

REPLIGEN CORP  
Form 10-K  
March 15, 2012  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended

OR

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

For the transition period from April 1, 2011 to December 31, 2011

Commission File Number 000-14656

**REPLIGEN CORPORATION**

(Exact name of registrant as specified in its charter)

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

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

**Title of Each Class**

**Common Stock, \$0.01 Par Value Per Share**

**Name of Exchange on Which Registered**

**The NASDAQ Stock Market LLC**

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

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

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):

## Edgar Filing: REPLIGEN CORP - Form 10-K

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of September 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was \$100,130,108.

The number of shares of the registrant's common stock outstanding as of March 6, 2012 was 30,724,757.

### Documents Incorporated By Reference

**The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the nine month fiscal year ended December 31, 2011. Portions of such proxy statement are incorporated by reference into Part III of this Transition Report on Form 10-K.**

---

**Table of Contents****Table of Contents**

|   | <b>PAGE</b> |
|---|-------------|
| PART I  |             |
| Item 1. <u>Business</u>   | 1           |
| Item 1A. <u>Risk Factors</u>  | 12          |
| Item 1B. <u>Unresolved Staff Comments</u>   | 22          |
| Item 2. <u>Properties</u>   | 22          |
| Item 3. <u>Legal Proceedings</u>  | 22          |
| Item 4. <u>Mine Safety Disclosures</u>  | 22          |
| PART II   |             |
| Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 23          |
| Item 6. <u>Selected Consolidated Financial Data</u>   | 25          |
| Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 26          |
| Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 39          |
| Item 8. <u>Financial Statements and Supplementary Data</u>  | 39          |
| Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 39          |
| Item 9A. <u>Controls and Procedures</u>   | 39          |
| Item 9B. <u>Other Information</u>   | 42          |
| PART III  |             |
| PART IV   |             |
| Item 15. <u>Exhibits and Financial Statement Schedules</u>  | 44          |
| <u>SIGNATURES</u>   | 48          |

---

**Table of Contents**

**PART I**

**Item 1. BUSINESS**

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

**Overview**

Repligen Corporation ( Repligen, the Company or we ) is a leading supplier of critical products used to manufacture biologic drugs. We manufacture Protein A for major life science companies under long term supply agreements and also sell products directly to end users for use in their manufacturing processes. We also apply our expertise in biologic product development to SecreFlo™ (RG1068), for which our first new drug application ( NDA ) has been submitted and accepted for priority review by the U.S. Food and Drug Administration ( FDA ) and for which we have submitted a marketing authorization application ( MAA ) to the European Medicines Agency ( EMA ). SecreFlo is a synthetic human hormone being developed by the Company as a novel imaging agent for the diagnosis of pancreatitis and potentially a variety of pancreatic diseases. We also have two early stage central nervous system ( CNS ) rare disease programs underway in Friedreich's ataxia and spinal muscular atrophy that are advancing into Phase 1 clinical trials. In addition, we have out-licensed certain intellectual property to Bristol-Myers Squibb Company ( Bristol ) from which we receive royalties on their net sales in the United States of their product Oren®ia

**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 also have a manufacturing facility located in Lund, Sweden.

**Acquisition of Novozymes Biopharma Sweden AB**

On December 20, 2011, pursuant to the terms of the Asset Transfer Agreement, dated as of October 27, 2011 (the Asset Transfer Agreement ), by and among the Company, Repligen Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of the Company ( Repligen Sweden ), Novozymes Biopharma DK A/S, a company organized under the laws of Denmark ( Novozymes Denmark ), and Novozymes Biopharma Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of Novozymes Denmark ( Novozymes Sweden and, together with Novozymes Denmark, Novozymes ), we acquired Novozymes' business headquartered at Novozymes Sweden's facility in Lund, Sweden and all related operations, 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 ). Pursuant to the Asset Transfer Agreement, Repligen Sweden (a) purchased all of the assets related to the Novozymes Biopharma Business and assumed certain specified liabilities related to the Novozymes Biopharma Business from Novozymes Sweden and (b) purchased contract rights and licenses used in the Novozymes Biopharma Business and other specified assets from Novozymes Denmark (collectively, the Transferred Business and the acquisition of the Transferred Business, the Novozymes Acquisition ). The Novozymes Biopharma Business now operates as Repligen Sweden. We paid a purchase price of 17.0 million Euros (~\$22.1 million) plus an additional net working capital adjustment of 3.65 million Euros (~\$4.8 million) for a total upfront cash payment of 20.65 million Euros (~\$26.9 million) to Novozymes for the Transferred Business upon the consummation of the Novozymes Acquisition. In addition, Novozymes has the right to contingent payments of up to 4.0 million Euros (~\$5.2 million) consisting of: (i) an earn-out of 1.0 million Euros (~\$1.3 million) if the Transferred Business achieves sales of a minimum quantity of a Novozymes product between January 1, 2012 and December 31,

---

## **Table of Contents**

2012; (ii) two milestone payments of 1.0 million Euros (~\$1.3 million) each if sales of certain Novozymes products achieve agreed levels for the combined calendar years 2012 and 2013 and for calendar year 2014, respectively; and (iii) technology transfer payments totaling 1.0 million Euros (~\$1.3 million) following the successful transfer of certain Novozymes manufacturing technology.

### **Change in Fiscal Year**

As previously announced, in 2011 we changed our fiscal year end from March 31 to December 31. This Transition Report on Form 10-K reports our financial results for the nine-month period from April 1, 2011 through December 31, 2011, which we refer to as the nine-month fiscal year ended December 31, 2011 throughout this report. Following this Transition Report, we will report on a twelve-month fiscal year beginning on January 1 and ending on December 31 of each year.

### **Currently Marketed Products**

We currently sell various commercial bioprocessing products based on Protein A and IFG-1 growth factors, as well as a line of pre-packed chromatography columns, which are used in the production of monoclonal antibodies and other biopharmaceutical products.

### **Products for Biologics Manufacturing**

Repligen is a leading manufacturer of a number of bioprocessing products including multiple products based on Protein A, growth factors used in fermentation and a line of pre-packed chromatography columns. Our bioprocessing products are used in the production of biologic drugs which include a wide range of recombinant therapeutic proteins, monoclonal antibodies and vaccines. Demand for our bioprocessing products has grown in concert with the expanding markets for biologics, particularly monoclonal antibodies. Most major pharmaceutical and biotechnology companies have made a significant investment in the development and commercialization of biologic drugs. The global biologics market was valued at approximately \$150 billion in 2010 and is expected to grow at a rate in the high single digits annually. Monoclonal antibodies are highly valuable therapeutic agents, examples of which include some of the best-selling drugs in the world such as Enbrel® and Remicade® for rheumatoid arthritis and other inflammatory disorders, and Rituxan® for Non-Hodgkin's Lymphoma. There are more than 50 approved monoclonal antibody products and 200 product candidates currently in clinical development, most of which are manufactured using Protein A.

For more than ten years, Repligen has been a well-respected global supplier of Protein A, a key consumable used in the purification of monoclonal antibody pharmaceuticals. Through the Novozymes Acquisition, we now manufacture a native Protein A product which is used in the production of several of the early blockbuster monoclonal antibody drugs. The combined company now manufactures all five forms of commercial scale Protein A and is well positioned to benefit from the expansion of the biologics market and in particular the growth of the monoclonal antibody market which will create increased demand for Protein A.

To be useful in manufacturing, Protein A is chemically bound to various manufacturers' proprietary chromatography media or small beads, which provide a rigid support required for processing. This media is then packed by end-users into cylindrical columns. After fermentation of a monoclonal antibody, the broth containing the monoclonal of interest as well as numerous fermentation by-products and contaminants is passed over a column filled with Protein A chromatography media which selectively captures the monoclonal. Protein A has a highly specific affinity for the monoclonal antibody and as a result, the antibody stays bound to the Protein A media and the impurities wash through. After the impurities are washed away, a change in conditions releases the purified antibody. The result is a highly purified and concentrated monoclonal antibody from a single purification step. Further purification steps are usually necessary to increase purity to a level greater than 98%.

The Company manufactures Protein A for major life science companies including GE Healthcare, EMD Millipore, and Life Technologies under long term supply agreements which extend to 2015-2021. Our customers incorporate various

---

## **Table of Contents**

forms of Protein A products into their proprietary chromatography media that they sell directly to the biopharmaceutical industry. The majority of our product sales for the last three years have been sales of Protein A products.

Most biopharmaceuticals are produced in mammalian fermentation supplemented by growth factors. Through the Novozymes Acquisition, the Company acquired four fermentation growth factor products. LONG<sup>®</sup>R3 IGF-I is a growth factor that is more biologically potent than either insulin or native IGF-1 and has been shown to significantly increase recombinant protein production in fermentation applications. LONG<sup>®</sup>R3 IGF-I is sold under a distribution agreement with Sigma-Aldrich Corporation ( Sigma ) which extends to 2021. Sigma has distribution rights for industrial cell culture applications, and the product is currently used in the manufacture of nine commercial biopharmaceuticals. Repligen sells the product for use in stem cell and other cell-based therapies. In addition, we acquired long epidermal growth factor (LONG<sup>®</sup>EGF), transforming growth factor alpha (LONG<sup>®</sup>TGF-a) supplements for serum-free or low serum culture in cell-based therapy application 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.

In January 2010, we acquired patented technology from BioFlash Partners, LLC ( BioFlash ) that enables reliable production of pre-packed chromatography columns for the purification of biologic drugs and vaccines. OPUS<sup>™</sup> columns have the potential to improve manufacturing efficiencies by reducing time for column packing, set-up and cleaning. Based on specific customer feedback and rising market demand for disposable biomanufacturing technologies, we have reengineered and expanded our OPUS product line to include larger scale columns. We recently introduced a new, process-scale product line which is suitable for the production of a broad range of clinical trial material and niche commercial products such as orphan biologics.

## **Research and Development**

We have devoted substantial resources to the research and development of therapeutic and imaging product candidates and our commercial products discussed herein. For the nine-month fiscal year ended December 31, 2011, we spent \$9,462,000 on company-sponsored research and development activities. For the fiscal years ended March 31, 2011 and 2010, we spent \$12,529,000 and \$14,160,000, respectively, on company-sponsored research and development activities.

## **Development Stage Products**

We currently have three active development stage programs underway including our diagnostic imaging program and two early stage central nervous system ( CNS ) rare disease programs. SecreFlo (RG0168, synthetic human secretin) is being developed to be used in combination with magnetic resonance imaging ( MRI ) to improve the detection of pancreatic abnormalities in patients with pancreatitis. SecreFlo has completed a successful pivotal Phase 3 study, and we submitted our first New Drug Application ( NDA ) to the Food and Drug Administration ( FDA ) for SecreFlo in December 2011. The FDA has granted our NDA priority review. Under the Prescription Drug User Fee Act ( PDUFA ), the FDA's goal for completing a priority review and delivering a decision on marketing approval is reduced to six months, compared to ten months for a standard review. The FDA has assigned a PDUFA goal date of June 21, 2012 to our SecreFlo NDA. In March 2012, we submitted a marketing authorization application ( MAA ) for SecreFlo for review by the European Medicines Agency ( EMA ) in the same initial indication. We also have two early stage rare disease clinical programs underway to evaluate the potential for our product candidates RG3039 and RG2822 to treat spinal muscular atrophy ( SMA ) and Friedreich's ataxia, respectively.

## **SecreFlo for Pancreatic Imaging**

SecreFlo is a synthetic version of the human hormone secretin. Secretin is a well-known gastrointestinal hormone produced in the small intestine that regulates the function of the pancreas as part of the process of digestion. We have completed a Phase 3 clinical trial evaluating the sensitivity and specificity of SecreFlo in combination with MRI to improve the detection of structural abnormalities of the pancreas relative to MRI alone. Structural abnormalities of the pancreas are often the cause of significant abdominal pain and can be associated

## **Table of Contents**

with diseases such as pancreatitis. When the pancreas is at rest and the pancreatic duct is empty, it is quite narrow and can be hard to visualize by MRI. SecreFlo stimulates secretion of watery fluid into the pancreatic ducts expanding the ducts and enabling them to be more effectively visualized by MRI as this imaging technique images water (water looks white in certain MRI images). Improvement in the detection and delineation of normal and abnormal structures with MRI is attractive for patient care as it can obviate the need for additional and potentially risky procedures such as endoscopy ( ERCP ). The FDA has granted Fast Track designation to the development of SecreFlo. Fast Track is a process designed to facilitate the development and expedite the review of drugs that treat serious diseases and fill an unmet medical need.

Our pivotal Phase 3 clinical trial was initiated in March 2008 and completed in December 2009. This was a multi-center, baseline controlled, single dose study in which 258 patients were enrolled at 23 clinical sites within the United States and Canada. Each patient in the study received an MRI of the pancreas with and without SecreFlo, and separately underwent ERCP as a diagnostic reference. The MRI images were randomized and independently read and reviewed by three central radiologists. The primary objectives of the Phase 3 study were to demonstrate that SecreFlo increases the sensitivity in detecting structural abnormalities of the pancreas by MRI, with minimal loss of specificity. The predetermined criteria for a successful study included the achievement of a statistically significant improvement in sensitivity with minimal loss in specificity from two of the three central radiologists reading the MRI images. In the initial read of the study, one radiologist achieved a statistically significant improvement in sensitivity with SecreFlo, while a second radiologist showed a trend but did not achieve statistical significance. There was minimal loss in specificity for all radiologists. Based on inconsistencies in the analysis of the radiographic images by the three radiologists hired to review the Phase 3 images, we submitted a request to the FDA and the EMA to re-analyze the Phase 3 data set ( Phase 3 re-read ). In May 2010, the FDA and EMA approved our plan for a re-analysis of images obtained from the Phase 3 trial. In March 2011, we announced positive results of the Phase 3 re-read, in which all three independent radiologists achieved a statistically significant improvement in sensitivity (all radiologists  $p < 0.0001$ ) with minimal loss in specificity ( $< 7.5\%$ ). All three secondary endpoints were also met, with each demonstrating highly statistically significant improvements ( $p < 0.0001$ ) in image quality, visualization of the main pancreatic duct and diagnostic confidence when compared to MRI alone.

Based on the positive re-read of the Phase 3 data, we filed an NDA with the FDA for SecreFlo on December 21, 2011, with a request for priority review. In February 2012, the FDA granted priority review for this NDA for SecreFlo. Under PDUFA, the FDA's goal for completing a priority review and delivering a decision on marketing approval is reduced to six months compared to ten months for a standard review. The FDA has assigned a PDUFA goal date of June 21, 2012 for a determination on this NDA for SecreFlo.

In March 2012, we filed an MAA for SecreFlo in the same indication, for potential approval by the EMA. Pending successful validation, the EMA would then require its Committee for Medicinal Products for Human Use (CHMP) to complete a full scientific assessment and deliver its opinion on marketing approval for SecreFlo, a process that is expected to be completed in approximately twelve months.

Pending FDA approval of SecreFlo, we expect to build a commercial infrastructure to support the launch of SecreFlo in the U.S., and we plan to seek to establish one or more partnerships for commercialization of SecreFlo outside the U.S. We have received an Orphan Drug designation from the FDA covering the use of SecreFlo in MRI which, if we are the first company to receive FDA approval for this use of secretin in the U.S., will provide seven years of marketing exclusivity in the U.S. following approval of the NDA.

We believe that there may be additional uses for SecreFlo, and we intend to evaluate whether SecreFlo has the potential to improve the detection of pancreatic cancer in combination with contrast-enhanced MRI or computed tomography ( CT ). We will also seek to acquire products that are complementary to SecreFlo, which we may be able to sell to gastroenterologists or radiologists.

### **RG3039 for Spinal Muscular Atrophy**

We are pursuing development of RG3039 for treatment of patients with spinal muscular atrophy ( SMA ). Our inhibitors have the potential to be first in class treatment for the disease. SMA is an inherited



---

## **Table of Contents**

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. There are approximately 20,000 people worldwide with SMA.

On October 22, 2009, we entered into an exclusive worldwide commercial license agreement (the FSMA License Agreement ) with Families of Spinal Muscular Atrophy ( FSMA ). Pursuant to the FSMA License Agreement, we obtained an exclusive license to develop and commercialize certain patented technology, and improvements thereon, owned or licensed by FSMA, relating to compounds which may have utility in treating SMA. If all milestones are achieved, total future financial obligations under this agreement, including milestone payments, sublicense fees, and other charges, could total approximately \$11,250,000.

In May 2011, we initiated a Phase 1 clinical study of RG3039 in healthy volunteers. We have received an Orphan Drug designation from the FDA for RG3039, which, if we are the first company to obtain market approval for RG3039 for SMA in the United States, will provide seven years of marketing exclusivity in the United States following NDA approval. We have received an Orphan Drug designation from the European Commission for RG3039, which, if granted, and if we are the first company to obtain market approval for RG3039 for SMA in Europe, will provide ten years of marketing exclusivity in Europe following MAA approval. The composition of RG3039 is covered by patent applications in the United States and Europe (see Patents, Licenses and Proprietary Rights section below.)

### **Histone Deacetylase Inhibitors for Friedreich s Ataxia, Huntington s Disease and Memory Disorders**

Friedreich s ataxia is an inherited neurodegenerative disease caused by a single gene defect that results in inadequate production of the protein frataxin. Low levels of frataxin lead to degeneration of both the nerves controlling muscle movements in the arms and legs and nerve tissue in the spinal cord. Symptoms of Friedreich s ataxia typically emerge between the ages of five and fifteen and often progress to severe disability, incapacitation or loss of life in early adulthood. There are approximately 15,000 patients worldwide with Friedreich s ataxia. There is currently no treatment for Friedreich s ataxia.

Repligen is developing RG2833, a class I histone deacetylase ( HDAC ) inhibitor, for the treatment of Friedreich s ataxia. In May 2010, we filed an Investigational New Drug Application ( IND ) for RG2833 with the FDA which is currently on clinical hold. In July 2011, we filed an application with the Italian Superior Institute of Health, commonly known as the ISS , to initiate a Phase 1 study of RG2833 in Italy. We plan to initiate a single, ascending dose Phase 1 study of RG2833 in Friedreich s ataxia patients in Italy, in the first quarter of 2012. We have 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. We have received an Orphan Drug designation from the FDA for RG2833, which, if we are the first company to obtain market approval for RG2833 for Friedreich s ataxia in the U.S., will provide seven years of marketing exclusivity in the U.S. following NDA approval. We have also received Orphan Drug designation from the European Commission for RG2833, which, if we are the first company to obtain market approval for RG2833 for Friedreich s ataxia in Europe, will provide ten years of marketing exclusivity in Europe following MAA approval. The composition of RG2833 is covered by patent applications in the U.S. and Europe (see Patents, Licenses and Proprietary Rights section below.)

Repligen is also exploring the applicability of HDAC inhibitors in the treatment of memory disorders and Huntington s disease. In 2010, the National Institute of Neurological Disorders and Stroke ( NINDS ) awarded a grant of \$6,000,000 over four years to The Scripps Research Institute and Repligen for the development of a novel HDAC inhibitor for Huntington s disease. Repligen is part of a collaborative network receiving the grant and has the potential to receive \$2,900,000 based on successful completion of various milestones during the four year program. The goals of the grant include the identification, characterization, optimization and preclinical GLP toxicology and safety testing of a novel HDAC inhibitor for Huntington s disease.

### **Uridine for Bipolar Depression**

Bipolar disorder, also known as manic depression, is a chronic illness marked by extreme changes in mood, thought, energy and behavior. Uridine is a biological compound that is essential for multiple biosynthetic

**Table of Contents**

processes including the synthesis of DNA and RNA, the basic hereditary material found in all cells and numerous other factors essential for cell metabolism. Researchers at McLean Hospital previously demonstrated that uridine is active in a well-validated animal model of depression. Literature reports indicate that certain genes that encode for mitochondrial proteins are significantly down-regulated in the brains of bipolar patients. This insight suggested that the symptoms of bipolar disorder may be linked to dysregulation of energy metabolism in the brain.

In March 2006, we initiated a Phase 2a clinical trial of RG2417, an oral formulation of uridine, in patients with bipolar disorder. The study showed a statistically significant improvement in the symptoms of depression in the patients treated with RG2417 when compared to placebo. Our Phase 2a data was reviewed by the FDA and served as the basis for a Phase 2b proof-of-concept clinical trial, which we initiated in November 2008. In March 2011, we announced the results from this Phase 2b study, which did not demonstrate a statistically significant improvement when compared to placebo in treating the symptoms of depression. At this time, we do not plan to invest additional resources in RG2417.

**Intellectual Property on CTLA4-Ig****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 1990s, 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.

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, 2011, we have paid approximately \$5,290,000 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, Life Technologies, Sigma Aldrich and distributors in certain foreign markets.

In December 2011, we filed an NDA covering the use of SecreFlo in combination with MRI to improve the detection of pancreatic duct abnormalities in patients with pancreatitis. In February 2012, the FDA granted priority review for this NDA for SecreFlo and assigned a PDUFA goal date of June 21, 2012 for completing its review and delivering a decision on marketing approval. Pending regulatory approvals, we plan to build a commercial infrastructure to support the launch of SecreFlo in the U.S. and to establish one or more partnerships for commercialization of SecreFlo outside the U.S.

---

## **Table of Contents**

### **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, diagnostics companies, biopharmaceutical companies and laboratory researchers. For the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, as well as the fiscal years ended March 31, 2011 and 2010, total revenues from sales to customers in the United States were approximately 48%, 48%, 50% and 57%, respectively. During the same periods, total revenues generated through sales to customers in Sweden were 44%, 45%, 42%, and 36%, respectively. For the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, as well as the fiscal years ended March 31, 2011 and 2010, royalty revenue from Bristol represented 37%, 37%, 38%, and 43% of total revenues, respectively. Our largest bioprocessing customer accounted for 44%, 45%, 42%, and 36% of total revenues in the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 as well as the fiscal years ended March 31, 2011 and 2010, respectively.

### **Employees**

As of February 14, 2012, we had 137 employees. Of those employees, 97 were engaged in research, development and manufacturing and 40 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 one collective bargaining agreement that covers our 69 employees in Sweden, comprising 50% of our total workforce. The current collective bargaining agreement expires on March 31, 2013. The Company considers its employee relations to be satisfactory.

### **Patents, Licenses and Proprietary Rights**

Repligen considers patents to be an important element in the protection of our competitive and proprietary position and actively, but 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 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.

### **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, Orenicia® through December 31, 2013.

## **Table of Contents**

### **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 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.

### **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. Repligen is prosecuting equivalent patent applications abroad.

### **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. These patent applications are currently being prosecuted in the United States and abroad.

### **OPUS**

Repligen has recently filed a provisional patent application with the U.S. Patent and Trademark Office 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.

### **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 financial, manufacturing and distribution resources significantly greater than ours.

The field of drug development is characterized by rapid technological change. New developments are expected to continue at a rapid pace in both industry and academia. There are many companies, both public and private, including large pharmaceutical companies, chemical companies and specialized biotechnology companies, engaged in developing products competitive with products that we have under development. Many of these companies have greater capital, human resources, research and development, manufacturing and marketing experience than we do. They may succeed in developing products that are more effective or less costly than any that we may develop. These competitors may also prove to be more successful than we are in production and marketing. In addition, academic, government and industry-based research groups compete intensely with us in recruiting qualified research personnel, in submitting patent filings for protection of intellectual property rights and in establishing corporate strategic alliances. We cannot be certain that research, discoveries and commercial developments by others will not render any of our programs or potential products noncompetitive.

---

## **Table of Contents**

### **Manufacturing**

#### **Bioprocessing Products**

Repligen is a leading supplier of a number of bioprocessing products including multiple products based on Protein A, a line of pre-packed chromatography columns and growth factors used in fermentation. Bioprocessing products are used in the production of biologics which include a wide range of protein-based drugs such as recombinant therapeutic proteins, monoclonal antibodies and vaccines. Demand for our bioprocessing products has grown in concert with the expanding markets for biologics, particularly monoclonal antibodies. There are more than 50 approved monoclonal antibody products and 200 candidates currently in clinical development, most of which are manufactured using Protein A.

For more than 10 years, Repligen has been a well-respected global supplier of Protein A, a key consumable used in the purification of monoclonal antibody pharmaceuticals. The Company manufactures all five forms of commercial scale Protein A including native Protein A which is used in the production of many of the early blockbuster monoclonal antibody drugs. The Company manufactures Protein A for major life science companies including GE Healthcare, EMD Millipore, and Life Technologies under long term supply agreements which extend to 2015-2021. Our customers incorporate various forms of Protein A products into their proprietary chromatography media that they sell directly to the biopharmaceutical industry.

We manufacture four cell culture growth factor products which are used primarily to supplement mammalian cell culture. LONG<sup>®</sup>R3 IGF-I is a growth factor that is more biologically potent than either insulin or native IGF-1 and has been shown to significantly increase recombinant protein production in cell culture applications. In addition, we manufacture long epidermal growth factor (LONG<sup>®</sup>EGF), transforming growth factor alpha (LONG<sup>®</sup>TGF-a) supplements for serum-free or low serum culture in cell based therapy application as well as recombinant transferrin (rTransferrin) which has been developed as an iron supplement for cell culture.

In January 2010, we acquired patented technology from BioFlash Partners, LLC ( BioFlash ) that enables reliable production of pre-packed chromatography columns in a format that is ready for use in manufacturing. OPUS columns have the potential to improve manufacturing efficiencies by reducing time for column packing, set-up and cleaning. Based on specific customer feedback and rising market demand for disposable biomanufacturing technologies, we have reengineered and expanded our OPUS product line to include larger scale columns. The current line of OPUS columns is suitable for the production of a broad range of clinical trial material and niche commercial products such as orphan biologics.

We 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 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 for cell bank manufacturing. 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.

#### **Therapeutic Product Candidates**

We currently rely, and expect to continue to rely, upon contract manufacturers for both the procurement of raw materials and the production of our product candidates for use in our clinical trials. Our product candidates will need to be manufactured in a facility and by processes that comply with the FDA's current good manufacturing practices and other similar regulations. It may take a substantial period of time to begin manufacturing our products in compliance with such regulations. If we are unable to establish and maintain

---

## **Table of Contents**

relationships with third parties for manufacturing sufficient quantities of our product candidates and their components that meet our planned time and cost parameters, the development and timing of our clinical trials may be adversely affected.

### **Shareholder Rights Plan**

In March 2003, the Company adopted a Shareholder Rights Agreement (the "Rights Agreement"). Under the Rights Agreement, the Company distributed certain rights to acquire shares of the Company's Series A junior participating preferred stock (the "Rights") as a dividend for each share of common stock held of record as of March 17, 2003. Each share of common stock issued after the March 17, 2003 record date had an attached Right. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock (20% in the case of a certain stockholder) (the "15% holder"), each Right permitted the holder (other than the 15% holder) to purchase common stock having a value equal to twice the exercise price of the Right, upon payment of the exercise price of the Right. In addition, in the event of certain business combinations after an acquisition by a person or group of 15% or more of the common stock (20% in the case of a certain stockholder), each Right entitled the holder (other than the 15% holder) to receive, upon payment of the exercise price, common stock having a value equal to twice the exercise price of the Right. The Rights had no voting privileges and, unless and until they became exercisable, were attached to, and automatically traded with, the Company's common stock. The Rights original termination date was upon the earlier of the date of their redemption or March 2013. On September 8, 2011, the Company amended the Rights Agreement to accelerate the expiration date to September 8, 2011, effectively terminating the Rights Agreement on September 8, 2011.

### **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.

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.

**Table of Contents**

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](http://www.repligen.com). We are not including the information contained on our website as a part of, or incorporating it by reference into, this Transition 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](http://www.sec.gov).

---

## **Table of Contents**

### **Item 1A. RISK FACTORS**

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

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

*This Transition 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 Transition Report on Form 10-K.*

#### **We may fail to realize benefits estimated from the Novozymes Acquisition.**

The success of our acquisition of the Novozymes Biopharma Business will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining our business with that of the Novozymes Biopharma Business. We may never realize these anticipated synergies, business opportunities and growth prospects. Integrating operations will be complex and will require 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 trying to integrate operations and corporate and administrative infrastructures from the Novozymes Denmark architecture into the correlative Repligen systems. If any of these factors limit our ability to 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, and will continue to incur, 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 are incurring integration costs as we integrate 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;



Edgar Filing: REPLIGEN CORP - Form 10-K

difficulties in operating the Novozymes Biopharma Business profitably;

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

potential loss of key employees;

unanticipated costs; and

potential disputes with Novozymes Denmark.

## **Table of Contents**

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 record 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 have 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 indefinite-lived 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 future sales outside of the United States have and will increase dramatically 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 recent instability within the European Union;

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

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 could have an adverse impact on our effective tax rate; 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.**

Upon acquiring the Novozymes Biopharma Business, we now face 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 combined organization could material 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 upon the consummation of the Novozymes Acquisition.**

## Edgar Filing: REPLIGEN CORP - Form 10-K

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. The Novozymes Biopharma Business involves the use of

## **Table of Contents**

similar hazardous materials as well as Staphylococcus aureus and toxins produced by Staphylococcus aureus. 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 increased materially following the Novozymes Acquisition. 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.

### **Pursuing and completing potential acquisitions, in addition to the consummation of the Novozymes Acquisition, could divert management attention and financial resources and may not produce the desired business results.**

While we currently do not have commitments or agreements with respect to any acquisitions, as part of our growth strategy, we may make selected acquisitions of complementary businesses, in addition to the Novozymes Acquisition. If we pursue any acquisition, our management, in addition to their operational responsibilities, could spend a significant amount of time and management and financial resources to pursue and integrate any acquired business with our existing business. To fund the purchase price of an acquisition, we might use capital stock, cash or a combination of both. Alternatively, we may borrow money from a bank or other lender. If we use capital stock, our stockholders will experience dilution. If we use cash, our financial liquidity may be reduced. If we take on debt, it may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In addition, from an accounting perspective, an acquisition may involve amortization of significant amounts of other intangible assets that could adversely affect our ability to maintain profitability.

Despite the investment of these management and financial resources, an acquisition may not produce the revenue, earnings or business synergies that we anticipated or may produce such synergies less rapidly than anticipated for a variety of reasons, including:

difficulties in the assimilation of the operations, operational systems deployments, technologies, services, products and personnel of the acquired company;

failure of acquired technologies and services to perform as expected;

risks of entering markets in which we have no, or limited, prior experience;

effects of any undisclosed or potential legal or tax liabilities of the acquired company;

compliance with additional laws, rules or regulations that we may become subject to as a result of an acquisition that might restrict our ability to operate; and

the loss of key employees of the acquired company.

We may not be able to successfully address these problems. Our future operating results may depend to a significant degree on our ability to successfully integrate acquisitions and manage operations while controlling expenses and cash outflows.

### **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 and diagnostic market is intensely competitive, subject to rapid change and significantly affected by new product introductions, including biosimilars, and other market activities of industry participants.

## Edgar Filing: REPLIGEN CORP - Form 10-K

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;

established relations with healthcare professionals, customers and third-party payors;

## Table of Contents

larger and more established distribution networks;

additional lines of products and the ability to offer rebates or 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 and obtaining regulatory approval; 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 changing their pricing model or by lowering the price of their products. If these competitors' products were to gain acceptance with healthcare professionals, a downward pressure on prices could result. If prices were to fall, we may not improve our gross margins or sales growth sufficiently to achieve 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.

### **Royalty revenue from Bristol-Myers Squibb Company for sales of Orencia® could fail to materialize.**

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. 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 are dependent on others to develop, conduct clinical trials for, manufacture, market and sell our diagnostic and therapeutic products.**

We conduct some of our diagnostic and therapeutic development and manufacturing activities through collaborations. These collaborations include academic medical centers, contracts with vendors and partnerships with major life science companies. Our collaborations are heavily dependent on the efforts and activities of our partners. Our existing and any future collaborations may not be technically or commercially successful. For example, if any of our collaborative partners were to breach or terminate an agreement with us, reduce its funding or otherwise fail to conduct the collaboration successfully, we may need to devote additional internal resources to the diagnostic or therapeutic program that is the subject of the collaboration, scale back or terminate the program or seek an alternative partner, any of which could lead to delays in the development, manufacturing or commercialization of our diagnostic and therapeutic products.

### **We have limited sales and marketing experience and capabilities.**

We are currently preparing to launch commercial sales of SecreFlo, if it is approved by the FDA. We have limited sales, marketing and distribution experience and capabilities and have never launched a commercial therapeutic product. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. In these instances, our future revenues will be materially dependent upon the success of the efforts of these third parties.

## **Table of Contents**

If in the future we determine to perform sales, marketing and distribution functions ourselves, including the commercial launch of SecreFlo, we would face a number of additional risks, including:

we may not be able to attract and build a significant marketing staff or sales force;

the cost of establishing a marketing staff or sales force may not be justifiable in light of any product revenues; and

our direct sales and marketing efforts may not be successful.

### **Our clinical trials may not be successful and we may not be able to develop and commercialize related products.**

In order to obtain regulatory approvals for the commercial sale of our future therapeutic products, we and our collaborative partners will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of the products. We have limited experience in conducting clinical trials.

The submission of an IND application may not result in FDA authorization to commence clinical trials. If clinical trials begin, we or our collaborative partners may not complete testing successfully within any specific time period, if at all, with respect to any of our products. Furthermore, we, our collaborative partners, or the FDA, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to unacceptable health risks. Clinical trials, if completed, may not show any potential product to be safe or effective. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, and the existence of competitive clinical trials. Delays in planned patient enrollment may result in increased costs and delays in completion of clinical trials.

### **We may not obtain regulatory approvals; the approval process is costly and lengthy.**

We must obtain regulatory approval for our ongoing development activities and before marketing or selling any of our future therapeutic products. We may not receive regulatory approvals to conduct clinical trials of our products or to manufacture or market our products. In addition, regulatory agencies may not grant such approvals on a timely basis or may revoke previously granted approvals.

The process of obtaining FDA and other required regulatory approvals, such as the approval we are seeking with our NDA submission for SecreFlo, is lengthy and may be expensive. The time required for FDA and other clearances or approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. Our SecreFlo NDA submission to the FDA and MAA submission to the EMA are based on a re-read of our single Phase 3 trial data. The FDA or the EMA may not deem this to be sufficient for approval. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay in obtaining or failure to obtain required clearance or approvals could materially adversely affect our ability to generate revenues from the affected product. We have only limited experience in filing and prosecuting applications necessary to gain regulatory approvals.

We are also subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our future products. The approval procedure varies among countries. The time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries (or vice versa).

All of the foregoing regulatory risks also are applicable to development, manufacturing and marketing undertaken by our collaborative partners or other third parties.

## **Table of Contents**

**Even if we obtain marketing approval, our diagnostic and therapeutic products will be subject to ongoing regulatory review, which may be expensive and may affect our ability to successfully commercialize our products.**

Even if we or our collaborative partners receive regulatory approval of a product, such approval may be subject to limitations on the indicated uses for which the product may be marketed, which may limit the size of the market for the product or contain requirements for costly post-marketing follow-up studies. The manufacturers of our products for which we or our collaborative partners have obtained marketing approval will be subject to continued review and periodic inspections by the FDA and other regulatory authorities. The subsequent discovery of previously unknown problems with the product, clinical trial subjects, or with a manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If we or our collaborative partners fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

**If we are unable to obtain, maintain and enforce patents or regulatory exclusivity (orphan drug or new chemical entity exclusivity) for our products, 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 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 biotechnology and pharmaceutical firms is often highly uncertain and usually involves complex legal and scientific questions. Moreover, no consistent policy has emerged in the United States or in many other countries regarding the breadth of claims allowed in biotechnology patents. Patents which may be granted to us in certain foreign countries may be subject to opposition proceedings brought by third parties or result in suits by us, which may be costly and result in adverse consequences for us.

In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to us or our licensors, to protect trade secrets, know-how or other intellectual property rights we own or to determine the scope and validity of the proprietary rights of



## Edgar Filing: REPLIGEN CORP - Form 10-K

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.

## **Table of Contents**

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

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

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

We conduct some of our development activities, and conduct most of our commercialization activities, through arrangements with third parties. 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.



---

**Table of Contents**

**We have limited pharmaceutical manufacturing capabilities and are and will continue to be dependent on third party manufacturers.**

We have limited pharmaceutical manufacturing experience and no commercial or pilot scale manufacturing facilities for the production of pharmaceuticals. In order to continue to develop pharmaceutical products, apply for regulatory approvals and, ultimately, commercialize any products, we may need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties, including our collaborative partners, to produce materials required for the commercial production of certain of our products if we succeed in obtaining the necessary regulatory approvals. We believe that there is no proprietary aspect to the manufacture of our product candidates. However, there are only a limited number of manufacturers that operate under the FDA's regulations for good manufacturing practices and are capable of and/or are approved to manufacture our product candidates. Timing for the initiation of new manufacturers is uncertain, and, if we are unable to arrange for third party manufacturing of our product candidates on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them, if they are approved.

The manufacture of products by us and our collaborative partners and suppliers is subject to regulation by the FDA and comparable agencies in foreign countries. Delay in complying or failure to comply with such manufacturing requirements could materially adversely affect the marketing of our products.

**If approved, we may not be able to manufacture an adequate supply of SecreFlo for successful commercialization.**

We have limited pharmaceutical manufacturing experience and no commercial or pilot scale manufacturing facilities for the production of pharmaceuticals. We will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities for SecreFlo, if approved. There are a limited number of manufacturers that operate under the FDA's regulations for good manufacturing practices and are capable of and/or are approved to manufacture our product candidates, including SecreFlo and there is no guarantee that we will be able to contract with a supplier who will be qualified to manufacture the product to our specifications or such manufacturers will have the manufacturing capacity to meeting anticipated demand for SecreFlo. We cannot assure you that we will be able to contract with any future manufacturer on acceptable terms or that any such supplier will not require capital investment from us in order for them to meet our requirements.

Additionally, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's current good manufacturing practices. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product.

**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, regulatory, clinical and marketing personnel. Potential employees with an expertise in the field of molecular biology, biochemistry, regulatory affairs and/or clinical development of new drug and biopharmaceutical manufacturing are not generally available in the market and are difficult to attract and retain. We also face significant competition for such personnel from other companies, research and academic institutions, government and other organizations who have superior funding and resources to be able to attract such personnel. The loss of key personnel or our inability to hire and retain personnel who have technical, scientific or regulatory compliance backgrounds could materially adversely affect our product development efforts and our business.

---

**Table of Contents**

**The market may not be receptive to our diagnostic, therapeutic or bioprocessing products upon their introduction.**

The commercial success of our diagnostic and therapeutic products will depend upon their acceptance by the medical community and third party payors as being clinically useful, cost effective and safe. The commercial success of certain bioprocessing products, including some products acquired in the Novozymes Acquisition and our OPUS products, will depend upon acceptance by the life science and biopharmaceutical industries. All of the products that we are developing are based upon new technologies or therapeutic approaches. As a result, it is hard to predict market acceptance of our products or changes in third party payor reimbursement practices in the U.S. and abroad.

Other factors that we believe will materially affect market acceptance of our products include:

*Diagnostics and therapeutic products:*

the timing of receipt of marketing approvals and the countries in which such approvals are obtained;

the safety, efficacy and ease of administration of our products;

the success of physician education programs;

the availability of government and third party payor reimbursement of our products;

additional data requests from third party payors to support cost effectiveness before reimbursement of our products;

competition from products which may offer better safety, efficacy or lower cost;

*Bioprocessing products:*

the integration of certain bioprocessing products acquired from Novozymes into the Company's bioprocessing product line; and

the timing of introductions of products that compete with our chromatography products including our OPUS pre-packed columns.

**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 pharmaceutical 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 opportunity. In addition, the pendency or approval of such proposals could result in a decrease in the price of

Edgar Filing: REPLIGEN CORP - Form 10-K

Repligen's common stock or limit our ability to raise capital or to enter into collaborations or license rights to our products.

---

**Table of Contents**

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

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

**We have incurred substantial losses, we may continue to incur operating losses and we will not be successful until we reverse this trend.**

Although the Company had significant net income in fiscal years 2009 and 2008 as a result of the ImClone and Bristol settlements, we have historically incurred operating losses since our founding in 1981. We incurred losses in the nine-month fiscal year ended December 31, 2011 and the fiscal years ended March 31, 2011 and 2010, and we may incur operating losses in the future.

While we generate revenue from bioprocessing product sales and began receiving royalty payments in fiscal year 2009 from Bristol for the net sales of their Orenicia<sup>®</sup> product in the United States, this revenue may not be sufficient to cover the costs of our clinical trials, drug development programs or the expansion of our bioprocessing business. We plan to continue to invest in key research and development activities and the expansion of our bioprocessing business. As a result, we will need to generate significant revenues in order to achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business.

**We may need to obtain additional capital resources for our drug development programs, or we may be unable to develop or discover new drugs.**

We may need additional long-term financing to develop our drug development programs through the clinical trial process as required by the FDA and to develop our commercial products business. We also may need additional long-term financing to support future operations and capital expenditures, including capital for additional personnel and facilities. If we spend more money than currently expected for our drug development programs and our commercial products business, we may need to raise additional capital by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. We may be unable to raise any additional amounts on reasonable terms or when they are needed due to the volatile nature of the biotechnology marketplace. If we are unable to raise this additional capital, we may have to delay or postpone critical clinical studies or abandon other development programs.

**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

---

## **Table of Contents**

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 development stage biotechnology companies, 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 biotechnology and pharmaceutical companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

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

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

### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

### **Item 2. PROPERTIES**

We currently lease and occupy approximately 25,000 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. On July 5, 2011, we entered into an agreement with the landlord to expand the leased premises to approximately 56,000 square feet and to extend the term by eleven years, which, depending on the commencement date of our occupancy of the expanded premises, should expire on or about 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 expires on May 31, 2012. Following the completion of the Novozymes Acquisition, we now 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 nine-month fiscal year ended December 31, 2011, we incurred total rental costs for all facilities of approximately \$528,000.

### **Item 3. LEGAL PROCEEDINGS**

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

### **Item 4. MINE SAFETY DISCLOSURES**

Not applicable.





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

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

|                | <b>Nine Months Ended December 31, 2011</b> |            |
|----------------|--|------------|
|                | <b>High</b>                                | <b>Low</b> |
| First Quarter  | \$ 4.12                                    | \$ 3.39    |
| Second Quarter | \$ 3.75                                    | \$ 3.20    |
| Third Quarter  | \$ 3.51                                    | \$ 3.11    |
|                | <b>Year Ended March 31, 2011</b>           |            |
|                | <b>High</b>                                | <b>Low</b> |
| First Quarter  | \$ 3.92                                    | \$ 3.13    |
| Second Quarter | \$ 3.56                                    | \$ 3.15    |
| Third Quarter  | \$ 4.75                                    | \$ 3.29    |
| Fourth Quarter | \$ 5.34                                    | \$ 3.36    |

**Stockholders and Dividends**

As of March 6, 2012, there were approximately 628 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 and our proprietary drug development programs. 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.

**Table of Contents**

**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. For the nine-month fiscal year ended December 31, 2011, the Company repurchased 100,000 shares of common stock, for an aggregate purchase price of \$330,867, leaving 657,173 shares remaining under this authorization. We did not repurchase any shares of common stock during the quarter ended December 31, 2011. We did not repurchase any shares of common stock during the fiscal years ended March 31, 2011 and 2010.

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

**Table of Contents****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 Transition Report and our Annual Reports on Form 10-K for the fiscal years ended March 31, 2011, 2010 and 2009.

|   | Nine Months Ended December 31,          |                 | Years ended March 31, |                   |                 |                  |
|---|---|-----------------|-----------------------|-------------------|-----------------|------------------|
|   | 2011                                    | 2010            | 2011                  | 2010              | 2009            | 2008             |
|   | (In thousands except per share amounts) |                 |                       |                   |                 |                  |
| <b>Revenue:</b>                             |   |                 |                       |                   |                 |                  |
| Product revenue                             | \$ 13,215                               | \$ 11,811       | \$ 14,961             | \$ 10,305         | \$ 14,529       | \$ 18,587        |
| Royalty and other revenue                   | 10,235                                  | 9,574           | 12,330                | 10,666            | 14,833          | 709              |
| <b>Total revenue</b>                        | <b>23,450</b>                           | <b>21,385</b>   | <b>27,291</b>         | <b>20,971</b>     | <b>29,362</b>   | <b>19,296</b>    |
| <b>Operating expenses:</b>                  |   |                 |                       |                   |                 |                  |
| Cost of product revenue                     | 5,157                                   | 4,187           | 5,580                 | 4,159             | 5,686           | 6,160            |
| Cost of royalty and other revenue           | 1,315                                   | 1,161           | 1,537                 | 1,347             | 1,091           |                  |
| Research and development                    | 9,462                                   | 8,745           | 12,529                | 14,160            | 12,772          | 7,241            |
| Selling, general and administrative         | 9,050                                   | 5,580           | 8,019                 | 7,072             | 5,933           | 10,173           |
| Gain on bargain purchase                    | (427)                                   |                 |                       |                   |                 |                  |
| Net gain from litigation settlement         |   |                 |                       |                   |                 | (40,170)         |
| <b>Total operating expenses (income)</b>    | <b>24,557</b>                           | <b>19,673</b>   | <b>27,665</b>         | <b>26,738</b>     | <b>25,482</b>   | <b>(16,596)</b>  |
| <b>(Loss) income from operations</b>        | <b>(1,107)</b>                          | <b>1,712</b>    | <b>(374)</b>          | <b>(5,767)</b>    | <b>3,880</b>    | <b>35,892</b>    |
| Investment income                           | 161                                     | 287             | 357                   | 870               | 1,896           | 2,051            |
| Interest expense                            | (28)                                    | (12)            | (26)                  | (2)               | (3)             | (9)              |
| Other expense                               | (623)                                   |                 |                       |                   |                 |                  |
| <b>Income (loss) before taxes</b>           | <b>(1,597)</b>                          | <b>1,987</b>    | <b>(43)</b>           | <b>(4,899)</b>    | <b>5,773</b>    | <b>37,934</b>    |
| Income tax (benefit) provision              | 16                                      |                 |                       | (835)             | 27              | 827              |
| <b>Net income (loss)</b>                    | <b>\$ (1,613)</b>                       | <b>\$ 1,987</b> | <b>\$ (43)</b>        | <b>\$ (4,064)</b> | <b>\$ 5,746</b> | <b>\$ 37,107</b> |
| <b>Earnings (loss) per share:</b>           |   |                 |                       |                   |                 |                  |
| Basic                                       | \$ (0.05)                               | \$ 0.06         | \$ (0.00)             | \$ (0.13)         | \$ 0.19         | \$ 1.20          |
| Diluted                                     | \$ (0.05)                               | \$ 0.06         | \$ (0.00)             | \$ (0.13)         | \$ 0.18         | \$ 1.18          |
| <b>Weighted average shares outstanding:</b> |   |                 |                       |                   |                 |                  |
| Basic                                       | 30,774                                  | 30,778          | 30,782                | 30,752            | 30,958          | 30,834           |
| Diluted                                     | 30,774                                  | 30,949          | 30,782                | 30,752            | 31,290          | 31,321           |
| <b>Balance Sheet Data:</b>                  |   |                 |                       |                   |                 |                  |
| Cash and marketable securities (1)          | \$ 36,025                               | \$ 60,285       | \$ 61,503             | \$ 59,146         | \$ 63,961       | \$ 60,589        |
| Working capital                             | 39,431                                  | 55,563          | 51,221                | 55,024            | 50,235          | 49,831           |
| Total assets                                | 76,057                                  | 73,099          | 72,294                | 71,420            | 73,755          | 68,840           |
| Long-term obligations                       | 2,606                                   | 617             | 584                   | 642               | 82              | 143              |

## Edgar Filing: REPLIGEN CORP - Form 10-K

|                      |           |           |           |           |           |           |
|----------------------|-----------|-----------|-----------|-----------|-----------|-----------|
| Accumulated deficit  | (119,307) | (115,934) | (117,965) | (117,921) | (113,857) | (120,577) |
| Stockholders' equity | (65,987)  | 68,882    | 67,087    | 66,120    | 69,123    | 64,107    |

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

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

This Transition 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 Transition Report on Form 10-K do not constitute guarantees of future performance. Investors are cautioned that statements in this Transition 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, 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 Transition 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 Transition Report on Form 10-K, except as required by law.

**Overview**

We are a world-leading supplier of critical biologic products used to manufacture biologic drugs. In December 2011, we acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB thereby diversifying and expanding our bioprocessing product offering and customer base, as well as doubling our manufacturing capacity. We also apply our expertise in biologic product development to SecreFlo, for which our first new drug application (NDA) has been submitted and accepted for priority review by the U.S. Food and Drug Administration (FDA) and for which we have submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA). SecreFlo is a synthetic version of the human hormone secretin being developed by the Company as a novel imaging agent for use in combination with magnetic resonance imaging (MRI) to improve the detection of pancreatic duct abnormalities in patients with pancreatitis. We have begun expending substantial resources on pre-commercialization activities for SecreFlo. If our NDA is approved, we expect these expenditures to increase materially as we seek to commence commercial sales of SecreFlo. We also have two early stage central nervous system (CNS) rare disease programs that are advancing through Phase 1 clinical trials in Friedreich's ataxia and spinal muscular atrophy. In addition, we have out-licensed certain intellectual property from which we receive royalties from Bristol-Myers Squibb Company (Bristol) on their net sales in the U.S. of their product Orencia®. Total revenue in the nine-month fiscal year ended December 31, 2011 increased as compared to the nine months ended December 31, 2010 and is primarily due to an increase in bioprocessing product sales orders from our single largest customer as well as increased royalty revenue from Bristol as their product Orencia® continues to penetrate the market.

On December 20, 2011, pursuant to the terms of the Asset Transfer Agreement, dated as of October 27, 2011 (the Asset Transfer Agreement), by and among the Company, Repligen Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of the Company (Repligen Sweden), Novozymes Biopharma DK A/S, a company organized under the laws of Denmark (Novozymes Denmark), and Novozymes Biopharma Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of Novozymes Denmark (Novozymes Sweden) and, together with Novozymes Denmark, Novozymes), we completed the acquisition of Novozymes' business headquartered at Novozymes Sweden's facility in Lund, Sweden and all related operations, including the manufacture and supply of Protein A affinity ligands and cell culture ingredients for use in industrial cell culture, stem and therapeutic cell culture and biopharmaceutical manufacturing (the Novozymes Biopharma Business). Pursuant to the Asset Transfer Agreement, Repligen Sweden (a) purchased all of the assets related to the Novozymes Biopharma Business and assumed certain specified liabilities related to the Novozymes Biopharma Business from Novozymes Sweden

**Table of Contents**

and (b) purchased contract rights and licenses used in the Novozymes Biopharma Business and other specified assets from Novozymes Denmark (collectively, the Transferred Business and the acquisition of the Transferred Business, the Novozymes Acquisition). The Novozymes Biopharma Business now operates as Repligen Sweden. We paid a purchase price of 17.0 million Euros (~\$22.1 million) plus an additional net working capital adjustment of 3.65 million Euros (~\$4.8 million) for a total upfront cash payment of 20.65 million Euros (~\$26.9 million) to Novozymes for the Transferred Business upon the consummation of the Novozymes Acquisition. In addition, Novozymes has the right to contingent payments of up to 4.0 million Euros (~\$5.2 million) consisting of: (i) an earn-out of 1.0 million Euros (~\$1.3 million) if the Transferred Business achieves sales of a minimum quantity of a Novozymes product between January 1, 2012 and December 31, 2012; (ii) two milestone payments of 1.0 million Euros (~\$1.3 million) each if sales of certain Novozymes products achieve agreed levels for the combined calendar years 2012 and 2013 and for calendar year 2014, respectively; and (iii) technology transfer payments totaling 1.0 million Euros (~\$1.3 million) following the successful transfer of certain Novozymes manufacturing technology. The Novozymes Acquisition has led to substantial increases in both the size and revenue of the combined company as well as operational costs associated with the combined business.

**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**

We generate product revenues 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 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.

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<sup>®</sup>, which is used in the treatment of rheumatoid arthritis. Pursuant to the settlement with Bristol, we recognized royalty revenue of \$8,769,000 for the nine-month fiscal year ended December 31, 2011 and \$10,251,000 and \$8,980,000 for the fiscal years ended March 31, 2011 and 2010, respectively. 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<sup>®</sup> by Bristol through December 31, 2013.

**Table of Contents**

Additionally, during the year ended March 31, 2010, we earned and recognized approximately \$1,009,000 in royalty revenue from ChiRhoClin, Inc. ( ChiRhoClin ) for their sales of secretin. Revenue earned from ChiRhoClin royalties was recorded in the periods when it was earned based on royalty reports sent by ChiRhoClin to us. As of December 31, 2009, ChiRhoClin had fulfilled its royalty obligations to us for its sales of secretin. We do not expect to recognize any further royalty revenue from ChiRhoClin.

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 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. In the fiscal year ended March 31, 2010, we recognized approximately \$677,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the Friedreich s Ataxia Research Alliance and the National Ataxia Foundation.

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

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

We do not currently have any revenue arrangements with multiple deliverables that would be accounted for pursuant to Accounting Standards Board Update ( ASU ) No. 2009-13, *Multiple Deliverable Revenue Arrangements*, ( ASU No. 2009-13 ) or arrangements pursuant to which we expect to receive significant milestone payments that would be accounted for under ASU No. 2010-17, *Revenue Recognition - Milestone Method*.

**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.



---

## **Table of Contents**

### **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.

The allocation of consideration transferred for the acquisition of the Novozymes Biopharma Business is preliminary as a result of a preliminary valuation report that includes a preliminary fair value assigned to fixed assets. We intend to finalize the valuation report and the fair value of fixed assets in the near term. As a result, the fair values assigned to intangible assets and fixed assets, and the resulting gain on bargain purchase could change in future reporting periods.

### **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 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 nine-month fiscal year ended December 31, 2011, the impairment test date was December 31, 2011.

---

## **Table of Contents**

### **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.

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

**Table of Contents**

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 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 years ended March 31, 2011 and 2010, we recorded stock-based compensation expense of approximately \$1,003,000 and \$1,007,000, respectively, for stock options granted under the 2001 Plan.

As of December 31, 2011, there was \$1,764,675 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 2.86 years. We expect 939,769 unvested options to vest over the next five years.

**RESULTS OF OPERATIONS**

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

**Revenues**

Total revenues for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 as well as the fiscal years ended March 31, 2011 and 2010 were comprised of the following:

|                               | Nine months ended December 31,     |                     |            | Year ended March 31, |                  |            |
|-------------------------------|------------------------------------|---------------------|------------|----------------------|------------------|------------|
|                               | 2011                               | 2010<br>(unaudited) | % Change   | 2011                 | 2010             | % Change   |
|                               | (in thousands, except percentages) |                     |            |                      |                  |            |
| Bioprocessing product revenue | \$ 13,215                          | \$ 11,811           | 12%        | \$ 14,961            | \$ 10,305        | 45%        |
| Royalty and other revenue     | 10,235                             | 9,574               | 7%         | 12,330               | 10,666           | 16%        |
| <b>Total revenue</b>          | <b>\$ 23,450</b>                   | <b>\$ 21,385</b>    | <b>10%</b> | <b>\$ 27,291</b>     | <b>\$ 20,971</b> | <b>30%</b> |

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 the nine-month fiscal year ended December 31, 2011, bioprocessing product sales increased by \$1,404,000 or 12% as compared to the nine months ended December 31, 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 the nine-month fiscal year ended December 31, 2011 as compared to the nine months ended December 31, 2010. 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.

During the fiscal year ended March 31, 2011, bioprocessing product sales increased by \$4,656,000 or 45% as compared to the fiscal year ended March 31, 2010. Volume increased 49% due to increased demand from

**Table of Contents**

certain key customers and other business events, and was offset by a 4% decrease in sales revenue due to changes in the mix of products sold in the fiscal year ended March 31, 2011 as compared to the fiscal year ended March 31, 2010.

Following the completion of the Novozymes Acquisition, we anticipate that bioprocessing product sales will more than double in the year ending December 31, 2012. Our bioprocessing product sales may be subject to quarterly fluctuations due to the timing of large-scale production orders.

Pursuant to the settlement with Bristol, we recognized royalty revenue of \$8,769,000 for the nine-month fiscal year ended December 31, 2011 as well as \$10,251,000 and \$8,980,000 for the fiscal years ended March 31, 2011 and 2010, respectively. For the year ending December 31, 2012, we expect royalty revenues to increase moderately over the prior year as Bristol's Orencea continues to penetrate the market. The royalty arrangement with Bristol expires on December 31, 2013.

Additionally, during the fiscal year ended March 31, 2010, we earned and recognized approximately \$1,009,000 in royalty revenue from ChiRhoClin for their sales of secretin. As of December 31, 2009, ChiRhoClin fulfilled its royalty obligations to us for its sales of our secretin. We do not expect to recognize any further royalty revenue from ChiRhoClin.

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, GoFar, and the Friedrich'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 Friedrich'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 Friedrich'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. In the fiscal year ended March 31, 2010, we recognized approximately \$677,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the Friedrich's Ataxia Research Alliance and the National Ataxia Foundation.

We expect research and license revenues to remain relatively consistent in the year ending December 31, 2012 as the Muscular Dystrophy Association grant related effort continues.

**Costs and operating expenses**

Total costs and operating expenses for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 as well as the fiscal years ended March 31, 2011 and 2010 were comprised of the following:

|                                     | Nine months ended December 31,     |                     |          | Year ended March 31, |           |          |
|-------------------------------------|------------------------------------|---------------------|----------|----------------------|-----------|----------|
|                                     | 2011                               | 2010<br>(unaudited) | % Change | 2011                 | 2010      | % Change |
|                                     | (in thousands, except percentages) |                     |          |                      |           |          |
| Cost of product revenue             | \$ 5,157                           | \$ 4,187            | 23%      | \$ 5,580             | \$ 4,159  | 34%      |
| Cost of royalty and other revenue   | 1,315                              | 1,161               | 13%      | 1,537                | 1,347     | 14%      |
| Research and development            | 9,462                              | 8,744               | 8%       | 12,529               | 14,160    | (12%)    |
| Selling, general and administrative | 9,050                              | 5,580               | 62%      | 8,019                | 7,072     | 13%      |
| Gain on bargain purchase            | (427)                              |                     |          |                      |           |          |
| Total costs and operating expenses  | \$ 24,557                          | \$ 19,672           | 25%      | \$ 27,665            | \$ 26,738 | 3%       |

---

**Table of Contents**

For the nine-month fiscal year ended December 31, 2011, cost of product revenue increased \$970,000 or 23% as compared to the nine months ended December 31, 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.

The increase in cost of product revenue of \$1,421,000 or 34% in the fiscal year ended March 31, 2011 as compared to the fiscal year ended March 31, 2010 is primarily due to a 45% increase in bioprocessing product sales and a change in product mix and is partially offset by favorable manufacturing variances.

As noted above, we anticipate revenues to more than double due to the Novozymes Acquisition. As these products are manufactured in a cGMP facility in Sweden, we anticipate gross margins may be lower in the year ending December 31, 2012.

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 nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, cost of royalty revenue was \$1,315,000 and \$1,161,000, respectively. For the fiscal years ended March 31, 2011 and 2010, cost of royalty revenue was \$1,537,000 and \$1,347,000, respectively. These increases are directly related to the increases in Bristol royalty revenues noted above.

Research and development costs primarily include costs of internal personnel, external pharmacology and toxicology research, clinical trials and the costs associated with the manufacturing and testing of clinical materials. Our NDA for SecreFlo for pancreatic imaging is currently under review by the FDA and our MAA is under review by the EMA. We anticipate spending approximately \$3.0 to \$4.0 million in research and development related to this program in the year ending December 31, 2012. In addition, we are preparing to initiate a Phase 1 clinical study of RG2833 in patients with Friedreich's ataxia, and we have initiated a Phase 1 clinical study for RG3039 for spinal muscular atrophy in healthy volunteers. 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 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 expenses tend to increase in later stages of development. Arrangements with commercial vendors and academic researchers accounted for 47% and 51% of our research and development expenses for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively. For the fiscal years ended March 31, 2011 and 2010, arrangements with commercial vendors and academic researchers accounted for 47% and 51%, 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 the nine-month fiscal year ended December 31, 2011, research and development expenses increased by \$718,000 or 8% as compared to the nine months ended December 31, 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

**Table of Contents**

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.

During the fiscal year ended March 31, 2011, research and development expenses decreased by \$1,631,000 or 12% as compared to the fiscal year ended March 31, 2010. This decrease is comprised primarily of (1) \$1,183,000 related to our secretin program for MRI imaging of the pancreas as the re-analysis of the images obtained from our Phase 3 clinical trial was completed in the fiscal year ended March 31, 2011 and the clinical trial was ongoing in the fiscal year ended March 31, 2010, (2) \$629,000 related to our uridine program to treat bipolar depression as we completed our Phase 2b trial in March 2011 and (3) \$449,000 related to our Friedreich's ataxia program. These decreases were partially offset by a \$548,000 increase related to our RG3039 program for the treatment of patients with spinal muscular atrophy.

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. We expect our research and development expenses in the year ending December 31, 2012 to increase primarily due to the Novozymes Acquisition, drug manufacturing, regulatory and filing fees associated with the regulatory approval of SecreFlo for MRI imaging of the pancreas and continued development and expansion of our OPUS product line. Also in the year ending December 31, 2012, we plan to continue our Phase 1 studies for RG2833 for Friedreich's ataxia and RG3039 for spinal muscular atrophy.

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 the nine-month fiscal year ended December 31, 2011, SG&A costs increased by \$3,470,000 or 62% as compared to the nine months ended December 31, 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 prepare 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 line.

In the fiscal year ended March 31, 2011, SG&A costs increased by \$947,000 or 13% as compared to the fiscal year ended March 31, 2010. This increase is primarily due to increased personnel expenses of approximately \$500,000 due to headcount increases in marketing and business development including salaries, stock-based compensation and recruiting costs, increased investor relations expenses of \$150,000, increased patent prosecution costs of \$150,000, and increased amortization expense of \$150,000 related to the acquisition of the assets of BioFlash Partners, LLC ( BioFlash ).

We expect SG&A expenses to increase in the year ending December 31, 2012 primarily due to the Novozymes Acquisition, commercialization efforts as we prepare to launch SecreFlo for MRI imaging of the pancreas, pending FDA approval, and slightly higher headcount and related personnel expenses.

For the nine-month fiscal year ended December 31, 2011, we recorded a \$427,000 gain on bargain purchase related to the Novozymes Acquisition on December 20, 2011.

**Table of Contents****Investment income**

Investment income includes income earned on invested cash balances. Investment income for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 was \$161,000 and \$287,000, respectively. Investment income for the fiscal years ended March 31, 2011 and 2010 was \$357,000 and \$870,000, respectively. The decrease of \$126,000 or 44% for the nine month fiscal year ended December 31, 2011 compared to the nine months ended December 31, 2010 as well as the decrease of \$513,000 or 59% in the fiscal year ended March 31, 2011 compared to the fiscal year ended March 31, 2010 are primarily attributable to lower interest rates. We expect interest income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

**Provision for (benefit from) income taxes**

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.

In the fiscal year ended March 31, 2010, we recorded a tax benefit of approximately \$835,000 primarily due to the Worker, Homeownership, and Business Assistance Act of 2009 (the Act) that was enacted in November 2009. Among other things, the Act suspended the limitation on the use of net operating losses to offset alternative minimum tax liabilities, which enabled us to recover \$835,000 of alternative minimum taxes paid in prior years. As a result, the Company had an effective tax rate of negative 17.0%.

**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 litigation settlements. Our revenue for the foreseeable future will be limited to our bioprocessing product revenue, royalties from Bristol's sales of Orencea 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, 2011, following the completion of the Novozymes Acquisition, we had cash and marketable securities of \$36,025,000 compared to \$61,503,000 at March 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, 2011 or March 31, 2011.

**Cash flows**

| (In thousands)                    | Nine months ended December 31, |          |                       | Year ended March 31, |            |                       |
|-----------------------------------|--------------------------------|----------|-----------------------|----------------------|------------|-----------------------|
|                                   | 2011                           | 2010     | Increase / (Decrease) | 2011                 | 2010       | Increase / (Decrease) |
| <b>Cash provided by (used in)</b> |                                |          |                       |                      |            |                       |
| Operating activities              | \$ 2,311                       | \$ 1,788 | \$ 523                | \$ 3,232             | \$ (2,448) | \$ 5,680              |
| Investing activities              | (5,011)                        | (4,488)  | (523)                 | (1,504)              | 9,921      | (11,425)              |
| Financing activities              | (331)                          | (31)     | (300)                 | (50)                 | 12         | (62)                  |
| <b>Operating activities</b>       |                                |          |                       |                      |            |                       |

For the nine-month fiscal year ended December 31, 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 the nine months ended December 31, 2010, our operating activities provided cash of \$1,788,000 reflecting net income of

**Table of Contents**

\$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.

For the fiscal year ended March 31, 2011, our operating activities provided cash of \$3,232,000 reflecting a net loss of \$43,000, which includes non-cash charges totaling \$2,683,000 including depreciation, amortization, and stock-based compensation charges. The remaining cash flow provided in operations resulted from favorable changes in various working capital accounts. For the fiscal year ended March 31, 2010, our operating activities consumed \$2,448,000 of cash, which reflects a net loss of \$4,064,000 and non-cash charges totaling \$2,386,000, 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 the nine-month fiscal year ended December 31, 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 debt securities of \$22,449,000. During the nine months ended December 31, 2010, our investing activities consumed \$4,488,000 of cash, which is primarily due to \$3,870,000 of net purchases of marketable debt securities, \$318,000 of capital expenditures and a \$300,000 milestone payment related to our acquisition of the assets of BioFlash.

In the fiscal year ended March 31, 2011, our investing activities consumed \$1,504,000 of cash, which is primarily due to net purchases of marketable debt securities of \$679,000, a \$300,000 milestone payment related to our acquisition of the assets of BioFlash and \$525,000 for capital expenditures. For the fiscal year ended March 31, 2010, our investing activities generated \$9,921,000 of cash, which was primarily due to net maturities of marketable debt securities of \$12,299,000 partially offset by \$1,780,000 of cash used to acquire the assets of BioFlash and \$597,000 for capital expenditures.

**Financing activities**

During the nine-month fiscal year ended December 31, 2011, the repurchase of common stock consumed \$331,000. Exercises of stock options provided cash receipts of \$25,000 in the nine months ended December 31, 2010 as well as \$7,000 and \$54,000 in the fiscal years ended March 31, 2011 and 2010, respectively.

**Off-balance sheet arrangements**

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

**Contractual obligations**

As of December 31, 2011, we had the following fixed obligations and commitments:

| (In thousands)               | Total     | Payments Due By Period |           |           |                   |
|------------------------------|-----------|------------------------|-----------|-----------|-------------------|
|                              |           | Less than 1 Year       | 1 3 Years | 3 5 Years | More than 5 Years |
| Operating lease obligations  | \$ 19,968 | \$ 2,123               | \$ 4,589  | \$ 4,578  | \$ 8,678          |
| Purchase obligations (1)     | 2,326     | 2,326                  |           |           |                   |
| Contingent consideration (2) | 740       | 35                     | 135       | 240       | 330               |
| Total                        | \$ 23,034 | \$ 4,484               | \$ 4,724  | \$ 4,818  | \$ 9,008          |

(1) Represents purchase orders for the procurement of raw material for manufacturing as well as clinical materials to support our upcoming trials.

(2)



## Edgar Filing: REPLIGEN CORP - Form 10-K

These minimum contingent consideration amounts relating to acquisitions are recorded in accrued expenses and long term liabilities on our consolidated balance sheets.

## **Table of Contents**

### **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;

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

the success of our clinical studies;

our ability to establish one or more partnerships for commercialization of SecreFlo outside the U.S.;

our ability to acquire additional 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.

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 to incur increased expenses in the year ending December 31, 2012. This is primarily due to the Novozymes Acquisition, commercialization efforts as we prepare to launch SecreFlo for MRI imaging of the pancreas, pending regulatory approval, the development and expansion of our OPUS product line, and our ongoing development of RG2833 for Friedreich's ataxia and RG3039 for spinal muscular atrophy. Our future capital requirements include, but are not limited to, continued investment in our research and development programs, the acquisition of additional products and technologies to complement our manufacturing capabilities, capital expenditures primarily associated with purchases of equipment 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. We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. 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**

## Edgar Filing: REPLIGEN CORP - Form 10-K

At December 31, 2011, we had net operating loss carryforwards of approximately \$58,243,000 and business tax credits carryforwards of approximately \$2,196,000 available to reduce future federal income taxes, if any. Additionally, at December 31, 2011, we had net operating loss carryforwards of approximately \$4,816,000 and business tax credits carryforwards of approximately \$2,986,000 available to reduce future state 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.

## **Table of Contents**

In the fiscal year ended March 31, 2010, we recorded a tax benefit of approximately \$835,000 primarily due to the Worker, Homeownership, and Business Assistance Act of 2009 (the Act) that was enacted in November 2009. Among other things, the Act suspended the limitation on the use of net operating losses to offset alternative minimum tax liabilities and enabled us to receive a refund of \$835,000 for alternative minimum taxes paid in prior years.

### **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.

### **Recent accounting pronouncements**

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2011-04, *Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). The amendments in this update will ensure that fair value has the same meaning in U.S. GAAP and in International Financial Reporting Standards and that their respective fair value measurement and disclosure requirements are the same. This update is effective prospectively for interim and annual periods beginning after December 15, 2011. Early adoption by public entities is not permitted, and the Company is therefore required to adopt this ASU on January 1, 2012. The Company has not completed its review of ASU 2011-04, but it does not expect the adoption to have a material impact on the Company's results of operations, financial position or cash flows.

In June 2011, the Financial Accounting Standards Board issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05), which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for us in the first quarter of fiscal year 2012 and will be applied retrospectively. The adoption of this standard will impact our financial statement presentation, but will not have a material impact on our financial position or results of operations.

---

**Table of Contents**

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**Interest rate risk**

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

We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines. A hypothetical 100 basis point decrease in interest rates would result in an approximate \$227,000 decrease in the fair value of our investments as of December 31, 2011. 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 AB, began on December 20, 2011 and 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 AB 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.

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

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

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

## Edgar Filing: REPLIGEN CORP - Form 10-K

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

**Table of Contents**

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, 2011. 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).

Management has excluded from our assessment of and conclusion on the effectiveness of internal controls the internal controls of Repligen Sweden AB, which was established in December 2011 to acquire the Novozymes Biopharma Business and is included in the consolidated financial statements of Repligen Corporation as of and for the nine-month fiscal year ended December 31, 2011 constituting \$31.8 million and \$0.3 million of total and net assets, respectively, as of December 31, 2011, and \$0.0 million and \$0.3 million of revenues and net income, respectively, for the nine-month fiscal year then ended.

Subject to the foregoing, based on this assessment, our management concluded that, as of December 31, 2011, 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 Transition Report on Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2011.

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.

/s/ REPLIGEN CORPORATION

March 15, 2012

---

**Table of Contents**

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

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Repligen Corporation:

We have audited Repligen Corporation's (the "Company") internal control over financial reporting as of December 31, 2011, 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 Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

As indicated in the accompanying Report of Management on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Repligen Sweden AB, which is included in the December 31, 2011 consolidated financial statements of Repligen Corporation and constituted \$31.8 million and \$0.3 million of total and net assets, respectively, as of December 31, 2011 and \$0.0 million and \$0.3 million of revenues and net income, respectively, for the nine-months then ended. Our audit of internal control over financial reporting of Repligen Corporation also did not include an evaluation of the internal control over financial reporting of Repligen Sweden AB.

In our opinion, Repligen Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, 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, 2011 and March 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the nine months ended December 31, 2011 and the fiscal years ended March 31, 2011 and 2010 of Repligen Corporation and our report dated March 15, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 15, 2012





**Table of Contents**

*(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, 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

**Table of Contents**

**PART III**

Pursuant to General Instructions G to Form 10-K, the information required for Part III, Items 10, 11, 12, 13 and 14, is incorporated herein by reference from the Company's proxy statement for the 2012 Annual Meeting of Stockholders.

---

**Table of Contents**

**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

The following documents are filed as part of this Transition 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:

|   | <b>Page</b> |
|---|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | 53          |
| <u>Consolidated Balance Sheets as of December 31, 2011 and March 31, 2011</u>   | 54          |
| <u>Consolidated Statements of Operations for the Nine Months Ended December 31, 2011 and 2010 (unaudited) and for the Years Ended March 31, 2011 and 2010</u> | 55          |
| <u>Consolidated Statements of Stockholders' Equity for the Nine Months Ended December 31, 2011 and for the Years Ended March 31, 2011 and 2010</u>            | 56          |
| <u>Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2011 and 2010 (unaudited) and for the Years Ended March 31, 2011 and 2010</u> | 57          |
| <u>Notes to Consolidated Financial Statements</u>   | 58          |

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

None.

**Table of Contents**

(a) (3) Exhibits:

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

**EXHIBIT INDEX**

| <b>Exhibit Number</b> | <b>Document Description</b>  |
|-----------------------|--|
| 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).   |
| 3.3                   | Amendment No. 1 to the Amended and Restated Bylaws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on December 20, 2011 and incorporated herein by reference).  |
| 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).     |
| 10.3*                 | Employment Agreement, dated March 14, 1996, between Repligen Corporation and James R. Rusche (filed as Exhibit 10.4 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).       |
| 10.4*                 | Employment Agreement, dated March 14, 1996, between Repligen Corporation and Daniel P. Witt (filed as Exhibit 10.5 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).        |
| 10.5*                 | 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).  |
| 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).                                    |

**Table of Contents**

| <b>Exhibit Number</b> | <b>Document Description</b>  |
|-----------------------|--|
| 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.   |
| 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.   |
| 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.   |
| 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.   |
| 21.1+                 | Subsidiaries of the Registrant.  |

**Table of Contents**

| <b>Exhibit Number</b> | <b>Document Description</b>   |
|-----------------------|---|
| 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 <sup>^</sup>      | The following materials from Repligen Corporation on Form 10-K for the nine-month fiscal year ended December 31, 2011, 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.

<sup>^</sup> 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 Transition Report on Form 10-K distributed to stockholders. Upon the request of any stockholder entitled to vote at the 2012 annual meeting, the Registrant will furnish that person without charge a copy of any exhibits listed above. Requests should be addressed to Repligen Corporation, 41 Seyon Street, Waltham, MA 02453.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of 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, 2012

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 William J. Kelly 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.

| <b>Signature</b>   | <b>Title</b>   | <b>Date</b>    |
|--|--|----------------|
| /s/ WALTER HERLIHY<br><b>Walter C. Herlihy, Ph.D.</b>      | President, Chief Executive Officer and Director<br><br>(Principal executive officer) | March 15, 2012 |
| /s/ WILLIAM J. KELLY<br><b>William J. Kelly</b>            | Chief Financial Officer<br><br>(Principal financial and accounting officer)          | March 15, 2012 |
| /s/ KAREN DAWES<br><b>Karen Dawes</b>                      | Chairperson of the Board   | March 15, 2012 |
| /s/ GLENN L. COOPER<br><b>Glenn L. Cooper, M.D.</b>        | Director   | March 15, 2012 |
| /s/ ALFRED L. GOLDBERG<br><b>Alfred L. Goldberg, Ph.D.</b> | Director   | March 15, 2012 |
| /s/ EARL W. HENRY<br><b>Earl W. Henry, M.D.</b>            | Director   | March 15, 2012 |



Edgar Filing: REPLIGEN CORP - Form 10-K

/s/ ALEXANDER RICH

Director

March 15, 2012

**Alexander Rich, M.D.**

/s/ THOMAS F. RYAN, JR.

Director

March 15, 2012

**Thomas F. Ryan, Jr.**

**Table of Contents****EXHIBIT INDEX**

| <b>Exhibit Number</b> | <b>Document Description</b>  |
|-----------------------|--|
| 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).   |
| 3.3                   | Amendment No. 1 to the Amended and Restated Bylaws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on December 20, 2011 and incorporated herein by reference).  |
| 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).     |
| 10.3*                 | Employment Agreement, dated March 14, 1996, between Repligen Corporation and James R. Rusche (filed as Exhibit 10.4 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).       |
| 10.4*                 | Employment Agreement, dated March 14, 1996, between Repligen Corporation and Daniel P. Witt (filed as Exhibit 10.5 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).        |
| 10.5*                 | 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).  |
| 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).   |

**Table of Contents**

| <b>Exhibit Number</b> | <b>Document Description</b>  |
|-----------------------|--|
| 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.   |
| 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.   |
| 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.   |
| 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.   |
| 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.  |

**Table of Contents**

| <b>Exhibit Number</b> | <b>Document Description</b>  |
|-----------------------|--|
| 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 nine-month fiscal year ended December 31, 2011, 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.

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

|   | <b>Page</b> |
|---|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | 53          |
| <u>Consolidated Balance Sheets as of December 31, 2011 and March 31, 2011</u>   | 54          |
| <u>Consolidated Statements of Operations for the Nine Months Ended December 31, 2011 and 2010 (unaudited) and for the Years Ended March 31, 2011 and 2010</u> | 55          |
| <u>Consolidated Statements of Stockholders' Equity for the Nine Months Ended December 31, 2011 and for the Years Ended March 31, 2011 and 2010</u>            | 56          |
| <u>Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2011 and 2010 (unaudited) and for the Years Ended March 31, 2011 and 2010</u> | 57          |
| <u>Notes to Consolidated Financial Statements</u>   | 58          |

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Repligen Corporation:

We have audited the accompanying consolidated balance sheets of Repligen Corporation as of December 31, 2011 and March 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the nine months ended December, 31, 2011 and the years ended March 31, 2011 and 2010. 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, 2011 and March 31, 2011, and the consolidated results of its operations, and its cash flows for the nine months ended December, 31, 2011 and the years ended March 31, 2011 and 2010, 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, 2011, 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, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 15, 2012

**Table of Contents**

**REPLIGEN CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**

|  | December 31, 2011    | March 31, 2011       |
|--|----------------------|----------------------|
| <b>Assets</b>  |                      |                      |
| Current assets:  |                      |                      |
| Cash and cash equivalents  | \$ 11,167,745        | \$ 14,203,544        |
| Marketable securities  | 15,421,436           | 35,421,520           |
| Accounts receivable, less reserve for doubtful accounts of \$10,000  | 2,825,414            | 1,259,607            |
| Royalties receivable   | 3,206,840            | 2,512,602            |
| Inventories, net   | 13,363,073           | 1,953,976            |
| Prepaid expenses and other current assets  | 910,298              | 492,767              |
| <b>Total current assets</b>  | <b>46,894,806</b>    | <b>55,844,016</b>    |
| Property, plant and equipment, at cost:  |                      |                      |
| Leasehold improvements   | 5,864,797            | 3,879,130            |
| Equipment  | 11,402,256           | 4,426,628            |
| Furniture and fixtures   | 1,137,802            | 644,541              |
| Construction in progress   | 209,860              |                      |
| <b>Total property, plant and equipment, at cost</b>  | <b>18,614,715</b>    | <b>8,950,299</b>     |
| Less: Accumulated depreciation   | (7,877,296)          | (6,793,984)          |
| <b>Property, plant and equipment, net</b>  | <b>10,737,419</b>    | <b>2,156,315</b>     |
| Long-term marketable securities  | 9,435,350            | 11,878,201           |
| Intangible assets, net   | 7,795,239            | 1,221,458            |
| Goodwill   | 994,000              | 994,000              |
| Restricted cash  | 200,000              | 200,000              |
| <b>Total assets</b>  | <b>\$ 76,056,814</b> | <b>\$ 72,293,990</b> |
| <b>Liabilities and stockholders' equity</b>  |                      |                      |
| Current liabilities:   |                      |                      |
| Accounts payable   | \$ 1,422,483         | \$ 930,601           |
| Accrued liabilities  | 6,041,038            | 3,692,523            |
| <b>Total current liabilities</b>   | <b>7,463,521</b>     | <b>4,623,124</b>     |
| Other long-term liabilities  | 2,469,412            | 584,162              |
| Long-term deferred tax liability   | 136,881              |                      |
| 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, 30,714,757 shares at December 31, 2011 and 30,812,257 shares at March 31, 2011 issued and outstanding | 307,148              | 308,123              |
| Additional paid-in capital   | 184,872,839          | 184,743,195          |
| Accumulated other comprehensive income   | 113,627              |                      |
| Accumulated deficit  | (119,306,614)        | (117,964,614)        |
| <b>Total stockholders' equity</b>  | <b>65,987,000</b>    | <b>67,086,704</b>    |
| <b>Total liabilities and stockholders' equity</b>  | <b>\$ 76,056,814</b> | <b>\$ 72,293,990</b> |

Edgar Filing: REPLIGEN CORP - Form 10-K

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



**Table of Contents**

**REPLIGEN CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

|   | Nine Months ended December 31, |                     | Years ended March 31, |                       |
|---|--------------------------------|---------------------|-----------------------|-----------------------|
|   | 2011                           | 2010<br>(unaudited) | 2011                  | 2010                  |
| <b>Revenue:</b>                             |                                |                     |                       |                       |
| Product revenue                             | \$ 13,215,053                  | \$ 11,810,869       | \$ 14,961,397         | \$ 10,304,727         |
| Royalty and other revenue                   | 10,235,194                     | 9,573,770           | 12,329,627            | 10,666,342            |
| <b>Total revenue</b>                        | <b>23,450,247</b>              | <b>21,384,639</b>   | <b>27,291,024</b>     | <b>20,971,069</b>     |
| <b>Operating expenses: (1)</b>              |                                |                     |                       |                       |
| Cost of product revenue                     | 5,157,135                      | 4,186,670           | 5,579,759             | 4,159,002             |
| Cost of royalty and other revenue           | 1,315,315                      | 1,160,775           | 1,537,666             | 1,347,168             |
| Research and development                    | 9,461,960                      | 8,744,548           | 12,528,819            | 14,159,721            |
| Selling, general and administrative         | 9,050,382                      | 5,580,215           | 8,018,851             | 7,071,859             |
| Gain on bargain purchase                    | (427,478)                      |                     |                       |                       |
| <b>Total operating expenses</b>             | <b>24,557,314</b>              | <b>19,672,208</b>   | <b>27,665,095</b>     | <b>26,737,750</b>     |
| (Loss) income from operations               | (1,107,067)                    | 1,712,431           | (374,071)             | (5,766,681)           |
| Investment income                           | 161,053                        | 287,430             | 356,729               | 870,043               |
| Interest expense                            | (27,773)                       | (12,683)            | (26,167)              | (1,972)               |
| Other expense                               | (623,094)                      |                     |                       |                       |
| (Loss) income before income taxes           | (1,596,881)                    | 1,987,178           | (43,509)              | (4,898,610)           |
| Income tax provision (benefit)              | 15,744                         |                     |                       | (834,766)             |
| <b>Net (loss) income</b>                    | <b>\$ (1,612,625)</b>          | <b>\$ 1,987,178</b> | <b>\$ (43,509)</b>    | <b>\$ (4,063,844)</b> |
| <b>Earnings (loss) per share:</b>           |                                |                     |                       |                       |
| Basic                                       | \$ (0.05)                      | \$ 0.06             | \$ (0.00)             | \$ (0.13)             |
| Diluted                                     | \$ (0.05)                      | \$ 0.06             | \$ (0.00)             | \$ (0.13)             |
| <b>Weighted average shares outstanding:</b> |                                |                     |                       |                       |
| Basic                                       | 30,774,467                     | 30,778,430          | 30,781,881            | 30,752,041            |
| Diluted                                     | 30,774,467                     | 30,949,264          | 30,781,881            | 30,752,041            |

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

**Table of Contents****REPLIGEN CORPORATION****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

|   | Common Stock        |            |                               | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Accumulated<br>Deficit | Stockholders<br>Equity |
|---|---------------------|------------|-------------------------------|---|------------------------|------------------------|
|   | Number of<br>Shares | Amount     | Additional<br>Paid-in Capital |   |                        |                        |
| Balance, March 31, 2009                     | 30,741,707          | \$ 307,417 | \$ 182,673,275                | \$  | \$ (113,857,261)       | \$ 69,123,431          |
| Net loss                                    |                     |            |                               |   | (4,063,844)            | (4,063,844)            |
| Share-based compensation expense            |                     |            | 1,006,798                     |   |                        | 1,006,798              |
| Exercise of stock options                   | 20,100              | 201        | 53,790                        |   |                        | 53,991                 |
| 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                |
| Comprehensive loss                          |                     |            |                               |   |                        | (1,498,998)            |
| 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          |

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

**Table of Contents****REPLIGEN CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

|  | Nine Months ended December 31, |                     | Years ended March 31, |                |
|--|--------------------------------|---------------------|-----------------------|----------------|
|  | 2011                           | 2010<br>(unaudited) | 2011                  | 2010           |
| <b>Cash flows from operating activities:</b>   |                                |                     |                       |                |
| Net income (loss):   | \$ (1,612,625)                 | \$ 1,987,178        | \$ (43,509)           | \$ (4,063,844) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: |                                |                     |                       |                |
| Depreciation and amortization  | 1,274,597                      | 1,274,247           | 1,674,528             | 1,378,999      |
| Stock-based compensation expense   | 730,136                        | 748,235             | 1,003,266             | 1,006,798      |
| Deferred tax expense   | 15,744                         |                     |                       |                |
| Gain on bargain purchase   | (427,478)                      |                     |                       |                |
| Loss on revaluation of contingent consideration  | 28,182                         |                     |                       |                |
| Loss on disposal of assets   | 2,826                          |                     | 5,597                 | 905            |
| <b>Changes in assets and liabilities:</b>  |                                |                     |                       |                |
| Accounts receivable  | 3,551,969                      | (601,141)           | (689,569)             | (29,259)       |
| Royalties receivable   | (694,238)                      | (450,600)           | (216,602)             | (259,200)      |
| Inventories  | (870,252)                      | 263,570             | 247,164               | 212,087        |
| Prepaid expenses and other current assets  | (190,007)                      | (708,311)           | 986,340               | (545,522)      |
| Accounts payable   | 247,222                        | (291,824)           | (60,404)              | (931,567)      |
| Accrued liabilities  | 243,182                        | (408,224)           | 383,237               | 782,200        |
| Long-term liabilities  | 11,487                         | (25,447)            | (58,285)              | 49             |
| Net cash provided by (used in) operating activities  | 2,310,745                      | 1,787,683           | 3,231,763             | (2,448,354)    |
| <b>Cash flows from investing activities:</b>   |                                |                     |                       |                |
| Purchases of marketable securities   | (49,465,924)                   | (58,095,140)        | (84,329,731)          | (47,038,060)   |
| Sales of marketable securities   | 26,290,378                     |                     |                       |                |
| Redemptions of marketable securities   | 45,624,819                     | 54,225,000          | 83,650,417            | 59,336,807     |
| Acquisition of assets of BioFlash Partners, LLC  |                                | (300,000)           | (300,000)             | (1,780,000)    |
| Novozymes Acquisition  | (26,884,428)                   |                     |                       |                |
| Purchases of property, plant and equipment   | (575,455)                      | (317,982)           | (524,666)             | (597,349)      |
| Net cash (used in) provided by investing activities  | (5,010,610)                    | (4,488,122)         | (1,503,980)           | 9,921,398      |
| <b>Cash flows from financing activities:</b>   |                                |                     |                       |                |
| Exercise of stock options  | 25                             | 25,758              | 6,571                 | 53,991         |
| Repurchase and retirement of treasury stock  | (330,867)                      |                     |                       |                |
| Principal payments under capital lease obligations   |                                | (56,850)            | (56,850)              | (42,405)       |
| Net cash (used in) provided by financing activities  | (330,842)                      | (31,092)            | (50,279)              | 11,586         |
| <b>Effect of exchange rate changes on cash and cash equivalents</b>                                |                                |                     |                       |                |
|  | (5,092)                        |                     |                       |                |
| Net (decrease) increase in cash and cash equivalents   | (3,035,799)                    | (2,731,531)         | 1,677,504             | 7,484,630      |
| Cash and cash equivalents, beginning of period   | 14,203,544                     | 12,526,040          | 12,526,040            | 5,041,410      |
| Cash and cash equivalents, end of period   | \$ 11,167,745                  | \$ 9,794,509        | \$ 14,203,544         | \$ 12,526,040  |

## Edgar Filing: REPLIGEN CORP - Form 10-K

### Supplemental disclosure of non-cash investing activities:

|   |              |    |    |    |
|---|--------------|----|----|----|
| Contingent consideration transferred in the Novozymes Acquisition | \$ 1,610,560 | \$ | \$ | \$ |
|---|--------------|----|----|----|

|   |    |    |    |            |
|---|----|----|----|------------|
| Contingent consideration transferred in acquisition of BioFlash Partners, LLC | \$ | \$ | \$ | \$ 560,000 |
|---|----|----|----|------------|

### Supplemental disclosure of cash flow information:

|                       |    |    |    |              |
|-----------------------|----|----|----|--------------|
| Income taxes refunded | \$ | \$ | \$ | \$ (135,157) |
|-----------------------|----|----|----|--------------|

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

---

**Table of Contents**

**REPLIGEN CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(Information as of December 31, 2010 and for the nine months then ended is unaudited)**

**1. Organization and Nature of Business**

Repligen Corporation ( Repligen or the Company ) is a world-leading supplier of critical biologic products used to manufacture biologic drugs. The Company also applies its expertise in biologic product development to SecreFlo™, for which the Company's first new drug application ( NDA ) has been submitted and accepted for priority review by the U.S. Food and Drug Administration ( FDA ) and for which we have submitted a marketing authorization application ( MAA ) to the European Medicines Agency ( EMA ). The Company also has two central nervous system ( CNS ) rare disease clinical programs underway in Friedreich's ataxia and spinal muscular atrophy. In addition, the Company has out-licensed certain biologics intellectual property from which we receive royalties from Bristol-Myers Squibb Company ( Bristol ) on their net sales in the United States of their product Orenicia®.

As previously announced, in 2011 the Company changed its fiscal year end from March 31 to December 31. This Transition Report on Form 10-K reports the Company's financial results for the nine-month period from April 1, 2011 through December 31, 2011, which is referred to as the nine-month fiscal year ended December 31, 2011 throughout this report. Following this Transition Report, the Company will report on a twelve-month fiscal year beginning on January 1 and ending on December 31 of each year.

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 collaborative arrangements, 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.

**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**

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



**Table of Contents**

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.

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 Orenzia<sup>®</sup>, which is used in the treatment of rheumatoid arthritis. Pursuant to the settlement with Bristol (see Note 9), the Company recognized royalty revenue of \$8,769,000 for the nine-month fiscal year ended December 31, 2011 as well as \$10,251,000 and \$8,980,000 for the fiscal years ended March 31, 2011 and 2010, respectively. 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.

During the year ended March 31, 2010, the Company earned and recognized approximately \$1,009,000 in royalty revenue from ChiRhoClin, Inc. (ChiRhoClin) for their sales of secretin. Revenue earned from ChiRhoClin royalties was recorded in the periods when it was earned based on royalty reports sent by ChiRhoClin to the Company. In December 2009, ChiRhoClin fulfilled its royalty obligations to the Company for its sales of secretin. The Company does not expect to recognize any further royalty revenue from ChiRhoClin.

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 Friedreich'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, 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. For the fiscal year ended March 31, 2010, the Company recognized \$677,000 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.

**Table of Contents**

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 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.

The Company does not have any revenue arrangements with multiple deliverables that would be accounted for pursuant to Accounting Standards Board Update (ASU) No. 2009-13, *Multiple Deliverable Revenue Arrangements* (ASU 2009-13), or arrangements pursuant to which the Company expects to receive significant milestone payments that would be accounted for under ASU No. 2010-17, *Revenue Recognition-Milestone Method*.

**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.

**Comprehensive Income (Loss)**

The Company's total comprehensive income (loss) consists of the following:

|                                    | <b>Nine Months ended December 31,</b> |                     | <b>Years ended March 31,</b> |                       |
|------------------------------------|---------------------------------------|---------------------|------------------------------|-----------------------|
|                                    | <b>2011</b>                           | <b>2010</b>         | <b>2011</b>                  | <b>2010</b>           |
| Net (loss) income                  | \$ (1,612,625)                        | \$ 1,987,178        | \$ (43,509)                  | \$ (4,063,844)        |
| Other comprehensive income:        |                                       |                     |                              |                       |
| Unrealized gain on investments     | 6,338                                 |                     |                              |                       |
| Foreign currency translation gain  | 107,289                               |                     |                              |                       |
| <b>Comprehensive income (loss)</b> | <b>\$ (1,498,998)</b>                 | <b>\$ 1,987,178</b> | <b>\$ (43,509)</b>           | <b>\$ (4,063,844)</b> |

**Cash, Cash Equivalents and Marketable Securities**

At 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, 2011 is approximately 10.97 months.

Prior to September 30, 2011, the marketable securities were classified as held-to-maturity investments as the Company had the positive intent and ability to hold the investments to maturity. These investments were therefore recorded on an amortized cost basis. As of September 30, 2011, the Company no longer had the intent to hold certain of the marketable securities to maturity due to its intent to liquidate certain securities in October 2011 in connection with the Asset Transfer Agreement with Novozymes Biopharma DK A/S and Novozymes Biopharma Sweden AB, as described in Note 11. The Company reassessed the classification of its marketable



**Table of Contents**

securities portfolio, accordingly, and concluded that the investment portfolio should be classified as available-for-sale. The transfer of held-to-maturity securities to available-for-sale securities was recorded at fair value, with the unrealized gain (loss) reported in other comprehensive income in accordance with Accounting Standards Codification 320-10, *Investments-Debt and Equity Securities*.

Management reviewed the Company's investments as of December 31, 2011 and concluded that there are no securities with other than temporary impairments in the investment portfolio. 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.

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           |
| <b>Marketable securities:</b>           |                      |                       |                       |                      |
| 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           |
| <b>Long-term marketable securities:</b> |                      |                       |                       |                      |
| 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            |
| <b>Total</b>                            | <b>\$ 24,850,448</b> | <b>\$ 11,032</b>      | <b>\$ (4,694)</b>     | <b>\$ 24,856,786</b> |

At December 31, 2011, the Company's investments included six debt securities in unrealized loss positions with a total unrealized loss of approximately \$5,000 and a total fair market value of approximately \$5,290,000. 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. There were no realized gains or losses on the investments for the nine-month fiscal year ended December 31, 2011 or the fiscal years ended March 31, 2011 and 2010.

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

|   |                      | March 31, 2011        |                       |                      |
|---|----------------------|-----------------------|-----------------------|----------------------|
|   | Amortized Cost       | Gross Unrealized Gain | Gross Unrealized Loss | Fair Value           |
| <b>Marketable securities:</b>           |                      |                       |                       |                      |
| U.S. Government and agency securities   | \$ 17,727,581        | \$ 9,189              | \$ (852)              | \$ 17,735,918        |
| Corporate and other debt securities     | 17,693,939           | 17,417                | (4,578)               | 17,706,778           |
|   | 35,421,520           | 26,606                | (5,430)               | 35,442,696           |
| <b>Long-term marketable securities:</b> |                      |                       |                       |                      |
| U.S. Government and agency securities   | 9,257,798            | 235                   | (15,613)              | 9,242,420            |
| Corporate and other debt securities     | 2,620,403            | 2,731                 | (1,744)               | 2,621,390            |
|   | 11,878,201           | 2,966                 | (17,357)              | 11,863,810           |
| <b>Total</b>                            | <b>\$ 47,299,721</b> | <b>\$ 29,572</b>      | <b>\$ (22,787)</b>    | <b>\$ 47,306,506</b> |



**Table of Contents**

The contractual maturities of debt securities at December 31, 2011 were as follows:

|                       | <b>Amortized<br/>Cost</b> | <b>Fair Value</b>    |
|-----------------------|---------------------------|----------------------|
| Due in 1 year or less | \$ 15,419,577             | \$ 15,421,436        |
| Due in 1 to 2 years   | 9,430,871                 | 9,435,350            |
|                       | <b>\$ 24,850,448</b>      | <b>\$ 24,856,786</b> |

**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.

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, 2011.

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 to be paid to Novozymes Biopharma DK A/S. The

**Table of Contents**

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. The following table provides a roll forward of the fair value of the contingent consideration:

|                                     |                     |
|-------------------------------------|---------------------|
| Balance at March 31, 2011           | \$ 558,484          |
| Additions                           | 1,610,560           |
| Payments                            |                     |
| Changes in Fair Value               | 28,182              |
| <b>Balance at December 31, 2011</b> | <b>\$ 2,197,226</b> |

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, 2011:

|                                       | Fair value measurement at reporting date using:                            |  |  | Total                |
|---------------------------------------|--|--|--|----------------------|
|                                       | Quoted prices in<br>active markets for<br>identical<br>assets<br>(Level 1) | Significant<br>other observable<br>inputs<br>(Level 2) | Significant<br>unobservable<br>inputs<br>(Level 3) |                      |
| Assets:                               |  |  |  |                      |
| Money market funds                    | \$ 3,539,038   | \$   | \$   | \$ 3,539,038         |
| U.S. Government and agency securities | 513,084  | 16,264,724   |  | 16,777,808           |
| Corporate and other debt securities   |  | 8,078,978  |  | 8,078,978            |
| <b>Total</b>                          | <b>\$ 4,052,122</b>  | <b>\$ 24,343,702</b>                                   | <b>\$</b>  | <b>\$ 28,395,824</b> |

There were no remeasurements to fair value during the nine months ended December 31, 2011 of financial assets and liabilities that are not measured at fair value on a recurring basis.

**Inventories**

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

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.

**Table of Contents**

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

|                   | December 31,<br>2011 | March 31,<br>2011 |
|-------------------|----------------------|-------------------|
| Raw Materials     | \$ 3,563,395         | \$ 944,259        |
| Work-in-process   | 5,936,578            | 518,374           |
| Finished products | 3,863,100            | 491,343           |
| Total             | \$ 13,363,073        | \$ 1,953,976      |

**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 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   |

**Table of Contents**

For depreciation of property and equipment, the Company expensed approximately \$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 and \$1,349,000 in the fiscal years ended March 31, 2011 and 2010, respectively. These amounts include depreciation of assets recorded under capitalized lease agreements of approximately \$82,000 in the nine months ended December 31, 2010 as well as \$82,000 and \$34,000 in the fiscal years ended March 31, 2011 and 2010, respectively. There was no depreciation of assets recorded under capitalized lease agreements in the nine-month fiscal year ended December 31, 2011.

**Earnings (Loss) Per Share**

The Company reports earnings (loss) per share in accordance with Accounting Standards Codification Topic 260, *Earnings Per Share*, which establishes standards for computing and presenting earnings 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. Common share equivalents have not been included in the net loss per share computation for the nine-month fiscal year ended December 31, 2011 or for the fiscal years ended March 31, 2011 and 2010 because their effect is anti-dilutive.

A reconciliation of basic and diluted share amounts for the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010 as well as the fiscal years ended March 31, 2011 and 2010 is as follows:

|  | Nine Months ended December 31, |              | Years ended March 31, |                |
|--|--------------------------------|--------------|-----------------------|----------------|
|  | 2011                           | 2010         | 2011                  | 2010           |
| <b>Numerator:</b>  |                                |              |                       |                |
| Net income (loss)  | \$ (1,612,625)                 | \$ 1,987,178 | \$ (43,509)           | \$ (4,063,844) |
| <b>Denominator:</b>  |                                |              |                       |                |
| Basic weighted average common shares outstanding   | 30,774,467                     | 30,778,430   | 30,781,881            | 30,752,041     |
| Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards |                                | 170,834      |                       |                |
| Diluted weighted average common shares outstanding   | 30,774,467                     | 30,949,264   | 30,781,881            | 30,752,041     |
| Basic net income (loss) per common share   | \$ (0.05)                      | \$ 0.06      | \$ (0.00)             | \$ (0.13)      |
| Diluted net income (loss) per common share   | \$ (0.05)                      | \$ 0.06      | \$ (0.00)             | \$ (0.13)      |

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.

**Table of Contents**

Diluted weighted average shares outstanding for the nine-month fiscal year ended December 31, 2011 and the fiscal years ended March 31, 2011 and 2010 do not include the impact of 2,823,400, 2,580,600 and 2,318,650 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 years ended March 31, 2011 and 2010.

**Segment Reporting**

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

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

|               | Nine Months ended December 31, |      | Years ended March 31, |      |
|---------------|--------------------------------|------|-----------------------|------|
|               | 2011                           | 2010 | 2011                  | 2010 |
| United States | 48%                            | 48%  | 50%                   | 57%  |
| Sweden        | 44%                            | 45%  | 42%                   | 36%  |
| Other         | 8%                             | 7%   | 8%                    | 7%   |
| Total         | 100%                           | 100% | 100%                  | 100% |

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

|               | December 31,<br>2011 | March 31,<br>2011 |
|---------------|----------------------|-------------------|
| United States | \$ 44,223,080        | \$ 72,293,990     |
| Sweden        | 31,833,734           |                   |
| Total         | \$ 76,056,814        | \$ 72,293,990     |

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

|               | December 31,<br>2011 | March 31,<br>2011 |
|---------------|----------------------|-------------------|
| United States | \$ 13,380,836        | \$ 16,449,974     |
| Sweden        | 15,781,172           |                   |
| Total         | \$ 29,162,008        | \$ 16,449,974     |

**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, 2011 and 2010 as well as March 31, 2011 and 2010, 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.



**Table of Contents**

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

|                                 | Nine Months ended December 31, |      | Years ended March 31, |      |
|---------------------------------|--------------------------------|------|-----------------------|------|
|                                 | 2011                           | 2010 | 2011                  | 2010 |
| Orencia® Royalties from Bristol | 37%                            | 37%  | 38%                   | 43%  |
| Bioprocessing Customer A        | 44%                            | 45%  | 42%                   | 36%  |

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

|                                 | December 31, 2011 | March 31, 2011 |
|---------------------------------|-------------------|----------------|
| Orencia® Royalties from Bristol | 53%               | 56%            |
| Bioprocessing Customer A        | 31%               | 21%            |

**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. 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, 2011. There were no goodwill impairment charges during the nine-month fiscal year ended December 31, 2011 or the fiscal year ended March 31, 2011.

*Other 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 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

**Table of Contents**

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, 2011.

Other intangible assets consisted of the following at December 31, 2011:

|                               | Gross Carrying<br>Amount | Accumulated<br>Amortization | Weighted<br>Average<br>Useful Life<br>(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 other intangible assets | \$ 8,161,711             | \$ (366,472)                | 8  |

Other intangible assets consisted of the following at March 31, 2011:

|                               | Gross Carrying<br>Amount | Accumulated<br>Amortization | Useful Life<br>(in years) |
|-------------------------------|--------------------------|-----------------------------|---------------------------|
| Technology developed          | \$ 760,000               | \$ (110,834)                | 8                         |
| Patents                       | 240,000                  | (35,000)                    | 8                         |
| Customer relationships        | 430,000                  | (62,708)                    | 8                         |
| Total other intangible assets | \$ 1,430,000             | \$ (208,542)                |                           |

Amortization expense for amortized intangible assets was approximately \$158,000 in the nine-month fiscal year ended December 31, 2011. The Company expects to record amortization expense of approximately \$978,000 in each of the next five years.

**Stock Based Compensation**

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.

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

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



**Table of Contents**

*Estimated forfeiture rates* The Company has applied, based on an analysis of its historical forfeitures, annual forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees to all unvested stock options as of December 31, 2011. 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.

**Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update ( ASU ) No. 2011-04, *Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* ( ASU 2011-04 ). The amendments in this update will ensure that fair value has the same meaning in U.S. GAAP and in International Financial Reporting Standards and that their respective fair value measurement and disclosure requirements are the same. This update is effective prospectively for interim and annual periods beginning after December 15, 2011. Early adoption by public entities is not permitted, and the Company is therefore required to adopt this ASU on January 1, 2012. The Company has not completed its review of ASU 2011-04, but it does not expect the adoption to have a material impact on the Company's results of operations, financial position or cash flows.

In June 2011, the Financial Accounting Standards Board issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* ( ASU 2011-05 ), which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for the Company in the first quarter of fiscal year 2012 and will be applied retrospectively. The adoption of this standard will impact the Company's financial statement presentation, but will not have a material impact on its financial position or results of operations.

**3. Income Taxes**

For the nine-month fiscal year ended December 31, 2011, the tax provision of \$16,000 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. For the fiscal year ended March 31, 2011, the Company had no current provisions for federal or state income taxes. For the fiscal year ended March 31, 2010, the tax benefit of (\$834,766) is comprised of a current benefit for federal income taxes of (\$834,766). The benefit for federal income taxes is due to the Worker, Homeownership, and Business Assistance Act of 2009 (the Act) that was enacted in November 2009. Among other things, the Act suspended the limitation on the use of net operating losses to offset alternative minimum tax liabilities. The Company paid a total of approximately \$835,000 of alternative minimum taxes in the fiscal years ended March 31, 2009 and 2008 combined. During the fiscal year ended March 31, 2011, the Company received a refund of approximately \$835,000 upon filing its tax return for the fiscal year ended March 31, 2010 and related carry-back claim.

At December 31, 2011, the Company had net operating loss carryforwards of approximately \$58,243,000 and business tax credits carryforwards of approximately \$2,196,000 available to reduce future federal income taxes, if any. Additionally, at December 31, 2011, the Company had net operating loss carryforwards of approximately \$4,816,000 and business tax credits carryforwards of approximately \$2,986,000 available to reduce future state income taxes, if any. The net operating loss and business tax credits carryforwards will continue to expire at various dates through December 2031. 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.

**Table of Contents**

Our consolidated deferred tax assets (liabilities) consist of the following:

|  | December 31, 2011   | March 31, 2011    |
|--|---------------------|-------------------|
| Deferred tax assets:                         |                     |                   |
| Temporary timing differences                 | \$ 4,277,000        | \$ 4,520,000      |
| Net operating loss carryforwards             | 20,065,000          | 19,587,000        |
| Tax business credits carryforwards           | 4,166,000           | 4,442,000         |
| <b>Total deferred tax assets</b>             | <b>28,508,000</b>   | <b>28,549,000</b> |
| Valuation allowance                          | (28,476,000)        | (28,549,000)      |
| <b>Net deferred tax assets</b>               | <b>\$ 32,000</b>    | <b>\$</b>         |
| Deferred tax liabilities:                    |                     |                   |
| Goodwill                                     | \$ (48,000)         | \$                |
| Acquired intangibles                         | (89,000)            |                   |
| <b>Net deferred tax assets (liabilities)</b> | <b>\$ (105,000)</b> | <b>\$</b>         |

At December 31, 2011 and March 31, 2011, a full valuation allowance has been provided against the U.S. deferred tax assets, as it is uncertain if the Company will realize the benefits of such U.S. deferred tax assets. The valuation allowance increased \$73,000 for the nine months ended December 31, 2011.

The reconciliation of the federal statutory rate to the effective income tax rate for the nine-month fiscal year ended December 31, 2011 and the fiscal years ended March 31, 2011 and 2010 is as follows:

|  | December 31, 2011 |             | Period Ended,<br>March 31, 2011 |          | March 31, 2010      |                |
|--|-------------------|-------------|---------------------------------|----------|---------------------|----------------|
|  | \$                | %           | \$                              | %        | \$                  | %              |
| Loss before income taxes                                   | \$ (1,596,881)    |             | \$ (43,509)                     |          | \$ (4,898,610)      |                |
| Expected tax (recovery) at statutory rate                  | (542,939)         | (34.0)%     | (14,793)                        | (34.0)%  | (1,665,527)         | (34.0)%        |
| Adjustments due to:  |                   |             |                                 |          |                     |                |
| Difference between U.S. and foreign tax                    | (19,287)          | (1.2)%      |                                 | (0.0)%   |                     | (0.0)%         |
| State income and franchise taxes                           | 52,905            | 3.3%        | 96,141                          | 221.0%   | (80,151)            | (1.6)%         |
| Utilization of loss carryforwards and business tax credits | (68,926)          | (4.3)%      | (66,126)                        | (152.0)% | (934,659)           | (19.1)%        |
| Transaction costs  | 240,842           | 15.1%       |                                 | 0.0%     |                     | 0.0%           |
| Gain on bargain purchase                                   | (112,427)         | (7.0)%      |                                 | (0.0)%   |                     | (0.0)%         |
| Permanent differences                                      | 218,989           | 13.7%       | 250,483                         | 575.7%   | 255,766             | 5.2%           |
| Change in valuation allowance                              | 246,587           | 15.4%       | (265,706)                       | (610.7)% | 1,589,805           | 32.5%          |
| <b>Provision (benefit) for income taxes</b>                | <b>\$ 15,744</b>  | <b>1.0%</b> | <b>\$ (0.0)%</b>                |          | <b>\$ (834,766)</b> | <b>(17.0)%</b> |

At December 31, 2011 as well as March 31, 2011 and 2010, 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 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, there are no proposed adjustments and the Company continues to

believe no reserve is required under ASC 740 *Income Taxes*.

---

**Table of Contents****4. Stockholders Equity  
Common Stock and Warrants**

At December 31, 2011, the Company has reserved 2,840,909 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.

**Shareholder Rights Plan**

In March 2003, the Company adopted a Shareholder Rights Agreement (the Rights Agreement). Under the Rights Agreement, the Company distributed certain rights to acquire shares of the Company's Series A junior participating preferred stock (the Rights) as a dividend for each share of common stock held of record as of March 17, 2003. Each share of common stock issued after the March 17, 2003 record date had an attached Right. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock (20% in the case of a certain stockholder) (the 15% holder), each Right permitted the holder (other than the 15% holder) to purchase common stock having a value equal to twice the exercise price of the Right, upon payment of the exercise price of the Right. In addition, in the event of certain business combinations after an acquisition by a person or group of 15% or more of the common stock (20% in the case of a certain stockholder), each Right entitled the holder (other than the 15% holder) to receive, upon payment of the exercise price, common stock having a value equal to twice the exercise price of the Right. The Rights had no voting privileges and, unless and until they became exercisable, were attached to, and automatically traded with, the Company's common stock. The Rights original termination date was upon the earlier of the date of their redemption or March 2013. On September 8, 2011, the Company amended the Rights Agreement to accelerate the expiration date to September 8, 2011, effectively terminating the Rights Agreement on September 8, 2011.

**Stock-Based Compensation**

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 years ended March 31, 2011 and 2010, we recorded stock-based compensation expense of approximately \$1,003,000 and \$1,007,000, respectively, for stock options granted under the 2001 Plan.

The 2001 Plan allows for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of common stock. Incentive options granted to employees under the 2001 Plan 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 2001 Plan generally vest over one year. Options granted under the 2001 Plan have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At December 31, 2011, options to purchase 2,823,400 shares were outstanding under the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the Plans). At December 31, 2011, 17,509 shares were available for future grant under the 2001 Plan.

**Table of Contents**

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

|                         | Nine Months ended December 31, |                 | Years ended March 31, |                 |
|-------------------------|--------------------------------|-----------------|-----------------------|-----------------|
|                         | 2011                           | 2010            | 2011                  | 2010            |
| Expected term (years)   | 6.5                            | 6.5             | 6.5                   | 6.5             |
| Volatility              | 53.09% - 55.76%                | 57.58% - 63.60% | 55.94% - 63.60%       | 58.12% - 65.14% |
| Risk-free interest rate | 1.25% - 2.38%                  | 1.81% - 2.62%   | 1.81% - 2.83%         | 2.54% - 3.14%   |
| Expected dividend yield |                                |                 |                       |                 |

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 has no awards with market or performance 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.

Information regarding option activity for the nine-month fiscal year ended December 31, 2011 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 April 1, 2011                 | 2,580,600           | \$ 4.15                                   |  |                           |
| Granted  | 350,500             | 3.35                                      |  |                           |
| Exercised  | (2,500)             | 0.01                                      |  |                           |
| Forfeited/cancelled                                  | (105,200)           | 4.11                                      |  |                           |
| Options outstanding at December 31, 2011             | 2,823,400           | \$ 4.05                                   | 6.19   | \$ 631,199                |
| Options exercisable at December 31, 2011             | 1,734,900           | \$ 4.08                                   | 4.83   | \$ 503,919                |
| Vested and expected to vest at December 31, 2011 (1) | 2,674,669           | \$ 4.05                                   | 6.08   | \$ 621,540                |

(1) This represents the number of vested options as of December 31, 2011 plus the number of unvested options expected to vest as of December 31, 2011 based on the unvested outstanding options at December 31, 2011 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, 2011 of \$3.47 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, 2011.

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 years ended March 31, 2011 and 2010 was \$2.11 and \$2.71, respectively. 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 \$817,000, respectively. The total fair value of stock options that vested during the fiscal years ended March 31, 2011 and 2010 was approximately \$993,000 and \$1,067,000, respectively.





**Table of Contents**

As of December 31, 2011, there was \$1,764,675 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 2.86 years. The Company expects 939,769 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, depending on the commencement date of our occupancy of the expanded premises is expected to expire on or about 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 balance sheet as of December 31, 2011 and March 31, 2011.

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 expire on May 31, 2012.

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, 2011 are approximately as follows:

| <b>Years Ending</b>           | <b>Operating Leases</b> |
|-------------------------------|-------------------------|
| December 31, 2012             | \$ 2,123,000            |
| December 31, 2013             | 2,296,000               |
| December 31, 2014             | 2,293,000               |
| December 31, 2015             | 2,289,000               |
| December 31, 2016             | 2,289,000               |
| Thereafter                    | 8,677,000               |
| <b>Minimum lease payments</b> | <b>\$ 19,967,000</b>    |

Rent expense charged to operations under operating leases was approximately \$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 and \$689,000 for the fiscal years ended March 31, 2011 and 2010, respectively. As of December 31, 2011 and March 31, 2011, the Company had deferred rent liabilities of \$15,000 and \$27,000, respectively, related to the escalating rent provisions for the Waltham headquarters.

*Licensing and Research Agreements*

The Company licenses certain technologies that are, or may be, incorporated into its technology under several agreements and also has entered into several clinical research agreements which require the Company to fund certain research projects. Generally, the license agreements require the Company to pay annual maintenance



**Table of Contents**

fees and royalties on product sales once a product has been established using the technologies. The Company has recorded research and development expenses associated with license agreements of approximately \$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 and \$643,000 for the fiscal years ended March 31, 2011 and 2010, respectively.

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, 2011 of approximately \$2,326,000 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:

|                                    | <b>December 31, 2011</b> | <b>March 31, 2011</b> |
|------------------------------------|--------------------------|-----------------------|
| Equipment maintenance and services | \$ 424,328               | \$ 179,153            |
| Interest receivable                | 106,695                  | 103,695               |
| Prepaid insurance                  | 251,418                  | 95,233                |
| Clinical and research expenses     | 13,714                   | 57,630                |
| Other                              | 114,143                  | 57,056                |
| Total                              | \$ 910,298               | \$ 492,767            |

**7. Accrued Liabilities**

Accrued liabilities consist of the following:

|                          | <b>December 31, 2011</b> | <b>March 31, 2011</b> |
|--------------------------|--------------------------|-----------------------|
| Employee compensation    | \$ 2,741,738             | \$ 1,466,225          |
| Professional fees        | 871,086                  | 87,634                |
| VAT liabilities          | 566,542                  |                       |
| Royalty and license fees | 499,776                  | 410,591               |
| Unearned revenue         | 469,046                  | 660,624               |
| Research and development | 142,695                  | 759,450               |
| Other accrued expenses   | 750,155                  | 307,999               |
| Total                    | \$ 6,041,038             | \$ 3,692,523          |

**Table of Contents****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 \$102,000 for the nine-month fiscal year ended December 31, 2011 as well as \$108,000 and \$117,000 for the fiscal years ended March 31, 2011 and 2010, respectively.

In Sweden, the Company contributes to a government-mandated occupational pension plan that is a qualified defined contribution plan. All employees in Sweden are eligible for this pension plan. The Company pays premiums to a third party occupational pension specialist who administers the pension plan. These premiums are based on various factors including each employee's age, salary, employment history and selected benefits in the pension plan. When an employee terminates or retires, these premium payments cease for that employee and the Company has no further pension-related obligations for that employee. For the 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 \$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, as well as \$10,251,000 and \$8,980,000 for the fiscal years ended March 31, 2011 and 2010, respectively.

The Company must also remit to the University of Michigan 15% of all royalty revenue received from Bristol. Royalty expense was \$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, as well as \$1,537,000 and \$1,347,000 for the fiscal years ended March 31, 2011 and 2010, respectively. This operating expense is included on the statements of operations under the line item Cost of royalty and other revenue.

**10. License Agreements***The Scripps Research Institute*

On April 6, 2007, the Company entered into an exclusive worldwide commercial license agreement ( 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.

Pursuant to the 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

**Table of Contents**

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 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, 2011, 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 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 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 denominated in Euros, but it is reflected here in U.S. dollars for presentation purposes. The Novozymes Acquisition diversifies and expands 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

**Table of Contents**

\$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 will operate as the Company's newly-formed, 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 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 approximately \$28,922,000, which exceeds 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 that 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 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                               | \$ 26,884,000        |
| Estimated fair value of contingent consideration | 1,611,000            |
| <b>Total consideration transferred</b>           | <b>\$ 28,495,000</b> |

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 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.

Acquisition related costs are not included as a component of consideration transferred, but are expensed in the periods in which the costs are incurred. The Company incurred approximately \$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.

**Table of Contents***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                               | 195,000       |
| Fixed assets                                   | 9,089,000     |
| Customer relationships and acquired technology | 6,705,000     |
| Deferred tax liability                         | (89,000)      |
| Accounts payable and other liabilities assumed | (2,563,000)   |
| Net assets acquired                            | \$ 28,922,000 |
| Less total consideration transferred           | (28,495,000)  |
| Gain on bargain purchase                       | \$ 427,000    |

The purchase price allocation is preliminary as a result of the fact that the Company has not yet received a final valuation report for the assets acquired and liabilities assumed. Adjustments to the allocation of fair value to the assets acquired and liabilities assumed could occur until such time as the final valuation report has been received.

*Revenue, Net Loss and Pro Forma Presentation*

Repligen Sweden AB recorded revenue of \$4,000 and net income of \$282,000 in the period from December 21, 2011 through December 31, 2011.

The Company has included the operating results of Repligen Sweden AB in its consolidated statements of operations since the December 20, 2011 acquisition date. The following table presents unaudited supplemental pro forma information as if the Novozymes Acquisition had occurred as of the first day of each period, April 1, 2011 and April 1, 2010, respectively.

|               | <b>Nine Months ended December 31,</b> |               |
|---------------|---------------------------------------|---------------|
|               | <b>2011</b>                           | <b>2010</b>   |
| Total revenue | \$ 36,516,279                         | \$ 32,330,882 |
| Net loss      | (5,987,923)                           | (2,083,490)   |

This unaudited pro forma financial information is presented for informational purposes only and is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of the beginning of the periods presented, and should not be taken as being representative of the future consolidated results of operations of the Company.

*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, a milestone payment of \$300,000 payable the earlier of (i) the date on which Repligen receives an acknowledgment executed by a specific customer or (ii) the second anniversary of the acquisition date, and future royalties based on product sales. The milestone payment was made to BioFlash in November 2010.



**Table of Contents**

The Company will manufacture and sell 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.

*Consideration Transferred*

The Company accounted for the acquisition of the assets of BioFlash as the purchase of a business under GAAP. Under the acquisition method of accounting, the assets of BioFlash were recorded as of the acquisition date, at their respective fair values, and consolidated with those of Repligen. The purchase price was based upon estimates of the fair value of assets acquired. The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates. The Company incurred transaction costs of \$90,707 associated with the acquisition of the assets of BioFlash.

The total consideration transferred follows:

|  |                  |
|--|------------------|
| Cash consideration                               | \$ 1,780,000     |
| Liability for additional payment                 | 300,000          |
| Estimated fair value of contingent consideration | 560,000          |
| <br>Total consideration transferred              | <br>\$ 2,640,000 |

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future royalty payments (and the fair value of a time-based additional payment) 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          |
| <br>Total                                 | <br>\$ 2,640,000 |

The Company believes that the intangible assets were recorded at fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets. The Company used the income approach to determine the fair value of the amortizable intangible assets.

Various factors contributed to the establishment of goodwill, including the expected business plans and opportunities to introduce future products to BioFlash's customer base.

**Table of Contents****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,<br>2011 | September 30,<br>2011 | June 30,<br>2011 | March 31,<br>2011 | December 31,<br>2010 | September 30,<br>2010 | June 30,<br>2010 | March 31,<br>2010 |
|---|----------------------|-----------------------|------------------|-------------------|----------------------|-----------------------|------------------|-------------------|
| (in thousands, except per share amounts)    |                      |                       |                  |                   |                      |                       |                  |                   |
| <b>Revenue:</b>                             |                      |                       |                  |                   |                      |                       |                  |                   |
| Product revenue                             | \$ 3,114             | \$ 5,742              | \$ 4,359         | \$ 3,150          | \$ 3,126             | \$ 4,416              | \$ 4,269         | \$ 2,225          |
| Royalty and other revenue                   | 4,051                | 2,889                 | 3,295            | 2,756             | 3,942                | 2,891                 | 2,741            | 2,647             |
| <b>Total revenue</b>                        | <b>7,165</b>         | <b>8,631</b>          | <b>7,654</b>     | <b>5,906</b>      | <b>7,068</b>         | <b>7,307</b>          | <b>7,010</b>     | <b>4,872</b>      |
| <b>Operating expenses:</b>                  |                      |                       |                  |                   |                      |                       |                  |                   |
| Cost of product revenue                     | 1,511                | 2,093                 | 1,553            | 1,393             | 1,449                | 1,472                 | 1,266            | 885               |
| Cost of royalty and other revenue           | 481                  | 418                   | 416              | 376               | 412                  | 377                   | 372              | 345               |
| Research and development                    | 2,870                | 3,075                 | 3,517            | 3,785             | 2,930                | 3,119                 | 2,695            | 3,453             |
| Selling, general and administrative         | 4,268                | 2,493                 | 2,289            | 2,438             | 1,980                | 1,813                 | 1,788            | 1,952             |
| Gain on bargain purchase                    | (427)                |                       |                  |                   |                      |                       |                  |                   |
| <b>Total operating expenses</b>             | <b>8,703</b>         | <b>8,079</b>          | <b>7,775</b>     | <b>7,992</b>      | <b>6,771</b>         | <b>6,781</b>          | <b>6,121</b>     | <b>6,635</b>      |
| (Loss) income from operations               | (1,538)              | 552                   | (121)            | (2,086)           | 297                  | 526                   | 889              | (1,763)           |
| Investment income                           | 43                   | 53                    | 66               | 69                | 92                   | 97                    | 99               | 134               |
| Interest expense                            | (28)                 |                       |                  | (13)              | (13)                 |                       |                  |                   |
| Other expense                               | (623)                |                       |                  |                   |                      |                       |                  |                   |
| (Loss) income before income taxes           | (2,146)              | 605                   | (55)             | (2,030)           | 376                  | 623                   | 988              | (1,629)           |
| Income tax provision                        | 16                   |                       |                  |                   |                      |                       |                  |                   |
| <b>Net (loss) income</b>                    | <b>\$ (2,162)</b>    | <b>\$ 605</b>         | <b>\$ (55)</b>   | <b>\$ (2,030)</b> | <b>\$ 376</b>        | <b>\$ 623</b>         | <b>\$ 988</b>    | <b>\$ (1,629)</b> |
| <b>Earnings (loss) per share:</b>           |                      |                       |                  |                   |                      |                       |                  |                   |
| Basic                                       | \$ (0.07)            | \$ 0.02               | \$ (0.00)        | \$ (0.06)         | \$ 0.01              | \$ 0.02               | \$ 0.03          | \$ (0.05)         |
| Diluted                                     | \$ (0.07)            | \$ 0.02               | \$ (0.00)        | \$ (0.06)         | \$ 0.01              | \$ 0.02               | \$ 0.03          | \$ (0.05)         |
| <b>Weighted average shares outstanding:</b> |                      |                       |                  |                   |                      |                       |                  |                   |
| Basic                                       | 30,715               | 30,797                | 30,812           | 30,782            | 30,787               | 30,780                | 30,768           | 30,752            |
| Diluted                                     | 30,715               | 30,934                | 30,812           | 30,782            | 31,005               | 30,920                | 30,926           | 30,752            |