000 (approximately \$1,052,000). The significant unobservable input used in the fair value measurement was actual 2016 revenue growth compared to 2015. The initial valuation of contingent consideration upon the Atoll Acquisition in April 2016 resulted in a fair value of 836,000 (approximately \$928,000). The estimated fair value of the contingent payment was increased by 164,000 (approximately \$182,000) based on Atoll achieving the targeted revenue growth in 2016.

In May 2016, the Company issued \$115 million aggregate principal amount of the Notes due June 1, 2021. Interest is payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2016. As of December 31, 2016, the carrying value of the Notes was \$95.3 million, net of unamortized discount, and the fair value of the Notes was approximately \$135.6 million. The fair value of the Notes was determined based on the most recent trade activity of the Notes as of December 31, 2016. The Notes are discussed in more detail in Note 10, Convertible Senior Notes.

There were no remeasurements to fair value during the year ended December 31, 2016 of financial assets and liabilities that are not measured at fair value on a recurring basis.

Inventories

Inventories relate to the Company's bioprocessing business. The Company values inventory at cost or, if lower, fair market value, using the first-in, first-out method. The Company reviews its inventories at least quarterly and records a provision for excess and obsolete inventory based on its estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in-process and finished products. Expected sales volumes are determined based on supply forecasts provided by key customers for the next 3 to 12 months. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and

inventory in excess of expected requirements to cost of product revenue. Manufacturing of bioprocessing finished goods is done to order and tested for quality specifications prior to shipment. Reserves for excess and obsolete inventory were \$435,000 and \$343,000 as of December 31, 2016 and 2015, respectively. The reserve balance at December 31, 2016 and 2015 is sufficient to cover excess or obsolete inventory for the consolidated Company.

Table of Contents

A change in the estimated timing or amount of demand for the Company's products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of inventory and reported operating results. During all periods presented in the accompanying financial statements, there have been no material adjustments related to a revised estimate of inventory valuations.

Work-in-process and finished products inventories consist of material, labor, outside processing costs and manufacturing overhead.

Inventories consist of the following (in thousands):

	December 31, 2016	December 31, 2015
Raw Materials	\$ 14,954	\$ 10,671
Work-in-process	2,789	1,586
Finished products	6,953	5,741
Total	\$ 24,696	\$ 17,998

Accrued Liabilities

The Company estimates accrued liabilities by identifying services performed on the Company's behalf, estimating the level of service performed and determining the associated cost incurred for such service as of each balance sheet date. For example, the Company would accrue for professional and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred or tracking costs incurred by service providers under fixed fee arrangements.

The Company has processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that the Company does not identify certain costs that have begun to be incurred or the Company under or over-estimates the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services often require the exercise of judgment. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

Income Taxes

Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly

basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Table of Contents***Property, Plant & Equipment***

Property, Plant & Equipment is recorded at cost less allowances for depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the asset as follows:

Classification	Estimated Useful Life
Leasehold improvements	Shorter of the term of the lease or estimated useful life
Equipment	Three to eight years
Furniture and fixtures	Three to eight years

Earnings Per Share

Basic earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common share equivalents consist of restricted stock awards and the incremental common shares issuable upon the exercise of stock options and warrants. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are included in the calculation of basic and diluted earnings per share.

A reconciliation of basic and diluted share amounts is as follows:

	Years ended December 31,		
	2016	2015	2014
Numerator:			
Net income	\$ 11,681,000	\$ 9,345,000	\$ 8,170,000
Denominator:			
Basic weighted average common shares outstanding	33,572,883	32,881,940	32,497,657
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards	526,015	695,151	766,010
Diluted weighted average common shares outstanding	34,098,898	33,577,091	33,263,667
Basic net income per common share	\$ 0.35	\$ 0.28	\$ 0.25
Diluted net income per common share	\$ 0.34	\$ 0.28	\$ 0.25

At December 31, 2016, there were outstanding options to purchase 1,236,586 shares of the Company's common stock at a weighted average exercise price of \$12.05 per share. For the fiscal year ended December 31, 2016, 381,686 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive. As provided by the terms of the indenture underlying the senior convertible notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The

Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. The Company applies the provisions of ASC 260, *Earnings Per Share*, Subsection 10-45-44, to determine the diluted weighted average shares outstanding as it relates to the conversion spread on its convertible notes. Accordingly, the par value of the Convertible Notes will not be included in the calculation of diluted income per share, but the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method. The dilutive impact of the Company's convertible notes is based on the difference between the Company's current period average stock price and the conversion price of the convertible notes, provided there is a premium. Pursuant to this accounting standard, there is no dilution from the accreted principal of the Convertible Notes.

At December 31, 2015, there were outstanding options to purchase 1,240,935 shares of the Company's common stock at a weighted average exercise price of \$10.44 per share. For the fiscal year ended December 31, 2015,

Table of Contents

196,209 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At December 31, 2014, there were outstanding options to purchase 1,225,117 shares of the Company's common stock at a weighted average exercise price of \$8.31 per share. For the fiscal year ended December 31, 2014, 307,475 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

Segment Reporting

The Company views its operations, makes decisions regarding how to allocate resources and manages its business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

The following table represents product revenues by product line (in thousands):

	December 31, 2016	December 31, 2015	December 31, 2014
Protein products	\$ 54,716	\$ 52,938	\$ 43,674
Filtration products	19,774 ⁽²⁾	15,676	6,739 ⁽¹⁾
Chromatography products	29,520 ⁽³⁾	14,613	9,811
Other	431	310	207
Total product revenues	\$ 104,441	\$ 83,537	\$ 60,431

(1) 2014 revenue for filtration products includes revenue related to the Refine Acquisition from June 2, 2014 through December 31, 2014.

(2) 2016 revenue for filtration products includes revenue related to the TangenX Acquisition from December 14, 2016 through December 31, 2016.

(3) 2016 revenue for chromatography products includes revenue related to the Atoll Acquisition from April 1, 2016 through December 31, 2016.

Revenue from protein products includes the Company's Protein A ligands and cell culture growth factors. Revenue from filtration products includes the Company's XCell ATF Systems and consumables and Sius filtration products. Revenue from chromatography products includes the Company's OPUS and OPUS PD chromatography columns, chromatography resins and ELISA test kits. Other revenue primarily consists of freight revenues.

The following table represents the Company's total revenue by geographic area (based on the location of the customer):

	Years ended December 31,		
	2016	2015	2014

Edgar Filing: REPLIGEN CORP - Form 10-K

Sweden	29%	37%	38%
United States	39%	28%	33%
United Kingdom	7%	17%	20%
Other	25%	18%	9%
Total	100%	100%	100%

Table of Contents

The following table represents the Company's total assets by geographic area (in thousands):

	December 31, 2016	December 31, 2015
United States	\$ 209,728	\$ 91,881
Sweden	53,089	54,313
Germany	26,056	
Singapore	40	43
Total	\$ 288,913	\$ 146,237

The following table represents the Company's long-lived assets by geographic area (in thousands):

	December 31, 2016	December 31, 2015
United States	\$ 77,039	\$ 36,350
Sweden	5,180	6,635
Germany	22,541	
Total	\$ 104,760	\$ 42,985

There were no long-lived assets in Singapore as of December 31, 2016 and 2015.

Concentrations of Credit Risk and Significant Customers

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and accounts receivable. Per the Company's investment policy, cash equivalents and marketable securities are invested in financial instruments with high credit ratings and credit exposure to any one issue, issuer (with the exception of U.S. treasury obligations) and type of instrument is limited. At December 31, 2016 and 2015, the Company had no investments associated with foreign exchange contracts, options contracts or other foreign hedging arrangements.

Concentration of credit risk with respect to accounts receivable is limited to customers to whom the Company makes significant sales. While a reserve for the potential write-off of accounts receivable is maintained, the Company has not written off any significant accounts to date. To control credit risk, the Company performs regular credit evaluations of its customers' financial condition.

Revenue from significant customers as a percentage of the Company's total revenue is as follows:

	Years ended December 31,		
	2016	2015	2014
GE Healthcare	29%	37%	38%

MilliporeSigma

28%

29%

33%

Significant accounts receivable balances as a percentage of the Company's total trade accounts receivable and royalties and other receivable balances are as follows:

	December 31, 2016	December 31, 2015
GE Healthcare	26%	13%
MilliporeSigma	8%	32%
Bioprocessing Customer C	1%	21%

Table of Contents***Goodwill, Other Intangible Assets and Acquisitions******Acquisitions***

Total consideration transferred for acquisitions is allocated to the assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Any excess of the fair value of the net tangible and intangible assets acquired over the purchase price is recognized in the statement of operations. The fair value of contingent consideration includes estimates and judgments made by management regarding the probability that future contingent payments will be made and the extent of royalties to be earned in excess of the defined minimum royalties. Management updates these estimates and the related fair value of contingent consideration at each reporting period. Changes in the fair value of contingent consideration are recorded in the consolidated statements of operations.

The Company uses the income approach to determine the fair value of certain identifiable intangible assets including customer relationships and developed technology. This approach determines fair value by estimating after-tax cash flows attributable to these assets over their respective useful lives and then discounting these after-tax cash flows back to a present value. The Company bases its assumptions on estimates of future cash flows, expected growth rates, expected trends in technology, etc. Discount rates used to arrive at a present value as of the date of acquisition are based on the time value of money and certain industry-specific risk factors.

Goodwill

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at December 31, 2016. There were no goodwill impairment charges during the fiscal years ended December 31, 2016, 2015 and 2014.

Intangible Assets

Intangible assets are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within cost of product revenue and selling, general and administrative expense in the statements of operations. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for our products or changes in the size of the market for our products. If impairment indicators are present, the Company determines whether the underlying intangible asset is recoverable through estimated future undiscounted cash flows. If the asset is not found to be recoverable, it is written down to the estimated fair value of the asset based on the sum of the future discounted cash flows expected to result from the use and disposition of the asset. If the estimate of an intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at December 31, 2016.

Intangible assets consisted of the following at December 31, 2016 (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 12,911	\$ (1,468)	17
Patents	240	(208)	8
Customer relationships	22,555	(4,995)	11
Trademark/ tradename	711		
Other intangibles	84	(24)	2
Total intangible assets	\$ 36,501	\$ (6,695)	13

Table of Contents

Intangible assets consisted of the following at December 31, 2015 (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 3,295	\$ (1,026)	12
In process research and development	1,600		
Patents	240	(177)	8
Customer relationships	11,805	(3,682)	9
Trademark/ tradename	700		
Total intangible assets	\$ 17,640	\$ (4,885)	10

Amortization expense for amortized intangible assets was approximately \$2,052,000, \$1,600,000 and \$1,425,000 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, the Company expects to record the approximate amortization expense (in thousands):

Year Ending	Amortization Expense
December 31, 2017	\$ 2,845
December 31, 2018	2,657
December 31, 2019	2,624
December 31, 2020	2,311
December 31, 2021	2,022

Stock Based Compensation

The Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognizes it as expense over the employee's requisite service period on a straight-line basis. The Company records the expense for share-based awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates whether the achievement of a performance-based milestone is probable as of the reporting date. The Company has no awards that are subject to market conditions. The Company recognizes stock-based compensation expense based upon options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted by an amount of estimated forfeitures.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The following assumptions are used in calculating the fair value of share-based awards:

Expected term The expected term of options granted represents the period of time for which the options are expected to be outstanding. For purposes of estimating the expected term, the Company has aggregated all individual option awards into one group as the Company does not expect substantial differences in exercise behavior among its employees.

Expected volatility The expected volatility is a measure of the amount by which the Company's stock price is expected to fluctuate during the expected term of options granted. The Company determines the expected volatility based primarily upon the historical volatility of the Company's common stock over a period commensurate with the option's expected term.

Risk-free interest rate The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date.

Expected dividend yield The Company has never declared or paid any cash dividends on any of its capital stock and does not expect to do so in the foreseeable future. Accordingly, the Company uses an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

Table of Contents

Estimated forfeiture rates The Company has applied, based on an analysis of its historical forfeitures, annual forfeiture rates of 8% for awards granted to non-executive level employees, 3% for awards granted to executive level employees and 0% for awards granted to non-employee members of the Board of Directors to all unvested stock options as of December 31, 2014. The Company reevaluates this analysis periodically and adjusts these estimated forfeiture rates as necessary. Ultimately, the Company will only recognize expense for those shares that vest.

Recently Issued Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-03, Interest Imputation of Interest (Topic 835): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability. The ASU became effective for public entities for fiscal years beginning after December 15, 2015. The Company applied the amended presentation requirements in conjunction with its issuance of convertible senior notes in the second quarter of 2016.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The adoption of this ASU will include updates as provided under ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date ; ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) ; ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing ; and ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. The Company intends to adopt the provisions of Topic 606 using the modified retrospective method effective January 1, 2018, and it has formed a project team to assess and implement this new standard. The Company has not made a determination on the impact to its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory (ASU 2015-11). ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value, and options that currently exist for market value be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective prospectively for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The Company does not expect the adoption of ASU 2015-11 to have a material impact on its consolidated financial statements, as it currently does not measure any inventory at market value.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (ASU 2016-02). ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability for most leases. Extensive quantitative and qualitative disclosures, including significant judgments made by management, will be required to provide greater insight into the extent of revenue and expense recognized and expected to be recognized from existing contracts. The accounting applied by a lessor is largely unchanged from that applied under the current standard. The standard must be adopted using a modified retrospective transition approach and provides for certain practical expedients. The ASU is effective for public entities for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has not yet completed its assessment of the impact of the new standard on its consolidated financial statements; however, the Company anticipates that it will recognize right-of-use assets and lease liabilities for leases on its current facilities.

In March 2016, the FASB issued ASU No. 2016-09, Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting , which aims to simplify several aspects of the

Table of Contents

accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification of certain items on the statement of cash flows and accounting for forfeitures. The ASU is effective for public entities for fiscal years beginning after December 15, 2016, with early adoption permitted. The Company intends to adopt the provisions of this ASU as of January 1, 2017; the Company does not expect the impact of this new standard to have a material effect on its 2017 consolidated financial statements, as the Company will not be required to change its accounting treatment of forfeitures, classification of current awards or cash flow disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 203): Classification of Certain Cash Receipts and Cash Payments*. ASU No. 2016-15 addresses eight specific cash flow issues and clarifies their presentation and classification in the Statement of Cash Flows. ASU No. 2016-15 is effective for fiscal years beginning after December 15, 2017 and is to be applied retrospectively with early adoption permitted. The Company currently classifies payments up to the amount of its contingent consideration liability recognized at the date of its acquisitions as financing activities, with additional payments classified as operating activities. As a result, the Company does not expect the adoption of ASU 2016-15 to have a material impact on its consolidated financial statements.

3. Acquisitions, Goodwill and Other Intangible Assets

Acquisitions

Atoll GmbH

On April 1, 2016, the Company's subsidiary Repligen Sweden acquired Atoll GmbH (*Atoll*) from UV-Cap GmbH & Co. KG (the *Seller*) pursuant to a Share Purchase Agreement (the *Share Purchase Agreement*), dated as of March 31, 2016 (such acquisition, the *Atoll Acquisition*), by and among Repligen Sweden, the Seller, and the Company, in its capacity as guarantor of the obligations of Repligen Sweden under the Share Purchase Agreement. The *Atoll Acquisition* was subject to certain closing conditions that did not occur until April 1, 2016. Payment for the *Atoll Acquisition* was denominated in Euros but is reflected here in U.S. dollars for presentation purposes.

In connection with the *Atoll Acquisition*, the Company issued and contributed 538,700 shares of the Company's common stock, par value of \$0.01 per share valued at \$14.1 million (the *Stock Consideration*) to Repligen Sweden through a transfer by the Company on behalf of Repligen Sweden to fulfill Repligen Sweden's obligation to deliver the *Stock Consideration* under the *Share Purchase Agreement*. The issuance of the *Stock Consideration* was not registered under the Securities Act of 1933, as amended (the *Securities Act*), in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act. The *Stock Consideration* was based on the fair value of the Company's common stock on April 1, 2016.

This acquisition strengthened Repligen's bioprocessing business by adding a complementary extension to an existing product line while expanding its direct sales presence worldwide. On September 20, 2016, *Atoll* changed its name to *Repligen GmbH*.

The *Atoll Acquisition* was accounted for as a purchase of a business under ASC 805, *Business Combinations*. The total purchase price of the *Atoll Acquisition* was \$25.3 million, consisting of an upfront cash payment of \$10.2 million, less \$74,000 as a result of the final determination of working capital, issuance of the *Stock Consideration*, and a future potential milestone payment of \$1.1 million if specific revenue growth targets are met for 2016. The \$1.1 million potential contingent consideration had an initial probability weighted fair value at the time of the closing of

the Atoll Acquisition of approximately \$952,000.

Consideration Transferred

The Company accounted for the Atoll Acquisition as the purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of Atoll were recorded as of the acquisition date, at their respective

Table of Contents

fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was approximately \$25.3 million.

The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

The total consideration transferred follows (in thousands):

Cash consideration, less \$74 of working capital adjustments	\$ 10,176
Value of common stock issued	14,138
Estimated fair value of contingent consideration	952
 Total consideration transferred	 \$ 25,266

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future milestone and settlement payments to be made to the Seller. The Company could make a contingent consideration payment of \$1.1 million if specific revenue growth targets are met for 2016. The liability for contingent consideration is included in current liabilities on the consolidated balance sheets. Because the contingent consideration relates only to 2016 sales growth, no further remeasurement of this liability is required as of December 31, 2016. See Note 9 Accrued Liabilities for further details.

Acquisition related costs are not included as a component of consideration transferred, but are expensed in the periods in which the costs are incurred. The Company incurred \$1,279,000 in transaction costs related to the Atoll Acquisition. The transaction costs are included in selling, general and administrative expenses in the consolidated statements of operations.

Fair Value of Net Assets Acquired

The allocation of purchase price was based on the fair value of assets acquired and liabilities assumed as of April 1, 2016. The components and allocation of the purchase price consists of the following amounts (in thousands):

Cash and cash equivalents	\$ 1,409
Accounts receivable	697
Inventory	155
Other current assets	169
Fixed assets	114
Customer relationships	5,318
Developed technology	2,175
Non-competition agreements	57
Trademark and trade name	11
Deferred tax assets	885
Accounts payable and other liabilities assumed	(599)

Edgar Filing: REPLIGEN CORP - Form 10-K

Deferred tax liabilities	(2,202)
Goodwill	17,077
Net assets acquired	\$ 25,266

Of the consideration paid, \$5.3 million represents the fair value of customer relationships that will be amortized over the determined useful life of 13 years and \$2.2 million represents the fair value of developed technology

Table of Contents

that will be amortized over a determined useful life of 14 years. \$57,000 represents the fair value of non-competition agreements and \$11,000 represents the fair value of trademarks and trade names that will be amortized over a determined useful life of 2 years. The aforementioned intangible assets will be amortized on a straight-line basis.

The goodwill of \$17.1 million represents future economic benefits expected to arise from synergies from combining operations, utilizing the Company's existing sales infrastructure to increase market presence and the extension of existing customer relationships.

TangenX Technology Corporation

On December 14, 2016, the Company acquired TangenX Technology Corporation (TangenX), pursuant to the terms of the Share Purchase Agreement, dated as of December 14, 2016 (the Share Purchase Agreement), by and among the Company and TangenX (such acquisition, the TangenX Acquisition). The Company acquired all outstanding shares and the business of TangenX, including TangenX's innovative single-use Sius line of tangential flow filtration (TFF) cassettes and hardware used in downstream biopharmaceutical manufacturing processes.

Sius TFF is used in the filtration of biological drugs, complimenting Repligen's OPUS line of pre-packed chromatography columns used in downstream purification. Pursuant to the Share Purchase Agreement, Repligen acquired all of the outstanding shares of TangenX, as well as certain assets and liabilities.

The TangenX Acquisition was accounted for as a purchase of a business under ASC 805, Business Combinations. The total purchase price of the TangenX Acquisition was \$37.1 million in cash.

Consideration Transferred

The Company accounted for the TangenX Acquisition as the purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of TangenX were recorded as of the acquisition date, at their respective fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was approximately \$37.1 million.

The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

The total consideration transferred follows (in thousands):

Cash consideration	\$ 37,532
Less: working capital adjustment	(467)
Net assets acquired	\$ 37,065

Acquisition related costs are not included as a component of consideration transferred, but are expensed in the periods in which the costs are incurred. The Company incurred \$935,000 in transaction costs related to the TangenX Acquisition. The transaction costs are included in 2016 selling, general and administrative expenses in the consolidated statements of operations.

Table of Contents*Fair Value of Net Assets Acquired*

The allocation of purchase price was based on the fair value of assets acquired and liabilities assumed as of December 14, 2016. The components and allocation of the purchase price consists of the following amounts (in thousands):

Cash and cash equivalents	\$ 1,218
Accounts receivable	459
Other receivables	111
Inventory	936
Other current assets	50
Fixed assets, net	215
Customer relationships	6,192
Developed technology	6,044
Non-competition agreements	21
Trademark and trade name	11
Accounts payable and other liabilities assumed	(3,083)
Deferred tax liabilities	(4,525)
Goodwill	29,416
Net assets acquired	\$ 37,065

The allocation of the purchase price related to this acquisition is preliminary and is based on management's judgments after evaluating several factors, including preliminary valuation assessments of tangible and intangible assets, and preliminary estimates of the fair value of liabilities assumed. The final allocation of the purchase price to the assets acquired and liabilities assumed will be completed when the final valuation assessments of tangible and intangible assets are completed and estimates of the fair value of liabilities assumed are finalized.

Of the consideration paid, \$6.2 million represents the fair value of customer relationships that will be amortized over the determined useful life of 13 years and \$6.0 million represents the fair value of developed technology that will be amortized over a determined useful life of 20 years. \$21,000 represents the fair value of non-competition agreements that will be amortized over a determined life of 5 years. \$11,000 represents the fair value of trademarks and trade names that will be amortized over a determined useful life of 2 years. The aforementioned intangible assets will be amortized on a straight-line basis.

The goodwill of \$29.4 million represents future economic benefits expected to arise from synergies from combining operations and the extension of existing customer relationships.

Revenue, Net Income and Pro Forma Presentation

The Company recorded revenue from TangenX of approximately \$119,000 from December 15, 2016 through December 31, 2016. The Company has included the operating results of TangenX in its consolidated statements of operations since the December 15, 2016 acquisition date. The following table presents unaudited supplemental pro forma information as if the TangenX Acquisition had occurred as of January 1, 2015 (in thousands, except per share data):

	December 31, 2016	December 31, 2015
Total revenue	110,228	88,437
Net income	5,744	13,208
Earnings per share:		
Basic	\$ 0.17	\$ 0.40
Diluted	\$ 0.17	\$ 0.39

Table of Contents

The unaudited pro forma information for the year ended December 31, 2016 and 2015 was calculated after applying the Company's accounting policies and the impact of acquisition date fair value adjustments. Unaudited pro forma net income for year ended December 31, 2016 was adjusted to exclude acquisition-related transaction costs, nonrecurring expenses related to the fair value adjustments associated with the acquisition, and income tax benefits resulting from the acquisition. In addition, the unaudited pro forma net income for the year ended December 31, 2016 was adjusted to include incremental amortization of intangible assets. These items have been factored to the unaudited pro forma net income for the year ended December 31, 2016. The unaudited pro forma net income for the year ended December 31, 2015 was adjusted to include these acquisition-related transaction costs, expenses related to the fair value adjustments, amortization of intangible assets, and income tax benefits resulting from the acquisition.

These pro forma condensed consolidated financial results have been prepared for comparative purposes only and include certain adjustments to reflect the pro forma results of operations as if the acquisition had occurred as of the beginning of the periods presented, such as fair value adjustments to inventory and increased amortization for the fair value of acquired intangible assets. The pro forma information does not reflect the effect of costs or synergies that would have been expected to result from the integration of the acquisition. The pro forma information does not purport to be indicative of the results of operations that actually would have resulted had the combination occurred at the beginning of each period presented, or of future results of the consolidated entities.

Refine Technology, LLC

On June 2, 2014, pursuant to the terms of the Asset Purchase Agreement, dated as of June 2, 2014 (the "Asset Purchase Agreement"), by and among the Company, Refine Technology, LLC (a limited liability company formed under the laws of the State of New Jersey) ("Refine"), the members of Refine Technology, LLC, Jerry Shevitz, Refine Technology Sales LLC (a limited liability company formed under the laws of the State of New Jersey) and Refine Technology Sales Asia PTE. LTD. (a limited private company organized in the Republic of Singapore), the Company acquired the business of Refine, including Refine's Alternating Tangential Flow ("ATF") System, a market-leading device used to significantly increase product yield during the fermentation step of the biologic drug manufacturing process (the "Refine Business" and the acquisition of the Refine Business, the "Refine Acquisition"). Pursuant to the Asset Purchase Agreement, Repligen purchased all of the assets related to Refine's ATF system and assumed certain specified liabilities related to Refine's ATF system. This acquisition strengthened Repligen's bioprocessing business by adding a complementary product line while expanding its direct sales presence worldwide. The transaction was accounted for as a purchase of a business under ASC 805, Business Combinations. The terms of the acquisition included an upfront cash payment of approximately \$21,236,000 less approximately \$66,000 as a result of the final determination of working capital, issuance of 215,285 shares of the Company's \$0.01 par value common stock valued at \$4,000,000, future potential milestone payments totaling up to \$10,900,000 if specific sales targets are met for the years 2014, 2015 and 2016, and future potential payments up to \$7,500,000 out of any amounts that might be received in connection with the resolution, withdrawal or settlement of certain patent disputes with a third party. The \$10,900,000 potential contingent consideration had an initial probability weighted fair value at acquisition of \$1,370,000. The \$7,500,000 potential contingent consideration had only a nominal probability weighted fair value at acquisition. In addition to the initial consideration, approximately \$774,000 was paid to Refine following the acquisition under a Transition Services Agreement under which certain employees of Refine provided services to the Company in support of the Refine Business. As these payments were contingent upon future service, they were recognized as operating expense, ratably while the services were provided.

Consideration Transferred

The Company accounted for the Refine Acquisition as the purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of the Refine Business were recorded as of the acquisition date, at their

respective fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was approximately \$26,540,000.

Table of Contents

The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

The total consideration transferred follows (in thousands):

Cash consideration, less \$66 of working capital adjustments	\$ 21,170
Value of common stock issued	4,000
Estimated fair value of contingent consideration	1,370
 Total consideration transferred	 \$ 26,540

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future milestone and settlement payments to be made to the seller. The Company paid \$4,350,000 to Refine in 2016 for achievements of sales targets met in 2015 and \$1,000,000 to Refine in 2015 for achievements of sales targets met in 2014, and could make payments of up to \$9,900,000 if specific sales targets are met in 2015 and 2016. In addition, the Company could pay Refine up to \$7,500,000 out of any receipts that might be received in connection with the resolution, withdrawal or settlement of certain patent disputes with a third party. The liability for contingent consideration is included in current and long-term liabilities on the consolidated balance sheets and will be remeasured at each reporting period until the contingency is resolved. Please see Note 9 Accrued Liabilities for further details.

Acquisition related costs are not included as a component of consideration transferred, but are expensed in the periods in which the costs are incurred. The Company incurred approximately \$818,000 in transaction costs related to the Refine Acquisition. The transaction costs are included in 2014 selling, general and administrative expenses in the consolidated statements of operations.

Fair Value of Net Assets Acquired

The allocation of purchase price was based on the fair value of assets acquired and liabilities assumed as of June 2, 2014. The components and allocation of the purchase price consists of the following amounts (in thousands):

Accounts receivable	\$ 1,647
Inventory	1,003
Other current assets	184
Fixed assets	85
Customer relationships	6,400
Developed technology	2,000
In process research and development (IPR&D)	1,600
Trademark and trade name	700
Accounts payable and other liabilities assumed	(431)
Goodwill	13,352

Net assets acquired	\$ 26,540
---------------------	-----------

Of the consideration paid, \$6,400,000 represents the fair value of customer relationships that will be amortized over the determined useful life of 10 years and \$2,000,000 represents the fair value of developed technology that will be amortized over a determined useful life of 15 years. \$700,000 represents the fair value of trademark and trade name determined to have an indefinite useful life and is not subject to amortization.

Table of Contents

\$1,600,000 of the consideration paid represents the fair value of acquired IPR&D projects that are considered identifiable assets as of the acquisition date. Those assets are considered indefinite lived until efforts associated with the projects are completed or abandoned. The major acquired technology IPR&D relates to the development of a single use system product extension to the XCell ATF System business. The Company launched its XCell ATF single-use product line in the third quarter of 2016. The Company performed an assessment of the in-process research and development assets and their estimated useful lives to determine if any circumstances exist that would result in an impairment. The Company has determined that the fair value of these intangible assets exceeds their carrying values and are therefore not impaired; accordingly, the Company reclassified in-process research and development intangible assets to developed technology and began to amortize these intangible assets in the third quarter of 2016.

The excess of the purchase price over the fair value of tangible and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. This goodwill is deductible for tax purposes over the next 15 years.

Revenue, Net Income and Pro Forma Presentation

The Company recorded revenue from Refine of \$6,793,000 from June 2, 2014 through December 31, 2014. The segregation of Refine's net income is administratively impractical, as the Company operates as one operating segment and does not separately allocate expenses. The Company has included the operating results of Refine in its fiscal 2016, 2015 and 2014 consolidated statements of operations since the June 2, 2014 acquisition date. The following table presents 2014 unaudited supplemental pro forma information as if the Refine Acquisition had occurred as of January 1, 2014 (in thousands, except per share data):

	December 31, 2014
Total revenue	\$ 67,330
Net income	9,493
Earnings per share:	
Basic	\$ 0.28
Diluted	\$ 0.27

The unaudited pro forma information for the year-ended December 31, 2014 was calculated after applying the Company's accounting policies and the impact of acquisition date fair value adjustments. Unaudited pro forma net income for year-ended December 31, 2014 was adjusted to exclude acquisition-related transaction costs. In addition, the unaudited pro forma net income for the year-ended December 31, 2014 was adjusted to exclude nonrecurring expenses related to the fair value adjustments associated with the acquisition of Refine that were recorded by the Company.

These pro forma condensed consolidated financial results have been prepared for comparative purposes only and include certain adjustments to reflect the pro forma results of operations as if the acquisition had occurred as of the beginning of the periods presented, such as fair value adjustments to inventory and increased amortization for the fair value of acquired intangible assets. The pro forma information does not reflect the effect of costs or synergies that would have been expected to result from the integration of the acquisition. The pro forma information does not purport to be indicative of the results of operations that actually would have resulted had the combination occurred at the beginning of each period presented, or of future results of the consolidated entities.

Table of Contents**Goodwill**

The changes in the carrying value of goodwill for the year ended December 31, 2016 is as follows (in thousands):

Balance at December 31, 2015	\$ 14,346
Goodwill arising from the Atoll Acquisition	17,077
Goodwill arising from the TangenX Acquisition	29,416
Foreign currency adjustments on goodwill from the Atoll Acquisition	(1,291)
Balance at December 31, 2016	\$ 59,548

Other Intangible Assets

Intangible assets, except for the ATF tradename, are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within selling, general and administrative expense in the Company's statements of comprehensive income. The ATF tradename are not amortized. The Company reviews its indefinite-lived intangible assets not subject to amortization to determine if adverse conditions exist or a change in circumstances exists that would indicate an impairment. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for our products or changes in the size of the market for our products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset. If the estimate of an intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at December 31, 2016.

4. Income Taxes

Income tax data for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	December 31, 2016	December 31, 2015	December 31, 2014
The components of income from operations before income taxes are as follows:			
Domestic	\$ (4,882)	\$ (2,490)	\$ (1,152)
Foreign	16,574	15,913	12,290
Total	\$ 11,692	\$ 13,423	\$ 11,138
The current and deferred components of the provision for income taxes on operations are as follows:			
Current	\$ 4,077	\$ 3,745	\$ 2,480

Edgar Filing: REPLIGEN CORP - Form 10-K

Deferred		(4,066)		333		488
Total	\$	11	\$	4,078	\$	2,968
The jurisdictional components of the provision for income taxes on operations are as follows:						
Federal	\$	(3,809)	\$	295	\$	214
State		(207)		276		(67)
Foreign		4,027		3,507		2,821
Total	\$	11	\$	4,078	\$	2,968

Table of Contents

At December 31, 2016, the Company had net operating loss carryforwards of approximately \$48,550,000 in the U.S., net operating loss carryforwards of approximately 2,287,000 (approximately \$2,407,000) in Germany, federal business tax credit carryforwards of \$1,745,000 and state business tax credit carryforwards of approximately \$442,000 available to reduce future domestic income taxes, if any. The net operating loss and business tax credits carryforwards will continue to expire at various dates through December 2036. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

	December 31, 2016	December 31, 2015
Deferred tax assets:		
Temporary timing differences:		
Stock compensation	\$ 1,722	\$ 1,079
Contingent consideration	3,333	2,126
Other	1,895	1,150
Total temporary timing differences	6,950	4,355
Net operating loss carryforwards	12,284	12,389
Tax business credits carryforwards	2,036	1,820
Total deferred tax assets	21,270	18,564
Valuation allowance	(9,979)	(18,514)
Net deferred tax assets	\$ 11,291	\$ 50
Deferred tax liabilities:		
Goodwill and intangible assets	\$ (7,346)	\$ (501)
Conversion option on convertible notes	(6,048)	
Total deferred tax liabilities	\$ (13,394)	\$ (501)
Net deferred tax liabilities	\$ (2,103)	\$ (451)

The net change in the total valuation allowance was a decrease of \$8,535,000 in the year ended December 31, 2016. U.S. jurisdiction deferred tax assets, previously subject to a valuation allowance, were initially recognized in 2016 due to the creation of a \$4,525,000 deferred tax liability resulting from the TangenX Acquisition and a \$6,514,000 deferred tax liability resulting from the issuance of the Company's convertible senior notes, partially offset by increases in deferred tax assets derived from temporary timing differences. The \$6,514,000 decrease to the valuation allowance was recorded to stockholder's equity. The cumulative U.S. federal net operating loss includes \$14,177,000 related to excess tax deductions from share-based payments, the tax benefit of which will be recognized as an increase to additional paid in capital when the deduction reduces current taxes payable. The valuation allowance increased by \$1,216,000 for the year ended December 31, 2015 and increased by \$727,000 for the year ended December 31, 2014. As of December 31, 2016, the Company continues to believe that realization of the remainder of its deferred tax assets beyond December 31, 2016 is not more likely than not, and the Company continues to maintain its valuation allowance against its remaining U.S. deferred tax assets with the exception for certain state tax credits.

Table of Contents

The reconciliation of the federal statutory rate to the effective income tax rate for the fiscal years ended December 31, 2016, 2015 and 2014 is as follows (amounts in thousands):

	Year Ended					
	December 31, 2016		December 31, 2015		December 31, 2014	
Income before income taxes	\$ 11,692		\$ 13,423		\$ 11,138	
Expected tax at statutory rate	3,975	34.0%	4,564	34.0%	3,787	34.0%
Adjustments due to:						
Difference between U.S. and foreign tax	(2,031)	(17.4%)	(1,910)	(14.2%)	(1,471)	(13.2%)
State income and franchise taxes	(326)	(2.8%)	563	4.2%	122	1.1%
Business tax credits	(236)	(2.0%)	(115)	(0.9%)		
Permanent differences	567	4.8%	118	0.9%	(172)	(1.5%)
Change in valuation allowance	(1,981)	(16.9%)	1,216	9.1%	727	6.5%
Other	43	0.4%	(358)	(2.7%)	(25)	(0.2%)
Provision (benefit) for income taxes	\$ 11	0.1%	\$ 4,078	30.4%	\$ 2,968	26.7%

In June 2015, the Company received a final assessment from the Massachusetts Department of Revenue (DOR) regarding an examination for the years ended March 31, 2010 and 2011 and the nine months ended December 31, 2011. This examination related to the qualification of Research and Development tax credits. The final settlement resulted in a payment to the DOR of approximately \$141,000, inclusive of interest and penalties.

In December 2015, the Company reached a negotiated settlement with the DOR regarding an appeal of an assessment made in 2013 for the years ended March 31, 2008 and 2009. The primary issues in the appeal related to the sourcing of intellectual property settlements and the qualification of Research and Development tax credits. The final settlement resulted in a payment to the DOR of approximately \$1,012,000, inclusive of interest. Of this amount, \$926,000 had been provided for as a liability for an uncertain tax position as of September 30, 2015.

The Company's tax returns are subject to examination by federal, state and international taxing authorities for the following periods:

Jurisdiction	Fiscal years subject to examination
United States	federal and state 2013-2016
Sweden	2011-2016
Germany	2012-2016

At December 31, 2016, the Company had accumulated Federal research credits of \$2,814,000 which were not recognized for financial statement purposes, as it was not more likely than not that the Company would have sufficient earnings to realize those benefits in addition to the benefits the Company may derive from use of its Net Operating Losses. However, given the past uncertainty at the state level regarding their sustainability under audit, the Company applied a reserve of \$1,407,000 against these cumulative Federal research credits.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands):

Unrecognized tax benefits at January 1, 2016	1,289
Gross increases tax positions in prior period	118
Unrecognized tax benefits at December 31, 2016	\$ 1,407

The amount of unrecognized tax benefits at December 31, 2015 that will impact our effective tax rate are \$1,407,000. For the year ended December 31, 2016, the Company recognized interest and penalties of \$16,000.

At December 31, 2016, the Company has not provided for U.S. income taxes or foreign withholding taxes on outside basis differences of foreign subsidiaries of approximately \$43,679,000 as it is the Company's current intention to permanently reinvest these earnings outside the U.S. It is not practical to estimate the additional taxes that may be payable upon repatriation.

Table of Contents**5. Stockholders Equity*****Common Stock and Warrants***

On April 6, 2007, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock at \$0.01 per share, as discussed in Note 10. The warrants have a seven-year term and are exercisable based on performance criteria as detailed in the warrant agreement during 2014. The warrant expired prior to the performance criteria being achieved.

Stock-Based Compensation

The Company recorded stock-based compensation expense of approximately \$4,595,000, \$3,598,000 and \$1,766,000 for the years ended December 31, 2016, 2015 and 2014, respectively, for share-based awards granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan) and the Repligen Corporation 2012 Stock Option and Incentive Plan (the 2012 Plan, and collectively with the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan, the Plans).

The following table presents stock-based compensation expense in the Company's consolidated statements of operations (in thousands):

	Years ended December 31,		
	2016	2015	2014
Cost of product revenue	\$ 341	\$ 213	\$ 128
Research and development	537	336	185
Selling, general and administrative	3,717	3,049	1,453
 Total	 \$ 4,595	 \$ 3,598	 \$ 1,766

During 2016, the Company modified certain stock option grants for its former senior vice president of research and development in conjunction with his retirement. As part of the April 2016 transition agreement, all outstanding equity awards continued to vest through December 31, 2016, and fifty percent (50%) of the option awards that are unvested on February 28, 2017 immediately vested and became exercisable as of that date. As a result of these modifications to his share-based payment arrangements, the Company incurred stock compensation expense of \$292,000 for the year ended December 31, 2016. This expense was recorded to research and development expense on the Company's consolidated statement of operations.

During 2015, the Company modified certain stock option grants for its former president and chief executive officer in conjunction with his retirement. As part of the January 2015 transition agreement, all outstanding equity awards continued to vest through December 31, 2015, and fifty percent (50%) of the option awards that are unvested on December 31, 2015 immediately vested and became exercisable as of that date. As a result of these modifications to his share-based payment arrangements, the Company incurred stock compensation expense of \$826,000 for the year ended December 31, 2015. This expense was recorded to selling, general and administrative expense on the Company's consolidated statement of operations.

The 2012 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock and other equity awards. Incentive options granted to employees under the Plans generally vest over a three to five-year period, with 20%-33% vesting on the first anniversary of the date of grant and the remainder vesting

in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At December 31, 2016, options to purchase 1,236,586 shares were outstanding under the Plans. At December 31, 2016, 1,821,576 shares were available for future grant under the 2012 Plan.

Table of Contents

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The fair value of share-based awards granted during the years ended December 31, 2016, 2015 and 2014 were calculated using the following estimated assumptions:

	2016		2015		2014	
Expected term (years)	6.7	7.1	6.6	7.2	6.5	
Volatility	50.85	51.01%	50.09	51.89%	51.00	51.71%
Risk-free interest rate	1.51	2.37%	1.67	2.03%	1.88	2.11%
Expected dividend yield						

Information regarding option activity for the year ended December 31, 2016 under the Plans is summarized below:

	Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	(in thousands) Aggregate Intrinsic Value
Options outstanding at December 31, 2015	1,054,584	\$ 12.28		
Granted	183,619	27.12		
Exercised	(266,863)	7.72		
Forfeited/cancelled	(88,592)	10.97		
Options outstanding at December 31, 2016	882,748	\$ 16.88	6.75	\$ 12,733
Options exercisable at December 31, 2016	427,310	\$ 11.11	5.23	\$ 8,617
Vested and expected to vest at December 31, 2016 ⁽¹⁾	837,660	\$ 16.82	6.70	\$ 12,140

- (1) Represents the number of vested options as of December 31, 2016 plus the number of unvested options expected to vest as of December 31, 2016 based on the unvested outstanding options at December 31, 2016 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the common stock on December 30, 2016, the last business day of 2016, of \$30.82 per share and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on December 31, 2016. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was approximately \$5,043,000, \$3,638,000 and \$9,656,000, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2016, 2015 and 2014 was \$14.16, \$16.05 and \$9.45, respectively. The total fair value of stock options that vested during the years ended December 31, 2016, 2015 and 2014 was approximately \$1,713,000, \$1,536,000 and \$751,000, respectively.

Table of Contents

Information regarding restricted stock unit activity for the year ended December 31, 2016 under the Plans is summarized below:

	Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	(in thousands) Aggregate Intrinsic Value
Restricted stock units outstanding at December 31, 2015	186,351	\$		
Granted	251,384			
Exercised	(63,017)			
Forfeited/cancelled	(20,880)			
Restricted stock units outstanding at December 31, 2016	353,838	\$	9.01	\$ 10,905
Restricted stock units exercisable at December 31, 2016		\$		\$
Vested and expected to vest at December 31, 2016 ⁽¹⁾	309,229	\$	9.01	\$ 9,530

(1) Represents the number of vested restricted stock units as of December 31, 2016 plus the number of unvested restricted stock units expected to vest as of December 31, 2016 based on the unvested outstanding restricted stock units at December 31, 2016 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (equal to the closing price of the common stock on December 30, 2016, the last business day of 2016, of \$30.82 per share, as restricted stock units do not have an exercise price) that would have been received by the restricted stock unit holders had all holders exercised on December 31, 2016. The aggregate intrinsic value of restricted stock units exercised during the years ended December 31, 2016, 2015 and 2014 was approximately \$1,671,000, \$1,304,000 and \$819,000, respectively.

The weighted average grant date fair value of restricted stock units granted during the years ended December 31, 2016, 2015 and 2014 was \$27.25, \$29.07 and \$16.79, respectively. The total fair value of restricted stock units that vested during the years ended December 31, 2016, 2015 and 2014 was approximately \$1,474,000, \$781,000 and \$333,000, respectively.

As of December 31, 2016, there was \$9,555,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.97 years. The Company expects 719,579 unvested options and restricted stock units to vest over the next five years.

6. Commitments and Contingencies

Lease Commitments

In 2001, the Company entered into a ten-year lease agreement for approximately 25,000 square feet of space located in Waltham, Massachusetts to be used for its corporate headquarters, manufacturing, research and development, and marketing and administrative operations. In July 2011, the Company amended this agreement to expand the lease to cover approximately 55,694 square feet and to extend the term of the lease by eleven years, which expires on May 31, 2023. In connection with this lease agreement, the Company issued a letter of credit in the amount of \$200,000 to the lessor. The letter of credit is collateralized by a certificate of deposit held by the

Table of Contents

bank that issued the letter of credit. The certificate of deposit is classified as restricted cash in the accompanying consolidated balance sheets.

In March 2014, the Company entered into an amendment of its existing lease to expand the rented space from 55,694 to 75,594 square feet at 41 Seyon Street, Waltham, Massachusetts. Pursuant to the terms of the amended lease, Repligen leased an additional 19,900 square feet (the Expansion Space) for a period of eight years and one month, commencing on August 1, 2014.

The amended lease provides for additional rent expense of approximately \$361,000 on an annualized basis. The amended lease also requires an increased security deposit from \$200,000 to \$450,000 and continues to require the Company to pay a proportionate share of certain of the landlord's annual operating costs and real estate taxes. Future minimum rental commitments under the amended lease as of December 31, 2016 are \$1,371,000 for the years ending December 31, 2017, 2018, 2019, 2020 and 2021, respectively.

In 2007, the Company entered into a five-year lease agreement for approximately 2,500 square feet of space in Waltham, Massachusetts to provide for expanded manufacturing operations. Adjacent to this space, the Company entered into a two-year lease in 2008 for approximately 7,350 square feet of additional space to be used for expanded manufacturing and administrative operations. Both of these leases expired on December 31, 2012. The Company converted to a month-to-month basis for both sites. The Company terminated the lease on the 7,350 square feet of space in the first quarter of 2015.

The Company leases four adjacent buildings in Lund, Sweden totaling approximately 45,000 square feet of space used primarily for biologics manufacturing and administrative operations. The lease was renewed during 2016 and expires on December 31, 2021. Future minimum rental commitments under the amended lease as of December 31, 2016 are \$984,000 for the years ending December 31, 2017, 2018, 2019, 2020 and 2021, respectively.

Obligations under non-cancelable operating leases, including the facility leases discussed above, as of December 31, 2016 are approximately as follows (in thousands):

Years Ending	Operating Leases
December 31, 2017	\$ 2,523
December 31, 2018	2,584
December 31, 2019	2,491
December 31, 2020	2,485
December 31, 2021	2,485
Thereafter	1,736
Minimum lease payments	\$ 14,304

Rent expense charged to operations under operating leases was approximately \$2,664,000, \$2,619,000 and \$2,735,000 for the fiscal years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, 2015 and 2014, the Company had deferred rent liabilities of \$1,792,000, \$1,899,000 and \$1,956,000, respectively, related to the escalating rent provisions for the Waltham headquarters.

Licensing and Research Agreements

The Company licenses certain technologies that are, or may be, incorporated into its technology under several agreements and also has entered into several clinical research agreements which require the Company to fund certain research projects. Generally, the license agreements require the Company to pay annual maintenance fees and royalties on product sales once a product has been established using the technologies. The Company recorded research and development expenses associated with license agreements of approximately \$5,000, \$7,000 and \$7,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Table of Contents

In October 2009, the Company entered into an exclusive worldwide commercial license agreement with Families of Spinal Muscular Atrophy (see Note 2). Pursuant to the License Agreement dated December 28, 2012, the Company transferred all rights and obligations related to the FSMA License Agreement to Pfizer. On January 26, 2015 Pfizer notified us that they were terminating the License Agreement, effective as of April 26, 2015.

Purchase Orders, Supply Agreements and Other Contractual Obligations

In the normal course of business, the Company has entered into purchase orders and other agreement with manufacturers, distributors and others. Outstanding obligations at December 31, 2016 of approximately \$10,008,000 are expected to be completed within one year.

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2016	December 31, 2015
Equipment maintenance and services	\$ 586	\$ 689
Prepaid VAT	553	558
Prepaid insurance	356	455
Deferred costs	5	206
Prepaid taxes	73	105
Interest receivable	29	63
Other	42	22
Total	\$ 1,644	\$ 2,098

8. Property, Plant and Equipment

Property, plant and equipment consist of the following (in thousands):

	December 31, 2016	December 31, 2015
Leasehold improvements	\$ 14,592	\$ 13,306
Equipment	15,214	13,758
Furniture and fixtures	3,218	2,808
Construction in progress	1,264	425
Total property, plant and equipment	34,288	30,297
Less: accumulated depreciation	(19,332)	(16,496)
Property, plant and equipment, net	\$ 14,956	\$ 13,801

Depreciation expense totaled approximately \$3,269,000, \$2,996,000 and \$2,594,000 in the fiscal years ended December 31, 2016, 2015 and 2014, respectively.

Table of Contents**9. Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	December 31, 2016	December 31, 2015
Employee compensation	\$ 5,586	\$ 4,680
Taxes	1,692	166
Current portion of contingent consideration	6,119	4,480
Professional fees	411	269
Unearned revenue	408	258
Other accrued expenses	1,798	2,204
Total	\$ 16,014	\$ 12,057

10. Convertible Senior Notes

The carrying value of the Company's convertible senior notes is as follows:

	December 31, 2016	December 31, 2015
2.125% Convertible Senior Notes due 2021:		
Principal amount	\$ 115,000	\$
Unamortized debt discount	(16,777)	
Unamortized debt issuance costs	(2,951)	
Total convertible senior notes	\$ 95,272	\$

On May 24, 2016, the Company issued \$115 million aggregate principal amount of its 2.125% Convertible Senior Notes due 2021 (the "Notes"). The net proceeds from the sale of the Notes, after deducting the underwriting discounts and commissions and other related offering expenses, were approximately \$111.1 million. The Notes bear interest at the rate of 2.125% per annum, payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2016.

The Notes will mature on June 1, 2021, unless earlier repurchased, redeemed or converted in accordance with their terms. Prior to March 1, 2021, the Notes will be convertible at the option of holders of the Notes only upon satisfaction of certain conditions and during certain periods, and thereafter, the notes will be convertible at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. Upon conversion, holders of the Notes will receive shares of the Company's common stock, cash or a combination thereof, at the Company's election. It is the Company's current intent and policy to settle all conversions through combination settlement, which involves satisfying the principal amount outstanding with cash and any note conversion value over the principal amount in shares of the Company's common stock.

The conversion rate for the Notes will initially be 31.1813 shares of the Company's common stock per \$1,000 principal amount of Notes, which is equivalent to an initial conversion price of approximately \$32.07 per common share, and is subject to adjustment under the terms of the Notes. Holders of the Notes may require the Company to repurchase their Notes upon the occurrence of a fundamental change prior to maturity for cash at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the repurchase date.

The Company will not have the right to redeem the Notes prior to June 5, 2019, but may redeem the Notes, at its option, in whole or in part, on any business day on or after June 5, 2019 and prior to the maturity date if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect

Table of Contents

for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides written notice of redemption. The redemption price will be equal to 100% of the principal amount of the principal amount of Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

The Notes contain customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the holders of at least 25% in aggregate principal amount of the outstanding Notes may declare 100% of the principal of, and any accrued and unpaid interest on, all of the Notes to be due and payable. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal of and accrued and unpaid interest, if any, on all of the Notes will become due and payable automatically. Notwithstanding the foregoing, the Notes provide that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants consist exclusively of the right to receive additional interest on the Notes. The Company is not aware of any events of default, current events or market conditions that would allow holders to call or convert the Notes as of December 31, 2016.

The cash conversion feature of the Notes required bifurcation from the Notes and was initially accounted for as an equity instrument classified to stockholders' equity, as the conversion feature was determined to be clearly and closely related to the Company's stock. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry and asset base and with similar maturity, the Company estimated the implied interest rate, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Notes, which resulted in a fair value of the liability component of \$96,289,000 upon issuance, calculated as the present value of implied future payments based on the \$115 million aggregate principal amount. The equity component of the Notes was recognized as a debt discount, recorded in additional paid-in capital, and represents the difference between the aggregate principal of the Notes and the fair value of the Notes without conversion option on their issuance date. The debt discount is amortized to interest expense using the effective interest method over five years, or the life of the Notes. The Company assesses the equity classification of the cash conversion feature quarterly, and it is not remeasured as long as it continues to meet the conditions for equity classification.

Interest expense recognized on the Notes during the year ended December 31, 2016 includes \$1,473,000, \$1,934,000 and \$340,000 for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively. The effective interest rate on the Notes is 6.6%, which includes the interest on the Notes, amortization of the debt discount and debt issuance costs. As of December 31, 2016, the carrying value of the Notes was approximately \$95.3 million and the fair value of the principal was approximately \$135.6 million. The fair value of the Notes was determined based on the most recent trade activity of the Notes as of December 31, 2016.

Table of Contents**11. Accumulated Other Comprehensive Income (Loss)**

Changes in accumulated other comprehensive income (loss) consisted of the following for the years ended December 31, 2016 and 2015 (in thousands):

	Unrealized gain (loss)		
	on	Foreign currency	
	investments	translation adjustment	Total
Balance as of December 31, 2014	(33)	(5,740)	(5,773)
Other comprehensive income (loss)	22	(2,815)	(2,793)
Balance as of December 31, 2015	(11)	(8,555)	(8,566)
Other comprehensive income (loss)	6	(5,189)	(5,183)
Balance as of December 31, 2016	\$ (5)	\$ (13,744)	\$ (13,749)

12. Employee Benefit Plans

In the U.S., the Repligen Corporation 401(k) Savings and Retirement Plan (the 401(k) Plan) is a qualified defined contribution plan in accordance with Section 401(k) of the Internal Revenue Code. All U.S. employees over the age of 21 are eligible to make pre-tax contributions up to a specified percentage of their compensation. Under the 401(k) Plan, the Company may, but is not obligated to match a portion of the employees' contributions up to a defined maximum. The match is calculated on a calendar year basis. The Company matched approximately \$184,000, \$141,000 and \$107,000 in the fiscal years ended December 31, 2016, 2015 and 2014, respectively.

In Sweden, the Company contributes to a government-mandated occupational pension plan that is a qualified defined contribution plan. All employees in Sweden are eligible for this pension plan. The Company pays premiums to a third party occupational pension specialist who administers the pension plan. These premiums are based on various factors including each employee's age, salary, employment history and selected benefits in the pension plan. When an employee terminates or retires, these premium payments cease for that employee and the Company has no further pension-related obligations for that employee. For the fiscal years ended December 31, 2016, 2015 and 2014, the Company contributed approximately \$519,000, \$485,000 and \$493,000, respectively, to the pension plan.

Table of Contents**13. Selected Quarterly Financial Data (Unaudited)**

The following table contains consolidated statements of operations information for each of the previous eight quarters. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
(in thousands, except per share amounts)								
Revenue:								
Product revenue	\$ 25,500	\$ 24,677	\$ 29,170	\$ 25,094	\$ 21,449	\$ 19,814	\$ 21,457	\$ 20,816
Royalty and other revenue	100							
Total revenue	25,600	24,677	29,170	25,094	21,449	19,814	21,457	20,816
Operating expenses:								
Cost of product revenue	12,162	11,242	12,644	11,069	10,148	8,444	8,586	8,073
Cost of royalty and other revenue								
Research and development	2,040	1,886	1,890	1,539	1,431	1,490	1,252	1,568
Selling, general and administrative	8,568	7,127	8,140	7,018	6,473	5,959	6,242	6,024
Contingent consideration fair value adjustments	(75)	675	637	2,005	1,969	233	768	1,112
Total operating expenses	22,695	20,930	23,311	21,631	20,021	16,126	16,848	16,777
Income from operations	2,905	3,747	5,859	3,463	1,428	3,688	4,609	4,039
Investment income	112	97	76	61	44	37	19	36
Interest expense	(1,570)	(1,555)	(638)	(5)	(8)	(8)	(8)	(9)
Other income (expense)	119	(75)	75	(979)	(270)	(38)	(269)	132
Income before income taxes	1,566	2,214	5,372	2,540	1,194	3,679	4,351	4,198
Income tax provision (benefit)	3,463	1,059	1,500	915	929	1,141	738	1,269
Net income (loss)	\$ 5,029	\$ 1,155	\$ 3,872	\$ 1,625	\$ 265	\$ 2,538	\$ 3,613	\$ 2,929
Earnings per share:								
Basic	\$ 0.15	\$ 0.03	\$ 0.12	\$ 0.05	\$ 0.01	\$ 0.08	\$ 0.11	\$ 0.09

Edgar Filing: REPLIGEN CORP - Form 10-K

Diluted	\$ 0.15	\$ 0.03	\$ 0.11	\$ 0.05	\$ 0.01	\$ 0.08	\$ 0.11	\$ 0.09
Weighted average shares outstanding:								
Basic	33,833	33,779	33,649	33,025	32,946	32,925	32,870	32,755
Diluted	34,369	34,313	34,175	33,494	33,577	33,690	33,671	33,451