

REPLIGEN CORP
Form 10-K
February 25, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

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

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

Title of Each Class

Common Stock, \$0.01 Par Value Per Share

Name of Exchange on Which Registered

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.

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):

Edgar Filing: REPLIGEN CORP - Form 10-K

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, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was \$1,348,697,533.

The number of shares of the registrant's common stock outstanding as of February 18, 2016 was 33,031,533.

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, 2015. 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>PART I</u>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	10
Item 1B. <u>Unresolved Staff Comments</u>	21
Item 2. <u>Properties</u>	21
Item 3. <u>Legal Proceedings</u>	21
Item 4. <u>Mine Safety Disclosures</u>	21
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	22
Item 6. <u>Selected Consolidated Financial Data</u>	25
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	38
Item 8. <u>Financial Statements and Supplementary Data</u>	38
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	38
Item 9A. <u>Controls and Procedures</u>	38
Item 9B. <u>Other Information</u>	41
<u>PART III</u>	42
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	43
<u>SIGNATURES</u>	47

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 Corporation (Repligen, the Company or we) is a bioprocessing company focused on the development, production and commercialization of innovative products used in the process of manufacturing biologic drugs (bioprocessing). Biologic drugs include monoclonal antibodies, recombinant proteins and vaccines and represent a growing area of drug development. Our customers include leading life sciences companies, global biopharmaceutical companies, and contract manufacturers worldwide. The high-value technologies that we provide enable biologics manufacturers to cost-effectively increase drug production yields while retaining the highest quality and safety standards.

Repligen is a longtime global market leader in the manufacture of Protein A ligands, sold to life sciences companies under long term supply agreements. Protein A is a critical reagent used to purify monoclonal antibodies (mAbs) on the market (over 50) or in development (over 300). In December 2011, we strengthened our Protein A market leadership with the acquisition of Novozymes 's bioprocessing business (Novozymes) in Lund, Sweden (the Novozymes Acquisition).

We established and have executed on a diversification strategy to selectively expand the number of bioprocessing products that we sell directly to end users. With the Novozymes Acquisition, we gained a portfolio of growth factors, led by LONG[®] R3 IGF-1, which is used in cell culture media to increase productivity. LONG[®]R3 IGF-1 is sold in collaboration with MilliporeSigma (formerly Sigma Aldrich), our exclusive distributor for the product. We also developed and directly market our OPUS[®] process-scale line of pre-packed chromatography columns for the capture and purification of biologic drugs in clinical development. Most recently, in June 2014, we acquired the business of Refine Technology, including Refine 's Alternating Tangential Flow (ATF) System, a best-in-class device used to generate extremely high cell concentrations during the fermentation step of the biologic drug manufacturing process (the Refine Business and the acquisition of the Refine Business, the Refine Acquisition).

We market our products globally through a direct commercial organization in the U.S., Europe and Asia, as well as through strategic partners in select markets. In 2014 and 2015, we invested in expanding our global commercial organization, adding sales, marketing and applications personnel who interact directly with our end users. Our customer base comprises of leading life sciences companies, major contract manufacturers and 20 of the top 25 biopharmaceutical companies.

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 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 regulatory hurdles, costs and uncertainties associated with displacing them.

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 \$83.5 million in 2015. To meet increased demand for our products, we have increased the volume and scale of manufacturing at our two manufacturing facilities in the U.S. and Sweden.

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. We conduct manufacturing in Waltham and at our facility in Lund, Sweden.

Our Market Opportunity

The global biologics drug market is estimated to be over \$200 billion. This market includes mAbs, proteins and vaccines. mAb-based biologics alone accounted for approximately \$80 billion of revenue, and represented six of the top 10 best-selling drugs across the pharmaceutical industry, in 2014. Industry sources project the biologics market to grow at approximately 8-10% annually over the next five years, driven by strength in the mAb class of biologics. This strength is evidenced by the rate of new approvals, expanded labels for marketed mAbs and the emergence of biosimilar versions of originator mAbs. In 2015, a record of nine therapeutic mAbs were approved by the U.S. Food and Drug Administration (FDA) to treat a diverse range of diseases, including the first-ever approvals of mAbs to control LDL or bad cholesterol. 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 and biobetters) 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 EU and U.S. For example, there are at least 12 companies attempting to market the first Humira® (adalimumab) biosimilar, which faces patent expiration in the U.S. 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 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 cost of goods 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.

Table of Contents

Our Products

Downstream 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 monoclonal antibody-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 23, 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. 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 mAbs, due to the ability of Protein A to selectively bind to or capture mAbs 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 mAb 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.

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 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 in the final product.

Chromatography columns, packed with chromatography media, are used in biomanufacturing to purify 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 is 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. Over the past three 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 45 cm diameter columns in 2014 and 60 cm 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.

Table of Contents

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® prepacked columns, including increased use by contract manufacturers, where quick turnover of multiple production runs is critical to profitability. We expect continued strong growth for this product line as we aim to expand geographically and provide best-in-class service and support.

Upstream Products

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. We anticipate continued growth for this product group as our pipeline of opportunities advances from early-stage clinical to late-stage clinical and commercial manufacturing processes.

ATF Systems

The ATF System is a technologically advanced filtration device used 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. The ATF System is designed to both increase the density of cells in a bioreactor and extend the production run, resulting in significantly greater product yield of up to two- to three-fold as well as reduced costs. This is important to biomanufacturers who seek to maximize output from their existing facilities. ATF Systems consist of a stainless steel housing that contains a consumable filter and an associated pump and controller. We sell the ATF System in a variety of sizes suitable for use in laboratory and scale-up all the way to production bioreactors as large as 2,000 liters. ATF Systems are used in the production of several FDA-approved monoclonal antibodies.

Following our acquisition of the ATF System from Refine Technology in 2014, we integrated the production of ATF into our operations in Waltham, MA.

We estimate that the current market for cell retention devices is approximately \$125-150 million. Within this market, we expect continued growth for our ATF franchise 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. The ATF System strengthens our upstream fermentation business and significantly broadens our technology base.

Research and Development

Our research activities are focused on developing new bioprocessing products. Specifically, we plan to focus these efforts on our ATF, OPUS and chromatography portfolio, including next generation Protein A ligands. Research and development expenses totaled approximately \$5.7 million, \$5.6 million and \$7.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Table of Contents**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 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.

SMA Agreement with Pfizer

On December 28, 2012, we entered into an exclusive worldwide licensing agreement (the "License Agreement") with 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 notified us that they were terminating the License Agreement for convenience, effective as of April 26, 2015. We do not intend to invest additional resources to the development of the SMA program.

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.

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

Table of Contents

the biotechnology and biopharmaceutical industries. Through our products and brands, including Protein A, LONG[®]R3 IGF-1, OPUS[®], ATF we provide premiere offerings and services to our bioprocess 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 23, 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 have invested in our commercial organization and now have 23 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. This organization also helps us identify market needs and 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, 2015, 2014 and 2013.

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,		
	2015	2014	2013
Sweden	37%	38%	35%
United States	28%	33%	51%
United Kingdom	17%	20%	12%
Other	18%	9%	2%
Total	100%	100%	100%

Royalty revenue from Bristol represented 27% of total revenues for the fiscal year ended December 31, 2013; no such revenues were generated in 2014 and 2015.

GE Healthcare, our largest bioprocessing customer, accounted for 37%, 38% and 35% of total revenues in the fiscal years ended December 31, 2015, 2014 and 2013, respectively. MilliporeSigma, our second largest bioprocessing customer, accounted for 29%, 33% and 25% of total revenues in the fiscal years ended December 31, 2015, 2014 and 2013, respectively.

Employees

As of February 18, 2016, we had 168 employees. Of those employees, 12 were engaged in engineering and research and development, 102 in manufacturing, 23 in sales and marketing and 31 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 36% of our total workforce. The current collective bargaining agreements expire on March 31, 2016. We are currently in negotiations to renew these collective bargaining agreements, and the risk of any work stoppage is low. The Company considers its employee relations to be satisfactory.

Patents, Licenses and Proprietary Rights

Repligen considers patents to be an important element in the protection of our competitive and proprietary position and actively, and selectively, pursues patent protection in the United States and in major countries

Table of Contents

abroad. As further described below, Repligen owns or has 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.

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 which 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 a recombinant gene 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, Repligen 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 the ease and flexibility of column packing, bed height adjustment and cleaning that 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, Australia, Canada, Europe, Hong Kong, India, and Japan.

ATF Systems

As part of the Refine Acquisition, Repligen 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, Canada, China, Europe, India, and Korea. Other additional improvements on the original ATF systems and methods are covered by patent applications pending in one or more of the US, Canada, China, Europe, India, Japan, and Korea.

Spinal Muscular Atrophy

In 2009, Repligen 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

Table of Contents

treatment of spinal muscular atrophy. 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 and 7,985,755, 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 U.S. Patent No. 7,888,366 (the 366 patent) is in 2028 with potential for patent term extension. The expiration date of U.S. Patent No. 7,985,755 (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 has 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.

Histone Deacetylase Inhibitors

Repligen has 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 have extended this original work and filed additional patent applications which claim both methods and compositions for treating Friedreich's ataxia. We 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. On January 21, 2014, we out-licensed our HDAC Inhibitor (HDACi) portfolio to BioMarin Pharmaceuticals Inc. 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.

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 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 2021. Native Protein A is manufactured in Sweden, while the recombinant forms are manufactured in Waltham, Massachusetts or in both Waltham, Massachusetts and Sweden. We currently manufacture our growth factor products in Sweden and our OPUS chromatography columns and ATF System products in Waltham, 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 ATF System products, one of which is the primary supplier of materials used for consumable ATF System products.

Table of Contents

We utilize our own facilities in Waltham, Massachusetts and 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 U.S. facility, located in Waltham, Massachusetts and our Sweden facility, located in Lund, are both 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.

Table of Contents

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

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 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.

Table of Contents

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 efforts.

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 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, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the growth factor products. In addition, in connection with the accounting for the Refine Acquisition, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the ATF system. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of intangible assets has been impaired. Intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of intangible assets 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 and the Refine 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;

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.

Edgar Filing: REPLIGEN CORP - Form 10-K

The Novozymes Acquisition, the Refine Acquisition, the continued expansion of our commercial sales operations, and our organic growth have increased the scope and complexity of our business. We will face

Table of Contents

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 and have increased since we completed the acquisition of the Novozymes Biopharma Business. 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 the Novozymes Acquisition and the Refine Acquisition, 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;

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;

Edgar Filing: REPLIGEN CORP - Form 10-K

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;

Table of Contents

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.

The ATF System business relies on a limited number of suppliers or, in some cases, one supplier, and may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on the ATF System business and our financial condition, results of operations and reputation.

There are only a limited number of suppliers of materials related to the ATF System products, one of which is the primary supplier of materials used for consumable 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.

We believe that only a small number of suppliers are currently qualified to supply materials for the ATF system. The use of materials furnished by these replacement suppliers would require us to alter our operations related to the ATF system. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our operations, could affect the performance specifications of the ATF system 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 ATF System products, our business related to these products and our financial condition, results of operations and reputation could be adversely affected.

Our royalty agreement with Bristol-Myers Squibb on sales of Orencia expired on December 31, 2013.

Our royalty agreement with Bristol provided for us to receive payments from Bristol based on their net sales of their Orencia® product in the United States through December 31, 2013. As a result, we no longer receive royalty payments under this agreement as of December 31, 2013.

Our license agreement with Pfizer expired on April 26, 2015.

Our licensing agreement with Pfizer provided for us to potentially receive payments from Pfizer based on milestones related to clinical development and initial commercial sales in specific geographies, as well as royalty payments from Pfizer based on its future sales of RG3039 or any SMA compounds developed under the license agreement. 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. As a result, we no longer receive milestone payments under this agreement.

Table of Contents

We have limited sales and marketing capabilities.

We have a small sales force and, historically, we have 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 the Refine Acquisition, 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.

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.

Edgar Filing: REPLIGEN CORP - Form 10-K

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.

Table of Contents

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 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 will seek 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

Table of Contents

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, such as a larger size version of our OPUS disposable chromatography products, the ATF System, and new growth factors. 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.

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

Table of Contents

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.

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.

Table of Contents

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 and is considering a number of proposals that are intended to reduce or limit the growth of health care costs and which could significantly transform the market for pharmaceuticals products. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which 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. The continuing efforts of 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.

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.

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 the Novozymes Acquisition. 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

Table of Contents

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.

Our growth potential is changing as we evolve from an organization that was heavily involved in research and development to an organization with a strategic focus on our bioprocessing business.

In connection with the Company's decision to focus its efforts on the growth of its core bioprocessing business, the Company has terminated its therapeutic product development activities. The core bioprocessing business on which the Company now focuses will provide growth opportunities that are different than those of a research and development oriented biotechnology company. As a result, the price of the Company's common stock may behave differently than it has historically and, during the shift in our business, may behave in a manner not expected by securities analysts and investors. If the Company's future business focused on bioprocessing generates results that fall below the revised expectations of securities analysts and investors, the trading price of the Company's common stock could decline.

As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or deliver the value thereof to our shareholders. If we are unsuccessful in consummating any such transaction, we may be required to reevaluate our business only after we have incurred substantial expenses and devoted significant management time and resources.

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 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, 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, 2015, 33% of our revenue and 23% of our costs and expenses were denominated in foreign currencies, primarily

Table of Contents

the Swedish Kroner, 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.

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.

Table of Contents

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 are implementing a new enterprise resource planning (ERP) system and 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.

ITEM 2. PROPERTIES

We currently lease and occupy approximately 76,000 square feet of space located in Waltham, Massachusetts which serves as our corporate headquarters. We also conduct manufacturing, research and development, marketing and administrative operations at this facility. This lease expires on May 31, 2023. We also rent approximately 2,500 square feet at a second location in Waltham, Massachusetts to provide for expanded manufacturing operations. This facility is rented on a month-to-month basis. We also lease four adjacent buildings in Lund, Sweden totaling approximately 45,000 square feet of space used primarily for manufacturing and administrative operations. The lease for three buildings totaling approximately 41,000 square feet expires on June 30, 2017, while the lease for the fourth building with approximately 4,000 square feet of space expires on September 30, 2019.

During the fiscal year ended December 31, 2015, we incurred total rental costs for all facilities of approximately \$2,619,000.

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, 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

	Year Ended December 31, 2014	
	High	Low
First Quarter	\$ 17.26	\$ 11.70
Second Quarter	\$ 23.14	\$ 12.60
Third Quarter	\$ 24.68	\$ 18.23
Fourth Quarter	\$ 26.75	\$ 19.02

Stockholders and Dividends

As of February 18, 2016, there were 438 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, 2015 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 exercise 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	1,240,935(1)	\$ 10.44(2)	2,441,761
Equity compensation plans not approved by security holders	N/A	\$ N/A	N/A
Total	1,240,935	\$ 10.44	2,441,761

Edgar Filing: REPLIGEN CORP - Form 10-K

- (1) Includes 1,054,584 shares of Common Stock issuable upon the exercise of outstanding options and 186,351 shares of Common Stock issuable upon the vesting of restricted stock units. No shares of restricted stock are outstanding.

Table of Contents

(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 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, 2015. 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 69-month 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 March 31, 2010 to December 31, 2015.

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.

Table of Contents

Recent Sales of Unregistered Securities and Equity Purchases by the Company

In June 2014, in connection with the Refine Acquisition, we issued and sold 215,285 unregistered shares of our common stock to Refine Technology, LLC, an accredited investor, in exchange for certain of Refine's assets and contract rights related to its ATF system. 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, 2014, 2013 and 2012 and our Transition Report on Form 10-K for the nine months ended December 31, 2011.

(In thousands, except per share data)	2015 (1)	2014	2013	2012 (2)	Nine Months Ended December 31, 2011
Revenue:					
Product revenue	\$ 83,537	\$ 60,431	\$ 47,482	\$ 41,834	\$ 13,215
Royalty and other revenue		3,117	20,687	20,433	10,235
Total revenue	83,537	63,548	68,169	62,267	23,450
Operating expenses:					
Cost of product revenue	35,251	28,022	22,481	24,957	5,157
Cost of royalty and other revenue			2,682	2,213	1,315
Research and development	5,740	5,609	7,341	10,490	9,462
Selling, general and administrative	24,699	17,154	12,701	13,227	9,050
Contingent consideration fair value adjustments	4,083	2,072	91	611	
Gain on bargain purchase				(314)	(427)
Total operating expenses	69,773	52,857	45,296	51,184	24,557
Income (loss) from operations	13,764	10,691	22,873	11,083	(1,107)
Investment income	136	309	301	219	161
Interest expense	(32)	(50)	(50)	(57)	(28)
Other income (expense)	(445)	188	(110)	26	(623)
Income (loss) before income taxes	13,423	11,138	23,014	11,271	(1,597)
Income tax (benefit) provision	4,078	2,968	6,921	(2,885)	16
Net income (loss)	\$ 9,345	\$ 8,170	\$ 16,093	\$ 14,156	\$ (1,613)
Earnings (loss) per share:					
Basic	\$ 0.28	\$ 0.25	\$ 0.51	\$ 0.46	\$ (0.05)
Diluted	\$ 0.28	\$ 0.25	\$ 0.50	\$ 0.45	\$ (0.05)
Weighted average shares outstanding:					
Basic	32,882	32,498	31,667	30,914	30,774
Diluted	33,577	33,264	32,407	31,253	30,774
Balance Sheet Data:					
Cash and marketable securities (3)	\$ 73,407	\$ 62,003	\$ 73,842	\$ 49,970	\$ 36,025
Working capital	84,471	70,264	75,049	55,457	39,431
Total assets	146,237	128,293	118,645	97,010	76,057
Long-term obligations	4,708	5,879	3,458	2,133	2,606
Accumulated deficit	(71,542)	(80,887)	(89,057)	(105,151)	(119,307)
Stockholders' equity	122,748	111,732	103,886	84,125	65,987

Edgar Filing: REPLIGEN CORP - Form 10-K

- (1) Includes the full year impact of the Refine Acquisition on June 2, 2014.
- (2) Includes the full year impact of the Novozymes Acquisition on December 20, 2011.
- (3) Excludes restricted cash of \$450,000 for the year ended December 31, 2015 and 2014 and \$200,000 for all other years presented related to our headquarters lease arrangement.

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

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.

Repligen Corporation (Repligen, the Company or we) is a bioprocessing company focused on the development, production and commercialization of innovative products used in the process of manufacturing biologic drugs (bioprocessing). Biologic drugs include monoclonal antibodies, recombinant proteins and vaccines and represent a growing area of drug development. Our customers include leading life sciences companies, global biopharmaceutical companies, and contract manufacturers worldwide. The high-value technologies that we provide enable biologics manufacturers to cost-effectively increase drug production yields while retaining the highest quality and safety standards.

Repligen is a longtime global market leader in the manufacture of Protein A ligands, sold to life sciences companies under long term supply agreements. Protein A is a critical reagent used to purify therapeutic monoclonal antibodies (mAbs) on the market (over 50) or in development (over 300). In December 2011, we strengthened our Protein A market leadership with the acquisition of Novozymes's bioprocessing business (Novozymes) in Lund, Sweden (the Novozymes Acquisition).

We established and have executed on a diversification strategy to selectively expand the number of bioprocessing products that we sell direct to end users. With the Novozymes Acquisition, we gained a portfolio of growth factors, led by LONG[®] R3 IGF-1, which is used in cell culture media to increase productivity. LONG[®]R3 IGF-1 is sold in collaboration with MilliporeSigma (formerly Sigma Aldrich), our exclusive distributor for the product. We also developed and directly market our OPUS[®] process-scale line of pre-packed chromatography columns for the capture and purification of biologic drugs in clinical development. Most recently, in June 2014, we acquired the business of Refine Technology, including Refine's Alternating Tangential Flow (ATF) System, a best-in-class device used to generate extremely high cell concentrations during the fermentation step of the biologic drug manufacturing process (the Refine Business and the acquisition of the Refine Business, the Refine Acquisition).

We market our products globally through a direct commercial organization in the U.S., Europe and Asia, as well as through strategic partners in select markets. In 2014 and 2015, we invested in expanding our global commercial organization, adding world-class sales, marketing and applications personnel who interact directly with our end users. Our customer base comprises of leading life sciences companies, major contract manufacturers and 20 of the top 25 biopharmaceutical companies.

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

Table of Contents

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 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 regulatory hurdles, costs and uncertainties associated with displacing them.

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 \$83.5 million in 2015. To meet increased demand for our products, we have increased the volume and scale of manufacturing at our two manufacturing facilities in the U.S. and Sweden.

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 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.

Table of Contents

Orencia Royalty

In April 2008, we settled our outstanding litigation with Bristol and began recognizing royalty revenue from that settlement in fiscal year 2009 for Bristol's net sales in the United States of Orencia[®], which is used in the treatment of rheumatoid arthritis. Pursuant to the settlement with Bristol, we recognized royalty revenue of \$17,881,000 for the fiscal year ended December 31, 2013. Revenue earned from Bristol royalties was recorded in the periods when it was earned based on royalty reports sent by Bristol to us. We have no continuing obligations to Bristol as a result of this settlement. Our royalty agreement with Bristol provided that we would receive such royalty payments on sales of Orencia[®] by Bristol through December 31, 2013. These royalty payments have ceased.

Pfizer License Agreement

In December 2012, we entered into an exclusive worldwide licensing agreement (the License Agreement) with 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.

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., or BioMarin. Under the terms of the agreement, Repligen 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, Repligen is eligible to receive royalties on sales of qualified products developed.

Research and Development Agreements

We did not recognize any revenue from sponsored research and development projects in the fiscal years ended December 31, 2015 and 2014. For the fiscal year ended December 31, 2013, we recognized \$1,589,000 of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, GoFar and the European Friedrich's Ataxia Consortium for Translational Studies.

Research revenue is recognized when the expense has been incurred and services have been performed. Determination of which incurred costs qualify for reimbursement under the terms of our contractual agreements and the timing of when such costs were incurred involves the judgment of management. Our calculations are based upon the agreed-upon terms as stated in the arrangements. However, should the estimated calculations change or be challenged by other parties to the agreements, research revenue may be adjusted in subsequent periods. The calculations have not historically changed or been challenged, and we do not anticipate any significant subsequent change in revenue related to sponsored research and development projects.

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

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

Table of Contents

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 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 Statement of Operations. The largest and most judgmental component of our contingent consideration relates to the contingent consideration tied to Refine sales targets. The remaining maximum potential liability related to Refine's sales based contingent consideration is \$9.9 million, and we have accrued approximately \$6.4 million as of December 31, 2015 as the estimated fair value. Fair value estimates are based on our projections of future Refine sales.

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 8 to 15 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

Table of Contents

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, 2015. 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 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

Table of Contents

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, 2015, 2014 and 2013, we recorded stock-based compensation expense of approximately \$3,598,000, \$1,766,000 and \$1,060,000, respectively, for share-based awards granted under all of the Company's stock plans.

As of December 31, 2015, there was \$6,547,000 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 3.08 years. We expect 623,652 unvested options to vest over the next five years.

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 2015, 2014, and 2013 were comprised of the following:

	Years ended December 31,			% Change	
	2015	2014	2013	2015 vs. 2014	2014 vs. 2013
	(in thousands, except percentages)				
Bioprocessing product revenue	\$ 83,537	\$ 60,431	\$ 47,482	38%	27%
Royalty and other revenue		3,117	20,687	(100%)	(85%)
Total revenue	\$ 83,537	\$ 63,548	\$ 68,169	31%	(7%)

Table of Contents

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. Sales of our bioprocessing products can therefore be impacted by the timing of large-scale production orders and the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

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 affinity ligand and ATF 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.

For fiscal 2014, bioprocessing product sales increased by \$12,949,000 or 27% as compared to fiscal 2013 primarily due to sales of the ATF System following the Refine Acquisition.

Pursuant to the settlement with Bristol, we recognized royalty revenue of \$17,881,000 in fiscal 2013. As this royalty arrangement with Bristol expired on December 31, 2013, we do not recognize any further royalty revenue from Bristol.

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 and \$1,217,000 of revenue for fiscal 2014 and 2013, respectively, from the out-license of our Spinal Muscular Atrophy program to Pfizer on December 28, 2012. In fiscal 2013, we also recognized \$1,589,000 of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, GoFar and the European Friedrich s Ataxia Consortium for Translational Studies. We did not recognize any such revenue in fiscal 2015, 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 2015, 2014, and 2013 were comprised of the following:

	Years ended December 31,			% Change	
	2015	2014	2013	2015 vs. 2014	2014 vs. 2013
	(in thousands, except percentages)				
Cost of product revenue	\$ 35,251	\$ 28,022	\$ 22,481	26%	25%
Cost of royalty and other revenue			2,682		(100%)
Research and development	5,740	5,609	7,341	2%	(24%)
Selling, general and administrative	24,699	17,154	12,701	44%	35%
Contingent consideration fair value adjustments	4,083	2,072	91	97%	2,177%
Total costs and operating expenses	\$ 69,773	\$ 52,857	\$ 45,296	32%	17%

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. For fiscal 2014, cost of product revenue increased \$5,541,000 or 25% as compared to fiscal 2013. This increase is primarily due to the increased product revenue noted above and the addition of the Refine Business.

Gross margins were 58%, 54%, and 53% for fiscal 2015, 2014, and 2013, respectively. During fiscal 2015, gross margins increased compared to fiscal 2014 due to favorable Refine margins, increased capacity utilization and product mix. During fiscal 2014, gross margins increased slightly compared to fiscal 2013 due to favorable Refine margins, increased capacity utilization and product yield which offset higher expenses related to our facility expansion to bring manufacturing for our ATF systems to our Waltham facility.

Table of Contents

Pursuant to the settlement with Bristol, we remitted 15% of royalty revenue received through the expiration of the agreement in December 2013 to the University of Michigan. Cost of royalty revenue for fiscal year 2013 was \$2,682,000. As this royalty arrangement with Bristol expired on December 31, 2013, we do not expect to incur any further cost of royalty revenue to the University of Michigan.

During fiscal 2015, 2014 and 2013, research and development expenses were primarily 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, the current single-use ATF project incurs expenses related to product development, sterilization, validation testing, and other research related expenses.

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

For fiscal 2014, research and development expenses decreased by \$1,732,000 or 24%. This decrease is directly related to our decision in 2012 to exit therapeutic drug development and is partially offset by an increase in bioprocessing research and development expense.

We expect our research and development expenses in the year ending December 31, 2016, which relate to bioprocessing product development, to increase.

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 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. We expect SG&A expenses to increase in the year ending December 31, 2016 as we continue to expand our sales and marketing activities to drive future sales of our bioprocessing products.

For fiscal 2014, SG&A costs increased by \$4,454,000 or 35% as compared to fiscal 2013. This increase is primarily due to the expansion of our sales and marketing activities and closing and transition costs associated with the Refine Acquisition.

Contingent Consideration

For fiscal 2015, our contingent consideration liability increased approximately \$2,943,000 compared to fiscal 2014. The increase is primarily attributed to a \$4,048,000 increase in the fair value of the contingent

Table of Contents

consideration stemming from the Refine acquisition, partially offset by payments of approximately \$1,139,000. The contingent consideration for this period stems from the BioFlash and Refine acquisitions. 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. The fair value of contingent consideration at December 31, 2015 and 2014 was \$6,788,000 and \$3,845,000, respectively.

For fiscal 2014, our contingent consideration liability increased approximately \$2,196,000 compared to fiscal 2013. The increase is primarily attributed to \$3,321,000 stemming from the Refine Acquisition. The contingent consideration for this period stems from the Novozymes, BioFlash and Refine acquisitions. The contingent consideration related to the Novozymes Acquisition is based upon actual amounts remaining to be paid to Novozymes Denmark per the Deed of Settlement and Amendment entered into on May 5, 2014. 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 2015, 2014, and 2013 was \$136,000, \$309,000, and \$301,000, respectively. The decrease of \$173,000 or 56% for fiscal 2015 was primarily due to lower invested funds during 2015 compared to 2014. The increase of \$8,000 or 3% for fiscal 2014 compared to fiscal 2013 was due to slightly higher interest rates and adjusted investment mix. 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, 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.

The provision for income taxes for the year ended December 31, 2014 totaled \$2,968,000. Our current tax provision of \$2,481,000 primarily relates to a foreign tax provision of \$2,670,000 and \$125,000 related to an uncertain tax position for historic research and development credits. Our deferred tax provision of \$488,000 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**Liquidity and capital resources**

We have financed our operations primarily through revenues derived from product sales, research grants, as well as proceeds and royalties from license arrangements and a litigation settlement. Our revenue for the foreseeable future will primarily be limited to our bioprocessing product revenue.

At December 31, 2015, we had cash and marketable securities of \$73,407,000 compared to \$62,003,000 at December 31, 2014. In fiscal 2014 we utilized \$21,236,000 of cash in the Refine Acquisition and invested an additional \$3,400,000 in the expansion of our Waltham manufacturing and administrative facility. A deposit for leased office space of \$450,000 and \$200,000 is classified as restricted cash and is not included in cash and marketable securities totals for December 31, 2015 or December 31, 2014, respectively.

Cash flows

(In thousands)

	Year ended December 31, 2015	Increase / (Decrease)	Year ended December 31, 2014	Increase / (Decrease)	Year ended December 31, 2013
Cash provided by (used in)					
Operating activities	\$ 15,053	\$ (3,348)	\$ 18,401	\$ (7,529)	\$ 25,930
Investing activities	4,791	24,583	(19,792)	(1,886)	(17,906)
Financing activities	767	(913)	1,680	(842)	2,522
Operating activities					

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.

For fiscal 2013, our operating activities provided cash of \$25,930,000 reflecting net income of \$16,093,000 and non-cash charges totaling \$7,055,000 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 in prepaid expenses and increases in accrued and long term liabilities provided an additional \$2,457,000 and \$2,458,000 of cash. Increases in accounts receivable and inventories as well as a decrease in accounts payable consumed \$1,400,000 and \$734,000 of cash.

Investing activities

We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines. For 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. 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

Table of Contents

expansion and a \$250,000 increase in restricted cash related to our amended lease for our Waltham facility and partially offset by \$7,296,000 of net redemptions of marketable securities. In fiscal 2013, our investing activities consumed \$17,906,000 of cash, which is comprised of \$13,272,000 of net purchases of marketable securities and \$4,635,000 of fixed asset additions as we completed the first phase of our Waltham facility expansion.

Financing activities

Exercises of stock options provided cash receipts of \$866,000, \$1,680,000 and \$2,450,000 in fiscal 2015, 2014 and 2013, respectively. In fiscal 2013, an excess tax benefit related to stock option exercises provided \$72,000. Payments to Refine in 2015 related to achieving 2014 sales goals totaled \$1,000,000, of which \$99,000 related to our 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, 2015, we had the following fixed obligations and commitments (in thousands):

	Total	Payments Due By Period			More than 5 Years
		Less than 1 Year	1 3 Years	3 5 Years	
Operating lease obligations	\$ 11,497	\$ 2,343	\$ 3,322	\$ 2,789	\$ 3,043
Purchase obligations (1)	5,729	5,729			
Contingent consideration (2)	6,788	4,480	2,308		
Total	\$ 24,014	\$ 12,552	\$ 5,630	\$ 2,789	\$ 3,043

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

(2) Represents the current estimated fair value of contingent consideration amounts relating to acquisitions. These amounts are recorded in accrued expenses and long term liabilities on our consolidated balance sheets. We have contingent consideration for an earnout pertaining to the Refine Acquisition, and upon the achievement of certain milestones in the Asset Purchase Agreement entered into with Refine, we could make additional payments of up to \$9.9 million. It is not possible to predict with reasonable certainty whether these milestones will be achieved or the timing for achievement.

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;

Edgar Filing: REPLIGEN CORP - Form 10-K

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, 2016 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, 2015, we had net operating loss carryforwards of approximately \$46,984,000 and business tax credits carryforwards of approximately \$1,920,000 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 2035. Net operating loss carryforwards and available tax credits 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.

Foreign earnings

At December 31, 2015, we have not provided for U.S. income taxes or foreign withholding taxes on outside basis differences of foreign subsidiaries of approximately \$30,322,000 as we have the ability and intend to indefinitely reinvest the undistributed earnings of Repligen Sweden 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 decrease in interest rates would result in an approximate \$93,000 decrease in the fair value of our investments as of December 31, 2015. 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 kronor, British pound sterling, U.S. dollars, or in Euros while the entity's functional currency is the Swedish krona. Certain sales transactions related to 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 and 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, 33% and 37% of total revenues during fiscal 2015 and 2014, respectively, were denominated in foreign currencies while 23% and 31% of our costs and expenses during fiscal 2015 and 2014, respectively, were denominated in foreign currencies, primarily operating expenses associated with cost of revenue, sales and marketing and general and administrative. In addition, 43% and 41% of our consolidated tangible assets were subject to foreign currency exchange fluctuations as of each of December 31, 2015 and 2014, respectively, while 21% and 27% of our consolidated liabilities were exposed to foreign currency exchange fluctuations as of each of December 31, 2015 and 2014, 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 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.

Table of Contents

(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, 2015. 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).

Subject to the foregoing, based on this assessment, our management concluded that, as of December 31, 2015, 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, 2015.

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, 2015, 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.

In our opinion, Repligen Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, 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, 2015 and 2014, 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, 2015 of Repligen Corporation and our report dated February 25, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 25, 2016

Table of Contents

(d) Changes in Internal Control Over Financial Reporting

Beginning in the second quarter of 2015, we added a number of new procedures to enhance our internal controls over revenue recognition and inventory costing. A number of these controls are automated system processes that were added in conjunction with the implementation of our enterprise resource planning (ERP) system. Additional controls were added to ensure that procedures were subject to proper review and to ensure the accuracy of information entered into our ERP system. We reviewed and tested these new controls as part of our assessment of the effectiveness of our internal controls as of and for the year ended December, 31, 2015.

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, 2015 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 2015 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 36 of this Report, as follows:

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	49
<u>Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014</u>	50
<u>Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2015, 2014 and 2013</u>	51
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, 2014 and 2013</u>	52
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013</u>	53
<u>Notes to Consolidated Financial Statements</u>	54

(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).
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).
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).

Table of Contents

Exhibit Number	Document Description
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	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).
10.11	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).
10.12#	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).
10.13#	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).
10.14#	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 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).
10.15*	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).
10.16*	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)
10.17#	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).
10.18#	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).
10.19	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).
10.20*	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).

Table of Contents

Exhibit Number	Document Description
10.21*	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).
10.22*	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).
10.23*	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).
10.24*	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).
21.1+	Subsidiaries of the Registrant.
23.1+	Consent of Ernst & Young LLP.
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, 2015, 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.

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 25, 2016

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 25, 2016
/s/ JON K. SNODGRES Jon K. Snodgres	Chief Financial Officer (Principal financial and accounting officer)	February 25, 2016
/s/ KAREN DAWES Karen Dawes	Chairperson of the Board	February 25, 2016
/s/ GLENN L. COOPER Glenn L. Cooper, M.D.	Director	February 25, 2016
/s/ JOHN G. COX John G. Cox	Director	February 25, 2016
/s/ ALFRED L. GOLDBERG Alfred L. Goldberg, Ph.D.	Director	February 25, 2016

Edgar Filing: REPLIGEN CORP - Form 10-K

/s/ GLENN P. MUIR

Director

February 25, 2016

Glenn P. Muir

/s/ THOMAS F. RYAN, JR.

Director

February 25, 2016

Thomas F. Ryan, Jr.

Table of Contents

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	49
<u>Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014</u>	50
<u>Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2015, 2014 and 2013</u>	51
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, 2014 and 2013</u>	52
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013</u>	53
<u>Notes to Consolidated Financial Statements</u>	54

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, 2015 and 2014, 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, 2015. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, 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 25, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 25, 2016

Table of Contents

REPLIGEN CORPORATION
CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 54,092	\$ 35,363
Marketable securities	17,682	23,090
Accounts receivable, less reserve for doubtful accounts of \$31 and \$41, respectively	11,300	7,760
Royalties and other receivables	82	240
Inventories, net	17,998	12,384
Deferred tax asset, net		5
Prepaid expenses and other current assets	2,098	2,104
Total current assets	103,252	80,946
Property, plant and equipment, net	13,801	14,526
Long-term marketable securities	1,633	3,550
Intangible assets, net	12,755	14,636
Goodwill	14,346	14,185
Restricted cash	450	450
Total assets	\$ 146,237	\$ 128,293
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,724	\$ 3,863
Accrued liabilities	12,057	6,819
Total current liabilities	18,781	10,682
Other long-term liabilities	4,708	5,879
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, 32,949,353 shares at December 31, 2015 and 32,774,374 shares at December 31, 2014 issued and outstanding	329	328
Additional paid-in capital	202,527	198,064
Accumulated other comprehensive loss	(8,566)	(5,773)
Accumulated deficit	(71,542)	(80,887)
Total stockholders' equity	122,748	111,732
Total liabilities and stockholders' equity	\$ 146,237	\$ 128,293

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,		
	2015	2014	2013
Revenue:			
Product revenue	\$ 83,537	\$ 60,431	\$ 47,482
Royalty and other revenue		3,117	20,687
Total revenue	83,537	63,548	68,169
Operating expenses:			
Cost of product revenue	35,251	28,022	22,481
Cost of royalty and other revenue			2,682
Research and development	5,740	5,609	7,341
Selling, general and administrative	24,699	17,154	12,701
Contingent consideration fair value adjustments	4,083	2,072	91
Total operating expenses	69,773	52,857	45,296
Income from operations	13,764	10,691	22,873
Investment income	136	309	301
Interest expense	(32)	(50)	(50)
Other income (expense)	(445)	188	(110)
Income before income taxes	13,423	11,138	23,014
Income tax (benefit) provision	4,078	2,968	6,921
Net income	\$ 9,345	\$ 8,170	\$ 16,093
Earnings per share:			
Basic	\$ 0.28	\$ 0.25	\$ 0.51
Diluted	\$ 0.28	\$ 0.25	\$ 0.50
Weighted average shares outstanding:			
Basic	32,881,940	32,497,657	31,667,015
Diluted	33,577,091	33,263,667	32,406,641
Other comprehensive income:			
Unrealized (loss) gain on investments	22	(28)	(19)
Foreign currency translation (loss) gain	(2,815)	(7,743)	106
Comprehensive income	\$ 6,552	\$ 399	\$ 16,180

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 Comprehensive Income (Loss)	Accumulated Deficit	Stockholders Equity
	Number of Shares	Amount	Additional Paid-in Capital			
Balance, December 31, 2012	31,195,041	\$ 312	\$ 187,051	\$ 1,911	\$ (105,150)	\$ 84,124
Net income					16,093	16,093
Unrealized loss on investments				(19)		(19)
Foreign currency translation adjustment				106		106
Share-based compensation expense			1,060			1,060
Exercise of stock options and vesting of restricted stock	730,700	7	2,515			2,522
Balance, December 31, 2013	31,925,741	\$ 319	\$ 190,626	\$ 1,998	\$ (89,057)	\$ 103,886
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

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,		
	2015	2014	2013
Cash flows from operating activities:			
Net income:	\$ 9,345	\$ 8,170	\$ 16,093
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	4,594	4,020	3,114
Stock-based compensation expense	3,598	1,766	1,060
Deferred tax expense (benefit)	(118)	295	2,788
Loss on revaluation of contingent consideration	4,083	2,072	91
Loss on disposal of assets	1	35	2
Changes in assets and liabilities:			
Accounts receivable	(3,729)	(1,597)	(774)
Royalties and other receivables	158	6,557	2,400
Inventories	(6,149)	(860)	(626)
Prepaid expenses and other current assets	(277)	(820)	58
Accounts payable	3,024	2,288	(734)
Accrued liabilities	(1,592)	(2,489)	1,257
Long-term liabilities	2,115	(1,036)	1,201
Net cash provided by operating activities	15,053	18,401	25,930
Cash flows from investing activities:			
Purchases of marketable securities	(20,168)	(27,508)	(42,480)
Redemptions of marketable securities	27,587	34,804	29,209
Acquisition of assets of Refine Technology, LLC		(21,236)	
Increase of restricted cash		(250)	
Purchases of property, plant and equipment	(2,628)	(5,602)	(4,635)
Net cash provided by (used in) investing activities	4,791	(19,792)	(17,906)
Cash flows from financing activities:			
Exercise of stock options	866	1,680	2,450
Excess tax benefit on exercise of stock options			72
Payments of contingent consideration	(99)		
Net cash provided by financing activities	767	1,680	2,522
Effect of exchange rate changes on cash and cash equivalents	(1,882)	(4,756)	74
Net increase (decrease) in cash and cash equivalents	18,729	(4,467)	10,620
Cash and cash equivalents, beginning of period	35,363	39,830	29,210
Cash and cash equivalents, end of period	\$ 54,092	\$ 35,363	\$ 39,830
Supplemental information:			
Income taxes paid	\$ 4,948	\$ 2,547	\$ 1,264
Business Acquisitions:			
Fair value of tangible assets acquired		1,175	
Fair value of accounts receivable		1,647	
Fair value of other assets		184	

Edgar Filing: REPLIGEN CORP - Form 10-K

Liabilities assumed	(365)
Fair value of stock issued	(4,000)
Cost in excess of fair value of assets acquired (Goodwill)	13,199
Acquired identifiable intangible assets	9,100
In-process research and development	1,600
	22,540
Less accrued contingent consideration	(1,370)
Working capital adjustment, reflected in other receivables as of December 31, 2014	66