REPLIGEN CORP
Form 10-K
March 15, 2013
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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, 2012

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	04-2729386
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

41 Seyon Street, Bldg. 1, Suite 100

Waltham, MA	02453
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: (781) 250-0111

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.01 Par Value Per Share	The NASDAQ Stock Market LLC

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

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

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 x.

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 x 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 x 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. x

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

Large accelerated filer ¨	Accelerated filer x	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 x.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2012, the last business day of the registrant s most recently completed second fiscal quarter, was $126,339,916.

The number of shares of the registrant s common stock outstanding as of February 20, 2013 was 31,219,541.

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, 2012. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 life sciences company that develops, manufactures and markets high-value, consumable bioprocessing products for life sciences companies and biopharmaceutical manufacturing companies worldwide. We are a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in biomanufacturing to separate and purify monoclonal antibodies, a type of biologic drug. We also supply several growth factor products used to increase cell culture productivity during the biomanufacturing process. In the burgeoning area of disposable biomanufacturing technologies, we have developed and currently market a series of OPUS® (Open-Platform, User-Specified) chromatography columns for use in clinical-scale manufacturing. These pre-packed, plug-and-play columns are uniquely flexible and customizable to our customers media and size requirements. We generally manufacture and sell Protein A and growth factors to life sciences companies under long-term supply agreements and sell our chromatography columns, as well as media and quality test kits, directly to biopharmaceutical companies or contract manufacturing organizations. We refer to these activities as our bioprocessing business.

On December, 20, 2011, we significantly increased the size of our bioprocessing business through a strategic acquisition. We acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB (Novozymes) in Lund, Sweden, including the manufacture and supply of cell culture ingredients and Protein A affinity ligands for use in industrial cell culture, stem and therapeutic cell culture and biopharmaceutical manufacturing (the Novozymes Biopharma Business and the acquisition of the Novozymes Biopharma Business, the Novozymes Acquisition) for a total upfront cash payment of 20.65 million Euros (~$26.9 million). As a result of the Novozymes Acquisition, we nearly doubled the size of our bioprocessing business.

Historically, Repligen also conducted activities aimed at developing proprietary therapeutic drug candidates, often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. In addition, we have out-licensed certain intellectual property to Bristol-Myers Squibb Company, or Bristol, from which we receive royalties on Bristol s net sales in the United States of their product Orencia®. As part of our strategic decision in 2012 to focus our efforts on our core bioprocessing business, we scaled back our efforts on our clinical development programs and increased our efforts to find collaboration partners to pursue the development and, if successful, commercialization of these drug programs. The current status of our development portfolio is:

On December 28, 2012, we out-licensed our SMA program, led by RG3039, to Pfizer Inc., or Pfizer. Pursuant to this license agreement, Pfizer will assume the majority of the costs associated with completing the required clinical trials for this program as well as obtaining U.S. Food and Drug Administration (FDA) approval of the respective new drug application (NDA). Under the license agreement, we are obligated to conduct additional activities in support of this program, which will include completing the second cohort of the current Phase I trial and supporting the transition of the program to Pfizer. We expect to complete these activities in the first half of 2013.

The most advanced product candidate in our development portfolio is RG1068, a synthetic human hormone being developed as a novel imaging agent for the improved detection of pancreatic duct

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abnormalities in combination with magnetic resonance imaging in patients with pancreatitis and potentially other pancreatic diseases. We submitted an NDA to the FDA and a marketing authorization application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2012. In the second quarter of 2012, we received a complete response letter from the FDA, indicating the need for additional clinical efficacy and safety trial data. We are currently working with the FDA on the details of an additional Phase III trial. We believe providing certainty as to the requirements of this additional Phase III trial may be an important factor in the decision by third-parties that may wish to pursue a development or commercialization agreement with us for RG1068.

Our third clinical development program was targeted at Friedrich s Ataxia and led by RG2833, a class I histone deacetylase (HDAC) inhibitor. RG2833 has received Orphan Drug designation from the FDA and European Commission. We initiated a single, ascending dose Phase 1 study of RG2833 in Friedreich s Ataxia patients in Italy in the fourth quarter of 2012 and expect to complete this trial in the first half of 2013. We believe the results of this trial may be an important consideration for any third-party that may wish to pursue a development or commercialization agreement with us for RG2833. We expect that any additional development activities that we may pursue in the future will be largely supported by sponsors or collaborators.

On April 7, 2008, we entered into a settlement agreement with Bristol in connection with a patent infringement lawsuit we filed against Bristol. Under the terms of the agreement, Bristol is obligated to pay us royalties on its U.S. net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500,000,000 of annual sales, 2.0% for the next $500,000,000 of annual sales and 4% of annual sales in excess of $1 billion. Under the terms of the agreement, we will not receive any future royalties on Bristol s sales of Orencia® made after December 31, 2013.

Corporate Background

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.

Change in Fiscal Year

In 2011 we changed our fiscal year end from March 31 to December 31. This Annual Report on Form 10-K reports our financial results for the twelve-month period from January 1, 2012 through December 31, 2012. This report also includes our financial results for the nine-month periods ending on December 31, 2011 and December 31, 2010 and the twelve-month period ending March 31, 2011.

Currently Marketed Products

We currently sell various commercial bioprocessing products based on Protein A and growth factors, as well as a line of pre-packed chromatography columns and quality test kits, which are used in the production of monoclonal antibodies and other biopharmaceutical products.

Our Products for Biologics Manufacturing

Repligen is a leading manufacturer of consumable bioprocessing products including multiple products based on Protein A, growth factors used in fermentation, quality test kits and chromatography products such as proprietary media and a line of pre-packed chromatography columns. These products are sold to life sciences companies, contract manufacturing organizations and biopharmaceutical companies for use in the production of monoclonal antibodies and other biologic drugs. Demand for our bioprocessing products has grown in concert with the expanding markets for biologics, particularly monoclonal antibodies, as well as a result of adding new product offerings through our acquisition of the Novozymes Biopharma Business in December 2011.

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In 2011, the global biologics market was valued at approximately $160 billion and is expected to grow at a rate in the high single digits annually. Market research indicates that the monoclonal antibody segment comprised approximately 32% of the overall biologics market in 2011 and is growing more rapidly than the overall market. Six of the ten worldwide best-selling drugs in 2012 are monoclonal antibodies and include products such as Enbrel® and Remicade® for rheumatoid arthritis and other inflammatory disorders, and Rituxan® for non-Hodgkin s lymphoma. There are more than 35 approved monoclonal antibody products and over 350 product candidates currently in clinical development, most of which are manufactured using Protein A.

Repligen has been a leading supplier of Protein A for more than ten years and manufactures five forms of Protein A for major life sciences companies including GE Healthcare and EMD Millipore under long-term supply agreements which extend to dates between 2016 and 2021. To be useful in manufacturing, Protein A is chemically bound to proprietary beads that are manufactured by life sciences companies, such as those mentioned above. These beads provide the rigid support required to use Protein A in the manufacturing process for monoclonal antibodies. The Protein A attached to the beads is known as Protein A chromatography media, which is packed by end-users into cylindrical columns and used to purify monoclonal antibodies. For example, after fermentation of a monoclonal antibody, the broth containing the monoclonal of interest as well as numerous fermentation by-products and contaminants is pumped through a column filled with Protein A chromatography media which selectively binds to and captures the monoclonal antibody. Protein A has a high affinity for the monoclonal antibody and as a result, the antibody stays bound to the Protein A media and the impurities flow through the column. After the impurities are washed away, a change in conditions releases the purified antibody. As a result, the monoclonal antibody product is highly purified and concentrated from a single purification step. Further purification steps are usually necessary to increase purity to a level greater than 98%. Over the past three years, the majority of our product sales have been sales of Protein A products.

Most biopharmaceuticals are produced through mammalian fermentation. In order to spur increased cell growth, manufacturers add growth factors and nutrients to the fermenter. As part of the Novozymes Acquisition, the Company acquired four fermentation and cell culture growth factor products. Among those products is LONG®R3 IGF-I, a growth factor that is more biologically potent than insulin, and that has been shown to significantly increase recombinant protein production in fermentation applications. LONG®R3 IGF-I is currently used in the manufacture of nine commercial biopharmaceutical products and is sold under a distribution agreement with Sigma-Aldrich Corporation (Sigma) which extends to 2021. Sigma has distribution rights for industrial cell culture applications while Repligen sells the product for use in stem cell and other cell-based therapies. In addition, we acquired long epidermal growth factor (LONG®EGF) and transforming growth factor alpha (LONG®TGF-a) supplements for serum-free or low serum culture in cell-based therapy applications, as well as recombinant transferrin (rTransferrin) which has been developed as an iron supplement for cell culture. There may be additional applications for these growth factors in stem cell and other cell-based therapies.

We also sell a number of products used for purification and quality control applications to contract manufacturers and biopharmaceutical companies including: pre-packed, disposable chromatography columns, proprietary Protein A chromatography media and quality test kits. Our pre-packed chromatography columns are sold in a variety of sizes with the customer s choice of media. This product line consists of patented technology that we acquired from BioFlash Partners, LLC (BioFlash) in January 2010 and products/technology that we developed as a result of our internal research and development efforts. We call this line of chromatography products OPUS (Open Platform User Specified). OPUS columns have the potential to improve manufacturing efficiencies and lower costs by reducing time for column packing, validation, set-up and cleaning. In addition, because OPUS columns are plug-and-play we believe they offer customers significantly greater manufacturing flexibility when used with other flexible, disposable technologies. In early 2012, we introduced new, process-scale OPUS chromatography columns with diameters of 20cm and 30cm. These new products are well suited for the production of a broad range of clinical trial material and niche commercial products such as orphan biologics.

Our proprietary Protein A chromatography media is used by contract manufacturers and biopharmaceutical companies in a variety of applications, including in the purification of some currently marketed biotherapeutics.

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Customers use our ELISA test kits to ensure that there are minimal levels of residual Protein A in the final bulk drug product.

Research and Development

We have conducted research activities aimed at developing proprietary therapeutic drug candidates in various stages of clinical development often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. As part of our strategic decision to focus the Company s efforts on our core bioprocessing business, we scaled back our research efforts on our clinical development programs and increased our efforts to find collaboration partners to finish their development and, if successful, commercialize these therapeutic drug candidates. Consequently, we believe that our research and development expenses will be lower in the future. We expect that any research and development activities that we undertake in the future with respect to our therapeutic drug candidates will be limited to those which could support the transition of development and commercialization activities for these programs to potential collaborators. In addition, we expect these activities will be substantially funded by potential sponsors, collaborators or licensees. We intend to focus the majority of our future research and development efforts on developing new bioprocessing products. Specifically, we plan to focus these efforts on our growth factor and chromatography product offerings because we believe those markets may offer a higher rate of growth than the Protein A market.

Therapeutic Product Candidates for Out-license

We currently have two therapeutic development programs available for outlicensing: RG1068, a diagnostic imaging agent for patients with pancreatic abnormalities; and RG2833, an early stage program for the treatment of Friedreich s Ataxia, a rare muscular disorder.

We completed a Phase 3 clinical trial evaluating the sensitivity and specificity of RG1068 (also known as SecreFlo) in combination with MRI to improve the detection of structural abnormalities of the pancreas relative to MRI alone. Based on the results of this trial, we submitted an NDA to the FDA for RG1068 in December 2011. In April 2012, we received a complete response letter from the FDA requesting additional clinical efficacy and safety trial data to support potential approval of the NDA. In 2012, we also submitted an MAA for RG1068 for review by the EMA in the same initial indication. In connection with our decision to focus on our core bioprocessing business, we withdrew this MAA in the fourth quarter of 2012. We are currently working with the FDA to identify the additional clinical requirements for this product candidate. Other than identifying the additional clinical requirements, we do not anticipate putting significant, additional development efforts into this product candidate unless such efforts are predominantly funded by a licensee or collaborator. In conjunction with this decision, we continue to seek development and commercialization partners for RG1068.

We also have a product candidate, RG2833, a class I HDAC inhibitor, in Phase 1 clinical development for the treatment of Friedreich s ataxia. 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. To date, the development of RG2833 has been partially funded by several groups including GoFAR, a patient advocacy based in Italy, the Friedreich s Ataxia Research Alliance (also known as FARA), the Muscular Dystrophy Association, the European Friedreich s Ataxia Consortium for Translations Studies (also known as EFACTS) and the National Ataxia Foundation (also known as NAF). We initiated a single, ascending dose Phase 1 study in Friedreich s ataxia patients in Italy in the first quarter of 2012 and expect to complete this trial in the first half of 2013. As part of the program, we developed methods to measure changes in frataxin levels in patient cells for use in our clinical trial which may enable us to gain an early insight into the potential benefit of treating patients with RG2833. Once the trial is complete, we do not anticipate making significant expenditures into this product candidate unless such expenditures are substantially funded by a collaborator or licensee. In conjunction with this decision, we are continuing to seek development and commercialization partners for RG2833.

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We were also developing RG3039 for treatment of patients with spinal muscular atrophy (SMA). This program was out-licensed to Pfizer in December 2012. SMA is an inherited neurodegenerative disease in which a defect in the survival motor neuron gene (SMN) results in low levels of the protein SMN which leads to progressive damage to motor neurons, loss of muscle function and, in many patients, early death.

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 and are entitled to receive up to $65 million in potential future milestone payments, a portion of which may be owed to third parties. These potential payments are approximately equally divided between milestones related to clinical development and initial commercial sales in specific geographies. In addition, we are entitled to receive royalties on any future sales of RG3039 or any SMA compounds developed under the License Agreement. The License Agreement also provides for tiered and increasing royalty rates which begin in the high single-digits for RG-3039 or lesser amounts for any backup compounds developed under the License Agreement. Our receipt of these royalties is subject to an obligation under an existing in-license agreement and other customary offsets and deductions. Royalties are payable, on a country-by-country basis, for a duration based upon the later of (a) expiration of the licensed patent(s) or (b) a predetermined time after the first commercial sale of the first such product in such country.

Pursuant to this license agreement, Pfizer will assume virtually all of the costs associated with completing the required clinical trials for this program as well as obtaining FDA approval of the respective NDA. Under the license agreement, we are obligated to conduct additional activities in support of this program, which will include completion of the second cohort of the current Phase I trial and supporting the transition of the program to Pfizer. We will also provide specific technology transfer services to Pfizer who will then assume full responsibility for the SMA program moving forward, including the conduct of any registration trials necessary for any product approvals. We expect to complete our work on this program in the first half of 2013. Pfizer may terminate the license agreement at any time for convenience.

Orencia® (CTLA4-Ig) Royalties

CTLA4 is a key regulator of the activity of the immune system. CTLA4 turns off the immune system after it has successfully cleared a bacterial or viral infection by blocking the activation of T-cells, the immune cells responsible for initiating an immune response. In the 1990 s, our collaborators at the University of Michigan and the U.S. Navy demonstrated in animal models that a fusion protein consisting of fragments of CTLA4 and an antibody (CTLA4-Ig) could be used to treat certain autoimmune diseases. This research finding resulted in the granting of U.S. patent No. 6,685,941 (the 941 Patent) covering the treatment of certain autoimmune disorders including rheumatoid arthritis with CTLA4-Ig. CTLA4-Ig s mechanism of action is different from the current therapies for autoimmune disease or organ transplant rejection, thus, it may provide a treatment for patients who are refractory to existing therapies.

In December 2005, the FDA approved Bristol s application to market CTLA4-Ig, under the brand name Orencia®, for treatment of rheumatoid arthritis. In January 2006, Repligen and the University of Michigan jointly filed a lawsuit against Bristol in the United States District Court for the Eastern District of Texas for infringement of the 941 Patent. In April 2008, Repligen and the University of Michigan entered into a settlement agreement with Bristol pursuant to which, Bristol made an initial payment of $5 million to us and agreed to pay us royalties on the U.S. net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500 million of annual sales, 2.0% for the next $500 million and 4.0% of annual sales in excess of $1 billion for each year from January 1, 2008 until December 31, 2013.

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The 941 Patent is owned by the University of Michigan and exclusively licensed to Repligen. In consideration of this exclusive license, Repligen agreed to pay the University of Michigan 15% of all royalty income received from Bristol, after deducting legal expenses. There are no annual or other fees associated with this agreement. As of December 31, 2012, we have paid approximately $7,503,000 to the University of Michigan under this agreement.

Sales and Marketing

We sell our bioprocessing products through our direct sales force, partners such as GE Healthcare, EMD Millipore, Sigma Aldrich and distributors in certain foreign markets.

Segment and Geographic Areas

We have one reportable segment. Segment and geographical information is contained in Note 2, the notes to our consolidated financial statements.

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. For the fiscal year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011, the nine-month period ended December 31, 2010 and the fiscal year ended March 31, 2011, total revenues from sales to customers in the United States were approximately 46%, 48%, 48% and 50%, respectively. During the same periods, total revenues generated though sales to customers in Sweden were 42%, 44%, 45% and 42%, respectively. For the fiscal year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011, the nine-month period ended December 31, 2010 and the fiscal year ended March 31, 2011, royalty revenue from Bristol represented 24%, 37%, 37% and 38% of total revenues, respectively. Our largest bioprocessing customer accounted for 42%, 44%, 45% and 42% of total revenues in the fiscal year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011, the nine-month period ended December 31, 2010 and the fiscal year ended March 31, 2011, respectively.

Employees

As of February 20, 2013, we had 120 employees. Of those employees, 92 were engaged in research, development and manufacturing and 28 were in administrative and marketing 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 55 employees in Sweden, comprising approximately 46% of our total workforce. The current collective bargaining agreements expire on March 31, 2013. The Company considers its employee relations to be satisfactory.

Patents, Licenses and Proprietary Rights

Repligen considers patents, trade secrets and know-how 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 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, orphan drug status and know-how, are also considered important elements of our proprietary strategy. With regard to protection of trade secrets and know-how, our policy is to require each of our employees, consultants, business partners and major customers to

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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 B2, 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 extension that was granted, will remain in effect until 2028. Foreign equivalents of this patent are being prosecuted outside of the United States.

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 and cleaning that is improved over existing 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.

CTLA4-Ig

The 941 patent, covering the use of CTLA4-Ig to treat specific autoimmune disorders including rheumatoid arthritis and multiple sclerosis was issued in February 2004. The patent is assigned to the University of Michigan and the U.S. Navy and is exclusively licensed to Repligen. In April 2008, Repligen granted Bristol an exclusive sublicense to this patent, pursuant to which Bristol pays us royalties on its U.S. net sales of its rheumatoid arthritis drug, Orencia® through December 31, 2013.

Spinal Muscular Atrophy

In 2009, Repligen entered into an exclusive license agreement with a non-profit organization, FSMA, for worldwide rights to patent applications related to compositions and methods for the 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. 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.

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. If we are successful in our efforts to enter into a development or commercialization partnership for RG2833, we intend to transfer the prosecution of these patent applications to such partner.

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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. These companies range in size from large, multi-national companies to small, private emerging growth companies. 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 five forms of commercial scale Protein A including native Protein A for life sciences companies including GE Healthcare and EMD Millipore under long-term supply agreements which expire between 2016 and 2021. Native Protein A is manufactured in Sweden, while the recombinant forms are manufactured in both Waltham and Sweden. We currently manufacture our growth factor products in Sweden and assemble and pack our pre-packed chromatography media columns in Waltham.

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. We utilize our own facilities in Waltham 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 is ISO 9001 certified and maintains a formal quality system to maintain process control, traceability, and product conformance. Our Sweden facility, located in Lund, is cGMP certified. 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.

Government Regulation

The development of drug candidates is subject to regulation in the United States by the FDA and abroad by foreign equivalents. Product development and approval within the FDA regulatory framework usually takes a significant number of years and involves the expenditure of substantial capital resources. Timelines for development are uncertain.

Before clinical testing in the United States of any drug candidate may begin, FDA requirements for preclinical efficacy and safety must be completed. Required toxicity testing typically involves characterization of the drug candidate in several animal species. Safety and efficacy data are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of human clinical trials.

Clinical trials involve the administration of the drug to human volunteers or patients under the supervision of a qualified investigator, usually a physician, with an FDA-approved protocol. Human clinical trials are typically conducted in three sequential phases:

Phase 1 clinical trials represent the initial administration of the investigational drug to a small group of human subjects to test for safety (pharmacovigilance), dose tolerability, absorption, biodistribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy and potential biomarkers.

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Phase 2 clinical trials typically involve a small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose tolerance and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.

Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 clinical trials are initiated to establish further clinical safety and efficacy of the investigational drug in a broader sample of the general patient population at multiple study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for product approval. The Phase 3 clinical development program consists of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product.

All data obtained from a comprehensive development program are submitted in an NDA to the FDA and the corresponding agencies in other countries for review and approval. The NDA includes information pertaining to clinical studies and the manufacture of the new drug. Review of an NDA by the FDA can be a time-consuming process, and the FDA may request that we submit additional data or carry out additional studies.

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.

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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 may fail to realize additional benefits from the Novozymes Acquisition.

We will be required to expend additional time and resources in order to realize all of the anticipated synergies, business opportunities and growth prospects that we anticipated at the time of the acquisition of the Novozymes Biopharma Business. We may never fully realize these anticipated synergies, business opportunities and growth prospects. Integrating operations is complex and requires significant efforts and expenditures. Assumptions underlying estimated benefits may be inaccurate and general industry and business conditions might deteriorate. Our management might have its attention diverted while continuing the integration of operations and corporate and administrative infrastructures from the Novozymes architecture into the correlative Repligen systems. If any of these factors limit our ability to fully-integrate our operations with those of the Novozymes Biopharma Business successfully or on a timely basis, the expectations of future results of operations, including synergies and other benefits expected to result from the Novozymes Acquisition, might not be met.

We incurred significant transaction, integration and other costs in connection with the Novozymes Acquisition and these costs may exceed the realized benefits, if any, of the synergies and efficiencies from the acquisition.

We have already incurred significant transaction costs related to the Novozymes Acquisition. In addition, we expect to continue to incur integration costs as we work toward completing the integration of the Novozymes Biopharma Business with our own. Financial, managerial and operational challenges of the Novozymes Acquisition may include:

- challenges associated with managing the larger, more complex, combined business;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in systems integration, particularly information technology and finance systems, and conforming standards, controls, procedures and policies, business cultures and compensation structures between the entities;
- difficulties in integrating the Novozymes Biopharma Business products and technologies;
- disruptions in relationships with customers and suppliers;
- coordinating geographically dispersed organizations;
- risks associated with acquiring intellectual property;

difficulties in operating the Novozymes Biopharma Business profitably;

the inability to achieve anticipated synergies, cost savings or growth;

potential loss of key employees;

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unanticipated costs; and

potential disputes with Novozymes Denmark.

No assurances can be given that the expected synergies and other benefits of the Novozymes Acquisition will exceed the transaction and integration costs and the costs associated with these potential financial, managerial and operational challenges, or that expected synergies and other benefits will be achieved in the near term or at all.

If intangible assets that we recorded in connection with the Novozymes Acquisition 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. 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 increased dramatically since the consummation of the Novozymes Acquisition.

Our operations and sales outside of the United States have increased and may continue to increase as a result of the Novozymes Acquisition. Risks related to these increased foreign operations include:

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

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

fluctuations in foreign currency exchange rates;

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 risks to which our exposure has increased following the Novozymes Acquisition. We cannot assure you that these and other related factors will not materially adversely affect our international operations or business as a whole since the consummation of the Novozymes Acquisition.

We may be unable to manage efficiently having become a larger and more geographically diverse organization since the consummation of the Novozymes Acquisition.

Since the acquisition of the Novozymes Biopharma Business, we have faced challenges inherent in efficiently managing 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

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combined organization could materially adversely affect our operating results and, as a result, the market price of our common stock.

The environmental risks of our business have increased dramatically since the Novozymes Acquisition.

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 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;
- 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 issuance of dilutive securities, assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash;
- any collaboration, strategic alliance and licensing arrangement may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us;
- diversion of management s attention and company resources from existing operations of the business;

inconsistencies in standards, controls, procedures, and policies;

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

assumption of, or exposure to, unknown contingent liabilities or 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,

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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.

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.

As a result, 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.

As we evolve from a company involved in research and development to a company with a strategic focus on our bioprocessing business, we may encounter difficulties in expanding our operations successfully.

In connection with the Company s decision to focus our efforts on the growth of our core bioprocessing business, we will continue to seek development and commercialization partnerships for our remaining portfolio of therapeutic and diagnostic assets. Our future financial performance will depend, in part, on our ability to successfully negotiate and consummate these partnerships. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from monetizing our clinical stage assets, including RG1068 and RG2833. There is also no guarantee that we will successfully expand our bioprocessing business as a result of this change in strategic focus and the Company s financial performance will likely suffer if we are unable to do so.

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

Our royalty agreement with Bristol provides 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 will no longer receive royalty payments under this agreement after December 31, 2013. If we are unable to replace these royalty payments with an alternative source of revenue and related income, our operating results will decline and, as a result, we may experience a decline in the price of our common stock. In addition, we have no control over Bristol s sales and marketing practices for Orencia®, and Bristol has no obligation to use commercially reasonable efforts to sell Orencia®. Bristol s sales could be significantly impacted by regulatory and market influences beyond our control, resulting in low or even no royalty revenue for us.

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, EMD Millipore, Sigma-Aldrich, Life Technologies and through other individual distributors. However, we expect a significant amount of our future revenue growth to come from bioprocessing products that we sell directly to end-users such as biopharmaceutical companies and contract manufacturing organizations. This may 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, 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

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opposition proceedings brought by third parties or result in suits by us, which may be costly and result in adverse consequences for us.

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

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

Since some of our U.S. patents covering recombinant Protein A have expired, 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 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.

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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 that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and with terms that are no less favorable to us than the current terms of the arrangements, our business, results of operations, financial condition, cash flow and future prospects may be harmed.

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

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

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

We expect a portion of our future revenue growth to come from introducing new bioprocessing products, such as a larger size version of our OPUS disposable chromatography products which we began selling in 2012. The commercial success of these new products as well as the products acquired in the Novozymes Acquisition 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 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

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harm our business. Such defects or errors could also narrow the scope of the use of our products, which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any lingering concerns in our target market regarding our technology or any manufacturing defects or performance errors in our products could continue to result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

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

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

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

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

We may be unsuccessful in negotiating and consummating development and commercialization partnerships for our remaining portfolio of therapeutic and diagnostic assets on acceptable terms, if at all.

Our decision to focus on the growth of the Company s core bioprocessing business will result in the Company seeking development or commercialization partners for our remaining portfolio of therapeutic and diagnostic assets. The consummation and performance of any such future development and commercialization transactions will involve risks, such as:

- diversion of managerial resources from day-to-day operations;
- exposure to litigation from the counterparties to any such transaction or other third parties;
- misjudgment with respect to value;
- higher than expected transaction costs; or
- an inability to successfully consummate any such transaction or collaboration.

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Our future revenues pursuant to our license agreement with Pfizer regarding the SMA program depends significantly on Pfizer s development and commercialization activities, over which we have little control. If Pfizer is unable or determines not to further develop or commercialize the SMA 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 a license agreement with Pfizer on December 28, 2012, related to the SMA program, which is led by RG3039 and also includes backup compounds and enabling technologies. We are dependent on Pfizer for the future success of this development program. Other than assisting in the completion of the first two cohorts of an active Phase 1 trial evaluating RG3039 in healthy volunteers, we will have no future control over the conduct and timing of development efforts with respect to the SMA program. Although we have had discussions with Pfizer regarding their current plans and intentions for the development of the SMA program, they may revise their plan in their sole discretion. Pfizer 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 license agreement and may preclude or delay commercialization of any product under the SMA program and any royalties we could receive on future commercial sales. Because the license we granted to Pfizer is exclusive, our future financial results may be harmed if Pfizer does not commercialize the SMA program successfully or on a timely basis or if Pfizer elects to terminate the license agreement prior to the achievement of any milestones or the payment of any royalties to us.

Healthcare 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 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. In addition, the pendency or approval of such proposals could result in a decrease in the price of Repligen s common stock or limit our ability to raise capital or to enter into collaborations or license rights to our products.

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.

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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 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 expects that its therapeutic product development activities will be significantly reduced. The core bioprocessing business on which the Company will focus 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 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

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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. In addition, these 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.

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.

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

The Company conducts a large portion of its business in international markets. For the fiscal year ended December 31, 2012, 28% of the Company s revenue and 39% of its costs and expenses were denominated in foreign currencies, primarily the Swedish Kroner. Therefore, the Company is exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U.S. Dollar, which would 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 weakness 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

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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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We currently lease and occupy approximately 56,000 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. In addition, we lease approximately 10,000 square feet of space at a second location in Waltham for expanded manufacturing and administrative operations. This lease expired on December 31, 2012 and we now rent 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, 2012, we incurred total rental costs for all facilities of approximately $2,183,000.

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.

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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, 2012	
	High	Low
First Quarter	$ 6.00	$ 3.40
Second Quarter	$ 7.29	$ 3.72
Third Quarter	$ 6.36	$ 3.78
Fourth Quarter	$ 6.80	$ 4.90

	Nine Months Ended December 31, 2011	
	High	Low
First Quarter	$ 4.20	$ 3.30
Second Quarter	$ 3.78	$ 3.17
Third Quarter	$ 3.72	$ 2.90

Stockholders and Dividends

As of February 19, 2013, there were approximately 601 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

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans.

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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, 2012. In prior years, we repurchased a total of 592,827 shares, leaving 657,173 shares remaining under this authorization.

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.

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Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data are derived from the audited financial statements of Repligen, except for the consolidated financial data at December 31, 2010 and for the nine months then ended which are derived from unaudited financial statements. 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 Transition Report on Form 10-K for the nine months ended December 31, 2011 and our Annual Reports on Form 10-K for the fiscal years ended March 31, 2011, and 2010.

	Year Ended December 31, 2012	Nine Months Ended December 31, 2011	Nine Months Ended December 31, 2010	Years Ended March 31, 2011	Years Ended March 31, 2010	Years Ended March 31, 2009
			(In thousands except per share amounts)			
Revenue:						
Product revenue	$ 41,834	$ 13,215	$ 11,811	$ 14,961	$ 10,305	$ 14,529
Royalty and other revenue	20,433	10,235	9,574	12,330	10,666	14,833
Total revenue	62,267	23,450	21,385	27,291	20,971	29,362
Operating expenses:						
Cost of product revenue	24,957	5,157	4,187	5,580	4,159	5,686
Cost of royalty and other revenue	2,213	1,315	1,161	1,537	1,347	1,091
Research and development	10,490	9,462	8,745	12,529	14,160	12,772
Selling, general and administrative	13,227	9,050	5,580	8,019	7,072	5,933
Contingent consideration fair value adjustments	611					
Gain on bargain purchase	(314)	(427)				
Total operating expenses	51,184	24,557	19,673	27,665	26,738	25,482
Income (loss) from operations	11,083	(1,107)	1,712	(374)	(5,767)	3,880
Investment income	219	161	287	357	870	1,896
Interest expense	(57)	(28)	(12)	(26)	(2)	(3)
Other income (expense)	26	(623)				
Income (loss) before income taxes	11,271	(1,597)	1,987	(43)	(4,899)	5,773
Income tax (benefit) provision	(2,885)	16			(835)	27
Net income (loss)	$ 14,156	$ (1,613)	$ 1,987	$ (43)	$ (4,064)	$ 5,746
Earnings (loss) per share:						
Basic	$ 0.46	$ (0.05)	$ 0.06	$ (0.00)	$ (0.13)	$ 0.19
Diluted	$ 0.45	$ (0.05)	$ 0.06	$ (0.00)	$ (0.13)	$ 0.18
Weighted average shares outstanding:						
Basic	30,914	30,774	30,778	30,782	30,752	30,958
Diluted	31,253	30,774	30,949	30,782	30,752	31,290

	As of December 31, 2012	As of December 31, 2011	As of December 31, 2010	As of March 31, 2011	As of March 31, 2010	As of March 31, 2009
			(In thousands)			
Balance Sheet Data:						
Cash and marketable securities (1)	$ 49,970	$ 36,025	$ 60,285	$ 61,503	$ 59,146	$ 63,961

Working capital	55,457	39,431	55,563	51,221	55,024	50,235
Total assets	97,010	76,057	73,099	72,294	71,420	73,755
Long-term obligations	2,133	2,606	617	584	642	82
Accumulated deficit	(105,151)	(119,307)	(115,934)	(117,965)	(117,921)	(113,857)
Stockholders equity	84,125	65,987	68,882	67,087	66,120	69,123

(1) Excludes restricted cash of $200 related to our headquarters lease arrangement for all years presented.

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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, clinical trials and results, litigation strategy, product candidate research, development and regulatory approval, 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.

Overview

We are a life sciences company that develops, manufactures and markets high-value, consumable bioprocessing products for life sciences companies and biopharmaceutical manufacturing companies worldwide. We are a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in biomanufacturing to separate and purify monoclonal antibodies, a type of biologic drug. We also supply several growth factor products used to increase cell culture productivity during the biomanufacturing process. In the burgeoning area of disposable biomanufacturing technologies, we have developed and currently market a series of OPUS (Open-Platform, User-Specified) chromatography columns for use in clinical-scale manufacturing. These pre-packed, plug-and-play columns are uniquely flexible and customizable to our customers media and size requirements. We generally manufacture and sell Protein A and growth factors to life sciences companies under long-term supply agreements and sell our chromatography columns, as well as media and quality test kits, directly to biopharmaceutical companies or contract manufacturing organizations. We refer to these activities as our bioprocessing business.

On December, 20, 2011, we significantly increased the size of our bioprocessing business through a strategic acquisition. We acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB (Novozymes) in Lund, Sweden, including the manufacture and supply of cell culture ingredients and Protein A affinity ligands for use in industrial cell culture, stem and therapeutic cell culture and biopharmaceutical manufacturing (the Novozymes Biopharma Business and the acquisition of the Novozymes Biopharma Business, the Novozymes Acquisition) for a total upfront cash payment of 20.65 million Euros (~$26.9 million). As a result of the Novozymes Acquisition, we nearly doubled the size of our bioprocessing business.

Historically, Repligen also conducted activities aimed at developing proprietary therapeutic drug candidates, often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. In addition, we have out-licensed certain intellectual property to Bristol-Myers Squibb Company, or Bristol, from which we receive royalties on Bristol s net sales in the United States of their product Orencia®. As part of our strategic decision in 2012 to focus our efforts on our core bioprocessing business, we scaled back our efforts on our clinical development programs and increased our efforts to find collaboration partners to pursue the development and, if successful, commercialization of these drug programs. The current status of our development portfolio is:

On December 28, 2012, we out-licensed our SMA program, led by RG3039, to Pfizer Inc., or Pfizer. Pursuant to this license agreement, Pfizer will assume the majority of the costs associated with

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completing the required clinical trials for this program as well as obtaining U.S. Food and Drug Administration (FDA) approval of the respective new drug application (NDA). Under the license agreement, we are obligated to conduct additional activities in support of this program, which will include completing the second cohort of the current Phase I trial and supporting the transition of the program to Pfizer. We expect to complete these activities in the first half of 2013.

The most advanced product candidate in our development portfolio is RG1068, a synthetic human hormone being 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. We submitted an NDA to the FDA and a marketing authorization application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2012. In the second quarter of 2012, we received a complete response letter from the FDA, indicating the need for additional clinical efficacy and safety trial data. We are currently working with the FDA on the details of an additional Phase III trial. We believe providing certainty as to the requirements of this additional Phase III trial may be an important factor in the decision by third-parties that may wish to pursue a development or commercialization agreement with us for RG1068.

Our third clinical development program was targeted at Friedrich s Ataxia and led by RG2833, a class I histone deacetylase (HDAC) inhibitor. RG2833 has received Orphan Drug designation from the FDA and European Commission. We initiated a single, ascending dose Phase 1 study of RG2833 in Friedreich s Ataxia patients in Italy in the fourth quarter of 2012 and expect to complete this trial in the first half of 2013. We believe the results of this trial may be an important consideration for any third-party that may wish to pursue a development or commercialization agreement with us for RG2833. We expect that any additional development activities that we may pursue in the future will be largely supported by sponsors or collaborators.

On April 7, 2008, we entered into a settlement agreement with Bristol in connection with a patent infringement lawsuit we filed against Bristol. Under the terms of the agreement, Bristol is obligated to pay us royalties on its U.S. net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500,000,000 of annual sales, 2.0% for the next $500,000,000 of annual sales and 4% of annual sales in excess of $1 billion. Under the terms of the agreement, we will not receive any future royalties on Bristol s sales of Orencia® made after December 31, 2013.

Total revenue for the fiscal year ended December 31, 2012 increased as compared to the nine-month fiscal year ended December 31, 2011 and is primarily due to the acquisition of the Novozymes business as well as increased royalty revenue from Bristol as their product Orencia® continues to penetrate the market.

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 products, licensing transactions and research and development collaborations. Our product revenues are from the sale of bioprocessing products to customers in the life science and biopharmaceutical industries. We recognize revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been

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met are based on management s judgments primarily regarding the fixed nature of the fee charged for the product delivered and the collectability of those fees. 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. Sales returns and warranty issues are infrequent and have had nominal impact on our financial statements historically.

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 $14,753,000 for the fiscal year ended December 31, 2012, $8,769,000 for the nine-month fiscal year ended December 31, 2011 and $10,251,000 for the fiscal year ended March 31, 2011. Revenue earned from Bristol royalties is recorded in the periods when it is 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 provides that we will receive such royalty payments on sales of Orencia® by Bristol through December 31, 2013.

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. Pursuant to the terms of the License Agreement, we received $5 million from Pfizer as an upfront payment on January 22, 2013 and are entitled to receive up to $65 million in potential future payments, a portion of which may be owed to third parties. These potential payments are approximately equally divided between milestones related to clinical development and initial commercial sales in specific geographies. In addition, we are entitled to receive royalties on any future sales of RG3039 or any SMA compounds developed under the License Agreement. The royalty rates are tiered and begin in the high single-digits for RG-3039 or lesser amounts for any backup compounds developed under the License Agreement. Our receipt of these royalties is subject to an obligation under an existing in-license agreement and other customary offsets and deductions. There are no refund provisions in this agreement.

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

- An exclusive license to research, develop, manufacture, commercialize and use RG3039 and backup compounds for the treatment of SMA and other disorders (the License);
- Research and development services designed to transition the SMA program to Pfizer pursuant to a transition plan (the Transition Services) ;
- The completion of the second cohort of a phase I clinical trial that was underway at the time the License Agreement was signed; and
- An inventory of RG3039, that could be used in clinical development, specifically to complete the phase I clinical trial, referenced immediately above (the Clinical Trial Material).

Two criteria must be met in order for a deliverable to be considered a separate unit of accounting. The first criterion requires that the delivered item or items have value to the customer on a stand-alone basis. The second

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criterion, which relates to evaluating a general right of return, is not applicable because such a provision does not exist in the License Agreement. The deliverables outlined above were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in this determination included, among other things, whether any other vendors sell the items separately and if Pfizer could use the delivered item for its intended purpose without the receipt of the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the multiple-element arrangements guidance addresses how to allocate the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price.

We identified the arrangement consideration to allocate among the units of accounting as the $5.0 million non-refundable up-front payment and excluded the potential milestone payments provided for in the License Agreement from the arrangement consideration as they were not considered fixed or determinable at the time the License Agreement was signed. Because we had not sold these items on a standalone basis previously, we had no vendor-specific objective evidence of selling price. Furthermore, we did not have detailed third-party evidence of selling price, and as a result we used our best estimate of selling price for each item. In determining these prices, we considered what we would be willing to sell the items for on a standalone basis, what the market would bear for such items and what another party might charge for these items.

The up-front arrangement consideration allocated to the License was recognized upon delivery of the License as the risks and rewards associated with the License transferred at that time. We used a discounted cash flow analysis to determine the value of the license. Key assumptions in the analysis included: the estimated market size for a compound targeted at SMA, the estimated remaining costs of development and time to commercialization, and the probability of successfully developing and commercializing the program. Based on this analysis, we allocated $4,876,000 to the value of the license and recognized this amount as revenue in the fiscal year ended December 31, 2012.

The remaining $124,000 of value was allocated based on the following:

- The estimated selling price of the Transition Services was approximately $600,000 resulting in consideration allocation of approximately $76,000. We were able to derive a price for these services, in part because they are similar to services provided by a contract research organization. We based the selling price of the Transition Services on internal full-time equivalent personnel costs and external costs that we expect to incur to transition the program to Pfizer. We applied a mark-up on the internal full-time equivalent personnel costs consistent with that of contract research organizations.

- The estimated selling price of the completion of the second cohort of the clinical trial was approximately $275,000 resulting in consideration allocation of approximately $35,000. This estimated selling price is based on the estimated, remaining costs to complete this cohort. Since the costs are pursuant to an arrangement negotiated with a third-party clinical site, we believe that the external cost estimate included in the agreement represents the best estimate of selling price for this unit of accounting.

- The estimated selling price of the Clinical Trial Material was approximately $105,000 resulting in consideration allocation of approximately $13,000. The estimated selling price is based upon the cost of procuring such material from the contract manufacturing organization that made the material. Since these costs were incurred pursuant to an arrangement negotiated with a third-party contract manufacturing organization, we believes that the costs included in the agreement represents the best estimate of selling price for this unit of accounting.

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

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We intend to recognize the revenues related to the transfer of Clinical Trial Material upon transfer of title and risk of loss to Pfizer, which we expect to occur in the first half of 2013. We expect to recognize revenues related to the Transition Services and the completion of the second cohort ratably over the first six months of 2013.

Future milestone payments, if any, under the License Agreement will be recognized under the provisions of ASC 605-28, which was adopted by Repligen on January 1, 2011. ASC 605-28 allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered an event if:

- It can only be achieved based in whole or in part on either (1) the Company s performance or (2) on the occurrence of a specific outcome resulting from the Company s performance;
- There is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and
- It would result in additional payments being due to the entity.

In addition to the $5 million up-front payment, we are also eligible to receive $65 million in potential milestone payments from Pfizer comprised of:

- Up to $30 million related to the achievement of specified clinical milestone events; and
- Up to $35 million related to the achievement of specified commercial sales events, specifically the first commercial sale in specific territories.

We believe that the $30 million of specified clinical milestone payments are substantive. We may receive all, or a portion of, the first clinical milestone of $2 million in 2013 depending upon the development path chosen by Pfizer. If we receive a portion of this milestone, we expect to receive the balance of it by the end of 2014.

Any milestones earned upon specified commercial sales events or future royalty payments, under the License Agreement will be recognized as revenue when they are earned.

Research and Development Agreements

In the fiscal year ended December 31, 2012, we also recognized $803,000 of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, GoFar, and the Friedreich s Ataxia Research Alliance. For the nine-month fiscal year ended December 31, 2011, we recognized approximately $1,466,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, Go Friedreich s Ataxia Research (GoFar), and the Friedreich s Ataxia Research Alliance. For the nine months ended December 31, 2010, we recognized $1,102,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, GoFar, and the Friedreich s Ataxia Research Alliance. During the fiscal year ended March 31, 2011, we recognized approximately $1,346,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, GoFar, and the Friedreich s Ataxia Research Alliance. In the fiscal year ended March 31, 2011, we also recognized approximately $733,000 in one-time grants under the Qualifying Therapeutic Discovery Project Program, which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

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

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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 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. Changes in the fair value of contingent consideration are recorded in our Statement of Operations.

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 and developed technology 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 8.5 years. We review our intangible assets subject to

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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. If the carrying value of an asset exceeds its 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 fourth quarter. For the fiscal year ended December 31, 2012, the impairment test date was December 31, 2012.

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. Examples of estimated accrued expenses include:

- Fees paid to contract manufacturers in conjunction with the production of clinical materials. These expenses are normally determined through a contract or purchase order issued by us;
- Service fees paid to organizations for their performance in conducting clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs that have been incurred as of each reporting date; and
- 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.

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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. Accordingly, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. In addition, for purposes of estimating the expected term, we have aggregated all individual option awards into one group as we do not expect substantial differences in exercise behavior among our employees. The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determined the expected volatility based upon the historical volatility of our common stock over a period commensurate with the option s expected term, exclusive of any events not reasonably anticipated to recur over 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 a straight-line basis over the requisite service period based upon 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 is a reasonable assumption 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 year ended December 31, 2012, we recorded stock-based compensation expense of approximately $1,024,000. For the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, we recorded stock-based compensation expense of approximately $730,000 and $748,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan). For the fiscal year ended March 31, 2011, we recorded stock-based compensation expense of approximately $1,003,000 for stock options granted under the 2001 Plan.

As of December 31, 2012, there was $1,605,995 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.76 years. We expect 739,009 unvested options to vest over the next five years.

Income Taxes

As of September 30, 2012, our U.S. net operating losses (NOL s) and other deferred tax assets were fully offset by a valuation allowance primarily because we were in a cumulative loss position and did not have sufficient history of income to conclude that it was more likely than not that we would be able to realize the tax benefits of those deferred tax assets. In the fourth quarter of 2012, we entered into a three-year cumulative pre-tax income position and concluded that it was more likely than not that we will generate sufficient taxable income in 2013 based on our 2013 projections to realize the tax benefit of a portion of our deferred tax assets. As such, we reversed $3,021,000 of the deferred tax asset valuation allowance in the U.S in the fourth quarter of 2012. The amount is recorded as a benefit for income taxes in the consolidated statement of operations. As a result of the fact that we will no longer receive royalty payments on Bristol s sales of Orencia after December 31, 2013, we concluded that realization of deferred tax assets beyond December 31, 2003 is not more likely than not, and as such, we continue to maintain a valuation allowance against those deferred tax assets estimated to reverse beyond 2013.

In supporting our conclusion that it was more likely than not that we would realize the tax benefits of certain of our deferred tax assets, we weighed the positive and negative evidence. The positive evidence included that

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fact that we had entered into a cumulative three-year pre-tax income position in the U.S. and were projecting significant pre-tax income in the U.S. in the year ending December 31, 2013, we have a history of operating within our projections, and the fact that a significant portion of our bioprocessing revenue and royalty payments on U.S. sales of Orencia are reasonably predictable due to our long-term supply agreements with certain customers and the fact that U.S. sales of Orencia have been increasing on a quarterly basis for several years. Our 2013 projections include estimates and assumptions as it relates to projected revenues and costs to be incurred. We believe that our projections are reasonable and supportable. Our projections also reflect significant planned reductions in research and development expenses associated with our therapeutic product candidates, as discussed elsewhere in this Form 10-K. We believe that this positive evidence outweighs the negative evidence, which included that fact that we were in a three-year cumulative loss position prior to the fourth quarter of 2012 and the fact that our projections for the year ending December 31, 2014 and beyond are significantly impacted by the fact that after December 31, 2013 we no longer receive royalty payments from Bristol on U.S. sales of Orencia.

RESULTS OF OPERATIONS

On December 15, 2011, we changed our fiscal year end from March 31 to December 31. As a result of this change, we filed a Transition Report on Form 10-K covering the nine-month transition period ending December 31, 2011. As a result of this change, Fiscal 2012 refers to the twelve month period from January 1, 2012 through December 31, 2012. Fiscal 2011 refers to the nine-month transition period from April 1, 2011 through December 31, 2011. Fiscal 2010 refers to the unaudited nine-month period from April 1, 2010 through December 31, 2010.

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 2012, 2011 and 2010 were comprised of the following:

	Year ended December 31,		Nine months ended December 31,	% Change	
	2012	2011	2010 (unaudited)	2012 vs. 2011	2011 vs. 2010
	(in thousands, except percentages)				
Bioprocessing product revenue	$ 41,834	$ 13,215	$ 11,811	217%	12%
Royalty and other revenue	20,433	10,235	9,574	100%	7%
Total revenue	$ 62,267	$ 23,450	$ 21,385	166%	10%

Substantially all of our bioprocessing products are based on recombinant Protein A and are sold to customers who incorporate our manufactured products into their proprietary antibody purification systems to be sold directly to the pharmaceutical industry. Monoclonal antibodies are a well-established class of drug with applications in rheumatoid arthritis, asthma and a variety of cancers. Sales of our bioprocessing products are therefore 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 2012, bioprocessing product sales increased by $28,619,000 or 217% as compared to fiscal 2011 driven predominantly by the acquisition of the Novozymes business which contributed $23,425,000 in revenue, the longer fiscal period in fiscal 2012 and increased demand from certain key customers. We sell our assorted bioprocessing products at various 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.

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For fiscal 2011, bioprocessing product sales increased by $1,404,000 or 12% as compared to fiscal 2010. Volume increased 14% due to increased demand from certain key customers and other business events, and was offset by a 2% decrease in sales revenue due to changes in the mix of products sold in fiscal 2011 as compared to fiscal 2010.

Pursuant to the settlement with Bristol, we recognized royalty revenue of $14,753,000 for fiscal 2012 as well as $8,769,000 and $7,739,000 for fiscal 2011 and 2010, respectively. For the year ending December 31, 2013, we expect royalty revenues to increase moderately over the prior year as Bristol s Orencia® continues to penetrate the market. The royalty arrangement with Bristol expires on December 31, 2013.

For fiscal 2012, we recognized $4,876,000 of revenue from the out-license of our Spinal Muscular Atrophy program to Pfizer on December 28, 2012. In fiscal 2012, we also recognized $803,000 of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, GoFar, and the Friedreich s Ataxia Research Alliance. For fiscal 2011, we recognized approximately $1,466,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, GoFar, and the Friedreich s Ataxia Research Alliance. For fiscal 2010, we recognized $1,102,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, GoFar, and the Friedreich s Ataxia Research Alliance.

Following the out-license of the Spinal Muscular Atrophy program to Pfizer in December 2012, we expect research and license revenues to decrease in the year ending December 31, 2013 unless we are successful in out-licensing or receiving incremental funding for RG1068 or RG2833.

Costs and operating expenses

Total costs and operating expenses for fiscal years 2012, 2011 and 2010 were comprised of the following:

	Year ended December 31,		Nine months ended December 31,	% Change	
	2012	2011	2010 (unaudited)	2012 vs. 2011	2011 vs. 2010
	(in thousands, except percentages)				
Cost of product revenue	$ 24,957	$ 5,157	$ 4,187	384%	23%
Cost of royalty and other revenue	2,213	1,315	1,161	68%	13%
Research and development	10,490	9,462	8,745	11%	8%
Selling, general and administrative	13,227	9,050	5,580	46%	62%
Contingent consideration fair value adjustments	611			100%	
Gain on bargain purchase	(314)	(427)		26%	
Total costs and operating expenses	$ 51,184	$ 24,557	$ 19,673	108%	25%

For fiscal 2012, cost of product revenue increased $19,800,000 or 384% as compared to fiscal 2011. This increase is primarily due to a 217% increase in bioprocessing product sales driven by the Novozymes acquisition and overall higher production costs at our newly acquired Sweden facility.

For fiscal 2011, cost of product revenue increased $970,000 or 23% as compared to fiscal 2010. This increase is primarily due to a 12% increase in bioprocessing product sales as well as the addition of the Novozymes Biopharma Business which accounts for $76,000 of the cost of product revenue increase.

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Gross margins were 40%, 61% and 65% for fiscal 2012, 2011 and 2010, respectively. During the current year, the Company began an extensive cost reduction initiative of both the Sweden and Waltham facilities. As a result of these efforts, we anticipate that gross margins will improve in the year ending December 31, 2013.

Pursuant to the settlement with Bristol, we must remit 15% of royalty revenue received through the expiration of the agreement in December 2013 to the University of Michigan. For the fiscal years 2012, 2011 and 2010, cost of royalty revenue was $2,213,000, $1,315,000 and $1,161,000, respectively. These increases are directly related to the increases in Bristol royalty revenues noted above.

Research and development costs represent bioprocessing product and therapeutic drug development and primarily include costs of internal personnel, supplies, external pharmacology and toxicology research, clinical trials and the costs associated with the manufacturing and testing of clinical materials. 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. Those efforts are ongoing. In December 2012, 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 future milestones, plus royalties.

In June 2012, we received a complete response letter from the NDA on our NDA for SecreFlo for pancreatic imaging indicating that additional clinical data would be required to support potential approval in the United States. We simultaneously withdrew our MAA for SecreFlo from consideration by the EMA. We believe that SecreFlo, if approved, would provide a safe and effective means to non-invasively image the pancreas with MRI and will meet an important unmet medical need for patients with pancreatitis. However, given the shift in strategic focus towards Bioprocessing product sales, we are seeking partners to either out-license or fund the development of this program and as such do not anticipate incurring material expenditures under this program without entering into such arrangements.

In addition, we are performing Phase 1 clinical study of RG2833 in patients with Friedreich s ataxia. We receive funding from a number of sponsors on this program that significantly mitigates the net expense of the programs and we are pursuing the clinical trial and other key program objectives that will enable the recognition of revenues under these sponsored research agreements and with the goal of making the program more viable from a partnering or out-licensing perspective.

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.

Each of our therapeutic research and development programs is subject to risks and uncertainties, including the requirement to seek regulatory approvals that are outside of our control. For example, our clinical trials may be subject to delays based on our inability to enroll patients at the rate that we expect to meet the schedule for our planned clinical trials. Moreover, the product candidates identified in these research programs, particularly in our early stage programs must overcome significant technological, manufacturing and marketing challenges before they can be successfully commercialized. For example, results from our preclinical animal models may not be replicated in our clinical trials with humans. As a result of these risks and uncertainties, we are unable to predict with any certainty the period in which material net cash inflows from such projects could be expected to commence or the completion dates of these programs.

These risks and uncertainties generally prevent us from estimating with any certainty the specific timing and future costs of our research and development programs, although historical trends within the industry suggest that gross expenses tend to increase in later stages of development. As mentioned above, however, we anticipate entering into partnering, outlicensing or other such arrangements in the coming year, similar to the Pfizer license,

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in order to fund those gross expenditures. Arrangements with commercial vendors and academic researchers accounted for 30%, 47% and 51% of our research and development expenses for fiscal 2012, 2011 and 2010, respectively. The outsourcing of such services provides us flexibility to discontinue or increase spending depending on the success of our research and development programs.

For fiscal 2012, research and development expenses increased by $1,028,000 or 11% as compared to fiscal 2011. This increase is comprised primarily of a $551,000 increase in bioprocessing process development costs due to the Novozymes acquisition and $245,000 of severance and related expenses associated with the shift towards bioprocessing and a longer fiscal period in 2012 versus 2011.

For fiscal 2011, research and development expenses increased by $718,000 or 8% as compared to fiscal 2010. This increase is comprised primarily of (1) a $1,939,000 increase in costs associated with drug product manufacturing and other costs associated with the NDA submission for SecreFlo for MRI imaging of the pancreas, offset by a $500,000 settlement related to this program from a dispute with Parexel International Corporation, the parent company of Perceptive Informatics, Inc. and (2) a $765,000 increase related to RG3039 for spinal muscular atrophy, which includes a $500,000 milestone payment made in April 2011 upon successful filing of our Investigational New Drug Application with the FDA, as well as other costs associated with the initiation of our Phase 1 clinical trial. These increases were partially offset by a $1,344,000 decrease related to RG2417 for the treatment of patients with bipolar disorder as we discontinued this program in March 2011 and a $603,000 decrease related to our Friedreich s ataxia program as we incurred higher costs in the prior period related to testing and drug substance manufacture in preparation for our upcoming Phase 1 study of RG2833 in adult patients with Friedreich s ataxia in Europe.

Future research and development expenses are dependent on a number of variables, including the cost and design of clinical trials and external costs such as manufacturing of clinical materials as well as the availability of external funding to support those programs. We expect our research and development expenses in the year ending December 31, 2013 to decrease significantly now that the Spinal Muscular Atrophy program was licensed to Pfizer and we focus our therapeutics efforts on finding partners to fund or out-license the SecreFlo and Friedreich s Ataxia programs.

Selling, general and administrative (SG&A) expenses include the costs associated with selling our commercial products and costs required to support our research and development efforts, including legal, accounting, patent, shareholder services, amortization of intangible assets and other administrative functions. In addition, SG&A expenses have historically included costs associated with various litigation matters.

For fiscal 2012, SG&A costs increased by $4,177,000 or 46% as compared to fiscal 2011. This increase is primarily comprised of an incremental $1,500,000 in SG&A from our newly acquired Swedish subsidiary, approximately $2,400,000 which represents an additional quarter of our traditional U.S. operations as fiscal 2012 was a longer fiscal period than fiscal 2011, and other miscellaneous expenses.

For fiscal 2011, SG&A costs increased by $3,470,000 or 62% as compared to fiscal 2010. This increase is primarily comprised of approximately $1,700,000 in transaction costs related to the Novozymes Acquisition, $380,000 related to commercialization efforts as we prepared to launch SecreFlo for MRI imaging of the pancreas, pending FDA approval, $420,000 due to headcount increases in marketing and business development, including salaries, stock-based compensation and recruiting costs, $410,000 related to business development activities, and $200,000 due to increased development and sales and marketing activities related to our OPUS product.

We expect SG&A expenses to decrease slightly in the year ending December 31, 2013 primarily because we do not expect a recurrence of the deal costs associated with the Novozymes Acquisition that we incurred in 2012. In addition, the prior year included certain marketing research expenditures associated with the anticipated approval of SecreFlo that have been eliminated going forward upon receipt of the complete response letter.

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For fiscal 2012 and 2011, we recorded a $314,000 and $427,000 gain on bargain purchase, respectively, related to the Novozymes Acquisition on December 20, 2011.

Investment income

Investment income includes income earned on invested cash balances. Investment income for fiscal 2012, 2011 and 2010 was $219,000, $161,000 and $287,000, respectively. The increase of $58,000 or 36% for fiscal 2012 compared to fiscal 2011 was due to slightly higher interest rates after an unusually low fiscal 2011 and a longer period in fiscal 2012. The decrease of $126,000 or 44% for fiscal 2011 compared to fiscal 2010 was primarily attributable to lower interest rates and a shorter period in fiscal 2011. We expect interest income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

(Benefit from) provision for income taxes

In the year ended December 31, 2012, we recorded a tax benefit of $2,885,000 that is comprised of the reversal of $3,021,000 of the valuation allowance on our deferred tax assets offset by a provision for a state tax liability. In the fourth quarter of 2012, we entered into a cumulative pre-tax income position and concluded that it was more likely than not that we will generate sufficient taxable income in 2013 based on our 2013 projections to realize the tax benefit of a portion of our deferred tax assets.

In the nine-month fiscal year ended December 31, 2011, we recorded a tax provision of $16,000 that is comprised of a $48,000 provision for a deferred tax liability related to goodwill amortization and a $32,000 benefit for a deferred tax asset related to a net operating loss for Repligen Sweden AB.

Liquidity and capital resources

We have financed our operations primarily through sales of equity securities, revenues derived from product sales, and research grants, as well as proceeds and royalties from license arrangements and a litigation settlement. Our revenue for the foreseeable future will be limited to our bioprocessing product revenue, royalties from Bristol s sales of Orencia through December 31, 2013, and research and development grants. Given the uncertainties related to pharmaceutical product development, we are currently unable to reliably estimate when, if ever, our therapeutic product candidates will generate revenue and cash flows.

At December 31, 2012, we had cash and marketable securities of $49,970,000 compared to $36,025,000 at December 31, 2011. A deposit for leased office space of $200,000 is classified as restricted cash and is not included in cash and marketable securities total for December 31, 2012 or December 31, 2011.

Cash flows

(In thousands)

Cash provided by (used in)	Year ended December 31, 2012	Increase / (Decrease)	Nine months ended December 31, 2011	Increase / (Decrease)	Nine months ended December 31, 2010 (unaudited)
Operating activities	$ 13,440	$ 11,127	$ 2,311	$ 523	$ 1,788
Investing activities	2,841	7,852	(5,011)	(523)	(4,488)
Financing activities	1,159	1,490	(331)	(300)	(31)

Operating activities

For fiscal 2012, our operating activities provided cash of $13,440,000 reflecting net income of $14,156,000 and non-cash charges totaling $2,383,000 including depreciation, amortization, stock-based compensation

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charges, deferred tax asset valuation allowance changes, the revaluation of contingent consideration and the gain on bargain purchase. Decreases in inventory and increases in accounts payable and accrued liabilities provided an additional $2,734,000 and $3,086,000 of cash. These increases were offset by an increase of $5,924,000 in royalties and other receivables associated primarily with the up-front payment pursuant to the Pfizer license agreement.

For fiscal 2011, our operating activities provided cash of $2,311,000 reflecting a net loss of $1,613,000 and non-cash charges totaling $1,624,000 including depreciation, amortization, stock-based compensation charges and the gain on bargain purchase. The remaining cash flow provided in operations resulted from favorable changes in various working capital accounts. For fiscal 2010, our operating activities provided cash of $1,788,000 reflecting net income of $1,987,000 and non-cash charges totaling $2,022,000 including depreciation, amortization, and stock-based compensation charges. The remaining cash flow used in operations resulted from unfavorable changes in various working capital accounts.

Investing activities

We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines. For fiscal 2012, our investing activities provided $2,841,000 of cash, which is primarily capital expenditures of $1,264,000, offset by net redemptions of marketable securities of $4,105,000. For fiscal 2011, our investing activities consumed $5,011,000 of cash, which is primarily due to the Novozymes Acquisition for $26,884,000 and capital expenditures of $575,000, offset by net redemptions of marketable securities of $22,449,000. During fiscal 2010, our investing activities consumed $4,488,000 of cash, which is primarily due to $3,870,000 of net purchases of marketable securities, $318,000 of capital expenditures and a $300,000 milestone payment related to our acquisition of the assets of BioFlash. We expect capital expenditures to increase in 2013 and 2014 as compared to 2012 as we expand our Waltham facility.

Financing activities

Exercises of stock options provided cash receipts of $1,159,000 and $25,000 in fiscal 2012 and 2010, respectively. In 2011, there were no stock option exercises. During fiscal 2011, the repurchase of common stock consumed $331,000.

Off-balance sheet arrangements

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

Contractual obligations

As of December 31, 2012, we had the following fixed obligations and commitments:

		Payments Due By Period			
(In thousands)	Total	Less than 1 Year	1 3 Years	3 5 Years	More than 5 Years
Operating lease obligations	$ 16,153	$ 2,222	$ 4,445	$ 3,878	$ 5,608
Purchase obligations (1)	2,872	2,872			
Contingent consideration (2)	2,900	1,377	1,199	207	117
Total	$ 21,925	$ 6,471	$ 5,644	$ 4,085	$ 5,725

(1) Primarily represents purchase orders for the procurement of raw material for manufacturing.
(2) These contingent consideration amounts relating to acquisitions are recorded in accrued expenses and long term liabilities on our consolidated balance sheets.

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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;
- the resources required to successfully integrate the Novozymes Biopharma Business and recognize expected synergies;
- our ability to establish one or more partnerships for development and commercialization of RG1068 or our early stage CNS programs;
- the scope of and progress made in our research and development activities;
- our ability to acquire additional bioprocessing products or product candidates;
- the extent of any share repurchase activity;
- the success of any proposed financing efforts; and
- the amount of royalty revenues we receive from Bristol through December 31, 2013.

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, 2013 to decrease significantly as we invest less in therapeutic drug development and simultaneously improve gross margins through greater optimization of our two production facilities and other process improvements we have developed internally. We expect to incur continued spending related to the development and expansion of our bioprocessing product lines for the foreseeable future. Our future capital requirements may include, but are not limited to, expansion of our Waltham facility and other 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 our efforts to identify and consummate development and commercialization partnerships. We actively evaluate various strategic transactions on an ongoing basis, including monetizing existing assets and licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. 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. This may require the issuance or sale of additional equity or debt securities. The sale of additional equity may result in additional dilution to our stockholders. Should we need to secure additional financing to acquire a product, fund future investment in research and development, or meet our future liquidity requirements, we may not be able to secure such financing, or obtain such financing on favorable terms because of the volatile nature of the biotechnology marketplace.

Net operating loss carryforwards

At December 31, 2012, we had net operating loss carryforwards of approximately $44,678,000 and business tax credits carryforwards of approximately $2,160,000 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 2031. 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.

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Foreign earnings

At December 31, 2012, we have not provided for U.S. income taxes or foreign withholding taxes on outside basis differences of foreign subsidiaries of approximately $477,000 as we have the ability and intend to indefinitely reinvest the undistributed earnings of Repligen Sweden 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.

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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 $172,000 decrease in the fair value of our investments as of December 31, 2012. 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. Exchange gains or losses resulting from the translation between the transactional currency and the functional currency of Repligen Sweden 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, 28% and 0% of total revenues during fiscal 2012 and 2011, respectively, were denominated in foreign currencies while 39% and 1% of our costs and expenses during fiscal 2012 and 2011, respectively, were denominated in foreign currencies, primarily operating expenses associated with cost of revenue, sales and marketing and general and administrative. In addition, 37% and 38% of our consolidated tangible assets were subject to foreign currency exchange fluctuations as of each of December 31, 2012 and 2011, respectively, while 48% and 44% of our consolidated liabilities were exposed to foreign currency exchange fluctuations as of each of December 31, 2012 and 2011, 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.

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(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, 2012. 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 (COSO).

Subject to the foregoing, based on this assessment, our management concluded that, as of December 31, 2012, 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, 2012.

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.

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(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 (the Company) internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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, 2012, 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, 2012 and December 31, 2011, and the related consolidated statements of operations and comprehensive income (loss), stockholders equity, and cash flows for the year ended December 31, 2012, the nine months ended December, 31, 2011 and the year ended March 31, 2011 of Repligen Corporation and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 15, 2013

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(d) Changes in Internal Control Over Financial Reporting.

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, 2012 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

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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 2013 Annual Meeting of Stockholders.

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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:

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

None.

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(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 and amended September 17, 1999 (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).
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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*	Consulting Agreement, dated November 1, 1981, between Dr. Alexander Rich and Repligen Corporation. (filed as Exhibit 10.2 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 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).
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10.5*	Employment Offer Letter dated February 29, 2008 by and between Repligen Corporation and William Kelly (filed as Exhibit 10.20 to Repligen Corporation s Annual Report on Form 10-K for the year ended March 31, 2008 and incorporated herein by reference).
10.6*	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).
10.7*	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).
10.8*	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).

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Exhibit Number	Document Description
10.8.1*	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).
10.8.2*	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).
10.9	Common Stock Purchase Warrant dated April 6, 2007 (filed as Exhibit 4.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 and incorporated herein by reference).
10.10#	Manufacturing Transfer Agreement dated as of December 17, 1998 among the Company and Amersham Pharmacia Biotech AB (filed as Exhibit 10.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended December 31, 1998 and incorporated herein by reference) (SEC File No. 000-14656).
10.11#	License Agreement dated as of July 24, 2000 with University of Michigan (filed as Exhibit 10.1 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).
10.12	Lease Between Repligen Corporation as Tenant and West Seyon LLC as Landlord, 35 Seyon Street, Waltham, MA (filed as Exhibit 10.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended December 31, 2001 and incorporated herein by reference) (SEC File No. 000-14656).
10.13#	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).
10.14#	Settlement and Release Agreement dated April 7, 2008 by and among Repligen Corporation, The Regents of the University of Michigan and Bristol-Myers Squibb Company (filed as Exhibit 10.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.15#	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).
10.16	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 5, 2011 and incorporated herein by reference).
10.17	Asset Transfer Agreement by and among Repligen Corporation, Repligen Sweden AB, Novozymes Biopharma DK A/S and Novozymes Biopharma Sweden AB, dated October 27, 2011 (filed as Exhibit 2.1 to Repligen Corporation s Current Report on Form 8-K filed on October 28, 2011 and incorporated herein by reference).
10.18	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).
10.19#	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).

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Exhibit Number	Document Description
10.20#	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).
10.21#	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).
10.22*	Repligen Corporation 2012 Stock Option and Incentive Plan (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on May 25, 2012 and incorporated herein by reference).
10.23*	Repligen Corporation Non-Employee Directors Deferred Compensation Plan (filed as Exhibit 10.2 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference).
10.24*	Letter Agreement, dated as of September 20, 2012, by and between Repligen Corporation and Jonathan I. Lieber (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on September 21, 2012 and incorporated herein by reference).
10.25#+	License Agreement, dated as of December 28, 2012, by and between Pfizer Inc. and Repligen Corporation.
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, 2012, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Statements of Operations, (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.
^ As provided in Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Form 10-K is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

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 2013 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.

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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: March 15, 2013

By: /s/ WALTER C. HERLIHY
Walter C. Herlihy

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 Walter C. Herlihy and Jonathan I. Lieber 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/ WALTER HERLIHY **Walter C. Herlihy, Ph.D.**	President, Chief Executive Officer and Director (Principal executive officer)	March 15, 2013
/s/ JONATHAN I. LIEBER **Jonathan I. Lieber**	Chief Financial Officer (Principal financial officer)	March 15, 2013
/s/ WILLIAM J. KELLY **William J. Kelly**	Chief Accounting Officer (Principal accounting officer)	March 15, 2013
/s/ KAREN DAWES **Karen Dawes**	Chairperson of the Board	March 15, 2013
/s/ GLENN L. COOPER **Glenn L. Cooper, M.D.**	Director	March 15, 2013
/s/ ALFRED L. GOLDBERG **Alfred L. Goldberg, Ph.D.**	Director	March 15, 2013

/s/ Michael A. Griffith **Michael A. Griffith**	Director	March 15, 2013
/s/ Earl W. Henry **Earl W. Henry, M.D.**	Director	March 15, 2013
/s/ Thomas F. Ryan, Jr. **Thomas F. Ryan, Jr.**	Director	March 15, 2013

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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, 2012, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Statements of Operations, (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.
^ As provided in Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Form 10-K is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

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INDEX TO FINANCIAL STATEMENTS

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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, 2012 and December 31, 2011, and the related consolidated statements of operations and comprehensive income (loss), stockholders equity, and cash flows for the year ended December 31, 2012, the nine months ended December, 31, 2011 and the year ended March 31, 2011. 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, 2012 and December 31, 2011, and the consolidated results of its operations and its cash flows for the year ended December 31, 2012, the nine months ended December, 31, 2011 and the year ended March 31, 2011, 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, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 15, 2013

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REPLIGEN CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 29,209,821	$ 11,167,745
Marketable securities	10,845,195	15,421,436
Accounts receivable, less reserve for doubtful accounts of $10,000	4,158,758	2,825,414
Royalties and other receivables	9,130,515	3,206,840
Inventories, net	11,143,695	13,363,073
Deferred tax asset, net	416,580	31,839
Prepaid expenses and other current assets	1,304,887	878,459
Total current assets	66,209,451	46,894,806
Property, plant and equipment, at cost:		
Leasehold improvements	5,200,271	5,083,852
Equipment	12,802,978	12,011,154
Furniture and fixtures	1,937,238	1,244,451
Construction in progress	338,814	275,258
Total property, plant and equipment, at cost	20,279,301	18,614,715
Less: Accumulated depreciation	(10,326,840)	(7,877,296)
Property, plant and equipment, net	9,952,461	10,737,419
Long-term deferred tax asset, net	2,557,384	
Long-term marketable securities	9,914,855	9,435,350
Intangible assets, net	7,182,012	7,795,239
Goodwill	994,000	994,000
Restricted cash	200,000	200,000
Total assets	$ 97,010,163	$ 76,056,814
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,454,238	$ 1,422,483
Accrued liabilities	8,297,990	6,041,038
Total current liabilities	10,752,228	7,463,521
Deferred tax liability		136,881
Other long-term liabilities	2,133,339	2,469,412
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, $.01 par value, 5,000,000 shares authorized, no shares issued or outstanding		
Common stock, $.01 par value, 40,000,000 shares authorized, 31,195,041 shares at December 31, 2012 and 30,714,757 shares at December 31, 2011 issued and outstanding	311,950	307,148
Additional paid-in capital	187,051,253	184,872,839
Accumulated other comprehensive income	1,911,970	113,627
Accumulated deficit	(105,150,577)	(119,306,614)
Total stockholders equity	84,124,596	65,987,000

Total liabilities and stockholders equity	$ 97,010,163	$ 76,056,814

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

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REPLIGEN CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Year ended December 31, 2012	Nine Months ended December 31, 2011	Nine Months ended December 31, 2010 (unaudited)	Year ended March 31, 2011
Revenue:				
Product revenue	$ 41,834,188	$ 13,215,053	$ 11,810,869	$ 14,961,397
Royalty and other revenue	20,432,348	10,235,194	9,573,770	12,329,627
Total revenue	62,266,536	23,450,247	21,384,639	27,291,024
Operating expenses:				
Cost of product revenue	24,957,243	5,157,135	4,186,670	5,579,759
Cost of royalty and other revenue	2,213,004	1,315,315	1,160,775	1,537,666
Research and development	10,489,811	9,461,960	8,744,548	12,528,819
Selling, general and administrative	13,226,732	9,050,382	5,580,215	8,018,851
Contingent consideration fair value adjustments	610,877			
Gain on bargain purchase	(314,244)	(427,478)		
Total operating expenses	51,183,423	24,557,314	19,672,208	27,665,095
Income (loss) from operations	11,083,113	(1,107,067)	1,712,431	(374,071)
Investment income	218,604	161,053	287,430	356,729
Interest expense	(56,714)	(27,773)	(12,683)	(26,167)
Other income (expense)	26,403	(623,094)		
Income (loss) before income taxes	11,271,406	(1,596,881)	1,987,178	(43,509)
Income tax (benefit) provision	(2,884,631)	15,744		
Net income (loss)	$ 14,156,037	$ (1,612,625)	$ 1,987,178	$ (43,509)
Earnings (loss) per share:				
Basic	$ 0.46	$ (0.05)	$ 0.06	$ (0.00)
Diluted	$ 0.45	$ (0.05)	$ 0.06	$ (0.00)
Weighted average shares outstanding:				
Basic	30,914,424	30,774,467	30,778,430	30,781,881
Diluted	31,253,434	30,774,467	30,949,264	30,781,881
Other comprehensive income (loss):				
Unrealized gain on investments	7,792	6,338		
Foreign currency translation gain	1,790,551	107,289		
Comprehensive income (loss)	$ 15,954,380	$ (1,498,998)	$ 1,987,178	$ (43,509)

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

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REPLIGEN CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock			Accumulated Other		
	Number of Shares	Amount	Additional Paid-in Capital	Comprehensive Income	Accumulated Deficit	Stockholders Equity
Balance, March 31, 2010	30,761,807	$ 307,618	$ 183,733,863	$	$ (117,921,105)	$ 66,120,376
Net loss					(43,509)	(43,509)
Share-based compensation expense			1,003,266			1,003,266
Exercise of stock options	50,450	505	6,066			6,571
Balance, March 31, 2011	30,812,257	$ 308,123	$ 184,743,195	$	$ (117,964,614)	$ 67,086,704
Net loss					(1,612,625)	(1,612,625)
Unrealized gain on investments				6,338		6,338
Foreign currency translation adjustment				107,289		107,289
Share-based compensation expense			730,136			730,136
Repurchase and retirement of treasury stock	(100,000)	(1,000)	(600,492)		270,625	(330,867)
Exercise of stock options	2,500	25				25
Balance, December 31, 2011	30,714,757	$ 307,148	$ 184,872,839	$ 113,627	$ (119,306,614)	$ 65,987,000
Net income					14,156,037	14,156,037
Unrealized gain on investments				7,792		7,792
Foreign currency translation adjustment				1,790,551		1,790,551
Share-based compensation expense			1,024,152			1,024,152
Exercise of stock options	480,284	4,802	1,154,262			1,159,064
Balance, December 31, 2012	31,195,041	$ 311,950	$ 187,051,253	$ 1,911,970	$ (105,150,577)	$ 84,124,596

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

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REPLIGEN CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	Nine Months ended December 31,		Year ended March 31,
	2012	2011	2010 (unaudited)	2011
Cash flows from operating activities:				
Net income (loss):	$ 14,156,037	$ (1,612,625)	$ 1,987,178	$ (43,509)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:				
Depreciation and amortization	3,508,592	1,274,597	1,274,247	1,674,528
Stock-based compensation expense	1,024,152	730,136	748,235	1,003,266
Deferred tax expense	(3,143,268)	15,744		
Gain on bargain purchase	(314,244)	(427,478)		
Loss on revaluation of contingent consideration	604,133	28,182		
Loss on disposal of assets		2,826		5,597
Changes in assets and liabilities:				
Accounts receivable	(1,211,343)	3,551,969	(601,141)	(689,569)
Royalties and other receivables	(5,923,675)	(694,238)	(450,600)	(216,602)
Inventories	2,734,239	(870,252)	263,570	247,164
Prepaid expenses and other current assets	30,266	(190,007)	(708,311)	986,340
Accounts payable	1,001,546	247,222	(291,824)	(60,404)
Accrued liabilities	2,083,964	243,182	(408,224)	383,237
Long-term liabilities	(1,110,791)	11,487	(25,447)	(58,285)
Net cash provided by operating activities	13,439,608	2,310,745	1,787,683	3,231,763
Cash flows from investing activities:				
Purchases of marketable securities	(39,109,959)	(49,465,924)	(58,095,140)	(84,329,731)
Sales of marketable securities		26,290,378		
Redemptions of marketable securities	43,214,487	45,624,819	54,225,000	83,650,417
Acquisition of assets of BioFlash Partners, LLC			(300,000)	(300,000)
Acquisition of assets and liabilities of Novozymes		(26,884,428)		
Purchases of property, plant and equipment	(1,263,647)	(575,455)	(317,982)	(524,666)
Net cash provided by (used in) investing activities	2,840,881	(5,010,610)	(4,488,122)	(1,503,980)
Cash flows from financing activities:				
Exercise of stock options	1,159,064	25	25,758	6,571
Repurchase and retirement of treasury stock		(330,867)		
Principal payments under capital lease obligations			(56,850)	(56,850)
Net cash provided by (used in) financing activities	1,159,064	(330,842)	(31,092)	(50,279)
Effect of exchange rate changes on cash and cash equivalents	602,523	(5,092)		
Net increase (decrease) in cash and cash equivalents	18,042,076	(3,035,799)	(2,731,531)	1,677,504
Cash and cash equivalents, beginning of period	11,167,745	14,203,544	12,526,040	12,526,040
Cash and cash equivalents, end of period	$ 29,209,821	$ 11,167,745	$ 9,794,509	$ 14,203,544

Supplemental disclosure of non-cash investing activities:				
Income taxes paid	$ 140,000	$	$	$
Contingent consideration transferred in the Novozymes Acquisition	$	$ 1,610,560	$	$

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

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REPLIGEN CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Information for the nine months ended December 31, 2010 is unaudited)

1. Organization and Nature of Business

Repligen Corporation (Repligen or the Company) is a life sciences company that develops, manufactures and markets high-value, consumable bioprocessing products for life sciences companies and biopharmaceutical manufacturing companies worldwide. The Company is a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in biomanufacturing to separate and purify monoclonal antibodies, a type of biologic drug. Repligen also supplies several growth factor products used to increase cell culture productivity during the biomanufacturing process. In the burgeoning area of disposable biomanufacturing technologies, the Company has developed and currently markets a series of OPUS (Open-Platform, User-Specified) chromatography columns for use in clinical-scale manufacturing. The Company generally manufactures and sells Protein A and growth factors to life sciences companies under long-term supply agreements and sells its chromatography columns, as well as media and quality test kits, directly to biopharmaceutical companies or contract manufacturing organizations. Repligen refers to these activities as its bioprocessing business. The Company manufactures its products in production facilities in the United States and Sweden.

Historically, Repligen also conducted activities aimed at developing proprietary therapeutic drug candidates, often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. In addition, the Company has out-licensed certain intellectual property to Bristol-Myers Squibb Company, or Bristol, from which Repligen receives royalties on Bristol s net sales in the United States of their product Orencia®. As part of Repligen s strategic decision in 2012 to focus the Company s efforts on its core bioprocessing business, the Company scaled back efforts on its clinical development programs and increased its efforts to find collaboration partners to finish their development and, if successful, commercialize these therapeutic drug candidates.

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

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Repligen Europe Limited and Repligen Sweden AB. All significant intercompany accounts and transactions have been eliminated in consolidation.

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Foreign Currency

The Company translates the assets and liabilities of foreign subsidiaries at rates in effect at the end of the reporting period. Revenues and expenses are translated at average rates in effect during the reporting period. Translation adjustments are included in accumulated other comprehensive income.

Revenue Recognition

Product Sales

The Company generates product revenues from the sale of bioprocessing products to customers in the pharmaceutical and process chromatography industries. The Company recognizes revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been met is based on management s judgments primarily regarding the fixed nature of the fee charged for the product delivered and the collectability of those fees. The Company has a few longstanding customers who comprise the majority of revenue and have excellent payment histories and therefore the Company does not require collateral. The Company has had no significant write-offs of uncollectible invoices in the periods presented.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and 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. Sales returns and warranty issues are infrequent and have had nominal impact on the Company s consolidated financial statements historically.

Orencia Royalty

In April 2008, the Company settled its outstanding litigation with Bristol and began recognizing royalty revenue 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 (see Note 9), the Company recognized royalty revenue of $14,753,000 for the fiscal year ended December 31, 2012, $8,769,000 for the nine-month fiscal year ended December 31, 2011 and $10,251,000 for the fiscal year ended March 31, 2011. Revenue earned from Bristol royalties is recorded in the periods when it is earned based on royalty reports sent by Bristol to the Company. The Company has no continuing obligations to Bristol as a result of this settlement. The Company s royalty agreement with Bristol provides that the Company will receive such royalty payments from Bristol through December 31, 2013.

Therapeutics Licensing Agreements

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

- The delivered item or items have value to the customer on a stand-alone basis.
- If there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within our control.

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of

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the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the Company allocates the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price. Revenue is recognized for each unit of accounting when the appropriate revenue recognition criteria are met.

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

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

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

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

The Company believes that the clinical milestone payments pursuant to the license agreement with Pfizer, Inc. (Pfizer), as described in Note 10, are substantive and thus will be recognized when achieved. The commercial milestone payments and royalty payments received under license agreements, if any, will be recognized as revenue when they are earned.

Research and Development Agreements

In the fiscal year ended December 31, 2012, the Company recognized $803,000 of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, GoFar, and the Friedreich s Ataxia Research Alliance.

For the nine-month fiscal year ended December 31, 2011, the Company recognized $1,466,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, the European Friedrich s Ataxia Consortium for Translational Studies, Go Friedreich s Ataxia Research (GoFar), and the Friedreich s Ataxia Research Alliance. For the nine-month period ended December 31, 2010, the Company recognized $1,102,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, GoFar, and the Friedreich s Ataxia Research Alliance. For the nine months ended December 31, 2010, the Company also recognized approximately $733,000 in one-time grants under the Qualifying Therapeutic Discovery Project Program, which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

In the fiscal year ended March 31, 2011, the Company recognized $1,346,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the National Institutes of Health / Scripps Research Institute, GoFar, and the Friedreich s Ataxia Research Alliance. During the year ended March 31, 2011, the Company also recognized approximately $733,000 in one-time grants under the Qualifying Therapeutic Discovery Project Program, which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

Research revenue is recognized when the expense has been incurred and services have been performed. Determination of which costs incurred qualify for reimbursement under the terms of the Company s contractual agreements and the timing of when such costs were incurred involves the judgment of management. The

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Company s 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 the Company does not anticipate any subsequent change in its revenue related to sponsored research and development projects.

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

Risks and Uncertainties

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

Cash, Cash Equivalents and Marketable Securities

At December 31, 2012 and December 31, 2011, the Company s investments included money market funds as well as short-term and long-term marketable securities. Marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are securities with maturities of greater than one year. The average remaining contractual maturity of marketable securities at December 31, 2012 is approximately 9.9 months.

Investments in debt securities consisted of the following at December 31, 2012:

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	$ 2,000,897	$ 353	$ (7)	$ 2,001,243
Corporate and other debt securities	8,835,098	8,854		8,843,952
	10,835,995	9,207	(7)	10,845,195
Long-term marketable securities:				
U.S. Government and agency securities	5,198,264	2,747		5,201,011
Corporate and other debt securities	4,711,679	3,525	(1,360)	4,713,844
	9,909,943	6,272	(1,360)	9,914,855
Total	$ 20,745,938	$ 15,479	$ (1,367)	$ 20,760,050

At December 31, 2012, the Company s investments included seven debt securities in unrealized loss positions with a total unrealized loss of approximately $1,000 and a total fair market value of approximately $2,667,000. All investments with gross unrealized losses have been in unrealized loss positions for less than 12 months. The unrealized losses were caused primarily by current economic and market conditions. There was no change in the credit risk of the securities. The Company does not intend to sell any investments in an unrealized loss position and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases. There were no realized gains or losses on the investments for the fiscal year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011 or the fiscal year ended March 31, 2011.

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Investments in debt securities consisted of the following at December 31, 2011:

	December 31, 2011			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	$ 8,373,355	$ 3,126	$ (233)	$ 8,376,248
Corporate and other debt securities	7,046,222	3,336	(4,370)	7,045,188
	15,419,577	6,462	(4,603)	15,421,436
Long-term marketable securities:				
U.S. Government and agency securities	8,399,428	2,223	(91)	8,401,560
Corporate and other debt securities	1,031,443	2,347		1,033,790
	9,430,871	4,570	(91)	9,435,350
Total	$ 24,850,448	$ 11,032	$ (4,694)	$ 24,856,786

The contractual maturities of debt securities at December 31, 2012 were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	$ 10,835,995	$ 10,845,195
Due in 1 to 2 years	9,909,943	9,914,855
	$ 20,745,938	$ 20,760,050

Fair Value Measurement

In determining the fair value of its assets and liabilities, the Company uses various valuation approaches. The Company employs a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

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

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

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The Company s fixed income investments are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2012.

The following fair value hierarchy table presents information about each major category of the Company s assets measured at fair value on a recurring basis as of December 31, 2012:

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 7,891,062	$	$	$ 7,891,062
U.S. Government and agency securities	2,901,209	5,201,011		8,102,220
Corporate and other debt securities		13,557,796		13,557,796
Total	$ 10,792,271	$ 18,758,807	$	$ 29,551,078

The Company has no other assets or liabilities for which fair value measurement is either required or has been elected to be applied, other than the liabilities for contingent consideration recorded in connection with the Novozymes Acquisition and the acquisition of the assets of BioFlash Partners, LLC (BioFlash). The contingent consideration related to Novozymes is valued using management s estimates of expected future milestone payments based upon a probability weighted analysis of amounts to be paid to Novozymes Denmark. 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. These valuations are Level 3 valuations as the primary inputs are unobservable. Changes in the fair value of contingent consideration in the year ended December 31, 2012 are primarily attributable to changes in the probability of the Company making certain contingent payments. The following table provides a roll forward of the fair value of the contingent consideration:

Balance at December 31, 2011	$ 2,197,226
Additions	
Payments	(35,000)
Changes in fair value	736,850
Balance at December 31, 2012	$ 2,899,076

There were no remeasurements to fair value during the year ended December 31, 2012 of financial assets and liabilities that are not measured at fair value on a recurring basis.

Inventories

Inventories relate to the Company s bioprocessing business. The Company values inventory at cost or, if lower, fair market value, using the first-in, first-out method. The Company reviews its inventories at least

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quarterly and records a provision for excess and obsolete inventory based on its estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in process and finished products. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to 12 months. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements to cost of product revenue. Manufacturing of bioprocessing finished goods is done to order and tested for quality specifications prior to shipment. Reserves for excess and obsolete inventory were $154,000 and $149,000 as of December 31, 2012 and 2011, respectively. At both December 31, 2010 and March 31, 2011, reserves for excess and obsolete inventory were $50,000.

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

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

	December 31, 2012	December 31, 2011
Raw Materials	$ 4,064,317	$ 3,563,395
Work-in-process	4,112,478	5,936,578
Finished products	2,966,900	3,863,100
Total	$ 11,143,695	$ 13,363,073

Accrued Liabilities

The Company estimates accrued liabilities by identifying services performed on the Company s behalf, estimating the level of service performed and determining the associated cost incurred for such service as of each balance sheet date. Examples of estimated accrued expenses include: (1) Fees paid to contract manufacturers in conjunction with the production of clinical materials. These expenses are normally determined through a contract or purchase order issued by the Company; (2) Service fees paid to organizations for their performance in conducting clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs which have been incurred as of each reporting date; and (3) Professional and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred or tracking costs incurred by service providers under fixed fee arrangements.

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

Income Taxes

Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company accounts for uncertain tax positions

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using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly basis. The Company also accrues for potential interest and penalties, related to unrecognized tax benefits in income tax expense.

Depreciation

Depreciation is calculated using the straight-line method over the estimated useful life of the asset as follows:

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

For depreciation of property and equipment, the Company expensed approximately $2,492,000 in the year ended December 31, 2012, $1,117,000 and $1,141,000 in the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively, as well as $1,496,000 in the fiscal year ended March 31, 2011. These amounts include depreciation of assets recorded under capitalized lease agreements of approximately $82,000 in the nine months ended December 31, 2010 and $82,000 in the fiscal year ended March31, 2011. Assets recorded under capital leases were fully depreciated at December 31, 2011.

Earnings (Loss) Per Share

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

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

	Year ended December 31, 2012	Nine Months ended December 31, 2011	2010	Year ended March 31, 2011
Numerator:				
Net income (loss)	$ 14,156,037	$ (1,612,625)	$ 1,987,178	$ (43,509)
Denominator:				
Basic weighted average common shares outstanding	30,914,424	30,774,467	30,778,430	30,781,881
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards	339,010		170,834	
Diluted weighted average common shares outstanding	31,253,434	30,774,467	30,949,264	30,781,881
Basic net income (loss) per common share	$ 0.46	$ (0.05)	$ 0.06	$ (0.00)
Diluted net income (loss) per common share	$ 0.45	$ (0.05)	$ 0.06	$ (0.00)

At December 31, 2012, there were outstanding options to purchase 2,315,090 shares of the Company s common stock at a weighted average exercise price of $4.20 per share. For the fiscal year ended December 31, 2012, 1,296,700 shares of the Company s common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At December 31, 2011, there were outstanding options to purchase 2,823,400 shares of the Company s common stock at a weighted average exercise price of $4.05 per share.

At December 31, 2010, there were outstanding options to purchase 2,566,450 shares of the Company s common stock at a weighted average exercise price of $4.08 per share. For the nine-month fiscal year ended December 31, 2010, 1,771,100 shares of the Company s common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

Diluted weighted average shares outstanding for the nine-month fiscal year ended December 31, 2011 and the fiscal year ended March 31, 2011 do not include the impact of 2,823,400 and 2,580,600 outstanding potential common shares for stock options, respectively, as they would be anti-dilutive. Accordingly, basic and diluted net loss per share are the same for the nine-month fiscal year ended December 31, 2011 and the fiscal year ended March 31, 2011.

Segment Reporting

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

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

	Year ended December 31, 2012	Nine Months ended December 31, 2011	2010	Year ended March 31, 2011
United States	46%	48%	48%	50%
Sweden	42%	44%	45%	42%
Other	12%	8%	7%	8%
Total	100%	100%	100%	100%

The following table represents the Company s total assets by geographic area:

	December 31, 2012	December 31, 2011
United States	$ 58,356,697	$ 44,223,080
Sweden	38,653,466	31,833,734
Total	$ 97,010,163	$ 76,056,814

The following table represents the Company s long-lived assets by geographic area:

	December 31, 2012	December 31, 2011
United States	$ 16,537,804	$ 13,380,836
Sweden	14,262,908	15,781,172
Total	$ 30,800,712	$ 29,162,008

Concentrations of Credit Risk and Significant Customers

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and accounts receivable. Per the Company s investment policy, cash equivalents and marketable securities are invested in financial instruments with high credit ratings and credit exposure to any one issue, issuer (with the exception of U.S. treasury obligations) and type of instrument is limited. At December 31, 2012 and 2011, the Company had no investments associated with foreign exchange contracts, options contracts or other foreign hedging arrangements.

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

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

	Year ended December	Nine Months ended December 31,		Year ended March

	31, 2012	2011	2010	31, 2011
Orencia® Royalties from Bristol	24%	37%	37%	38%
Bioprocessing Customer A	42%	44%	45%	42%

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

	December 31, 2012	December 31, 2011
Orencia® Royalties from Bristol	31%	53%
Bioprocessing Customer A	21%	31%
Pfizer	38%	

Goodwill, Other Intangible Assets and Acquisitions

Acquisitions

Total consideration transferred for acquisitions (see Note 11) is allocated to the assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Any excess of the fair value of the net tangible and intangible assets acquired over the purchase price is recognized in the statement of operations. The fair value of contingent consideration includes estimates and judgments made by management regarding the probability that future contingent payments will be made and the extent of royalties to be earned in excess of the defined minimum royalties. Management updates these estimates and the related fair value of contingent consideration at each reporting period. Changes in the fair value of contingent consideration are recorded in the consolidated statements of operations.

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

Goodwill

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at December 31, 2012. There were no goodwill impairment charges during the fiscal year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011, the nine-month period ended December 31, 2010 or the fiscal year ended March 31, 2011.

Intangible Assets

Intangible assets are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within cost of product revenue and selling, general and administrative expense in the statements of operations. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for our products or changes in the size of the market for our products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset based on the sum of the future undiscounted cash flows expected to result from the use and disposition of the asset. If the estimate of an intangible asset s remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at December 31, 2012.

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Intangible assets consisted of the following at December 31, 2012:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	$ 1,452,729	$ (360,748)	8
Patents	240,000	(87,500)	8
Customer relationships	6,872,383	(934,852)	8
Total intangible assets	$ 8,565,112	$ (1,383,100)	8

Intangible assets consisted of the following at December 31, 2011:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	$ 1,413,564	$ (184,402)	8
Patents	240,000	(57,500)	8
Customer relationships	6,508,147	(124,570)	8
Total intangible assets	$ 8,161,711	$ (366,472)	8

Amortization expense for amortized intangible assets was approximately $1,017,000 for the year ended December 31, 2012, $158,000 for the nine-month fiscal year ended December 31, 2011, $134,000 for the nine-month period ended December 31, 2010 and $179,000 for the fiscal year ended March 31, 2011. The Company expects to record amortization expense of approximately $1,000,000 in each of the next five years.

Stock Based Compensation

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

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

Expected term The expected term of options granted represents the period of time for which the options are expected to be outstanding. The expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. In addition, for purposes of estimating the expected term, the Company has aggregated all individual option awards into one group as the Company does not expect substantial differences in exercise behavior among its employees.

Expected volatility The expected volatility is a measure of the amount by which the Company s stock price is expected to fluctuate during the expected term of options granted. The Company determines the expected volatility based primarily upon the historical volatility of the Company s common stock over a period commensurate with the option s expected term, exclusive of any events not reasonably anticipated to recur over the option s expected term.

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

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

Estimated forfeiture rates The Company has applied, based on an analysis of its historical forfeitures, annual forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees to all unvested stock options as of December 31, 2012. The Company reevaluates this analysis periodically and adjusts these estimated forfeiture rates as necessary. Ultimately, the Company will only recognize expense for those shares that vest.

3. Income Taxes

Income tax data for the year ended December 31, 2012, the nine months ended December 31, 2011 and the year ended March 31, 2011:

	December 31, 2012	December 31, 2011	March 31, 2011
The components of income from operations before income taxes are as follows:			
Domestic	$ 11,175,638	$ (1,845,024)	$ (43,509)
Foreign	95,768	248,143	
Total	$ 11,271,406	$ (1,596,881)	$ (43,509)
The current and deferred components of the provision for income taxes on operations are as follows:			
Current	$ 312,630	$	$
Deferred	(3,197,261)	15,774	
Total	$ (2,884,631)	$ 15,774	$
The jurisdictional components of the provision for income taxes on operations are as follows:			
Federal	$ (2,915,673)	$ 48,000	$
State	115,307		
Foreign	(84,265)	(32,226)	
Total	$ (2,884,631)	$ 15,774	$

At December 31, 2012, the Company had net operating loss carryforwards of approximately $44,678,000 and business tax credits carryforwards of approximately $2,160,000 available to reduce future federal income taxes, if any. The U.S. federal net operating loss includes $441,000 related to excess tax deductions from share-based payments, the tax benefit of which will be recognized as an increase to additional paid in capital when the deduction reduces current taxes payable. The net operating loss and business tax credits carryforwards will continue to expire at various dates through December 2032. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

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The Company s consolidated deferred tax assets (liabilities) consist of the following:

	December 31, 2012	December 31, 2011
Deferred tax assets:		
Temporary timing differences	$ 4,152,000	$ 4,277,000
Net operating loss carryforwards	15,041,000	20,065,000
Tax business credits carryforwards	2,160,000	4,166,000
Total deferred tax assets	21,353,000	28,508,000
Valuation allowance	(18,307,000)	(28,476,000)
Net deferred tax assets	$ 3,046,000	$ 32,000
Deferred tax liabilities:		
Goodwill	$ (72,000)	$ (48,000)
Acquired intangibles		(89,000)
Net deferred tax assets (liabilities)	$ 2,974,000	$ (105,000)

The net change in the total valuation allowance was a decrease of $10,169,000 in the year ended December 31, 2012. The valuation allowance increased by $73,000 for the nine months ended December 31, 2011 and increased by $2,227,000 for the year ended March 31, 2011. As of September 30, 2012, the Company s U.S. net operating losses (NOL s) and other deferred tax assets were fully offset by a valuation allowance primarily because the Company was in a cumulative loss position and did not have sufficient history of income to conclude that it was more likely than not that the Company would be able to realize the tax benefits of those deferred tax assets. In the fourth quarter of 2012, the Company entered into a three-year cumulative pre-tax income position and concluded that it was more likely than not that it will generate sufficient taxable income in 2013 based on its 2013 projections to realize the tax benefit of a portion of its deferred tax assets. Thus, the Company reversed $3,021,000 of the deferred tax asset valuation allowance in the U.S in the fourth quarter of 2012. The amount is recorded as a benefit for income taxes in the Company s consolidated statements of operations and comprehensive income (loss). The Company concluded that realization of deferred tax assets beyond December 31, 2013 is not more likely than not as a result of the fact that the Company will not receive royalty payments from Bristol on U.S. net sales of Orencia after December 31, 2013, and as such, the Company continues to maintain a valuation allowance against those deferred tax assets estimated to reverse beyond 2013.

The reconciliation of the federal statutory rate to the effective income tax rate for the year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011 and the fiscal year ended March 31, 2011 is as follows:

	Period Ended,					
	December 31, 2012		December 31, 2011		March 31, 2011	
Income (loss) before income taxes	$ 11,271,406	%	$ (1,596,881)	%	$ (43,509)	%
Expected tax (recovery) at statutory rate	3,944,996	35.0%	(542,939)	(34.0)%	(14,793)	(34.0)%
Adjustments due to:						
Difference between U.S. and foreign tax	(8,332)	(0.1)%	(19,287)	(1.2)%		(0.0)%
State income and franchise taxes	357,866	3.2%	52,905	3.3%	96,141	221.0%
Business tax credits	(67,276)	(0.6)%	(68,926)	(4.3)%	(66,126)	(152.0)%
Transaction costs		0.0%	240,842	15.1%		0.0%
Gain on bargain purchase	(82,422)	(0.7)%	(112,427)	(7.0)%		(0.0)%
Permanent differences	242,629	2.1%	218,989	13.7%	250,483	575.7%
Change in valuation allowance	(7,272,092)	(64.5)%	246,587	15.4%	(265,706)	(610.7)%
Provision (benefit) for income taxes	$ (2,884,631)	(25.6)%	$ 15,744	1.0%	$	(0.0)%

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At December 31, 2012 and 2011 as well as March 31, 2011, the Company had no material unrecognized tax benefits.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. No interest and penalties have been recognized by the Company to date.

The fiscal years ended March 31, 2007 through March 31, 2011 as well as the nine-month fiscal year ended December 31, 2011 and the year ended December 31, 2012 are subject to examination by the federal and state taxing authorities. Currently, a corporate excise tax audit is underway in the Commonwealth of Massachusetts for the fiscal years ended March 31, 2007 and 2008. To date, no assessments have been made and the Company continues to believe no reserve is required.

At December 31, 2012, the Company has not provided for U.S. income taxes or foreign withholding taxes on outside basis differences of foreign subsidiaries of approximately $477,000 as it is the Company s current intention to permanently reinvest these earnings outside the U.S.

4. Stockholders Equity

Common Stock and Warrants

At December 31, 2012, the Company has reserved 3,893,210 shares of common stock pursuant to the Plans, as described below. On April 6, 2007, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock at $0.01 per share, as discussed in Note 11. The warrants have a seven-year term and are exercisable based on performance criteria as detailed in the warrant agreement. At this time, the Company does not believe that the performance criteria are probable of being achieved in the near future.

Stock-Based Compensation

The Company recorded stock-based compensation expense of approximately $1,024,000 for the year ended December 31, 2012 for share-based awards granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan) and the Repligen Corporation 2012 Stock Option and Incentive Plan (the 2012 Plan, and collectively with the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan, the Plans). We recorded stock-based compensation expense of approximately $730,000 for the nine-month fiscal year ended December 31, 2011, and $748,000 for the nine-month period ended December 31, 2010 for share-based awards granted under the Plans. For the fiscal year ended March 31, 2011, we recorded stock-based compensation expense of approximately $1,003,000 for stock options granted under the 2001 Plan.

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

	Year ended December 31, 2012	Nine Months ended December 31, 2011	Nine Months ended December 31, 2010 (unaudited)	Year ended March 31, 2011
Cost of product revenue	$ 45,000	$ 35,000	$ 38,000	$ 48,000
Research and development	219,000	191,000	164,000	226,000
Selling, general and administrative	760,000	504,000	546,000	729,000
Total	$ 1,024,000	$ 730,000	$ 748,000	$ 1,003,000

The 2012 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock and other equity awards. Incentive options granted to employees under the Plans generally vest over a four to five-year period, with 20%-25% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair

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market value of the Company s common stock on the date of grant. At December 31, 2012, options to purchase 2,315,090 shares were outstanding under the Plans. At December 31, 2012, 1,578,120 shares were available for future grant under the 2012 Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The fair value of share-based awards granted during the year ended December 31, 2012, the nine-month fiscal year ended December 31, 2011, the nine-month period ended December 31, 2010 and the fiscal year ended March 31, 2011 were calculated using the following estimated assumptions:

	Year ended December 31, 2012	Nine Months ended December 31, 2011	2010	Years ended March 31, 2011
Expected term (years)	6.5	6.5	6.5	6.5
Volatility	49.76% - 53.54%	53.09% - 55.76%	57.58% - 63.60%	55.94% - 63.60%
Risk-free interest rate	0.89% - 1.06%	1.25% - 2.38%	1.81% - 2.62%	1.81% - 2.83%
Expected dividend yield				

Information regarding option activity for the year ended December 31, 2012 under the Plans is summarized below:

	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2011	2,823,400	$ 4.05		
Granted	368,690	3.65		
Exercised	(609,400)	3.06		
Forfeited/cancelled	(267,600)	4.44		
Options outstanding at December 31, 2012	2,315,090	$ 4.20	6.16	$ 4,854,412
Options exercisable at December 31, 2012	1,447,600	$ 4.39	4.96	$ 2,783,183
Vested and expected to vest at December 31, 2012 (1)	2,186,609	$ 4.21	6.05	$ 4,570,615

(1) This represents the number of vested options as of December 31, 2012 plus the number of unvested options expected to vest as of December 31, 2012 based on the unvested outstanding options at December 31, 2012 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the common stock on December 31, 2012 of $6.28 per share and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on December 31, 2012. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2012 was approximately $1,384,000. The aggregate intrinsic value of stock options exercised during the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 was approximately $8,000 and $43,000, respectively. The aggregate intrinsic value of stock options exercised during the fiscal year ended March 31, 2011 was approximately $76,000.

The weighted average grant date fair value of options granted during the year ended December 31, 2012 was $3.62. The weighted average grant date fair value of options granted during the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 was $1.89 and $1.95, respectively. The weighted average grant date fair value of options granted during the fiscal year ended March 31, 2011 was $2.11. The total fair value of stock options that vested during the year ended December 31, 2012 was approximately $931,000. The total fair value of stock options that vested during the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 was approximately $804,000 and

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$817,000, respectively. The total fair value of stock options that vested during the fiscal year ended March 31, 2011 was approximately $993,000.

As of December 31, 2012, there was $1,605,995 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.76 years. We expect 739,009 unvested options to vest over the next five years.

5. Commitments and Contingencies

Lease Commitments

In 2001, the Company entered into a ten-year lease agreement for approximately 25,000 square feet of space located in Waltham, Massachusetts to be used for its corporate headquarters, manufacturing, research and development, and marketing and administrative operations. In July 2011, the Company amended this agreement to expand the lease to cover approximately 56,000 square feet and to extend the term of the lease by eleven years, which expires on May 31, 2023. In connection with this lease agreement, the Company issued a letter of credit in the amount of $200,000 to the lessor. The letter of credit is collateralized by a certificate of deposit held by the bank that issued the letter of credit. The certificate of deposit is classified as restricted cash in the accompanying consolidated balance sheets.

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

Following the completion of the Novozymes Acquisition, the Company now leases four adjacent buildings in Lund, Sweden totaling approximately 45,000 square feet of space used primarily for biologics manufacturing and administrative operations. The lease 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.

Obligations under non-cancelable operating leases, including the facility leases discussed above, as of December 31, 2012 are approximately as follows:

Years Ending	Operating Leases
December 31, 2013	$ 2,222,000
December 31, 2014	2,222,000
December 31, 2015	2,222,000
December 31, 2016	2,222,000
December 31, 2017	1,655,000
Thereafter	5,611,000
Minimum lease payments	$ 16,154,000

Rent expense charged to operations under operating leases was approximately $2,183,000 for the fiscal year ended December 31, 2012, $528,000 and $510,000 for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively, and $686,000 for the fiscal year ended March 31, 2011. As of December 31, 2012 and December 31, 2011, the Company had deferred rent liabilities of $329,000 and $15,000, respectively, related to the escalating rent provisions for the Waltham headquarters.

Licensing and Research Agreements

The Company licenses certain technologies that are, or may be, incorporated into its technology under several agreements and also has entered into several clinical research agreements which require the Company to

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fund certain research projects. Generally, the license agreements require the Company to pay annual maintenance fees and royalties on product sales once a product has been established using the technologies. The Company recorded research and development expenses associated with license agreements of approximately $55,000 for the fiscal year ended December 31, 2012, $525,000 and $343,000 for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively, as well as $374,000 for the fiscal year ended March 31, 2011.

In October 2009, the Company entered into an exclusive worldwide commercial license agreement with Families of Spinal Muscular Atrophy (see Note 10). The initial license fee of $500,000 and a related sublicense fee of $175,000 were charged to research and development expenses in the fiscal year ended March 31, 2010. A related sublicense fee of $65,000 was charged to research and development expenses in the fiscal year ended March 31, 2011. A related milestone payment of $500,000 was charged to research and development expenses in the nine month fiscal year ended December 31, 2011. If all milestones are achieved, total financial obligations under this agreement, including milestone payments, sublicense fees, and other charges, could total approximately $16,000,000. Given the uncertain nature of such a development program, the likelihood that products or services will result from the research program is not known at this time.

Purchase Orders, Supply Agreements and Other Contractual Obligations

In the normal course of business, the Company has entered into purchase orders and other agreement with manufacturers, distributors and others. Outstanding obligations at December 31, 2012 of approximately $2,872,000 are expected to be completed within one year.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2012	December 31, 2011
Equipment maintenance and services	747,273	424,328
Prepaid insurance	365,167	251,418
Interest receivable	140,363	106,695
Clinical and research expenses	15,354	13,714
Other	36,730	82,304
Total	$ 1,304,887	$ 878,459

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2012	December 31, 2011
Employee compensation	$ 3,634,839	$ 2,741,738
Royalty and license fees	1,459,680	499,776
Contingent consideration	1,376,877	35,000
Unearned revenue	599,120	469,046
Professional fees	418,800	871,086
VAT liabilities	98,162	566,542
Research and development	18,300	142,695
Other accrued expenses	692,212	715,155
Total	$ 8,297,990	$ 6,041,038

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8. Employee Benefit Plans

In the U.S., the Repligen Corporation 401(k) Savings and Retirement Plan (the 401(k) Plan) is a qualified defined contribution plan in accordance with Section 401(k) of the Internal Revenue Code. All U.S. employees over the age of 21 are eligible to make pre-tax contributions up to a specified percentage of their compensation. Under the 401(k) Plan, the Company may, but is not obligated to match a portion of the employees contributions up to a defined maximum. The match is calculated on a calendar year basis. The Company matched approximately $103,000 for the year ended December 31, 2012, $102,000 for the nine-month fiscal year ended December 31, 2011, and $108,000 for both the nine-month period ended December 31, 2010 and the year ended March 31, 2011.

In Sweden, the Company contributes to a government-mandated occupational pension plan that is a qualified defined contribution plan. All employees in Sweden are eligible for this pension plan. The Company pays premiums to a third party occupational pension specialist who administers the pension plan. These premiums are based on various factors including each employee s age, salary, employment history and selected benefits in the pension plan. When an employee terminates or retires, these premium payments cease for that employee and the Company has no further pension-related obligations for that employee. For the fiscal year ended December 31, 2012, the Company contributed approximately $532,000 to the pension plan. For the period from the completion of the Novozymes Acquisition on December 20, 2011 to December 31, 2011, the Company contributed approximately $10,000 to the pension plan.

9. Royalty Arrangement with Bristol Myers Squibb Company (Bristol)

In 2008, the Company together with the University of Michigan entered into a settlement agreement with Bristol related to alleged patent infringement of a certain patent related to the treatment of rheumatoid arthritis. The settlement provides for Bristol to pay royalties on the United States net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500 million of annual net sales, 2.0% for the next $500 million of annual net sales and 4% of annual net sales in excess of $1 billion for each year from January 1, 2008 until December 31, 2013.

Pursuant to the Bristol Settlement, the Company recognized royalty revenue of $14,753,000 for the year ended December 31, 2012, $8,769,000 and $7,739,000 for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively, and $10,251,000 for the fiscal year ended March 31, 2011.

The Company must also remit to the University of Michigan 15% of all royalty revenue received from Bristol. Royalty expense was $2,213,000 for the year ended December 31, 2012, $1,315,000 and $1,161,000 for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively, and $1,537,000 for the fiscal year ended March 31, 2011. Royalty expense is included on the statements of operations under the line item Cost of royalty and other revenue.

10. License Agreements

Pfizer

On December 28, 2012, the Company entered into an exclusive worldwide outlicensing 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, the Company received a $5 million upfront payment on January 22, 2013 and is entitled to receive up to $65 million in potential future milestone payments, a portion of which may be owed to third parties. These potential payments are approximately equally divided between milestones related to clinical development and initial commercial sales in specific geographies. In addition, the Company is entitled to receive royalties on any future sales of RG3039 or

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any SMA compounds developed under the License Agreement. The License Agreement also provides for tiered and increasing royalty rates which begin in the high single-digits for RG-3039 or lesser amounts for any backup compounds developed under the License Agreement. The Company s receipt of these royalties is subject to an obligation under an existing in-license agreement and other customary offsets and deductions. Royalties are payable, on a country-by-country basis, for a duration based upon the later of (a) expiration of the licensed patent(s) or (b) a predetermined time after the first commercial sale of the first such product in such country.

Pursuant to the License Agreement, Pfizer will assume virtually all of the costs associated with completing the required clinical trials for the SMA program as well as obtaining FDA approval of the respective NDA. The Company is obligated to conduct additional activities in support of this program, which include completion of the second cohort of the ongoing Phase I trial and supporting the transition of the program to Pfizer. The Company will also provide specific technology transfer services to Pfizer who will then assume full responsibility for the SMA program moving forward, including the conduct of any registration trials necessary for any product approvals. The Company expects to complete its obligation with respect to this program in the first half of 2013. Pfizer may terminate the license agreement at any time for convenience. There are no refund provisions in the License Agreement.

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

- An exclusive license to research, develop, manufacture, commercialize and use RG3039 and backup compounds for the treatment of SMA and other disorders (the License);
- Research and development services designed to transition the SMA program to Pfizer pursuant to a transition plan (the Transition Services) ;
- The completion of the second cohort of a phase I clinical trial that was underway at the time the License Agreement was signed; and
- An inventory of RG3039, that could be used in clinical development, specifically to complete the phase I clinical trial, referenced immediately above (the Clinical Trial Material).

The deliverables outlined above were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in this determination included, among other things, whether any other vendors sell the items separately or whether or not Pfizer had the ability to resell and if Pfizer could use the delivered item for its intended purpose without the receipt of the remaining deliverables. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price.

The Company identified the arrangement consideration to allocate among the units of accounting as the $5.0 million non-refundable up-front payment and excluded the potential milestone payments provided for in the License Agreement from the arrangement consideration as they were not considered fixed or determinable at the time the License Agreement was signed. Because Repligen had not sold these items on a standalone basis previously, there was no vendor-specific objective evidence of selling price. Furthermore, the Company did not have detailed third-party evidence of selling price, and as a result used a best estimate of selling price for each item. In determining these prices, the Company considered what it would be willing to sell the items for on a standalone basis, what the market would bear for such items and what another party might charge for these items.

The Company used a discounted cash flow analysis to determine the value of the license. Key assumptions in the analysis included: the estimated market size for a compound targeted at SMA, the estimated remaining costs of development and time to commercialization, and the probability of successfully developing and commercializing the program. A change in the key assumptions used to determine best estimate of selling price for each of the deliverables would not have a significant effect on the allocation of arrangement consideration.

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Based on this analysis, the Company allocated $4,876,000 to the value of the license and recognized this amount as revenue in the year ended December 31, 2012 upon delivery as the risks and rewards associated with the License transferred at that time.

The remaining $124,000 of value was allocated based on the following:

The estimated selling price of the Transition Services was approximately $600,000 resulting in consideration allocation of approximately $76,000. Repligen was able to derive a price for these services, in part because they are similar to services provided by a contract research organization. The selling price of the Transition Services was based on the Company s internal FTE costs and external costs that it expects to incur to transition the program to Pfizer. The Company applied a mark-up on the internal FTE costs consistent with that of contract research organizations.

The estimated selling price of the completion of the second cohort of the clinical trial was approximately $275,000 resulting in consideration allocation of approximately $35,000. This estimated selling price is based on the estimated, remaining costs to complete this cohort. Since the costs are pursuant to an arrangement negotiated with a third-party (the clinical site), the Company believes that the external cost estimate included in the agreement represents the best estimate of selling price for this unit of accounting.

The estimated selling price of the Clinical Trial Material was approximately $105,000 resulting in consideration allocation of approximately $13,000. The estimated selling price is based upon the cost of procuring such material from the contract manufacturing organization that made the material. Since these costs were incurred pursuant to an arrangement negotiated with a third-party (the contract manufacturing organization), the Company believes that the costs included in the agreement represents the best estimate of selling price for this unit of accounting.

The Company intends to recognize the revenues related to the transfer of Clinical Trial Material upon transfer of title and risk of loss to Pfizer. The Company expects to recognize revenues related to the Transition Services and the completion of the second cohort ratably over the first six months of 2013.

In addition to the $5 million up-front payment, the Company is also eligible to receive $65 million in potential milestone payments comprised of: (i) up to $30 million related to the achievement of specified clinical milestone events; and (ii) up to $35 million related to the achievement of specified commercial sales events, specifically first commercial sale in specific territories. The Company may receive all, or a portion of, the first clinical milestone of $2 million in 2013 depending upon the development path chosen by Pfizer. If the Company receives a portion of this milestone, it expects to receive the balance of it by the end 2014.

Any future royalty payments, under the License Agreement will be recognized as revenue when they are earned.

The Scripps Research Institute

On April 6, 2007, the Company entered into an exclusive worldwide commercial license agreement (Scripps License Agreement) with The Scripps Research Institute (Scripps). Pursuant to the License Agreement, the Company obtained a license to use, commercialize and sublicense certain patented technology and improvements thereon, owned or licensed by Scripps, relating to compounds that may have utility in treating Friedreich s ataxia, an inherited neurodegenerative disease. Research in tissues derived from patients, as well as from mice, indicates that the licensed compounds increase production of the protein frataxin, which suggests potential utility of these compounds in slowing or stopping progression of the disease. There are currently no approved treatments for Friedreich s ataxia in the U.S.

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

In connection with the Scripps License Agreement, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. The warrants have a seven-year term and are exercisable based on performance criteria as detailed in the warrant agreement governing such warrants. No expense has been recorded related to these warrants through December 31, 2012, as none of the performance criteria have been achieved. At this time, the Company does not believe that the performance criteria are probable of being achieved.

The Scripps License Agreement with Scripps expires or may be terminated (i) when all of the royalty obligations under the License Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the License Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating to the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the License Agreement; or (iv) by the Company upon 90 days written notice.

Families of Spinal Muscular Atrophy

On October 22, 2009, the Company entered into an exclusive worldwide commercial license agreement (FSMA License Agreement) with Families of Spinal Muscular Atrophy (FSMA). Pursuant to the FSMA License Agreement, the Company obtained an exclusive license to develop and commercialize certain patented technology, and improvements thereon, owned or licensed by FSMA, relating to compounds that may have utility in treating spinal muscular atrophy (SMA). SMA is an inherited neurodegenerative disease in which a defect in the survival motor neuron gene (SMN) results in low levels of the protein SMN and leads to progressive damage to motor neurons, loss of muscle function and, in many patients, early death.

Pursuant to the FSMA License Agreement, the Company paid FSMA an initial license fee of $500,000 and a related sublicense fee of $175,000 in the year ended March 31, 2010. In April 2011, the Company paid an additional $500,000 milestone payment to FSMA. These license fees were recorded as research and development expense in the statements of operations. If all milestones are achieved, total financial obligations under this agreement, including milestone payments, sublicense fees, and other charges, could total approximately $16,000,000. Given the uncertain nature of such a development program, the likelihood that products or services will result from the research program is not known at this time. The Company has therefore ascribed no value to the license or the related liability.

The License Agreement with FSMA expires or may be terminated (i) on the later of: (a) when all related patents have expired or been abandoned, or (b) 10 years following the first commercial sale of a licensed product; (ii) by FSMA if the Company (a) fails to make payments under the License Agreement, (b) fails to use commercially reasonable efforts towards development and commercial objectives, (c) fails to maintain the required insurance or becomes insolvent, or (d) defaults in its performance under the License Agreement.

11. Acquisitions

Novozymes Biopharma Sweden AB

On December 20, 2011, the Company acquired the Novozymes Biopharma Business from Novozymes, for total consideration transferred of $28,495,000. The terms of the transaction required that the payment be

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denominated in Euros, but it is reflected here in U.S. dollars for presentation purposes. The Novozymes Acquisition diversified and expanded Repligen s bioprocessing product offering and customer base while doubling the Company s manufacturing capacity. The terms of the acquisition included an upfront payment of $26,884,000 and future potential milestone payments totaling up to 4,000,000, if specific sales targets are met for certain products by various dates ending on December 31, 2014 and upon the transfer of manufacturing processes for certain products. This business operates as the Company s wholly-owned subsidiary, Repligen Sweden AB. The 4,000,000 contingent consideration had an initial probability-weighted fair value at acquisition of $1,611,000.

Consideration Transferred

The Company accounted for the Novozymes Acquisition as the purchase of a business under GAAP. Under the acquisition method of accounting, the assets and certain liabilities of the Novozymes Biopharma Business were recorded as of the acquisition date, at their respective fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was originally estimated to be $28,922,000, which exceeded the total consideration transferred of $28,495,000. Accordingly, the Company recognized the excess of the fair value of the net assets over the purchase price of approximately $427,000 as a gain on bargain purchase. During the year ended December 31, 2012, the fair value of the net assets acquired increased to $29,236,000, due primarily to working capital adjustments on the purchased assets. These adjustments resulted in an additional gain on bargain purchase of $314,000 which was recorded in the year ended December 31, 2012 and is shown separately within income from operations in the consolidated statements of operations.

The Company believes that it was able to acquire the Novozymes Biopharma Business for less than the fair value of its assets because of (i) the Company s unique position as a market leader in this industry segment and (ii) the seller s intent to exit this industry segment, which was only a small part of the seller s overall business and no longer fit its strategy.

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

The total consideration transferred follows:

Cash consideration	$ 26,445,000
Estimated fair value of contingent consideration	1,611,000
Total consideration transferred	$ 28,056,000

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future milestone payments to be made to the seller. The Company could make payments of up to 4,000,000 if specific sales targets are met for certain products by various dates ending on December 31, 2014 and upon the transfer of manufacturing processes for certain products. The Company recorded a $618,000 increase in the liability for contingent consideration in the year ended December 31, 2012 to reflect updates to the Company s probability analysis and for the time value of money. At December 31, 2012, $1,322,000 of the liability for contingent consideration is included in current liabilities and $1,033,000 is included in other long-term liabilities in the consolidated balance sheet. The liability will be remeasured at each reporting period until the contingency is resolved.

The Company incurred approximately $1.7 million in transaction costs related to the Novozymes Acquisition. The transaction costs are included in selling, general and administrative expenses in the consolidated statements of operations in the period ended December 31, 2011.

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Fair Value of Net Assets Acquired

The following chart summarizes the allocation of the fair value of assets acquired and liabilities assumed:

Accounts receivable	$ 5,088,000
Inventory	10,497,000
Prepaid expenses	180,000
Fixed assets	9,089,000
Customer relationships and acquired technology	6,705,000
Deferred tax liability	(198,000)
Accounts payable and other liabilities assumed	(2,563,000)
Net assets acquired	$ 28,798,000
Less total consideration transferred	(28,056,000)
Gain on bargain purchase	$ 742,000

The Company finalized its fixed asset valuation analysis in the quarter ended September 30, 2012 and the purchase price allocation is now considered final.

BioFlash Partners, LLC

On January 29, 2010, the Company acquired the assets of BioFlash Partners, LLC (BioFlash), including a technology platform for the production of pre-packed, plug and play chromatography columns for total consideration transferred of $2.6 million. This patented technology enables economical production of chromatography columns in a format that is ready for use in the production of a broad range of biopharmaceuticals, including monoclonal antibodies, vaccines and recombinant proteins. The terms of the acquisition included an upfront payment of $1.8 million and a milestone payment of $300,000 that was made in November 2010.

The Company manufactures and sells these pre-packed columns under the brand name OPUS. OPUS pre-packed chromatography columns have the potential to improve manufacturing efficiencies by reducing time for column packing, set-up and cleaning.

Total consideration transferred was $2,640,000 comprised of cash payments of $2,080,000 and the fair value of contingent consideration of $560,000.

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future royalty payments to be made to former shareholders of BioFlash. The liability for contingent consideration is included in current and long-term liabilities on the consolidated balance sheets and will be remeasured at each reporting period until the contingency is resolved.

Allocation of Consideration Transferred

The following chart summarizes the allocation of consideration transferred:

Intangible assets subject to amortization	$ 1,430,000
Goodwill	994,000
Equipment	216,000
Total	$ 2,640,000

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12. Selected Quarterly Financial Data (Unaudited)

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

	December 31, 2012	September 30, 2012	June 30, 2012	March 31, 2012	December 31, 2011	September 30, 2011	June 30, 2011	March 31, 2011
	(in thousands, except per share amounts)							
Revenue:								
Product revenue	$ 9,710	$ 11,123	$ 11,659	$ 9,342	$ 3,114	$ 5,742	$ 4,359	$ 3,150
Royalty and other revenue	9,104	3,981	3,865	3,482	4,051	2,889	3,295	2,756
Total revenue	18,814	15,104	15,524	12,824	7,165	8,631	7,654	5,906
Operating expenses:								
Cost of product revenue	5,920	6,419	7,345	5,273	1,511	2,093	1,553	1,393
Cost of royalty and other revenue	620	594	537	462	481	418	416	376
Research and development	2,343	2,433	2,906	2,808	2,870	3,075	3,517	3,785
Selling, general and administrative	3,253	3,126	3,418	3,428	4,268	2,493	2,289	2,438
Contingent consideration fair value adjustments	267	344			(427)			
Gain on bargain purchase				(314)	(427)			
Total operating expenses	12,403	12,916	14,206	11,657	8,703	8,079	7,775	7,992
Income (loss) from operations	6,411	2,188	1,318	1,167	(1,538)	552	(121)	(2,086)
Investment income	62	95	29	31	43	53	66	69
Interest expense	(14)	7	(27)	(22)	(28)			(13)
Other income (expense)	(41)	(500)	458	109	(623)			
Income (loss) before income taxes	6,418	1,790	1,778	1,285	(2,146)	605	(55)	(2,030)
Income tax provision (benefit)	(3,135)	(16)	208	59	16			
Net income (loss)	$ 9,553	$ 1,806	$ 1,570	$ 1,226	$ (2,162)	$ 605	$ (55)	$ (2,030)
Earnings (loss) per share:								
Basic	$ 0.31	$ 0.06	$ 0.05	$ 0.04	$ (0.07)	$ 0.02	$ (0.00)	$ (0.06)
Diluted	$ 0.30	$ 0.06	$ 0.05	$ 0.04	$ (0.07)	$ 0.02	$ (0.00)	$ (0.06)
Weighted average shares outstanding:								
Basic	31,132	30,948	30,845	30,730	30,715	30,797	30,812	30,782
Diluted	31,600	31,256	31,149	31,010	30,715	30,934	30,812	30,782