

REPLIGEN CORP  
Form 10-K  
June 10, 2010  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended March 31, 2010

OR

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

For the transition period from            to

Commission file number: 000-14656

**REPLIGEN CORPORATION**

(Exact name of Registrant as specified in its charter)

Edgar Filing: REPLIGEN CORP - Form 10-K

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

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

**Title of Each Class**

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

**Series A Junior Participating Preferred Stock Purchase Rights**

**Name of Each Exchange on Which Registered**

**The NASDAQ Stock Market LLC**

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

**Title of Each Class**

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

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

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No .

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No .

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

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

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

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

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, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$154,098,617.

The number of shares of outstanding of the registrant's common stock as of May 31, 2010 was 30,766,807.

### DOCUMENTS INCORPORATED BY REFERENCE

**Portions of the Company's definitive Proxy Statement in connection with the 2010 annual meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.**

**Table of Contents**

**Table of Contents**

	<b>PAGE</b>
PART I	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	11
Item 1B. <u>Unresolved Staff Comments</u>	18
Item 2. <u>Properties</u>	18
Item 3. <u>Legal Proceedings</u>	18
Item 4. <u>Removed and Reserved</u>	19
PART II	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	20
Item 6. <u>Selected Financial Data</u>	22
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
Item 8. <u>Financial Statements and Supplementary Data</u>	34
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	34
Item 9A. <u>Controls and Procedures</u>	34
Item 9B. <u>Other Information</u>	37
PART III	
PART IV	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	39
<u>SIGNATURES</u>	42

---

**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.*

Repligen Corporation ( Repligen, the Company or we ) is a biopharmaceutical company focused on the development and commercialization of innovative therapies that harness biological pathways and deliver value to patients and clinicians in neurology, gastroenterology and orphan diseases. We are currently conducting a number of drug development programs for diseases such as pancreatitis, bipolar disorder, Friedreich's ataxia and spinal muscular atrophy. We also have a bioprocessing business that focuses on the development and commercialization of products that are used for the production of biopharmaceuticals. In addition, we receive royalties from Bristol-Myers Squibb Company ( Bristol ) on their net sales in the United States of their product Orenicia®. We seek to invest the profits from our current commercial products, royalty and other revenues, as well as use our existing financial resources to advance the development of our therapeutic product candidates and our bioprocessing business.

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

**Currently Marketed Products**

We currently sell a line of commercial bioprocessing products based on Protein A, as well as single or limited campaign use pre-packed chromatography columns, which are used in the production of monoclonal antibodies and other biopharmaceutical manufacturing applications.

**Protein A Products for Antibody Manufacturing**

Protein A is widely used in the purification of therapeutic monoclonal antibodies. Most therapeutic monoclonal antibodies are manufactured by the fermentation of mammalian cells that express the monoclonal antibody. The monoclonal antibody is typically produced by a process in which an impure fermentation broth containing the desired monoclonal antibody is passed over a solid support to which Protein A has been chemically attached or immobilized. The immobilized Protein A binds the monoclonal antibody while other impurities are washed away. The monoclonal antibody is then recovered from the support in a substantially purified form.

We manufacture and market several products based on recombinant forms of Protein A. Our primary customers incorporate our Protein A products into their proprietary monoclonal antibody purification products that they sell directly to the biopharmaceutical industry. We primarily supply Protein A products to GE Healthcare ( GEHC ) under a supply agreement which extends through 2015. The majority of our product sales for the last three years have been sales of Protein A products and related detection assays.

The global monoclonal antibody market was valued at approximately \$40 billion in 2009 and is expected to exceed \$65 billion by 2015. Examples of therapeutic antibodies include Enbrel® and Remicade® for rheumatoid arthritis and other inflammatory disorders, and Rituxan® for rheumatoid arthritis and Non-Hodgkin's Lymphoma, among others. There are more than 200 additional monoclonal antibodies in various stages of clinical testing which may lead to additional growth of the antibody market and in turn, increased demand for Protein A.

---

## **Table of Contents**

### **SecreFlo® for Pancreatic Diagnosis**

We discontinued distribution of SecreFlo® in the second quarter of fiscal year 2009 due to the expiration of our agreement with ChiRhoClin, Inc. Previously, we recorded sales of SecreFlo®, a synthetic form of porcine (pig-derived) secretin. SecreFlo® is approved by the U.S. Food and Drug Administration ( FDA ) as an aid in the diagnosis of chronic pancreatitis and gastrinoma (a form of cancer) and as an aid during endoscopic retrograde cholangiopancreatography ( ERCP ), a gastrointestinal procedure.

### **Intellectual Property on Monoclonal Antibody and Antibody Fusion Products**

#### **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. 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 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.

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 Repligen 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, after deducting legal expenses. There are no annual or other fees associated with this agreement. Under this agreement, since its inception through fiscal year 2010, Repligen has paid approximately \$2,438,000 to the University of Michigan.

#### **Erbix®**

Erbix® is a monoclonal antibody developed by ImClone Systems Incorporated ( ImClone ) which was approved by the FDA in February 2004 for the treatment of certain forms of colon cancer and in March 2006 for the treatment of head and neck cancer. Erbix® is manufactured with a cell line which contains certain genetic technologies ( DNA enhancers ) which increase the productivity of a cell line. A U.S. patent covering the use of DNA enhancers, which expired in May of 2004, was assigned to The Massachusetts Institute of Technology ( MIT ) and exclusively licensed to Repligen. In May 2004, Repligen and MIT jointly filed a lawsuit against ImClone in U.S. District Court for Massachusetts alleging that ImClone had infringed our patent rights in its production of Erbix®. In September 2007, Repligen and MIT entered into a settlement agreement under which ImClone was granted a license to the DNA enhancer patent and certain other intellectual property in exchange for a payment of \$65,000,000.

### **Research and Development**

For the past three years, we have devoted substantial resources to the research and development of therapeutic product candidates and our commercial products and product candidates discussed herein. We spent

---

## **Table of Contents**

\$14,160,000, \$12,772,000 and \$7,241,000 in fiscal years 2010, 2009 and 2008, respectively, on company-sponsored research and development activities.

### **Development Stage Products**

#### **Secretin for MRI Imaging of the Pancreas**

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 are currently evaluating the sensitivity and specificity of secretin in combination with MRI to improve the detection of structural abnormalities of the pancreas relative to MRI alone. Detailed visual assessment of the pancreatic ducts and identification of structural abnormalities is important in the assessment, diagnosis and treatment of diseases such as acute and chronic pancreatitis. The use of secretin during MRI harnesses the natural biologic properties of secretin, which signals the release of water-rich fluids into the ducts of the pancreas. 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 more invasive endoscopic procedures.

We initiated a Phase 2 clinical trial in June 2006 to evaluate the use of RG1068, synthetic human secretin, as an agent to improve the detection of structural abnormalities of the pancreatic ducts during MRI imaging of the pancreas. This was a multi-center, baseline controlled, single dose study in which 76 patients with a history of pancreatitis received an RG1068-MRI and an MRI alone of the pancreas. In May 2007, we announced positive results from this Phase 2 clinical trial. The study showed an improvement in sensitivity of detection of structural abnormalities of the pancreatic duct of approximately 20% with no loss in specificity. In addition, the study showed highly significant increases in the following three assessments: physician confidence in their ability to identify structural abnormalities, the number of pancreatic duct segments visualized, and improvement in the overall quality of the MRI images. Our Phase 2 data was reviewed by the FDA and served as the basis for a pivotal, Phase 3 study.

This 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 with a history of pancreatitis at 23 clinical sites within the United States and Canada received an MRI of the pancreas with and without RG1068. The primary objectives of the Phase 3 study were to demonstrate that RG1068 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 this study, one radiologist achieved a statistically significant improvement in sensitivity with RG1068, while a second radiologist showed a trend but did not achieve statistical significance. There was minimal loss in specificity for all radiologists.

Based on numerous deficiencies with the analysis of the radiographic images by the contract research organization hired to oversee analysis of the Phase 3 trial data, we submitted a request to the FDA and the European Medicines Agency ( 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 and we anticipate that preliminary results will be available by the end of fiscal year 2011, ending on March 31, 2011. We believe that a successful Phase 3 re-read may provide the basis for filing a New Drug Application ( NDA ) with the FDA for approval to market RG1068 for this use in the United States.

We have received an Orphan Drug designation from the FDA covering the use of RG1068 in MRI which, provided we are the first company to receive FDA approval for this use of secretin, will provide seven years of marketing exclusivity in the United States following approval of the NDA. We also have received fast track designation from the FDA which may provide the basis for an expedited review of this NDA by the FDA.

---

**Table of Contents**

**Uridine for Bipolar Depression**

Uridine is a biological compound essential for multiple biosynthetic processes including the synthesis of DNA and RNA, the basic hereditary material found in all cells and numerous other factors essential for cell metabolism. Uridine is synthesized by the power plant of the human cell known as the mitochondria. The rationale for uridine therapy in central nervous system ( CNS ) disorders is supported by pre-clinical and clinical research. 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 suggests that the symptoms of bipolar disorder may be linked to dysregulation of energy metabolism in the brain.

Bipolar disorder, also known as manic depression, is a chronic illness marked by extreme changes in mood, thought, energy and behavior in which a person's mood alternates between the poles of mania (highs) and depression (lows). Bipolar disorder affects more than 5 million adults worldwide and is usually diagnosed in late adolescence or early adulthood. Bipolar disorder is associated with substantial morbidity and mortality, ranking worldwide behind only unipolar depression and alcohol abuse among psychiatric illnesses for related disabilities and overall economic burden of illness. The average lifetime financial burden of bipolar disorder in the United States is more than \$600,000 per patient. Although lithium and anticonvulsants such as valproic acid have substantially improved the prognosis of bipolar disorder, many individuals are unable to tolerate treatment-related side effects, and incomplete clinical response, lack of compliance in taking medication, and relapse remain common clinical problems.

In March 2006, we initiated a Phase 2a clinical trial of RG2417, an oral formulation of uridine, in patients with bipolar depression. This was a multi-center, dose escalating study in 83 patients which compared daily, oral dosing with either RG2417 or a placebo for six weeks. Patients were evaluated weekly for the safety and effectiveness of RG2417 on the symptoms of bipolar depression. The study showed a statistically significant improvement in the symptoms of depression over the six-week course of treatment in the patients treated with RG2417 when compared to placebo as measured by the Montgomery-Asberg Depression Rating Scale. RG2417 was well tolerated by patients with a safety profile similar to those treated with a placebo. Our Phase 2a data was reviewed by the FDA and served as the basis for a Phase 2b study.

In November 2008, we initiated this Phase 2b proof-of-concept clinical trial for RG2417 as a potential treatment for the depressive symptoms associated with bipolar disorder. This study, currently in progress, is a multi-center, randomized, double-blind, placebo-controlled clinical trial in which approximately 150 patients with bipolar depression will receive either RG2417 or placebo twice daily for eight weeks. We anticipate that preliminary results from this Phase 2b clinical trial will be available by the end of fiscal year 2011, ending on March 31, 2011.

**Histone Deacetylase Inhibitors for Friedreich's Ataxia**

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 the 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.

In April 2007, we entered into an exclusive commercial license (the Scripps License Agreement ) with The Scripps Research Institute ( Scripps ) for intellectual property covering compounds which may have utility in treating Friedreich's ataxia. Our preclinical studies with several chemically synthesized libraries of compounds have identified selective HDAC inhibitors. Some of these compounds increase production of the protein frataxin which may have the potential to arrest disease progression in patients with Friedreich's ataxia. Repligen is currently developing RG2833, a selective histone deacetylase 3 ( HDAC-3 ) inhibitor for the treatment of



---

## **Table of Contents**

Friedreich's ataxia. We recently filed an Investigational New Drug ( IND ) application with the FDA for a Phase 1 study for a double-blind, single ascending dose study in healthy volunteers to evaluate the pharmacokinetic and safety profile of RG2833 in up to 40 subjects. This study will also evaluate the pharmacodynamic response of various biomarkers in peripheral blood to 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, will provide seven years of marketing exclusivity in the United States following NDA approval.

### **DcpS Inhibitors for Spinal Muscular Atrophy**

We are pursuing development of a drug that targets the scavenger mRNA decapping enzyme, DcpS, for treatment of patients with spinal muscular atrophy ( SMA ). Our inhibitors have the potential to be the first in class treatment for this disease. 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.

On October 22, 2009, we entered into an exclusive worldwide commercial license agreement ( 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 financial obligations under this agreement, including milestone payments, sublicense fees, and other charges, could total approximately \$16,000,000.

Repligen's compounds, known as DcpS inhibitors, increase the production of SMN in preclinical studies of cells derived from patients. Further preclinical testing of these compounds in models of SMA has demonstrated significantly increased survival, suggesting potential clinical utility. Repligen is currently evaluating a lead DcpS inhibitor in preclinical studies for future clinical trials in patients with SMA.

### **Sales and Marketing**

We sell our bioprocessing products primarily through value-added resellers such as GEHC as well as through distributors in certain foreign markets. Prior to its discontinuation in the second quarter of fiscal year 2009, we marketed SecreFlo® directly to hospital-based gastroenterologists in the United States.

### **Significant Customers and Geographic Reporting**

Customers for our bioprocessing products include chromatography companies, diagnostics companies, biopharmaceutical companies and laboratory researchers. In April 2008, we settled our litigation with Bristol regarding their sales of Orenicia® for which we now receive a royalty. For fiscal years 2010 and 2009, royalty revenue from Bristol represented 43% and 46% of total revenues, respectively. Our largest bioprocessing customer accounted for 36%, 36% and 72% of total revenues in fiscal years 2010, 2009 and 2008, respectively. In fiscal year 2008, another bioprocessing customer also represented 16% of total revenue.

In fiscal years 2010, 2009 and 2008, total revenues from sales to customers in the United States were approximately 57%, 59% and 32%, respectively. During the same fiscal periods, total revenues generated through sales to customers in Sweden were 36%, 37% and 61%, respectively.

### **Employees**

As of May 6, 2010, we had 68 employees. Of those employees, 50 were engaged in research, development and manufacturing and 18 were in administrative and marketing functions. Thirty-one of our employees hold doctorates or other advanced degrees. Each of our employees has signed a confidentiality agreement. None of our employees are covered by collective bargaining agreements.

## **Table of Contents**

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

Repligen actively pursues patent protection in the United States and in major countries abroad and believes that patents are an important element in the protection of our competitive and proprietary position. Other forms of protection, including trade secrets, orphan drug status and know-how, are also considered important elements of our proprietary strategy. 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. For each of our license agreements where we license the rights to patents or patent applications, the license will terminate on the day that the last to expire patent covered by each such license agreement expires.

We also rely upon trade secret protection for our confidential and proprietary information. Our policy is to require each of our employees, consultants, business partners and significant scientific collaborators to execute confidentiality agreements upon the commencement of an employment, consulting or business relationship with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's 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 was issued in February 2004, covering the use of CTLA4-Ig to treat specific autoimmune disorders including rheumatoid arthritis and multiple sclerosis. 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 (see Legal Proceedings ).

#### **Uridine**

In 2009, Repligen entered into an exclusive license agreement with McLean Hospital for the worldwide rights to an internationally filed patent application which covers the use of uridine in the treatment of patients with bipolar disorder. Repligen has recently received a Notice of Allowance from the U.S. Patent and Trademark Office for this patent which, upon issue, will remain in force until 2025 prior to any regulatory extensions. Under the terms of the license agreement, McLean received an upfront payment, and is eligible to receive payments upon certain product development milestones and royalties upon successful commercialization of uridine for bipolar disorder. Foreign equivalents of this patent are being prosecuted outside of the United States.

#### **Protein A**

We own a broad U.S. patent covering recombinant Protein A, which expired in September 2009, as well as significant know-how in the manufacture of high-purity Protein A. We recently 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 will remain in effect until 2028. Foreign equivalents of this patent are being prosecuted outside of the United States.

#### **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 ( HDAC ). We have identified the specific HDAC that is the target of these inhibitors and have filed additional patent applications claiming methods and compositions for treating Friedreich's ataxia. These patent applications are currently being prosecuted in the United States and abroad.

## **Table of Contents**

### **Spinal Muscular Atrophy**

In 2009, Repligen entered into an exclusive license agreement with a non-profit organization, the Families of Spinal Muscular Atrophy ( 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. Repligen is prosecuting these patent applications in the U.S. and abroad.

### **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.

### **Manufacturing**

#### **Protein A for Antibody Manufacturing**

We manufacture Protein A bioprocessing products from recombinant strains of bacteria. We manufacture Protein A for GEHC under a supply agreement which extends through 2015. 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 facility and third parties to carry out certain fermentation and recovery operations, while the purification, immobilization, packaging and quality control testing of our Protein A bioprocessing products are conducted at our facilities. We are ISO 9001 certified and utilize a formal quality system to maintain process control, traceability, and product conformance. We also practice continuous improvement initiatives based on routine internal audits, customer feedback and audits performed by our partners and customers. In addition, our business continuity management system 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 will continue to rely for at least the next few years, 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 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 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.

## **Table of Contents**

### **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 Investigational New Drug application 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.

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 annual report on Form 10-K. We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the Securities and Exchange Commission. Our Code of Business Conduct and Ethics is also available free of charge through our website.

In addition, the public may read and copy any materials that we file with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. Also, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at [www.sec.gov](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 annual report on Form 10-K contains forward looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this annual report on Form 10-K.*

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

We conduct some of our development activities, and conduct most of our commercialization activities, through collaborations. These collaborations include academic researchers as well as contracts with vendors. Our collaborations are heavily dependent on the efforts and activities of our collaborative 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 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 development and/or commercialization of our products.

**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. 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.

**Our research activities may not identify a clinical candidate with appropriate efficacy, safety and pharmacology to support clinical trials in humans.**

In order to conduct phase 1 clinical trials in humans, we must first demonstrate suitable efficacy, safety and pharmacology characteristics of any potential drug candidates. If we are unsuccessful in these efforts, we may be forced to identify alternative drug candidates at substantial cost, or possibly abandon certain pre-clinical research activities.

## **Table of Contents**

### **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 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 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.

### **Even if we obtain marketing approval, our 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

## **Table of Contents**

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 third parties. Such litigation could result in substantial cost to us and diversion of our resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on our business, financial condition and results of operations.

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





---

## **Table of Contents**

**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 unfavorably 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.

For more information about the legal proceedings in which we were involved but which have been settled, please see [Legal Proceedings](#).

**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 collaborations with collaborative partners. Therefore, any disputes with such partners that lead to

## **Table of Contents**

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.

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

We have limited sales, marketing and distribution experience and capabilities. 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.

If in the future we determine to perform sales, marketing and distribution functions ourselves, 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.

### **We have limited pharmaceutical manufacturing capabilities and will 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 which are capable of and/or 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 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

## **Table of Contents**

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.

### **The market may not be receptive to our products upon their introduction.**

The commercial success of our therapeutic products that are approved for marketing will depend upon their acceptance by the medical community and third party payors as being clinically useful, cost effective and safe. 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.

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

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; and

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

### **Healthcare reform measures could adversely affect our business.**

The efforts of governmental and third-party payors to contain or reduce the costs of healthcare may adversely affect the business and financial condition of pharmaceutical and biotechnology companies. 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 has just passed the America Affordable Health Choices Act of 2009 and is considering a number of proposals that are intended to reduce or limit the growth of health care costs and which could significantly transform the market for pharmaceuticals products. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or 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 Repligen's common stock or limit our ability to raise capital or to enter into collaborations or license rights to our products.

### **We compete with 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. Pharmaceutical and biotechnology companies may have substantially greater financial, manufacturing, marketing, and research and development resources than we have. New approaches by these competitors may make our products and technologies obsolete or noncompetitive.

---

**Table of Contents**

**We 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 a loss for fiscal 2010 and we expect to incur operating losses for the foreseeable 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 Oncia<sup>®</sup> product in the United States, this revenue may not be sufficient to cover the costs of our clinical trials and drug development programs. We plan to continue to invest in key research and development activities. 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. 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.

**Our stock price could be volatile, which could cause you to lose part or all of your 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.

**Provisions in our certificate of incorporation and by-laws and of Delaware law may prevent or delay an acquisition of our Company, which could decrease the trading price of our common stock.**

Our certificate of incorporation, by-laws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirors to negotiate with our Board of Directors rather than to attempt a hostile takeover. These provisions include our Board of Directors' ability to issue preferred stock without stockholder approval and Delaware law's various restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock. In addition, we maintain a shareholder rights plan which may deter a potential acquiror from pursuing an offer for our company.

We believe these provisions protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board of Directors and by providing our Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our Board of Directors determines is not in the best interests of our company and our stockholders.

**Table of Contents****Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 2. PROPERTIES**

We lease 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. In addition, we lease approximately 10,000 square feet of space at a second location in Waltham for expanded manufacturing and administrative operations. Both of these leases expire in 2012. During fiscal 2010, we incurred total rental costs for both facilities of approximately \$689,000.

**Item 3. LEGAL PROCEEDINGS*****ImClone Systems***

In May 2004, Repligen and the Massachusetts Institute of Technology ( MIT ) filed an action in the United States District Court for the District of Massachusetts against ImClone Systems, Incorporated ( ImClone ) for infringement of U.S. Patent No. 4,663,281 (the 281 patent ) based on ImClone s manufacture and sale of Erbitu®. The 281 patent, which covers the use of certain genetic elements that increase protein production in a mammalian cell, is assigned to MIT and exclusively licensed to Repligen.

On September 10, 2007, the Company and MIT entered into a settlement agreement (the ImClone Settlement ) with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the ImClone Settlement, ImClone made a payment of \$65 million to Repligen and MIT that resulted in net proceeds to Repligen of \$40.17 million, as follows:

Gross proceeds from ImClone Settlement agreement	\$ 65,000,000
Less: Amounts paid to MIT	(11,000,000)
Less: Legal fees and other costs	(13,830,000)
 Net gain on litigation settlement	 \$ 40,170,000

The ImClone Settlement served as the basis for the Company and MIT to dismiss the lawsuit against ImClone and for the Company to grant ImClone a non-exclusive sublicense to the 281 patent and certain other intellectual property. There are no further obligations to the Company with respect to the sublicenses. The net gain on the litigation settlement was recorded as a separate component of operating expenses in the Company s statement of operations in fiscal 2008.

***Bristol-Myers Squibb Company***

In January 2006, Repligen and the University of Michigan jointly filed a complaint against Bristol in the United States District Court for the Eastern District of Texas for infringement of U.S. Patent No. 6,685,941 (the 941 patent ) for the commercial sale of Orencia®. The 941 patent, entitled Methods of Treating Autoimmune Disease via CTLA4-Ig, covers methods of using CTLA4-Ig to treat rheumatoid arthritis, as well as other therapeutic methods. Repligen has exclusive rights to this patent from its owners, the University of Michigan and the U.S. Navy. In February 2006, Bristol answered the complaint and counterclaimed seeking a declaratory judgment that the 941 patent is invalid and unenforceable and that Bristol does not infringe the patent.

On April 7, 2008, Repligen and the University of Michigan entered into a settlement agreement (the Bristol Settlement ) with Bristol relating to the lawsuit against Bristol for infringement of the 941 patent. Pursuant to the Bristol Settlement, Bristol made an initial payment of \$5 million to Repligen. The Bristol Settlement further 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%

**Table of Contents**

of annual net sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013. The Bristol Settlement served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against Bristol and for Repligen and the University of Michigan to grant to Bristol an exclusive license to the 941 patent and certain other intellectual property. Repligen has no continuing obligations to Bristol as a result of this settlement. Pursuant to the Bristol Settlement, Repligen has recognized \$8,980,000 and \$13,383,000 in fiscal years 2010 and 2009, respectively. The \$9.0 million recognized in fiscal year 2010 was for sales of Orencia® from January 1, 2009 through December 31, 2009. The \$13.4 million recognized in fiscal year 2009 was comprised of a \$5 million initial payment, \$1.3 million for sales of Orencia® from January 1, 2008 through December 31, 2008, and \$7.1 million for sales in fiscal year 2009 (see Note 2).

Repligen must also remit to the University of Michigan 15% of all royalty revenue received from Bristol, after deducting certain legal and other costs incurred related to the Bristol Settlement. Repligen incurred approximately \$6.1 million in such legal costs. Royalty expense for fiscal years 2010 and 2009 was \$1,347,000 and \$1,091,000, respectively. This operating expense has been included on the statements of operations under the line item Cost of royalty and other revenue.

***Other***

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. (REMOVED AND RESERVED)**

**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 table.

	<b>Fiscal Year 2010</b>		<b>Fiscal Year 2009</b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 5.50	\$ 3.92	\$ 6.23	\$ 4.72
Second Quarter	\$ 5.55	\$ 4.96	\$ 5.58	\$ 4.51
Third Quarter	\$ 5.13	\$ 3.74	\$ 4.78	\$ 3.30
Fourth Quarter	\$ 4.06	\$ 3.35	\$ 4.79	\$ 3.56

**Stockholders and Dividends**

As of June 2, 2010, there were approximately 666 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.

**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 twelve-month period ended March 31, 2009, the Company repurchased 492,827 shares of common stock, for an aggregate purchase price of \$1,969,240, leaving 757,173 shares remaining under this authorization.

**Table of Contents**

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 FINANCIAL DATA**

The following selected financial data are derived from the audited financial statements of Repligen. The selected financial data set forth below should be read in conjunction with our financial statements and the related notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report and our Annual Report on Form 10-K for the years ended March 31, 2009, 2008, 2007 and 2006.

	2010	2009	Years ended March 31,		2006
			2008	2007	
	(In thousands except per share amounts)				
<b>Revenue:</b>					
Product revenue	\$ 10,305	\$ 14,529	\$ 18,587	\$ 13,074	\$ 12,529
Royalty and other revenue	10,666	14,833	709	1,000	382
Total revenue	20,971	29,362	19,296	14,074	12,911
<b>Operating expenses:</b>					
Cost of product revenue	4,159	5,686	6,160	3,615	3,551
Cost of royalty and other revenue	1,347	1,091			
Research and development	14,160	12,772	7,241	5,924	5,163
Selling, general and administrative	7,072	5,933	10,173	6,360	5,417
Net gain from litigation settlement			(40,170)		
Total operating expenses	26,738	25,482	(16,596)	15,899	14,131
(Loss) income from operations	(5,767)	3,880	35,892	(1,825)	(1,220)
Interest expense	(2)	(3)	(9)	(11)	(3)
Investment income	870	1,896	2,051	947	750
Other income					1,170
(Loss) income before taxes	(4,899)	5,773	37,934	(889)	697
Income tax (benefit) provision	(835)	27	827		
Net (loss) income	\$ (4,064)	\$ 5,746	\$ 37,107	\$ (889)	\$ 697
<b>Earnings per share:</b>					
Basic	\$ (0.13)	\$ 0.19	\$ 1.20	\$ (0.03)	\$ 0.02
Diluted	\$ (0.13)	\$ 0.18	\$ 1.18	\$ (0.03)	\$ 0.02
<b>Weighted average shares outstanding:</b>					
Basic	30,752	30,958	30,834	30,379	30,125
Diluted	30,752	31,290	31,321	30,379	30,691
	2010	2009	As of March 31,		2006
			2008	2007	
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash and marketable securities (1)	\$ 59,146	\$ 63,961	\$ 60,589	\$ 22,627	\$ 23,408
Working capital	55,024	50,235	49,831	22,394	18,575
Total assets	71,420	73,755	68,840	29,076	28,599
Long-term obligations	642	82	143	200	231
Accumulated deficit	(117,921)	(113,857)	(120,577)	(157,683)	(156,794)
Stockholders' equity	66,120	69,123	64,107	25,538	25,433

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

**Overview**

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies that harness biological pathways and deliver value to patients and clinicians in neurology, gastroenterology and orphan diseases. We are currently conducting a number of drug development programs for diseases such as pancreatitis, bipolar disorder, Friedreich's ataxia and spinal muscular atrophy. We also have a bioprocessing business that focuses on the development and commercialization of products that are used for the production of biopharmaceuticals. In addition, we receive royalties from Bristol-Myers Squibb Company (Bristol) on their net sales in the United States of their product Orenicia®. Total revenue in fiscal 2010 decreased significantly as compared to fiscal 2009 due to a decrease in our bioprocessing product sales as we experienced lower customer demand for our Protein A products due to the current economic environment and a one-time royalty payment from Bristol recognized as revenue in the prior year. We seek to invest the profits from our current commercial products and royalty and other revenues, as well as use our existing financial resources, to advance the development of our therapeutic product candidates and our bioprocessing 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 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 and Results of Operations 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 pharmaceutical and process chromatography 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 product delivered, and the collectability of those fees. We have a few longstanding customers who comprise the majority of revenue and have excellent payment history and therefore we do not require collateral. We have had no significant write-offs of uncollectible invoices in the periods presented.

**Table of Contents**

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 in fiscal year 2009 for Bristol's net sales in the United States of Orencia® which is used in the treatment of rheumatoid arthritis. Pursuant to the Bristol Settlement, we recognized \$13,383,000 in royalty revenue in fiscal 2009, which included a \$5.0 million initial payment and \$1.3 million for sales of Orencia® prior to fiscal 2009, in addition to royalties earned on sales of Orencia® during our fiscal 2009. We recognized \$8,980,000 in royalty revenue for sales of Orencia® in fiscal 2010. 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.

Additionally, during fiscal years 2010, 2009 and 2008, we earned and recognized approximately \$1,009,000, \$776,000 and \$244,000, respectively in royalty revenue from ChiRhoClin for their sales of secretin. Revenue earned from ChiRhoClin royalties is recorded in the periods when it is earned based on royalty reports sent by ChiRhoClin to us. As of December 31, 2009, ChiRhoClin has fulfilled its royalty obligations to us for its sales of secretin. We do not expect to recognize any further royalty revenue from ChiRhoClin.

In fiscal 2010, we recognized \$552,000 and \$125,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association (MDA) and jointly with the Friedreich's Ataxia Research Alliance and the National Ataxia Foundation, respectively. During fiscal 2009, we recognized approximately \$564,000 and \$110,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association (MDA) and Comitato RUDI onlus GoFAR (GoFAR), respectively. During the fiscal year ended March 31, 2008, we recognized \$365,000 of revenue from a sponsored research and development project under an agreement with the Stanley Medical Research Institute.

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 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.

**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 twelve 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.

## **Table of Contents**

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 financial statements, there have been no material adjustments related to a revised estimate of inventory valuations.

### **Business Combinations**

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

### **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 which have been incurred as of each reporting date;

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 which 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 are often judgmental. 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. The

**Table of Contents**

expected life of stock options granted is based on the simplified method. 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 its employees. The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determined the expected volatility based upon the historical volatility of our common stock over a period commensurate with the option's expected term, exclusive of any events not reasonably anticipated to recur over the option's expected term. The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date. We have never declared or paid any cash dividends on any of our capital stock and do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

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

For the years ended March 31, 2010, 2009 and 2008, we recorded stock-based compensation expense of approximately \$1,007,000, \$823,000 and \$524,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the "2001 Plan").

As of March 31, 2010, there was \$1,919,119 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 3.11 years. We expect 823,294 in 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 financial statements and the related footnotes thereto.

**Revenues**

Total revenues for fiscal 2010, 2009 and 2008 were \$20,971,000, \$29,362,000, and \$19,296,000, respectively, and were primarily comprised of sales of our bioprocessing products and royalties. Our total revenue was comprised of:

	Year ended March 31,			% Change	
	2010	2009	2008	2010 vs. 2009	2009 vs. 2008
	(in thousands, except percentages)				
Bioprocessing	\$ 10,305	\$ 14,361	\$ 16,321	(28%)	(12%)
SecreFlo®		168	2,266	(100%)	(93%)
Product revenue	\$ 10,305	\$ 14,529	\$ 18,587	(29%)	(22%)
Royalty and other revenue	10,666	14,833	709	(28%)	1992%
Total revenue	\$ 20,971	\$ 29,362	\$ 19,296	(29%)	52%

---

**Table of Contents**

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.

During fiscal 2010, bioprocessing product sales decreased by \$4,056,000 or 28% as compared to fiscal 2009. Volume decreased 26% due to decreased demand from certain key customers in reaction to current economic conditions and other business events. Changes in the mix of products sold in fiscal 2010 as compared to fiscal 2009 comprised the remaining 2% decrease. We sell various 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 fiscal 2009, bioprocessing product sales decreased by \$1,960,000 or 12% as compared to fiscal 2008. Volume decreased 5% due to decreased demand from certain key customers in reaction to the current credit crisis and other business events. Changes in the mix of products sold in fiscal 2009 as compared to fiscal 2008 comprised the remaining 7% decrease.

We anticipate that bioprocessing product sales will increase in fiscal 2011 as our customers respond to an anticipated economic recovery during the year. In addition, our bioprocessing product sales may be subject to quarterly fluctuations due to the timing of large-scale production orders.

Sales of SecreFlo® decreased \$2,098,000 in fiscal 2009 as we discontinued selling this product in the second quarter of fiscal 2009. The settlement in fiscal 2005 with our sole supplier of SecreFlo®, ChiRhoClin, provided for a certain amount of vials of product that we could ultimately ship. The final shipment of SecreFlo® to us from ChiRhoClin was received in fiscal 2008 and we discontinued selling SecreFlo® in the second quarter of fiscal 2009.

Pursuant to the Bristol Settlement (as defined in Note 10), we recognized royalty revenue of approximately \$8,980,000 and \$13,383,000 in fiscal years 2010 and 2009, respectively. The \$13,383,000 recognized in fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia® from January 1, 2008 to March 31, 2008, as well as \$7.1 million for sales in fiscal year 2009. For fiscal 2011, we expect royalty revenues to increase moderately over fiscal 2010 as Bristol's Orencia continues to penetrate the market.

Also, during fiscal years 2010, 2009 and 2008, we earned and recognized approximately \$1,009,000, \$776,000 and \$244,000, respectively, in royalty revenue from ChiRhoClin. As of December 31, 2009, ChiRhoClin has fulfilled its royalty obligations to us for its sales of our secretin. We do not expect to recognize any further royalty revenue from ChiRhoClin.

In fiscal 2010, we recognized \$552,000 and \$125,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association (MDA) and jointly with the Friedreich's Ataxia Research Alliance and the National Ataxia Foundation, respectively. During fiscal 2009, we recognized approximately \$564,000 and \$110,000 of revenue from sponsored research and development projects under agreements with the MDA and Comitato RUDI onlus GoFAR (GoFAR), respectively. During the fiscal year ended March 31, 2008, we recognized \$365,000 of revenue from a sponsored research and development project under an agreement with the Stanley Medical Research Institute.

We expect research and license revenues will remain relatively consistent in fiscal 2011 as the MDA grant related effort continues.

**Table of Contents****Costs and operating expenses**

Total costs and operating expenses for fiscal 2010, 2009 and 2008 consist of the following:

(In thousands)	Year ended March 31,			% Change	
	2010	2009	2008	2010 vs. 2009	2009 vs. 2008
Costs and operating expenses:					
Cost of product revenue	\$ 4,159	\$ 5,686	\$ 6,160	(27%)	(8%)
Cost of royalty and other revenue	1,347	1,091		23%	
Research and development	14,160	12,772	7,241	11%	76%
Selling, general and administrative	7,072	5,933	10,173	19%	(42%)
Net gain from litigation settlement			(40,170)		
<b>Total costs and operating expenses</b>	<b>\$ 26,738</b>	<b>\$ 25,482</b>	<b>\$ (16,596)</b>	<b>5%</b>	<b>254%</b>

The decrease in cost of product revenue of \$1,527,000 or 27% in fiscal 2010 as compared to fiscal 2009 is primarily due to a 29% decrease in bioprocessing product sales as well as favorable manufacturing variances. This decrease is partially offset by higher depreciation costs of approximately \$156,000 related to investments in our manufacturing facilities.

The decrease in cost of product revenue of \$474,000 or 8% in fiscal 2009 as compared to fiscal 2008 was primarily due to a 12% decrease in bioprocessing sales. This decrease was partially offset by increased direct labor costs of approximately \$193,000 due primarily to additional quality assurance and control personnel hired to meet growing customer demand for increased product quality assurance efforts and to support ISO 9001 certification. It was also partially offset by higher depreciation and occupancy costs of approximately \$357,000 primarily associated with our manufacturing and administrative expansion at a second site located in Waltham, MA.

Pursuant to the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the agreement in December 2013, after deducting certain allowable legal and other costs, to the University of Michigan. For fiscal 2010 and 2009, this cost of royalty revenue was approximately \$1,347,000 and \$1,091,000, respectively. This increase is directly related to the increase in Bristol royalty revenue 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. We currently have ongoing clinically enabled research and development programs that support our secretin and uridine product candidates. In addition, we are pursuing pre-clinical activities in Friedreich's ataxia and spinal muscular atrophy that may or may not be further developed. 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 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 date of these programs.

These risks and uncertainties also 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



---

**Table of Contents**

expenses tend to increase in later stages of development. Collaborations with commercial vendors and academic researchers accounted for 51%, 59%, and 45% of our research and development expenses for fiscal 2010, 2009, and 2008, respectively. The outsourcing of such services provides us flexibility to discontinue or increase spending depending on the success of our research and development programs.

During fiscal 2010, research and development expenses increased by \$1,388,000 or 11% as compared to fiscal 2009. This increase is comprised primarily of 1) \$909,000 related to our new DcpS program to develop a drug for the treatment of patients with spinal muscular atrophy, 2) \$891,000 related to Friedreich's ataxia as we identified a clinical candidate and began preparing for a phase 1 clinical trial and 3) \$236,000 related to increased personnel expenses primarily due to headcount additions in clinical and regulatory areas. These increases were partially offset by a \$746,000 decrease as we approached the end of our phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging.

During fiscal 2009, research and development expenses increased by \$5,531,000 or 76% as compared to fiscal 2008. This increase was comprised primarily of 1) \$1,869,000 related to the continued phase 3 clinical trial for RG1068, evaluating the use of human secretin in pancreatic imaging, 2) \$1,500,000 related to the phase 2b clinical trial for RG2417, evaluating the use of uridine to treat bipolar depression and 3) \$1,388,000 related to Friedreich's ataxia as we continued to search for a clinical candidate. Additionally, there were increased personnel expenses of \$724,000 primarily due to headcount additions in clinical, regulatory and research and development areas.

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 fiscal 2011 to decrease moderately primarily due to the secretin clinical trial ending in fiscal 2010, the timing of certain expenditures associated with our Friedreich's ataxia program for which we recently filed an IND application with the FDA, partially offset by increased spending on our DcpS program for treatment of patients with spinal muscular atrophy. In addition, we will have a re-analysis performed on the images obtained from our Phase 3 clinical trial for secretin to improve pancreatic diagnostic imaging and anticipate that preliminary results will be available by the end of fiscal year 2011, ending on March 31, 2011. We will continue our Phase 2b clinical trial for uridine to treat bipolar depression and anticipate that preliminary results will also be available by the end of fiscal year 2011. There may be further increases in expenses if we acquire additional product candidates.

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

In fiscal 2010, SG&A costs increased by \$1,139,000 or 19% as compared to fiscal 2009. This increase is primarily due to increased personnel expenses of \$1,001,000 primarily due to headcount increases in marketing and business development including salaries and stock-based compensation.

During fiscal 2009, SG&A costs decreased by \$4,240,000 or 42% as compared to fiscal 2008. This decrease is primarily due to \$4,841,000 of litigation costs incurred in fiscal 2008 relating to the Bristol and ImClone settlements, and a \$238,000 decrease in recruiting and relocation costs as certain key board and management positions were filled in fiscal 2008. These decreases are partially offset by increased personnel expenses of \$899,000 primarily due to headcount increases in marketing and business development including salaries and stock-based compensation.

We expect SG&A expenses to increase moderately in fiscal 2011 primarily due to slightly higher headcount and related personnel expenses.

**Table of Contents****Net gain from litigation settlement**

On September 10, 2007, Repligen and MIT entered into the ImClone Settlement relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the ImClone Settlement, ImClone made a payment of \$65 million to Repligen and MIT that resulted in net proceeds to Repligen of \$40,170,000 after litigation costs of \$13,830,000 and proceeds to MIT of \$11,000,000. The ImClone Settlement served as the basis to dismiss the lawsuit against ImClone and for Repligen to grant ImClone a non-exclusive sublicense to the 281 patent and certain other intellectual property.

**Investment income**

Investment income includes income earned on invested cash balances. Investment income for fiscal 2010, 2009 and 2008 was approximately \$870,000, \$1,896,000 and \$2,051,000, respectively. The decrease of \$1,026,000 or 54% in fiscal 2010 compared to fiscal 2009 and the decrease of \$155,000 or 8% in fiscal 2009 compared to fiscal 2008 are primarily attributable to lower interest rates resulting from overall economic conditions. We expect interest income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

**Benefit from income taxes**

In fiscal year 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 we expect will enable 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, 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 March 31, 2010, we had cash and marketable securities of \$59,146,000 compared to \$63,961,000 at March 31, 2009. Deposits for leased office space of \$200,000 is classified as restricted cash and is not included in cash and marketable securities total for either 2010 or 2009.

**Cash flows**

(In thousands)	Year ended March 31,				
	2010	Increase / (Decrease)	2009	Increase / (Decrease)	2008
<b>Cash provided by (used in)</b>					
Operating activities	\$ (2,448)	\$ (8,755)	\$ 6,307	\$ (32,160)	\$ 38,467
Investing activities	9,921	42,153	(32,232)	(18,003)	(14,229)
Financing activities	12	1,608	(1,596)	(2,194)	598
<b>Operating activities</b>					

In fiscal 2010, our operating activities consumed \$2,448,000 of cash which reflects a net loss of approximately \$4,064,000 and non-cash charges totaling approximately \$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.



Edgar Filing: REPLIGEN CORP - Form 10-K

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

our ability to acquire additional products or product candidates;

---

**Table of Contents**

the extent of any share repurchase activity;

the success of any proposed financing efforts; and

the ability to sustain sales and profits of our bioprocessing products; 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 twenty-four months. We expect to incur moderately increased expenses in fiscal 2011 compared to fiscal 2010. This is primarily due to increases in cost of product revenue associated with higher anticipated product revenue, increased personnel expenses, offset by moderately lower research and development costs. 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 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**

At March 31, 2010, we had net operating loss carryforwards of approximately \$63,903,000 and business tax credits carryforwards of approximately \$2,118,000 available to reduce future federal income taxes, if any. Additionally, at March 31, 2010, we had net operating loss carryforwards of approximately \$3,061,000 and business tax credits carryforwards of approximately \$5,615,000 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 March 2030. 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.

In fiscal year 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 will enable us to receive a refund of \$835,000 for alternative minimum taxes paid in prior years. In fiscal 2009 and 2008, we utilized our net operating loss carryforwards to reduce our income tax provision.

**Effects of inflation**

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

---

**Table of Contents****Recent accounting pronouncements**

In October 2009, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2009-13, *Multiple-Deliverable Arrangements a consensus of the FASB Emerging Issues Task Force* ( ASU 2009-13 ). This ASU establishes the accounting and reporting guidance for arrangements under which a vendor will perform multiple revenue-generating activities. Specifically, the provisions of this update address how to separate deliverables and how to measure and allocate arrangement consideration to one or more units of accounting. This update is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We have not yet completed our evaluation of ASU 2009-13, but we do not currently believe that adoption will have a material impact on our results of operations, financial position or cash flows.

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* ( ASU 2010-06 ). This ASU requires new disclosures and clarifies some existing disclosure requirements about fair value measurements codified within ASC 820, Fair Value Measurements and Disclosures, including significant transfers into and out of Level 1 and Level 2 investments of the fair value hierarchy. ASU 2010-06 also requires additional information in the roll forward of Level 3 investments including presentation of purchases, sales, issuances, and settlements on a gross basis. Further clarification for existing disclosure requirements provides for the disaggregation of assets and liabilities presented, and the enhancement of disclosures around inputs and valuation techniques. This update is effective for the first interim or annual reporting period beginning after December 15, 2009, except for the additional information in the roll forward of Level 3 investments. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim reporting periods within those fiscal years. We adopted ASU 2010-06 in January 2010. The adoption of this update did not have a material impact on our results of operations, financial position or cash flows.

In April 2010, the FASB issued ASU No. 2010-17, *Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force* ( ASU 2010-17 ). This ASU provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. We have not yet completed our evaluation of ASU 2010-17, but we do not currently believe that adoption will have a material impact on our results of operations, financial position or cash flows.

---

**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 \$254,000 decrease in the fair value of our investments as of March 31, 2010. 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. We intend to hold the majority of our investments to maturity, in accordance with our business plans.

**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 in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

*(b) Management's Annual Report on Internal Control Over Financial Reporting.*

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

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

**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.

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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of March 31, 2010. 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). Based on this assessment, our management concluded that, as of March 31, 2010, our internal control over financial reporting is effective based on those criteria. Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this annual report on Form 10-K, has issued an attestation report on our internal control over financial reporting as of March 31, 2010. Please see Item 9A of this Form 10-K.

/s/ REPLIGEN CORPORATION

June 10, 2010



---

**Table of Contents**

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

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Repligen Corporation:

We have audited Repligen Corporation's internal control over financial reporting as of March 31, 2010, 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.

In our opinion, Repligen Corporation maintained, in all material respects, effective internal control over financial reporting as of March 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Repligen Corporation as of March 31, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2010 of Repligen Corporation and our report dated June 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

June 10, 2010

**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 March 31, 2010 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 2010 Annual Meeting of Stockholders.

**Table of Contents****PART IV****Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

(a) (1) *Financial Statements:*

The financial statements required by this item are submitted in a separate section beginning on page 38 of this Report, as follows:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	46
<u>Balance Sheets as of March 31, 2010 and 2009</u>	47
<u>Statements of Operations for the Years Ended March 31, 2010, 2009 and 2008</u>	48
<u>Statements of Stockholders' Equity for the Years Ended March 31, 2010, 2009 and 2008</u>	49
<u>Statements of Cash Flows for the Years Ended March 31, 2010, 2009 and 2008</u>	50
<u>Notes to Financial Statements</u>	51

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

None.

(a) (3) *Exhibits:*

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

**EXHIBIT INDEX**

<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	Certificate of Designation of Series A Junior Participating Preferred Stock dated March 4, 2003 (filed as Exhibit A of Exhibit 1 to Repligen Corporation's Registration Statement on Form 8-A filed March 4, 2003 and incorporated herein by reference) (SEC File No. 000-14656).
3.3	Amended and Restated By-laws (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).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
4.2	Rights Agreement, dated as of March 3, 2003, between Repligen Corporation and American Stock Transfer & Trust Company (filed as Exhibit 4.1 to Repligen Corporation's Current Report on Form 8-K filed March 4, 2003 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).



**Table of Contents**

<b>Exhibit Number</b>	<b>Document Description</b>
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 Second Amended and Restated 2001 Repligen Corporation Stock Option Plan, Form of Incentive Stock Option Plan (filed as Exhibit 10.14 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2005 and incorporated herein by reference).
10.8.2*	The Amended and Restated 2001 Repligen Corporation Stock Plan, Form of Restricted Stock Agreement (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on January 9, 2006 and incorporated herein by reference).
10.9	Common Stock Purchase Warrant dated April 6, 2007 (filed as Exhibit 4.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 and incorporated herein by reference).
10.10#	Manufacturing Transfer Agreement dated as of December 17, 1998 among the Company and Amersham Pharmacia Biotech AB (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 1998 and incorporated herein by reference) (SEC File No. 000-14656).
10.11#	License Agreement dated as of July 24, 2000 with University of Michigan (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 and incorporated herein by reference) (SEC File No. 000-14656).
10.12	Lease Between Repligen Corporation as Tenant and West Seyon LLC as Landlord, 35 Seyon Street, Waltham, MA (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2001 and incorporated herein by reference) (SEC File No. 000-14656).
10.13#	Settlement Agreement by and between ChiRhoClin, Inc. and Repligen Corporation, and dated as of May 9, 2005 (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference).

**Table of Contents**

<b>Exhibit Number</b>	<b>Document Description</b>
10.14#	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).
10.15#	Settlement Agreement and Releases dated September 10, 2007 by and among Repligen Corporation, Massachusetts Institute of Technology and ImClone Systems Incorporated (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
10.16#	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).
10.17#+	Strategic Supplier Alliance Agreement dated January 28, 2010 by and between Repligen Corporation and GE Healthcare Bio-Sciences AB.
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.

# Confidential treatment obtained as to certain portions.

\* Management contract or compensatory plan or arrangement.

+ Filed herewith.

The exhibits listed above are not contained in the copy of the Annual Report on Form 10-K distributed to stockholders. Upon the request of any stockholder entitled to vote at the 2010 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: June 10, 2010

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 <b>Walter C. Herlihy, Ph.d.</b>	President, Chief Executive Officer and Director (Principal executive officer)	June 10, 2010
/s/ WILLIAM J. KELLY <b>William J. Kelly</b>	Chief Financial Officer (Principal financial and accounting officer)	June 10, 2010
/s/ ALEXANDER RICH <b>Alexander Rich, M.D.</b>	Chairman of the Board	June 10, 2010
/s/ KAREN DAWES <b>Karen Dawes</b>	Director	June 10, 2010
/s/ ALFRED L. GOLDBERG <b>Alfred L. Goldberg, Ph.D.</b>	Director	June 10, 2010
/s/ EARL W. HENRY <b>Earl W. Henry, M.D.</b>	Director	June 10, 2010



Edgar Filing: REPLIGEN CORP - Form 10-K

/s/ THOMAS F. RYAN, JR.

Director

June 10, 2010

**Thomas F. Ryan, Jr.**

/s/ GLENN L. COOPER

Director

June 10, 2010

**Glenn L. Cooper, M.D.**

**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	Certificate of Designation of Series A Junior Participating Preferred Stock dated March 4, 2003 (filed as Exhibit A of Exhibit 1 to Repligen Corporation's Registration Statement on Form 8-A filed March 4, 2003 and incorporated herein by reference) (SEC File No. 000-14656).
3.3	Amended and Restated By-laws (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).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
4.2	Rights Agreement, dated as of March 3, 2003, between Repligen Corporation and American Stock Transfer & Trust Company (filed as Exhibit 4.1 to Repligen Corporation's Current Report on Form 8-K filed March 4, 2003 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 Second Amended and Restated 2001 Repligen Corporation Stock Option Plan, Form of Incentive Stock Option Plan (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#	Settlement Agreement by and between ChiRhoClin, Inc. and Repligen Corporation, and dated as of May 9, 2005 (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference).
10.14#	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).
10.15#	Settlement Agreement and Releases dated September 10, 2007 by and among Repligen Corporation, Massachusetts Institute of Technology and ImClone Systems Incorporated (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
10.16#	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).
10.17#+	Strategic Supplier Alliance Agreement dated January 28, 2010 by and between Repligen Corporation and GE Healthcare Bio-Sciences AB.
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.

# Confidential treatment obtained as to certain portions.

\* Management contract or compensatory plan or arrangement.

+ Filed herewith.

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	46
<u>Balance Sheets as of March 31, 2010 and 2009</u>	47
<u>Statements of Operations for the Years Ended March 31, 2010, 2009 and 2008</u>	48
<u>Statements of Stockholders' Equity for the Years Ended March 31, 2010, 2009 and 2008</u>	49
<u>Statements of Cash Flows for the Years Ended March 31, 2010, 2009 and 2008</u>	50
<u>Notes to Financial Statements</u>	51

**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 balance sheets of Repligen Corporation as of March 31, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 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 financial position of Repligen Corporation at March 31, 2010 and 2009, and the results of its operations, and its cash flows for each of the three years in the period ended March 31, 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 March 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated June 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

June 10, 2010

**Table of Contents****REPLIGEN CORPORATION****BALANCE SHEETS**

	March 31, 2010	March 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 12,526,040	\$ 5,041,410
Marketable securities	40,608,710	43,817,915
Accounts receivable, less reserve for doubtful accounts of \$10,000	570,038	540,779
Royalties receivable	2,296,000	2,036,800
Inventories	2,201,140	2,413,227
Prepaid expenses and other current assets	1,479,107	933,585
<b>Total current assets</b>	<b>59,681,035</b>	<b>54,783,716</b>
Property, plant and equipment, at cost:		
Leasehold improvements	3,855,616	3,845,247
Equipment	4,176,281	3,527,469
Furniture and fixtures	567,480	513,501
<b>Total property, plant and equipment, at cost</b>	<b>8,599,377</b>	<b>7,886,217</b>
Less: Accumulated depreciation	(5,466,354)	(4,216,430)
<b>Property, plant and equipment, net</b>	<b>3,133,023</b>	<b>3,669,787</b>
Long-term marketable securities	6,011,697	15,101,239
Intangible assets, net	1,400,208	
Goodwill	994,000	
Restricted cash	200,000	200,000
<b>Total assets</b>	<b>\$ 71,419,963</b>	<b>\$ 73,754,742</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 991,005	\$ 1,922,572
Accrued liabilities	3,666,135	2,626,341
<b>Total current liabilities</b>	<b>4,657,140</b>	<b>4,548,913</b>
Long-term liabilities	642,447	82,398
<b>Total liabilities</b>	<b>5,299,587</b>	<b>4,631,311</b>
Commitments and contingencies (Notes 5, 10, 11 and 12)		
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; issued and outstanding 30,761,807 shares at March 31, 2010 and 30,741,707 shares at March 31, 2009	307,618	307,417
Additional paid-in capital	183,733,863	182,673,275
Accumulated deficit	(117,921,105)	(113,857,261)
<b>Total stockholders' equity</b>	<b>66,120,376</b>	<b>69,123,431</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 71,419,963</b>	<b>\$ 73,754,742</b>

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



**Table of Contents**

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

	2010	Years ended March 31, 2009	2008
<b>Revenue:</b>			
Product revenue	\$ 10,304,727	\$ 14,528,916	\$ 18,587,376
Royalty and other revenue	10,666,342	14,832,605	708,905
<b>Total revenue</b>	<b>20,971,069</b>	<b>29,361,521</b>	<b>19,296,281</b>
<b>Operating expenses: (1)</b>			
Cost of product revenue	4,159,002	5,685,577	6,147,745
Cost of royalty and other revenue	1,347,168	1,091,297	12,500
Research and development	14,159,721	12,771,573	7,240,812
Selling, general and administrative	7,071,859	5,933,090	10,173,400
Net gain from litigation settlement			(40,170,000)
<b>Total operating expenses</b>	<b>26,737,750</b>	<b>25,481,537</b>	<b>(16,595,543)</b>
(Loss) income from operations	(5,766,681)	3,879,984	35,891,824
Investment income	870,043	1,895,706	2,051,258
Interest expense	(1,972)	(2,963)	(9,097)
(Loss) income before taxes	(4,898,610)	5,772,727	37,933,985
Income tax (benefit) provision	(834,766)	26,699	827,471
<b>Net (loss) income</b>	<b>\$ (4,063,844)</b>	<b>\$ 5,746,028</b>	<b>\$ 37,106,514</b>
<b>Earnings per share:</b>			
Basic	\$ (0.13)	\$ 0.19	\$ 1.20
Diluted	\$ (0.13)	\$ 0.18	\$ 1.18
<b>Weighted average shares outstanding:</b>			
Basic	30,752,041	30,957,957	30,834,491
Diluted	30,752,041	31,290,233	31,320,997

(1) Includes non-cash stock-based compensation as follows:

Cost of product revenue	\$ 40,941	\$ 47,686	\$ 28,134
Research and development	209,335	172,872	106,870
Selling, general and administrative	756,522	602,687	389,383

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



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

	Common Stock		Additional	Accumulated	Stockholders
	Number of Shares	Amount	Paid-in Capital	Deficit	Equity
Balance, March 31, 2007	30,477,635	\$ 304,776	\$ 182,916,856	\$ (157,683,334)	\$ 25,538,298
Share-based compensation expense			524,387		524,387
Issuance of common stock for license	87,464	875	299,125		300,000
Exercise of stock options	507,835	5,078	632,577		637,655
Net income				37,106,514	37,106,514
Balance, March 31, 2008	31,072,934	\$ 310,729	\$ 184,372,945	\$ (120,576,820)	\$ 64,106,854
Share-based compensation expense			823,245		823,245
Repurchase and retirement of treasury stock	(492,827)	(4,928)	(2,923,058)	973,530	(1,954,456)
Exercise of stock options	161,600	1,616	400,143		401,759
Net income				5,746,028	5,746,028
Balance, March 31, 2009	30,741,707	\$ 307,417	\$ 182,673,275	\$ (113,857,261)	\$ 69,123,431
Share-based compensation expense			1,006,798		1,006,798
Exercise of stock options	20,100	201	53,790		53,991
Net loss				(4,063,844)	(4,063,844)
Balance, March 31, 2010	30,761,807	\$ 307,618	\$ 183,733,863	\$ (117,921,105)	\$ 66,120,376

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

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

	2010	Years ended March 31, 2009	2008
<b>Cash flows from operating activities:</b>			
Net (loss) income:	\$ (4,063,844)	\$ 5,746,028	\$ 37,106,514
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Issuance of common stock for license			300,000
Depreciation and amortization	1,378,999	1,077,347	824,626
Stock-based compensation expense	1,006,798	823,245	524,387
Loss on disposal of assets	905	6,123	9,559
Changes in assets and liabilities:			
Accounts receivable	(29,259)	520,822	260,528
Royalties receivable	(259,200)	(1,972,600)	(242,635)
Inventories	212,087	391,020	(1,289,676)
Prepaid expenses and other current assets	(545,522)	(226,238)	(261,932)
Accounts payable	(931,567)	(799,337)	1,560,405
Accrued liabilities	782,200	801,379	(267,876)
Long-term liabilities	49	(60,645)	(57,299)
Net cash (used in) provided by operating activities	(2,448,354)	6,307,144	38,466,601
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(47,038,060)	(56,865,473)	(54,797,953)
Redemptions of marketable securities	59,336,807	25,973,235	41,671,877
Acquisition of assets of BioFlash Partners, LLC	(1,780,000)		
Purchases of property, plant and equipment	(597,349)	(1,339,999)	(1,102,585)
Net cash provided by (used in) investing activities	9,921,398	(32,232,237)	(14,228,661)
<b>Cash flows from financing activities:</b>			
Exercise of stock options	53,991	401,759	637,655
Repurchase of common stock		(1,954,456)	
Principal payments under capital lease obligations	(42,405)	(42,938)	(39,962)
Net cash provided by (used in) financing activities	11,586	(1,595,635)	597,693
Net increase (decrease) in cash and cash equivalents	7,484,630	(27,520,728)	24,835,633
Cash and cash equivalents, beginning of period	5,041,410	32,562,138	7,726,505
Cash and cash equivalents, end of period	\$ 12,526,040	\$ 5,041,410	\$ 32,562,138
<b>Supplemental disclosure of non-cash investing activities:</b>			
Consideration transferred in acquisition of BioFlash Partners, LLC	\$ 560,000	\$	\$
<b>Supplemental disclosure of cash flow information:</b>			
Income taxes (refunded) paid	\$ (135,157)	\$ 166,000	\$ 800,000
Non-cash tender of common stock to exercise stock options	\$	\$	\$ 564,003

Edgar Filing: REPLIGEN CORP - Form 10-K

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

---

**Table of Contents**

**REPLIGEN CORPORATION**

**NOTES TO FINANCIAL STATEMENTS**

**1. Organization and Nature of Business**

Repligen Corporation ( Repligen or the Company ) is a biopharmaceutical company focused on the development and commercialization of innovative therapies that harness biological pathways and deliver value to patients and clinicians in neurology, gastroenterology and orphan diseases. The Company is currently conducting a number of drug development programs for diseases such as pancreatitis, bipolar disorder, Friedreich's ataxia and spinal muscular atrophy. Repligen also has a bioprocessing business that focuses on the development and commercialization of products that are used for the production of biopharmaceuticals. In addition, the Company receives royalties from Bristol-Myers Squibb Company ( Bristol ) on their net sales in the United States of their product Orenbia

The Company's business strategy is to invest the profits from current bioprocessing products sales and royalty and other revenues, as well as use existing financial resources to advance the development of its therapeutic product candidates and our bioprocessing business.

The Company is subject to a number of risks typically associated with companies in the biotechnology industry. Principally those risks 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 U.S. Food and Drug Administration 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 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.

**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 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 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 history 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

---

## **Table of Contents**

issues is largely diminished. Sales returns and warranty issues are infrequent and have had nominal impact on the Company's 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 Orencia® which is used in the treatment of rheumatoid arthritis. Pursuant to the Bristol Settlement (as defined in Note 10), the Company recognized royalty revenue of approximately \$8,980,000 and \$13,383,000 in fiscal years 2010 and 2009, respectively. The \$13,383,000 recognized in fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia® from January 1, 2008 to March 31, 2008, as well as \$7.1 million for sales in fiscal year 2009. 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.

Additionally, the Company earned and recognized approximately \$1,009,000, \$776,000 and \$244,000 in fiscal years 2010, 2009 and 2008, respectively, in royalty revenue from ChiRhoClin for their sales of secretin. Revenue earned from ChiRhoClin royalties is recorded in the periods when it is 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.

In fiscal years 2010 and 2009, the Company recognized approximately \$552,000 and \$564,000, respectively, of revenue from a sponsored research and development project under an agreement with the Muscular Dystrophy Association. In addition, the Company recognized approximately \$125,000 and \$110,000 in fiscal years 2010 and 2009, respectively, under other sponsored research and development projects. During fiscal 2008, the Company recognized approximately \$365,000 under an agreement with the Stanley Medical Research Institute and \$100,000 under another sponsored research and development project.

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 financial statements.

## **Risks and Uncertainties**

The Company evaluates its operations periodically to determine if any risks and uncertainties exist that could impact its operations in the near term. The Company does not believe that there are any significant risks which have not already been disclosed in the 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)**

Comprehensive income is defined as the change in equity of a business enterprise during a period resulting from transactions and other events and circumstances from non-owner sources. The Company's comprehensive income/loss is equal to the reported net income/loss for all periods presented.

**Table of Contents**

**Cash, Cash Equivalents and Marketable Securities**

At March 31, 2010, the Company's investments included money market funds as well as short-term and long-term marketable securities, which are classified as held-to-maturity investments as the Company has the positive intent and ability to hold the investments to maturity. These investments are therefore recorded on an amortized cost basis. 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.

Cash, cash equivalents and marketable securities consist of the following:

	As of March 31,	
	2010	2009
Cash and cash equivalents	\$ 12,526,040	\$ 5,041,410
Marketable securities:		
U.S. Government and agency securities	23,009,237	20,871,059
Corporate and other debt securities	17,599,473	22,946,856
	\$ 40,608,710	\$ 43,817,915
Long-term marketable securities:		
U.S. Government and agency securities	3,261,524	5,032,385
Corporate and other debt securities	2,750,173	10,068,854
	\$ 6,011,697	\$ 15,101,239
Total	\$ 59,146,447	\$ 63,960,564

The average remaining maturity of marketable securities at March 31, 2010 is approximately 6.5 months.

Management reviewed the Company's investments as of March 31, 2010 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 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 at maturity. There were no realized gains or losses on the investments for the years ended March 31, 2010, 2009 and 2008.

Investments in held-to-maturity debt securities consisted of the following at March 31, 2010:

	March 31, 2010			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	\$ 23,009,237	\$ 25,883	\$ (1,748)	\$ 23,033,372
Corporate and other debt securities	17,599,473	82,760		17,682,233
	40,608,710	108,643	(1,748)	40,715,605
Long-term marketable securities:				
U.S. Government and agency securities	3,261,524	10,849	(8,546)	3,263,827
Corporate and other debt securities	2,750,173	28,105		2,778,278
	6,011,697	38,954	(8,546)	6,042,105

Edgar Filing: REPLIGEN CORP - Form 10-K

Total	\$ 46,620,407	\$ 147,597	\$ (10,294)	\$ 46,757,710
-------	---------------	------------	-------------	---------------

All investments in held-to-maturity debt securities with gross unrealized losses have been in unrealized loss positions for less than 12 months.

**Table of Contents**

Investments in held-to-maturity debt securities consisted of the following at March 31, 2009:

	March 31, 2009			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>Marketable securities:</b>				
U.S. Government and agency securities	\$ 20,871,059	\$ 113,154	\$ (1,051)	\$ 20,983,162
Corporate and other debt securities	22,946,856	77,916	(82,088)	22,942,684
	43,817,915	191,070	(83,139)	43,925,846
<b>Long-term marketable securities:</b>				
U.S. Government and agency securities	5,032,385	21,835		5,054,220
Corporate and other debt securities	10,068,854	56,742	(20,714)	10,104,882
	15,101,239	78,577	(20,714)	15,159,102
<b>Total</b>	<b>\$ 58,919,154</b>	<b>\$ 269,647</b>	<b>\$ (103,853)</b>	<b>\$ 59,084,948</b>

The contractual maturities of held-to-maturity debt securities at March 31, 2010 were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 40,608,710	\$ 40,715,605
Due in 1 to 2 years	6,011,697	6,042,105
	<b>\$ 46,620,407</b>	<b>\$ 46,757,710</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.





**Table of Contents**

The Company's held-to-maturity securities, which are fixed income investments, are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These held-to-maturity securities are recorded at amortized cost and are therefore not included in the Company's market value measurement disclosure. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. 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 liability for contingent consideration recorded in connection with the acquisition of BioFlash Partners, LLC ( BioFlash ) (See Note 13). The contingent consideration is valued using management's estimates of royalties to be paid to the former shareholders of BioFlash based on sales of the acquired assets. This valuation is a Level 3 valuation as the primary inputs are unobservable. The following table provides a roll forward of the fair value of the contingent consideration:

Balance at April 1, 2009	\$
Additions	560,000
Changes in Fair Value	
Balance at March 31, 2010	\$ 560,000

The following fair value hierarchy table presents information about each major category of the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2010:

	Fair value measurement at reporting date using:			Balance as of March 31, 2010
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 8,237,402			\$ 8,237,402

There were no remeasurements to fair value during the year ended March 31, 2010 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 twelve 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 has 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:

	As of March 31,	
	2010	2009
Raw Materials	\$ 1,067,823	\$ 1,400,408
Work-in-process	395,088	791,465
Finished products	738,229	221,354
Total	\$ 2,201,140	\$ 2,413,227

**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; 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 which 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 are often judgmental. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

**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 five years
Furniture and fixtures	Three years

For depreciation of property and equipment, the Company expensed approximately \$1,349,000, \$1,077,000, and \$825,000 in fiscal 2010, 2009, and 2008, respectively. These amounts include depreciation of assets recorded under capitalized lease agreements of approximately \$34,000, \$38,000, and \$43,000 in 2010, 2009, and 2008, respectively.

**Earnings (Loss) Per Share**

Basic earnings (loss) per share for the years ended March 31, 2010, 2009 and 2008 were computed on the basis of the weighted average number of shares of common stock outstanding during the period. Diluted earnings

**Table of Contents**

(loss) per share is computed on the basis of the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period using the treasury stock method. Dilutive potential common shares include outstanding stock options, restricted stock and warrants.

Basic and diluted weighted average shares outstanding were as follows:

	Year Ended March 31,		
	2010	2009	2008
Weighted average common shares	30,752,041	30,957,957	30,834,491
Dilutive common stock options		332,276	486,506
Weighted average common shares, assuming dilution	30,752,041	31,290,233	31,320,997

Diluted weighted average shares outstanding for the year ended March 31, 2010 does not include the impact of 2,318,650 outstanding potential common shares for stock options as they would be anti-dilutive. Accordingly, basic and diluted net losses per share are the same for the year ended March 31, 2010.

For years ended March 31, 2009 and 2008, options to purchase 938,000 and 443,000 shares 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.

**Segment Reporting**

The Company views its operations, makes decisions regarding how to allocate resources and manages the 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):

	Year ended March 31,		
	2010	2009	2008
US	57%	60%	32%
Sweden	36%	36%	61%
Other	7%	4%	7%
Total	100%	100%	100%

The following table represents the Company's total revenue by product type:

	Year ended March 31		
	2010	2009	2008
Bioprocessing	\$ 10,304,727	\$ 14,361,025	\$ 16,321,065
SecreFlo®		167,891	2,266,311
Product revenue	\$ 10,304,727	\$ 14,528,916	\$ 18,587,376
Royalty and other revenue	10,666,342	14,832,605	708,905
Total revenue	\$ 20,971,069	\$ 29,361,521	\$ 19,296,281

Edgar Filing: REPLIGEN CORP - Form 10-K

All of the Company's assets are located in the United States for fiscal years ended March 31, 2010, 2009 and 2008.

**Table of Contents****Concentrations of Credit Risk and Significant Customers**

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and 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 March 31, 2010 and 2009, the Company had no investments associated with foreign exchange contracts, options contracts or other foreign hedging arrangements.

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

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

	Years Ended March 31,		
	2010	2009	2008
Orencia® Royalties from Bristol	43%	46%	
Bioprocessing Customer A	36%	36%	61%
Bioprocessing Customer B	1%	4%	14%

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

	As of March 31,	
	2010	2009
Orencia® Royalties from Bristol	80%	70%
Bioprocessing Customer B	2%	12%
Bioprocessing Customer C	13%	

**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 extent of royalties to be earned in excess of the defined minimum royalties. Management will update these estimates and the related fair value of contingent consideration at each reporting period.

**Goodwill and Intangible Assets**

Intangible assets are amortized over their useful lives using the estimated economic benefit method, as applicable.

Goodwill is not amortized. Instead goodwill is reviewed for impairment at least annually. There was no evidence of impairment to goodwill for fiscal year 2010.

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

---

**Table of Contents**

landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the market place including changes in the prices paid for our products or changes in the size of the market for our products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset based on the sum of the future undiscounted cash flows expected to result from the use and disposition of the asset. If the estimate of an intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. There were no indicators of impairment in fiscal year 2010.

**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 and is derived from the Company's historical stock option exercise experience and option expiration data. 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.

*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 March 31, 2010. 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 October 2009, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2009-13, *Multiple-Deliverable Arrangements - a consensus of the FASB Emerging Issues Task Force* ( ASU 2009-13 ). This ASU establishes the accounting and reporting guidance for arrangements under which a vendor will perform multiple revenue-generating activities. Specifically, the provisions of this update address how to separate deliverables and how to measure and allocate arrangement consideration to one or more units of accounting. This update is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company has not yet completed its evaluation of ASU 2009-13, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

**Table of Contents**

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* ( ASU 2010-06 ). This ASU requires new disclosures and clarifies some existing disclosure requirements about fair value measurements codified within ASC 820, *Fair Value Measurements and Disclosures*, including significant transfers into and out of Level 1 and Level 2 investments of the fair value hierarchy. ASU 2010-06 also requires additional information in the roll forward of Level 3 investments including presentation of purchases, sales, issuances, and settlements on a gross basis. Further clarification for existing disclosure requirements provides for the disaggregation of assets and liabilities presented, and the enhancement of disclosures around inputs and valuation techniques. This update is effective for the first interim or annual reporting period beginning after December 15, 2009, except for the additional information in the roll forward of Level 3 investments. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim reporting periods within those fiscal years. The Company adopted ASU 2010-06 in January 2010. The adoption of this update did not have a material impact on its results of operations, financial position or cash flows.

In April 2010, the FASB issued ASU No. 2010-17, *Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force* ( ASU 2010-17 ). This ASU provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The Company has not yet completed its evaluation of ASU 2010-17, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

**3. Income Taxes**

The tax benefit of (\$834,766) for the year ended March 31, 2010 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. The Company expects to receive a refund of approximately \$835,000 upon filing its tax return for the year ended March 31, 2010. This refundable tax amount is included in prepaid expenses and other current assets on the balance sheet at March 31, 2010. For the year ended March 31, 2009, the tax provision of \$26,699 is comprised of a current provision for federal income taxes of \$29,557 and a current benefit for state income taxes of (\$2,858). For the year ended March 31, 2008, the tax provision of \$827,471 is comprised of a current provision for federal income taxes of \$736,805 and a current provision for state income taxes of \$90,666.

At March 31, 2010, the Company had net operating loss carryforwards of approximately \$63,903,000 and business tax credits carryforwards of approximately \$2,118,000 available to reduce future federal income taxes, if any. Additionally, at March 31, 2010, we had net operating loss carryforwards of approximately \$3,061,000 and business tax credits carryforwards of approximately \$5,615,000 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 March 2030. 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 deferred tax assets consist of the following:

	As of March 31,	
	2010	2009
Temporary timing differences	\$ 4,700,000	\$ 4,716,000
Net operating loss carryforwards	21,919,000	19,957,000
Tax business credits carryforwards	4,157,000	4,646,000
Total deferred tax assets	30,776,000	29,319,000
Valuation allowance	(30,776,000)	(29,319,000)
Net deferred tax asset	\$	\$

At March 31, 2010 and 2009, a full valuation allowance has been provided against the deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

The reconciliation of the federal statutory rate to the effective income tax rate for the years ended March 31, 2010, 2009 and 2008 is as follows:

	Years Ended March 31,					
	2010		2009		2008	
Income (loss) before income taxes	\$ (4,898,610)	%	\$ 5,772,727	%	\$ 37,933,985	%
Expected tax (recovery) at statutory rate	(1,665,527)	(34.0)%	1,962,727	34.0%	12,897,555	34.0%
Adjustments due to:						
State income and franchise taxes	(80,151)	(1.6)%	287,822	5.0%	1,620,725	4.3%
Utilization of loss carryforwards and business tax credits	(934,659)	(19.1)%	(1,891,597)	(32.8)%	(13,987,955)	(36.9)%
Alternative minimum tax			96,540	1.7%	732,817	1.9%
Permanent differences	255,766	5.2%	207,508	3.6%	191,459	0.5%
Change in valuation allowance	1,589,805	32.5%	(636,301)	(11.0)%	(627,130)	(1.6)%
(Benefit) provision for income taxes	\$ (834,766)	(17.0)%	\$ 26,699	0.5%	\$ 827,471	2.2%

At March 31, 2010, 2009 and 2008, 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.

Fiscal years 2006 through 2010 are subject to examination by the federal and state taxing authorities. There are no income tax examinations currently in process.

#### 4. Stockholders Equity

##### Common Stock and Warrants

At March 31, 2010, the Company has reserved 2,893,859 shares of common stock pursuant to the Plans. As discussed in Note 11 below, on April 6, 2007, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. The warrants have a 7-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.



**Table of Contents****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 has 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 permits 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 entitles 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 have no voting privileges and, unless and until they become exercisable, are attached to, and automatically trade with, the Company's common stock. The Rights will terminate upon the earlier of the date of their redemption or March 2013.

**Stock Based Compensation**

For fiscal years ended March 31, 2010, 2009 and 2008, the Company recorded stock-based compensation expense of approximately \$1,007,000, \$823,000 and \$524,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (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 March 31, 2010, options to purchase 2,318,650 shares were outstanding under the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the "Plans"). At March 31, 2010, 575,209 shares were available for future grant under the 2001 Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The fair value of share-based awards granted during the fiscal years ended March 31, 2010, 2009 and 2008 were calculated using the following estimated weighted-average assumptions:

	Years Ended March 31,		
	2010	2009	2008
Expected term (years)	6.5	6.5	6.5
Volatility	58.12% - 65.14%	60.47% - 64.07%	64.46% - 76.85%
Risk-free interest rate	2.54% - 3.14%	1.88% - 3.71%	2.81% - 4.97%
Expected dividend yield			

The Company recognizes stock-based 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.

**Table of Contents**

Information regarding option activity for the year ended March 31, 2010 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, 2009	2,213,550	\$ 4.37		
Granted	247,000	4.55		
Exercised	(20,100)	2.69		
Forfeited/Cancelled	(121,800)	4.99		
Options outstanding at March 31, 2010	2,318,650	\$ 4.37	6.14	\$ 1,174,676
Options exercisable at March 31, 2010	1,371,250	\$ 4.09	4.61	\$ 1,020,881
Vested and expected to vest at March 31, 2010 (1)	2,194,544	\$ 4.35	6.02	\$ 1,147,354

(1) This represents the number of vested options as of March 31, 2010 plus the number of unvested options expected to vest as of March 31, 2010 based on the unvested outstanding options at March 31, 2010 adjusted for estimated forfeitures.

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 March 31, 2010 of \$4.06 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 March 31, 2010.

The weighted average grant date fair value of options granted during the fiscal years ended March 31, 2010 and 2009 was \$2.71 and \$3.17, respectively. The total fair value of stock options that vested during fiscal years ended March 31, 2010, 2009 and 2008 was approximately \$1,067,000, \$655,000 and \$494,000, respectively. The total intrinsic value of options exercised during the years ended March 31, 2010, 2009 and 2008 was \$43,875, \$418,366 and \$1,672,260, respectively, determined as of the date of exercise. The Company received \$53,991, \$401,759 and \$637,655 from stock option exercises during the years ended March 31, 2010, 2009 and 2008, respectively.

As of March 31, 2010, there was \$1,919,119 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 3.11 years. The Company expects 823,294 in 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 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 March 31, 2010 and 2009. 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.



**Table of Contents**

In fiscal 2006, Repligen entered into a capital lease agreement to provide the Company with manufacturing equipment over a five-year period. In fiscal 2005, the Company entered into two capital lease agreements to provide us with two pieces of office equipment for approximately \$33,000. The lease terms were three and five years beginning in June and October of 2004, respectively. As of March 31, 2010, the Company has no remaining capital lease obligations.

Obligations under non-cancelable operating leases, including the facility leases discussed above, as of March 31, 2010 are as follows:

<b>Years Ending</b>	<b>Operating Leases</b>
March 31, 2011	\$ 572,079
March 31, 2012	423,948
March 31, 2013	9,264
Minimum lease payments	\$ 1,005,291

Rent expense charged to operations under operating leases was approximately \$689,000, \$631,000 and \$512,000 for the years ended March 31, 2010, 2009 and 2008, respectively. As of March 31, 2010, 2009 and 2008, the Company had a deferred rent liability of \$64,000, \$100,600 and \$118,900, respectively related to the escalating rent provisions for the Waltham headquarters.

*Licensing and Research Agreements*

The Company licenses certain technologies that are, or may be, incorporated into its technology under several agreements and also has entered into several clinical research agreements which require the Company to fund certain research projects. Generally, the license agreements require the Company to pay annual maintenance fees and royalties on product sales once a product has been established using the technologies.

In October 2009, the Company entered into an exclusive worldwide commercial license agreement with Families of Spinal Muscular Atrophy (see Note 12). The initial license fee of \$500,000 and a related sublicense fee of \$175,000 have been charged to research and development expenses in fiscal 2010. In April 2007 the Company entered into an exclusive license agreement with the Scripps Research Institute (see Note 11). The initial license fee under this agreement aggregated \$600,000 in a combination of cash and Company common stock and was charged to research and development expenses in fiscal 2008. The Company has recorded research and development expenses associated with license agreements of approximately \$643,000, \$326,000, and \$681,000 for fiscal years 2010, 2009 and 2008, respectively.

*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 March 31, 2010 are approximately \$1,933,000 where approximately \$1,908,000 is expected to be completed within one year and the remaining amount to be substantially completed within two years.

**Table of Contents****6. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	As of March 31,	
	2010	2009
Interest receivable	\$ 223,290	\$ 354,416
Prepaid taxes	882,439	182,830
Prepaid insurance	169,829	155,321
Clinical and research expenses	80,031	133,133
Equipment and services	109,358	93,725
Other	14,160	14,160
<b>Total</b>	<b>\$ 1,479,107</b>	<b>\$ 933,585</b>

**7. Accrued Liabilities**

Accrued liabilities consist of the following:

	As of March 31,	
	2010	2009
Employee compensation	\$ 1,285,172	\$ 1,040,529
Research and development	787,267	769,793
Royalty and license fees	881,900	269,850
Unearned revenue	306,794	125,000
Professional fees	216,086	94,572
Other accrued expenses	133,554	110,059
Other current liabilities	55,362	216,538
<b>Total</b>	<b>\$ 3,666,135</b>	<b>\$ 2,626,341</b>

**8. Employee Benefit Plan**

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 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 \$117,000, \$85,278, and \$56,647 for the fiscal years ended March 31, 2010, 2009, and 2008 respectively.

**9. Related Party Transactions**

The Company paid Dr. Alexander Rich, Chairman of the Board of Directors, \$47,400 and \$43,200 in fiscal years 2009 and 2008, respectively, per a consulting agreement that automatically extended for successive one-year terms unless terminated by either party at least 90 days prior to the next anniversary date. Effective January 2009, this consulting agreement was terminated and Dr. Rich is now paid a monthly retainer similar to the Company's other directors. Dr. Rich received no additional cash compensation for attendance at Board of Directors meetings or otherwise as director.

The Company paid Dr. Paul Schimmel, former Co-Chairman of the Board of Directors, \$32,800 in fiscal year 2008 pursuant to a consulting agreement. This agreement automatically extended for successive one-year terms unless terminated by either party at least 90 days prior to the

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

next anniversary date. Dr. Schimmel retired from the Board of Directors as of the Company's annual meeting in September 2007, and accordingly, the consulting agreement with Dr. Schimmel was terminated at that time. Dr. Schimmel received no additional cash compensation for attendance at Board of Directors meetings or otherwise as director.



**Table of Contents****10. Legal Proceedings***ImClone Systems*

In May 2004, Repligen and the Massachusetts Institute of Technology ( MIT ) filed an action in the United States District Court for the District of Massachusetts against ImClone Systems, Incorporated ( ImClone ) for infringement of U.S. Patent No. 4,663,281 ( the 281 patent ) based on ImClone s manufacture and sale of Erbitu<sup>®</sup>. The 281 patent, which covers the use of certain genetic elements that increase protein production in a mammalian cell, is assigned to MIT and exclusively licensed to Repligen.

On September 10, 2007, Repligen and MIT entered into a settlement agreement (the ImClone Settlement ) with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the ImClone Settlement, ImClone made a payment of \$65 million to Repligen and MIT that resulted in net proceeds to Repligen of \$40.17 million, as follows:

Gross proceeds from Settlement Agreement	\$ 65,000,000
Less: Amounts paid to MIT	(11,000,000)
Less: Legal fees and other costs	(13,830,000)
 Net gain on litigation settlement	 \$ 40,170,000

The ImClone Settlement served as the basis for the Company and MIT to dismiss the lawsuit against ImClone and for the Company to grant ImClone a non-exclusive sublicense to the 281 patent and certain other intellectual property. There are no further obligations to the Company with respect to the sublicenses. The net gain on litigation settlement was recorded as a separate component of operating expenses in the statement of operations in fiscal 2008.

*Bristol-Myers Squibb Company ( Bristol )*

In January 2006, Repligen and the University of Michigan jointly filed a complaint against Bristol in the United States District Court for the Eastern District of Texas for infringement of U.S. Patent No. 6,685,941 ( the 941 patent ) for the commercial sale of Orencia<sup>®</sup>. The 941 patent, entitled Methods of Treating Autoimmune Disease via CTLA4-Ig, covers methods of using CTLA4-Ig to treat rheumatoid arthritis, as well as other therapeutic methods. Repligen has exclusive rights to this patent from its owners, the University of Michigan and the U.S. Navy. In February 2006, Bristol answered the complaint and counterclaimed seeking a declaratory judgment that the 941 patent is invalid and unenforceable and that Bristol does not infringe the patent.

On April 7, 2008, Repligen and the University of Michigan entered into a settlement agreement (the Bristol Settlement ) with Bristol relating to the lawsuit against Bristol for infringement of the 941 patent. Pursuant to the Bristol Settlement, Bristol made an initial payment of \$5 million to Repligen. The settlement further provides for Bristol to pay royalties on the United States net sales of Orencia<sup>®</sup> 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. The Bristol Settlement served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against Bristol and for Repligen and the University of Michigan to grant to Bristol an exclusive worldwide license to the 941 patent and certain other intellectual property.

Pursuant to the Bristol Settlement, the Company recognized royalty revenue in fiscal years 2010 and 2009 of approximately \$8,980,000 and \$13,383,000, respectively. The \$13,383,000 recognized in fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia<sup>®</sup> from January 1, 2008 to March 31, 2008, as well as \$7.1 million for sales in fiscal year 2009 (see Note 2).

Repligen must also remit to the University of Michigan 15% of all royalty revenue received from Bristol, after deducting certain legal and other costs incurred related to the Bristol Settlement. The Company incurred

**Table of Contents**

approximately \$6.1 million in such legal costs. Royalty expense for fiscal years 2010 and 2009 was approximately \$1,347,000 and \$1,091,000, respectively. This operating expense has been included on the statements of operations under the line item Cost of royalty and other revenue.

**11. Scripps Agreements***License Agreement*

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 which may have utility in treating Friedreich s ataxia, an inherited neurodegenerative disease. Research in tissues derived from patients, as well as, in 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 commercial milestones, certain additional milestone payments. Total future milestone payments, were all milestones achieved, would be approximately \$4.3 million. 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. The Company recorded the initial license payment and the value of the shares issued as research and development costs in the statements of operations in fiscal 2008.

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 7-year term and are exercisable based on performance criteria as detailed in the warrant agreement. No expense has been recorded related to these warrants through March 31, 2010, 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 in the near future.

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.

*Research Funding and Option Agreement*

On October 26, 2007, the Company entered into a research funding and option agreement ( Funding Agreement ) with Scripps to fund a research program for the research and development of compounds that may have utility in the treatment of Friedreich s ataxia. Pursuant to the Funding Agreement, the Company is required to fund approximately \$35,000 per quarter which is recorded as research and development expenses. In exchange for funding the research, Scripps will grant an exclusive option to the Company to acquire a sole, worldwide license, including the right to sublicense, manufacture and sell products, and services that result from the research program. There are no guaranties or warranties that products or services may result from the research program and the Company has therefore ascribed no value to the license. The Funding Agreement expires or may be terminated (i) when all of the royalty obligations under the Funding Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the Funding Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the Funding Agreement; or (iv) by the Company upon 90 days written notice.

**Table of Contents**

The Company made payments to Scripps of approximately \$123,000, \$133,000 and \$105,000 for fiscal years 2010, 2009 and 2008, respectively, in connection with the Funding Agreement, as amended.

**12. FSMA License Agreement**

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 which 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 which have been recorded as research and development expense in the statements of operations in fiscal 2010. 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; or (iii) by the Company upon 30 days written notice.

**13. BioFlash Acquisition**

On January 29, 2010, the Company acquired the assets of 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 include 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 Company will manufacture and sell these pre-packed columns under the brand name Opus™. Opus™ pre-packed chromatography columns have the potential to improve the speed of process development and reduce the cost of biopharmaceutical manufacturing by decreasing the time associated with set-up, cleaning and validation of traditional manufacturing technologies.

*Consideration Transferred*

The Company has accounted for the acquisition of the assets of BioFlash as the purchase of a business under U.S. Generally Accepted Accounting Principles. 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 is 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

**Table of Contents**

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 is as follows:

Cash consideration	\$ 1,780,000
Liability for additional payment	300,000
Estimated fair value of contingent consideration	560,000
 Total consideration transferred	 \$ 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 long-term liabilities on the balance sheet at March 31, 2010 and will be remeasured at each reporting period until the contingency is resolved.

*Allocation of Consideration Transferred*

The following chart summarizes the allocation of consideration transferred:

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

The excess of the consideration transferred over the fair value of net tangible assets acquired was allocated to specific intangible asset categories as follows:

	Amount Assigned	Amortization Period	Accumulated Amortization March 31, 2010
<b>Amortizable intangible assets</b>			
Technology developed	\$ 760,000	8 years	\$ 15,834
Patents	240,000	8 years	5,000
Customer relationships	430,000	8 years	8,958
	<b>\$ 1,430,000</b>		<b>\$ 29,792</b>
Goodwill	994,000		

The Company believes that the intangible assets are 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. The Company expects to record amortization expense of \$178,750 in each of the next five years.

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****14. Valuation and Qualifying Accounts**

	Balance at Beginning of Period	Additions	Reversal without Utilization	Balance at End of Period
Allowance for Doubtful Accounts:				
2008	\$ 10,000	\$ 5,000	\$ 5,000	\$ 10,000
2009	\$ 10,000			\$ 10,000
2010	\$ 10,000			\$ 10,000

**15. Selected Quarterly Financial Data (Unaudited)**

The following table contains statements of operations information for each quarter of fiscal 2010 and 2009. 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.

	Q4 FY10	Q3 FY10	Q2 FY10	Q1 FY10	Q4 FY09	Q3 FY09	Q2 FY09	Q1 FY09
	(in thousands, except per share amounts)							
Revenue:								
Product revenue	\$ 2,225	\$ 2,865	\$ 2,742	\$ 2,473	\$ 2,558	\$ 3,294	\$ 2,984	\$ 5,693
Royalty and other revenue	2,647	2,752	2,679	2,588	2,036	2,724	2,106	7,967
Total revenue	4,872	5,617	5,421	5,061	4,594	6,018	5,090	13,660
Operating expenses:								
Cost of product revenue	885	1,085	918	1,271	1,342	1,287	1,211	1,846
Cost of royalty and other revenue	345	343	341	318	270	286	210	325
Research and development	3,453	3,845	3,479	3,383	4,645	3,579	2,463	2,084
Selling, general and administrative	1,952	1,714	1,889	1,517	1,552	1,404	1,530	1,447
Total operating expenses	6,635	6,987	6,627	6,489	7,809	6,556	5,414	5,702
Income (loss) from operations	(1,763)	(1,370)	(1,206)	(1,428)	(3,215)	(538)	(324)	7,958
Investment income	134	187	227	322	375	473	515	533
Interest income (expense)		(1)	(1)		(1)	(1)	1	(2)
Income (loss) before taxes	(1,629)	(1,184)	(980)	(1,106)	(2,841)	(66)	192	8,489
Income tax (benefit) provision		(835)			148	84	(50)	(210)
Net income (loss)	\$ (1,629)	\$ (349)	\$ (980)	\$ (1,106)	\$ (2,693)	\$ 18	\$ 142	\$ 8,279
Earning per share:								
Basic	\$ (0.05)	\$ (0.01)	\$ (0.03)	\$ (0.04)	\$ (0.09)	\$ 0.00	\$ 0.00	\$ 0.27
Diluted	\$ (0.05)	\$ (0.01)	\$ (0.03)	\$ (0.04)	\$ (0.09)	\$ 0.00	\$ 0.00	\$ 0.26
Weighted average shares outstanding:								
Basic	30,752	30,759	30,746	30,742	30,698	30,809	31,173	31,153
Diluted	30,752	30,759	30,746	30,742	30,962	31,025	31,556	31,585