

REPLIGEN CORP
Form 10-K
June 13, 2008
[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, 2008

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

Delaware
(State or other jurisdiction of
incorporation or organization)

04-2729386
(I.R.S. Employer
Identification No.)

41 Seyon Street, Building #1,

Suite 100, Waltham, Massachusetts
(Address of Principal executive offices)

02453
(Zip Code)

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

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

Title of Each Class

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 ☐ Smaller reporting company ☐
(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, 2007, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$133,761,208.

The number of shares of outstanding of the registrant's common stock as of June 6, 2008 was 31,172,234.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement in connection with the 2008 annual meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

Table of Contents

Table of Contents

	PAGE
<u>PART I</u>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	8
Item 1B. <u>Unresolved Staff Comments</u>	13
Item 2. <u>Properties</u>	13
Item 3. <u>Legal Proceedings</u>	14
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	14
<u>PART II</u>	
Item 5. <u>Market for the Registrant's Common Stock and Related Security Holder Matters</u>	14
Item 6. <u>Selected Financial Data</u>	16
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
Item 8. <u>Financial Statements and Supplementary Data</u>	25
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	25
Item 9A. <u>Controls and Procedures</u>	25
Item 9B. <u>Other Information</u>	27
<u>PART III</u>	
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	28
<u>SIGNATURES</u>	32

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 developing novel therapeutics primarily for the treatment of diseases of the central nervous system. Our business strategy is to maintain full commercial rights to our product candidates through proof of principle clinical studies after which we may seek corporate partners for further development and marketing. For the next several years, we expect to fund the development of our proprietary therapeutic product candidates primarily through royalty payments received from Bristol-Myers Squibb Corporation (Bristol) based on their United States sales of Orencia® and the profits from the sales of our Protein A products which are used in the production of many therapeutic monoclonal antibodies. This will enable us to independently advance our product candidates through proof of principle clinical trials with reduced financial risk.

We were incorporated in May 1981, under the laws of the State of Delaware. Our principle 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 products based on Protein A, which is used in the production of monoclonal antibodies, and SecreFlo®, a synthetic form of the hormone secretin, which is used as an aid in the diagnosis of certain diseases of the pancreas.

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 systems that they sell directly to the biotechnology and pharmaceutical industry. We supply Protein A products to GE Healthcare (GEHC) under a supply agreement which extends through 2010 and to Applied Biosystems, Inc. under a supply agreement that extends until 2011. The majority of our product sales for the last three years have been sales of Protein A products.

Sales of therapeutic monoclonal antibodies have increased from \$300 million in 1997 to approximately \$25 billion in 2007. This growth is based on the increasing use of therapeutic antibodies, including Avastin® for colon cancer, Synagis® for RSV infection and Remicade® for Crohn's disease and arthritis. There are more than 150 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.

SecreFlo® for Pancreatic Diagnosis

In fiscal year 2008, we also 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. We will discontinue distribution of SecreFlo® in the first half of fiscal year 2009 when our product supply will cease.

Intellectual Property on Monoclonal Antibody and Antibody Fusion Products

Erbix®

Edgar Filing: REPLIGEN CORP - Form 10-K

Erbitux® 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. Erbitux® is manufactured with a cell line which contains certain genetic technologies (DNA enhancers) which increase the productivity of a cell line. This U.S. patent covering the use of DNA enhancers, which expired in May of 2004,

Table of Contents

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 has infringed our patent rights in its production of Erbitux®. 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.

CTLA4-Ig

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

In December 2005, the FDA approved Bristol s application to market CTLA4-Ig, under the brand name Orencia®, for treatment of rheumatoid arthritis. In January 2006, Repligen and the University of Michigan jointly filed a lawsuit against Bristol in the United States District Court for the Eastern District of Texas for patent infringement. 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 will 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% of annual sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013.

Development Stage Products

Secretin for MRI

Secretin is a well-known hormone produced in the small intestine that regulates the function of the pancreas as part of the process of digestion. We are currently evaluating secretin for improvement of MRI imaging of structural abnormalities of the pancreas.

Several reports published in the literature support the use of secretin with abdominal MRI imaging to improve visualization of pancreaticobiliary structures and to increase diagnostic sensitivity relative to unenhanced abdominal MRI. MRI technology images water thus 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 risky invasive endoscopic procedures.

In June 2006, we initiated a Phase 2 clinical trial 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 a secretin-enhanced MRI and an unenhanced MRI of the pancreas.

In May 2007, we announced positive results from this Phase 2 clinical trial to evaluate the use of RG1068 to improve the assessment of pancreatic duct structures by MRI. 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. 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.

Our Phase 2 data was reviewed by the FDA and has served as the basis for the design of a pivotal, Phase 3 study. The Phase 3 study will seek to recruit approximately 250 patients at 25 clinical sites in the United States and Canada. The primary objective of the Phase 3 study is to demonstrate that secretin improves the ability to detect structural abnormalities of the pancreas by MRI. We believe that a successful Phase 3 study will provide the basis for filing a New Drug Application (NDA) with the FDA for approval to market secretin for this use in the United States. We have received an Orphan Drug designation from the FDA for this use of secretin, which means we will have 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 means our NDA will receive expedited review 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, or 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. Recent 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 of the brain.

Bipolar disorder, also known as manic depression, is marked by extreme changes in mood, energy and behavior in which a person can alternate between mania (highs) and depression (lows). Bipolar disorder affects more than 2 million adults in the United States. Current drug therapy for bipolar disorder includes the use of lithium and anti-psychotic drugs. However, side effects are frequent and troublesome, and patients do not respond fully, leading to poor patient compliance with therapy and frequent recurrences of mania and depression.

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 82 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 compared to placebo. In addition, the patients treated with RG2417 showed a greater improvement in a global assessment of their overall symptoms of bipolar disorder compared to placebo-treated patients. RG2417 was well tolerated by patients and had a good safety profile. This study was partially supported by the Stanley Medical Research Institute. We are currently planning a larger Phase 2b trial to reproduce and extend the results of the Phase 2a study.

Transcription Enhancers for Friedreich's Ataxia

Symptoms of Friedreich's ataxia typically emerge between the ages of five and 15 and often progress to severe disability, incapacitation or loss of life in early adulthood. Friedreich's ataxia is caused by a single gene defect that results in inadequate production of the protein frataxin. The protein frataxin appears to be essential for the proper functioning of the mitochondria, the power plant of both neural and muscle cells. Low levels of frataxin leads to degeneration of both the nerves controlling muscle movements in the arms and legs and the nerve tissue in the spinal cord. Approximately one in every 50,000 people in the United States has 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. Research in cells 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 is currently no treatment for Friedreich's ataxia.

We have chemically synthesized several libraries of compounds related to the initial compounds licensed from Scripps. Some of these compounds have higher potency or improved specificity in laboratory assays. These compounds are currently being evaluated in a variety of animal models for safety and efficacy to determine if one may be a suitable candidate for clinical trials. Preliminary data also suggests that these compounds may have utility in treating other disorders such as Spinal Muscular Atrophy and Huntington's disease.

Sales and Marketing

We sell our Protein A products primarily through value-added resellers including GEHC and Applied Biosystems, Inc., as well as through distributors in certain foreign markets. We market SecreFlo® directly to hospital-based gastroenterologists in the United States.

Significant Customers and Geographic Reporting

Customers for our Protein A products include chromatography companies, diagnostics companies, biopharmaceutical companies and laboratory researchers. During fiscal years 2008, 2007 and 2006, the customers that accounted for more than 10% of our total revenue were GEHC and Applied Biosystems, Inc.

Of our fiscal 2008 product revenue, 36% is attributable to U.S. customers and 64% is attributable to foreign customers, of which 74% is attributable to two customers. Of our fiscal 2007 product revenue, 47% is attributable to U.S. customers and 53% is attributable to foreign customers, of which 72% is attributable to two customers. Of our fiscal 2006 revenue, 48% is attributable to U.S. customers and 52% is attributable to foreign customers, of which 75% is attributable to two customers.

Table of Contents

Employees

As of May 27, 2008, we had 56 employees. Of those employees, 43 were engaged in research, development and manufacturing and 13 in administrative and marketing functions. Twenty 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.

Patents, Licenses and Proprietary Rights

Our policy is to seek patent protection for our therapeutic product candidates. We pursue patent protection in the United States and file corresponding patent applications in relevant foreign jurisdictions. We believe that patents are an important element in the protection of our competitive and proprietary position, but other elements, including trade secrets, orphan drug status and know-how, are also important. We own or have exclusive rights to more than 15 issued U.S. patents and corresponding foreign equivalents. The terms of such patents expire at various times between 2009 and 2021. No patent material to our business expires before 2009. In addition, we have rights to more than 20 U.S. pending patent applications and corresponding foreign applications. The invalidation 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 generally 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

We are the exclusive licensee of all CTLA4-Ig patent rights owned by the University of Michigan. In February 2004, the 941 patent issued, to which we own the exclusive rights through license agreements with the University of Michigan and the U.S. Navy. The 941 patent has claims that cover the use of CTLA4-Ig to treat rheumatoid arthritis, multiple sclerosis and certain other autoimmune disorders and is assigned to the University of Michigan and the U.S. Navy. This patent is exclusively sub-licensed by Repligen to Bristol-Myers Squibb as of April 2008 (see Legal Proceedings).

Uridine

In November 2000 and December 2000, Repligen entered into two license agreements (the UCSD Uridine License Agreements) with the University of California, San Diego (UCSD) for certain patent applications pertaining to the use of uridine and uridine derivatives for the treatment of mitochondrial disease and purine autism. On June 21, 2001, Pro-Neuron, Inc. filed a complaint (the Pro-Neuron Complaint) against the Regents of the University of California (the Regents) and Repligen in the Superior Court of California, County of San Diego seeking to void the UCSD Uridine License Agreement relating to treatment of mitochondrial disease entered into between Repligen and the UCSD. Pro-Neuron, Inc. subsequently amended the complaint to include the UCSD Uridine License Agreement related to purine autism and claims for misappropriation of trade secrets.

In June 2003, Repligen agreed to restructure the UCSD License Agreements to exclude the field of acylated pyrimidines, including triacetyluridine.

In April 2004, a U.S. patent was issued to Repligen and UCSD, which claims methods of treating certain developmental disorders, including certain forms of autism, with uridine compositions which expires in October 2020. Foreign equivalents of this patent are pending. A patent with similar claims has recently issued in Australia.

Protein A

We own a U.S. patent covering recombinant Protein A, which expires in September 2009, as well as significant know-how in the manufacture of high-purity Protein A. We also own a U.S. patent covering modified forms of Protein A, which was non-exclusively licensed to Amersham Biosciences (now GEHC) in 1998 as part of a ten-year agreement, which was amended and extended in 2005 until 2010, covering the supply of Protein A to GEHC.

Table of Contents

In addition to its utility in monoclonal antibody manufacturing, Protein A may also be useful in human therapy based on its activity as a B-cell toxin. Repligen has exclusively licensed rights from UCSD to a U.S. patent application which claims a variety of potential therapeutic uses of Protein A. Foreign equivalents of this patent application are also pending.

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 \$7,241,000 in fiscal 2008, \$5,924,000 in fiscal 2007, and \$5,163,000 in fiscal 2006 on company-sponsored research and development activities.

Competition

Our Protein A and SecreFlo® 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 products from recombinant strains of bacteria. We manufacture Protein A for GEHC under a supply agreement which extends through 2010. In addition, we have a long term supply agreement with Applied Biosystems, Inc. that provides that Repligen will be the preferred provider of recombinant protein A to Applied Biosystems, Inc. until 2011. 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 Protein A are conducted at our facilities. We maintain an active quality assurance effort to support the regulatory requirements of our customers. 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.

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.

We purchase raw materials from more than one commercially established company. Our necessary raw materials are currently commercially available in quantities that far exceed the scale required to complete all of our future planned clinical trials.

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.

Edgar Filing: REPLIGEN CORP - Form 10-K

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 (IND) and are reviewed by the FDA prior to the commencement of human clinical trials.

Table of Contents

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 (adverse effects), dose tolerance, absorption, biodistribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

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

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

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

Available Information

We maintain a website with the address www.repligen.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this annual report on Form 10-K. We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the Securities and Exchange Commission.

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 system at www.sec.gov.

Item 1A. RISK FACTORS

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

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

This annual report on Form 10-K contains forward looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this annual report on Form 10-K.

We 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

Edgar Filing: REPLIGEN CORP - Form 10-K

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.

Table of Contents

We depend 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.

In fiscal 2008, 2007 and 2006, two customers accounted for 74%, 72% and 75%, respectively, of our net sales. 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, we face potentially significant credit risk as those customers comprise 44%, 62% and 75% of our outstanding accounts receivable as of March 31, 2008, 2007 and 2006, respectively. 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.

If our clinical trials are not successful, we will not be able to develop and commercialize any related products.

In order to obtain regulatory approvals for the commercial sale of our future 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 Investigational New Drug (IND) 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 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 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 products will be subject to ongoing regulatory review which will be expensive and may affect our ability to successfully commercialize our products.

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

or manufacturer, including withdrawal of the product from the market.

Table of Contents

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 for our products, we will not be able to succeed commercially.

We must obtain and maintain patent and trade secret protection for those of our products and processes for which patent protection is 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 nor 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.

We have been and may in the future be involved in expensive patent litigation or other intellectual property proceedings which could result in liability for damages or stop our development and commercialization efforts.

Edgar Filing: REPLIGEN CORP - Form 10-K

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.

Table of Contents

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. We may not be able to obtain any required license on commercially acceptable terms or at all.

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 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 manufacturing capabilities and will be dependent on third party manufacturers.

We have limited 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 necessary regulatory approvals. We believe that there is no proprietary aspect to the manufacture of our products. 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 products. Timing for the initiation of new manufacturers is uncertain, and, if we are unable to arrange for third party manufacturing of our products on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them. We currently rely upon third parties for fermentation relating to certain Protein A products.

We believe that there is no proprietary aspect to the manufacture of our commercial products. However, timing for the initiation of new manufacturers is uncertain, and, if we are unable to arrange for third party manufacturing of our products on a timely basis, or to do so on

Edgar Filing: REPLIGEN CORP - Form 10-K

commercially reasonable terms, we may not be able to complete development of our products or market them. To the extent that we enter into manufacturing arrangements with third parties, we are dependent upon these third parties to perform their obligations in a timely manner. If such third party suppliers fail to perform their obligations, we may be adversely affected in a number of ways, including:

we may not be able to meet commercial demands for our products;

we may not be able to initiate or continue clinical trials of products that are under development;

we may be delayed in completing our clinical trials of products under development; and

Table of Contents

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

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

The commercial success of our 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.

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.

We have incurred substantial losses, we may to 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 year 2008 as a result of a one-time litigation settlement, we have incurred operating losses in every other year since our founding in 1981. We may continue to incur operating losses in the foreseeable future.

While we generate revenue from product sales and will begin receiving royalty payments in fiscal year 2009 from Bristol from sales of their Oncia® product, 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.

Table of Contents

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 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.

If we do not obtain additional capital for our drug development programs, 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.

Anti-takeover provisions may deter a third party from acquiring us, limiting our stockholders' ability to profit from such a transaction.

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock, of which 40,000 have been reserved for issuance in connection with our stockholder rights plan, and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our stockholders. We also adopted a poison pill stockholder rights plan that will dilute the stock ownership of acquirers of our common stock upon the occurrence of certain events. This stockholder rights plan could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person becomes an interested stockholder, unless the business combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change of control of the Company. Section 203 and the stockholder rights plan may have the effect of deterring hostile takeovers or delaying or preventing changes in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

Item 1B. UNRESOLVED STAFF COMMENTS

NONE

Item 2. PROPERTIES

We lease approximately 25,000 square feet of space located in Waltham, Massachusetts to be used for our corporate headquarters, manufacturing, research and development, marketing and administrative operations. This lease expires in 2011. We also lease approximately 2,500 square feet of space in an offsite facility also in Waltham to provide for expanded manufacturing operations. This lease expires in 2012. During fiscal 2008, we incurred aggregate rental costs for our facility of approximately \$504,000.

Table of Contents

Item 3. LEGAL PROCEEDINGS

ImClone

In May 2004, Repligen and MIT filed an action in the United States District Court for the District of Massachusetts against ImClone for infringement of U.S. Patent No. 4,663,281 (the 281 patent) based on ImClone s manufacture and sale of Enbrel[®]. 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) 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 after payment of obligations to MIT and legal expenses. The ImClone Settlement served as the basis for Repligen and MIT 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.

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 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 settlement further provides for Bristol to pay 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% of annual sales in excess of \$1 billion for each year 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.

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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of the security holders of the Company through the solicitation of proxies or otherwise, during the last quarter of the fiscal year ended March 31, 2008.

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 following table sets forth for the periods indicated the high and low closing prices for the common stock as reported by Nasdaq.

	Fiscal Year 2008		Fiscal Year 2007	
	High	Low	High	Low
First Quarter	\$ 3.94	\$ 3.14	\$ 3.82	\$ 2.58
Second Quarter	\$ 5.01	\$ 3.74	\$ 3.40	\$ 2.27
Third Quarter	\$ 6.55	\$ 4.12	\$ 3.41	\$ 2.70
Fourth Quarter	\$ 6.86	\$ 4.32	\$ 3.30	\$ 2.80

Table of Contents

Stockholders and Dividends

As of June 1, 2008 there were approximately 748 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.

Issuer Purchases of Equity Securities

We purchased, by means of employee forfeiture, 10,000 shares of unvested restricted stock during the year ended March 31, 2007 at an average price of \$0.01 in connection with the termination of employment by the holder of such restricted stock.

Equity Compensation Plan Information

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

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, 2007, 2006, 2005 and 2004.

	2008 (2)	2007	Years ended March 31,			2004
			2006	2005		
			(In thousands except per share amounts)			
Revenue:						
Product revenue	\$ 18,587	\$ 13,074	\$ 12,529	\$ 9,360	\$ 6,843	
Other revenue	709	1,000	382		71	
Total revenue	19,296	14,074	12,911	9,360	6,914	
Operating expenses:						
Cost of product revenue	6,160	3,615	3,551	3,888	3,248	
Research and development	7,241	5,924	5,163	5,037	6,484	
Selling, general and administrative	10,173	6,360	5,417	4,597	4,710	
Net gain from litigation settlement	(40,170)					
Impairment of long lived asset					2,413	
Total operating expenses	(16,596)	15,899	14,131	13,522	16,855	
Income (loss) from operations	35,892	(1,825)	(1,220)	(4,162)	(9,941)	
Interest expense	(9)	(11)	(3)			
Investment income	2,051	947	750	428	390	
Other income			1,170	750		
Income (loss) before income taxes	37,934	(889)	697	(2,984)	(9,551)	
Provision for income taxes	827					
Net income (loss)	\$ 37,107	\$ (889)	\$ 697	\$ (2,984)	\$ (9,551)	
Earnings Per Share:						
Basic	\$ 1.20	\$ (0.03)	\$ 0.02	\$ (0.10)	\$ (0.32)	
Diluted	\$ 1.18	\$ (0.03)	\$ 0.02	\$ (0.10)	\$ (0.32)	
Weighted average shares outstanding:						
Basic	30,834	30,379	30,125	30,062	29,686	
Diluted	31,321	30,379	30,691	30,062	29,686	
	2008	2007	As of March 31,		2005	2004
			2006			
			(In thousands)			
Balance Sheet Data:						
Cash and marketable securities(1)	\$ 60,589	\$ 22,627	\$ 23,408	\$ 23,523	\$ 24,269	
Working capital	49,831	22,394	18,575	15,673	13,684	
Total assets	68,840	29,076	28,599	27,607	29,615	
Long-term obligations	143	200	231	120	86	
Accumulated deficit	(120,577)	(157,683)	(156,794)	(157,491)	(154,507)	
Stockholders equity	64,107	25,538	25,433	24,290	27,164	

- (1) Excludes restricted cash of \$200 restricted as part of our headquarters lease arrangement for all years presented.
- (2) 2008 includes \$40,170 net gain from litigation settlement.

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, research and development 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 primarily on the development of novel therapeutics for diseases that affect the central nervous system. A number of drug development programs are currently being conducted to evaluate our drug candidates in diseases such as bipolar disorder and neurodegeneration. In addition, we sell two commercial products, Protein A for monoclonal antibody purification and SecreFlo® for assessment of pancreatic disorders. In fiscal 2008, we experienced growth in sales and profits from our commercial products business. Our business strategy is to deploy the profits from our current commercial products and patent licensing revenues to enable us to invest in the development of our therapeutic product candidates while reducing our financial risk.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

While our significant accounting policies are more fully described in 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 and any associated risks related to these policies on our business operations is 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 apply Staff Accounting Bulletin No. 104, "Revenue Recognition" (SAB No. 104) to our revenue arrangements. We generate product revenues from the sale of our Protein A products to customers in the pharmaceutical and process chromatography industries and from the sale of SecreFlo® to hospital-based gastroenterologists. In accordance with SAB No. 104, 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 collectibility of those fees. We have a few longstanding customers who comprise the majority of our revenue and have excellent payment history. We have had no significant write-offs of uncollectible invoices in the periods presented. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

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 our 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 returns, warranty or other issues is largely diminished. Sales returns and warranty issues are infrequent and have had nominal impact on our financial statements historically. Should changes in conditions cause management to determine that warranty, returns or other sale-related reserves are necessary for certain future transactions, revenue recognized for any reporting period could be adversely affected.

During the fiscal years ended March 31, 2008 and March 31, 2007, we recognized \$365,000 and \$825,000, respectively, of revenue from a sponsored research and development project under an agreement with the Stanley Medical

Table of Contents

Research Institute (SMRI). Research revenue is recognized on a cost plus fixed-fee basis when the expense has been incurred and services have been performed. Determination of which costs incurred qualify for reimbursement under the terms of our contractual agreement 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 our arrangement. However, should our estimated calculations change or be challenged by SMRI, research revenue may be adjusted in subsequent periods. Our calculations have not historically changed or been challenged and we do not anticipate any subsequent change in our revenue related to this sponsored research and development project.

Additionally, during fiscal years 2008 and 2007, the Company earned and recognized approximately \$244,000 and \$175,000, respectively in royalty revenue from ChiRhoClin for their sales of secretin. Revenues earned from ChiRhoClin royalties are recorded in the periods when they are earned based on royalty reports sent by ChiRhoClin to the Company.

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 Protein A business. We value inventory at cost or, if lower, fair market value. We determine cost using the first-in, first-out method. We review our inventories 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 our 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 Protein A finished goods is done to order and tested for quality specifications prior to shipment.

A change in the estimated timing or amount of demand for our products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of our 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.

Accrued Liabilities

We prepare our financial statements in accordance with accounting principles generally accepted in the United States. These principles require that we estimate accrued liabilities. This process involves identifying services, which have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of estimated accrued expenses include: 1) Fees paid to our 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 our clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs which have been incurred as of each reporting date; and 3) Professional and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred, or tracking costs incurred by service providers under fixed fee arrangements. 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, our 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 to us 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 has been no material adjustments to our accrued liabilities in any of the periods presented in the accompanying financial statements.

Stock-Based Compensation

Effective April 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95, or SFAS No. 123R, using the

Table of Contents

modified prospective transition method. Under this transition method, compensation cost recognized in the statement of operations for the year ended March 31, 2007 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123 and (b) compensation cost for all share-based payments granted, modified or settled subsequent to April 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated.

Effective with the adoption of SFAS No. 123R, we have elected to use the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date.

The expected term of options granted represents the period of time for which the options are expected to be outstanding and is derived from our historical stock option exercise experience and option expiration data. For option grants made subsequent to the adoption of SFAS No. 123R, the expected life of stock options granted is based on the simplified method allowable under SAB No. 107. 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. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS No. 123R, we accounted for forfeitures upon occurrence as permitted under SFAS No. 123. Based on an analysis of historical data, we have calculated an 8% annual forfeiture rate for non-director level employees, a 3% annual forfeiture rate for director 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.

Prior to April 1, 2006, we applied the pro forma disclosure requirements under SFAS No. 123 and accounted for our stock-based employee compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, (APB No. 25) and related interpretations. Accordingly, no stock-based employee compensation cost was recognized in the statement of operations for the year ended March 31, 2006, as all stock options granted under our existing stock plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

For the years ended March 31, 2008 and 2007, we recorded stock-based compensation expense of approximately \$524,000 and \$837,000, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan.

As of March 31, 2008, there was \$1,030,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.39 years. The Company expects approximately 539,000 of unvested shares of common stock pursuant to outstanding options to vest over the next five years.

Table of Contents**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 revenue for fiscal 2008, 2007 and 2006 were \$19,296,000, \$14,074,000, and \$12,911,000, and were primarily comprised of sales of our commercial products, Protein A and SecreFlo®. During fiscal 2008, 2007 and 2006 sales of our commercial products were:

	Year ended March 31			% Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
	(in thousands, except percentages)				
Protein A	\$ 16,321	\$ 11,127	\$ 10,540	47%	6%
SecreFlo®	2,266	1,947	1,989	16%	-2%
Product revenue	\$ 18,587	\$ 13,074	\$ 12,529	42%	4%

Substantially all of our products based on recombinant Protein A 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, Crohn's disease and a variety of cancers. Sales of Protein A are therefore impacted by the timing of large-scale production orders and on the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

During fiscal 2008, Protein A sales increased by \$5,194,000 or 47% over fiscal 2007. We shipped 45% more volume of Protein A in fiscal 2008 compared to fiscal 2007 due to increased demand by our customers as the monoclonal antibody market continues to grow. The increase in volume predominantly drove the increase in Protein A revenue, with price increases comprising the difference. The Company sells different Protein A products at different price points. The mix of products sold varies and impacts the fluctuations in total product revenue from year to year.

During fiscal 2007, Protein A sales increased by \$587,000 or 6% over fiscal 2006. We shipped 13% less volume of Protein A in fiscal 2007 compared to fiscal 2006. The decrease in volume however did not reduce revenue compared to fiscal 2006, as the mix of products sold had more favorable pricing resulting in a 19% positive impact on total product revenue.

We anticipate that sales of Protein A will decline moderately in fiscal 2009 and continue to be subject to quarterly fluctuations due to timing of large-scale production orders.

Sales of SecreFlo® increased \$319,000 in fiscal 2008 primarily as a result of increased sales to new customers and higher prices.

Sales of SecreFlo® decreased \$42,000 or 2% in fiscal 2007 primarily as a result of direct competition with ChiRhoClin, our sole supplier of SecreFlo® and reduced sales and marketing efforts. Decreases in sales volume impacted sales by 1% of the prior year's total. To remain competitive with ChiRhoClin, we reduced sales prices, which resulted in an unfavorable impact of 1% on SecreFlo® revenues.

The settlement in fiscal 2005 with our sole supplier of SecreFlo® provides for a certain amount of vials of product that we can ultimately ship. The last shipment of SecreFlo® to the Company from ChiRhoClin was received in fiscal 2008 and is expected to allow us to fill sales orders into fiscal 2009. We expect SecreFlo® revenues will decline by ninety percent in fiscal 2009 as we expect to sell our remaining inventory in the first half of the year.

During the fiscal 2008 and 2007, we recognized \$365,000 and \$825,000, respectively, of revenue from a sponsored research and development project under a cost plus fixed-fee agreement with the Stanley Medical Research Institute (SMRI). During fiscal 2008, we recognized \$100,000 under an agreement with the Friedrich's Ataxia Research Alliance. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Additionally, during fiscal 2008 and 2007, we earned and recognized approximately \$244,000 and \$175,000, respectively, in royalty revenue from ChiRhoClin. We expect that total research and license revenues will decrease slightly in fiscal 2009 as we conclude our SMRI

agreement. Royalty revenues should increase significantly as we will begin to receive payments from Bristol as a result of sales of their Orencia® product in fiscal 2009.

Table of Contents*Costs and Operating expenses*

Total costs and operating expenses for fiscal 2008, 2007 and 2006 were approximately (\$16,596,000), \$15,900,000, and \$14,131,000, respectively.

	Year ended March 31,			% Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
(In thousands)					
Costs and operating expenses:					
Cost of product revenue	\$ 6,160	\$ 3,615	\$ 3,551	70%	2%
Research and development	7,241	5,925	5,163	22%	15%
Selling, general and administrative	10,173	6,360	5,417	60%	17%
Net gain from litigation settlement	(40,170)				
Total operating expenses	\$ (16,596)	\$ 15,900	\$ 14,131	(204)%	13%

The increase in cost of product revenue of \$2,545,000 or 70% in fiscal 2008 is attributable primarily to a 42% increase in product sales. In addition, fiscal 2008 revenue growth was driven by lower margin products, resulting in a greater increase in cost of product revenue. Specifically, these newer products are produced on a lower scale, resulting in higher overall production and quality costs per unit sold. Further, depreciation costs have increased \$197,000 associated with expansion of our fermentation facility, and occupancy costs have increased \$136,000 due to our expanded facilities.

The increase in cost of product revenue of \$64,000 or 2% in fiscal 2007 is attributable to several factors. These include a decrease in Protein A material costs of \$267,000 related to lower volume of Protein A production in fiscal 2007 compared to fiscal 2006 and lower costs of \$39,000 related to SecreFlo® sales. These decreases were off-set by an increase of \$163,000 in consulting costs and a \$128,000 increase in occupancy and depreciation costs. Consulting, occupancy and depreciation costs increased due to the costs associated with implementation of our fermentation facility in fiscal 2007, as well as spending to improve our quality and redundancy systems to meet customer expectations. Additionally, we incurred \$26,000 in stock based compensation expense pursuant to the adoption of SFAS No. 123R and had an increase in labor costs of \$147,000 compared to fiscal 2006.

Research and development costs primarily include costs of internal personnel, external research collaborations, clinical trials and the costs associated with the manufacturing and testing of clinical materials. We currently have ongoing research and development programs that support our product candidates of secretin and uridine. In addition, we are involved with a number of early stage programs 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 such as facility costs, depreciation, and supplies, we do not track all our expenses by program.

Each of our 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 expenses tend to increase in later stages of development. Collaborations with commercial vendors and academic researchers accounted for 45%, 40%, and 36% of our research and development expenses for fiscal 2008, 2007 and 2006, respectively. The outsourcing of such services provides us flexibility to discontinue or increase spending depending on the success of our research and development programs.

Research and development expenses increased by \$1,316,000, or 22%, during fiscal 2008. This increase is largely attributable to a \$1,133,000 increase in spending related to Friedreich's Ataxia as we continue to search for a drug candidate. This increase in spending for Friedreich's Ataxia includes \$300,000 relating to common stock issued to the Scripps Research Institute and its designees for the acquisition of a license to use, commercialize and sublicense certain patented technology and improvements thereon, owned or licensed by Scripps. Spending related to uridine

Edgar Filing: REPLIGEN CORP - Form 10-K

for bipolar disorder also increased \$261,000 as we continue our phase 2 trials. Spending related to secretin for diagnostic imaging decreased by \$54,000 as we completed our phase 2 trial and begin preparations for phase 3 in early fiscal 2009.

Research and development expenses increased by \$761,000, or 15%, during fiscal 2007. This increase is largely attributable to higher clinical trial expenses of \$959,000, as the Company enrolled the majority of the patients in our two clinical trial programs for uridine for bipolar disorder and secretin for diagnostic imaging. Additionally, there were increased

Table of Contents

personnel expenses of \$66,000 due to a slightly higher headcount. The Company incurred stock-based compensation expense pursuant to the adoption of SFAS No. 123R in fiscal 2007 of \$229,000. These increases were offset by reductions in external research expenses of \$465,000. This was due to a reduction in activities related to secretin drug manufacturing compared to fiscal 2006.

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 2009 to increase due to clinical trial expenses as we continue studies of secretin for diagnostic imaging, continues drug manufacturing activities for secretin and begins the Friedreich's Ataxia research and development program which was recently licensed by us. Additionally, there may be further increases in expenses if we acquire additional product candidates.

Selling, general and administrative expenses (SG&A) 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.

During fiscal 2008, SG&A costs increased by approximately \$3,813,000 or 60%. This increase was mainly the result of \$3,361,000 incremental litigation costs associated with our patent infringement lawsuits against Bristol and other patent prosecution costs. As noted below, the Company also incurred an additional \$13,830,000 of litigation costs associated with the ImClone settlement. The Company also incurred additional recruiting and related costs of \$263,000 due to the turnover of certain board of director and employee positions.

During fiscal 2007, SG&A costs increased by approximately \$943,000 or 17%. This increase was mainly the result of the stock based compensation expense recorded pursuant to the adoption of SFAS No. 123R of \$582,000 and personnel expenses which increased by \$287,000 due to compensation and benefit increases. Investor relation expenses also increased \$78,000 due to expanded outreach to the investment community. Legal expenses were consistent with fiscal 2006 as we continue to prosecute patent infringement lawsuits against Bristol and ImClone.

We expect SG&A expenses to decrease significantly in fiscal 2009 due to anticipated decreases in litigation expenses as the Bristol and ImClone cases have been successfully concluded, offset by slightly higher headcount and related personnel expenses.

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 2008, 2007 and 2006 was approximately \$2,051,000, \$948,000 and \$750,000, respectively. The increase of \$1,104,000 or 116% in fiscal 2008 is attributable to higher overall cash and marketable securities, up \$37,962,000 due primarily to the proceeds from the ImClone litigation. The increase of \$198,000 or 21% in fiscal 2007 is attributable to higher interest rates. We expect interest income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

Provision for income taxes

As a result of the significant increase in net income in fiscal 2008, the Company was liable for Alternative Minimum Tax, for which net operating loss carryforwards are only partially deductible. As a result, the company had an effective tax rate of 2% as we provided \$827,000 for income taxes in fiscal 2008.

Liquidity and Capital Resources

We have financed our operations primarily through sales of equity securities, revenues derived from product sales, grants, and proceeds from litigation settlements. Our revenue for the foreseeable future will be limited to our Protein A product revenue, royalties from Bristol, and research and development grants. Revenues derived from the sales of SecreFlo vials are expected only through March 2009. Given the uncertainties related to pharmaceutical product development, we are currently unable to reliably estimate when, if ever, our therapeutic product

candidates or our patents will generate revenue and cash flows.

Table of Contents

At March 31, 2008, we had cash and marketable securities of \$60,589,000 compared to \$22,627,000 at March 31, 2007. 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 2008 or 2007.

Cash Flows

(In thousands)

	Year ended March 31,				
	2008	Increase / (Decrease)	2007	Increase / (Decrease)	2006
Cash provided by (used in)					
Operating Activities	\$ 38,467	\$ 38,062	\$ 405	\$ (10)	\$ 415
Investing Activities	(14,229)	(16,004)	1,775	311	1,464
Financing Activities	598	480	118	(215)	333

Operating Activities

In fiscal 2008, our operating activities provided cash of \$38,467,000 which reflects net income of approximately \$37,107,000 which includes non-cash charges totaling approximately \$1,659,000 including depreciation, amortization, stock-based compensation charges and the acquisition of the Scripps license for stock. The remaining cash flow from operations resulted from unfavorable changes in various working capital accounts.

In fiscal 2007, our operating activities provided cash of \$405,000 which reflects a net loss of approximately \$889,000 which includes non-cash charges totaling approximately \$1,376,000 including depreciation, amortization and stock based compensation charges. The remaining cash flow from operations resulted from unfavorable changes in various working capital accounts.

Investing Activities

In fiscal 2008, our investing activities consumed \$14,229,000 of cash, which is primarily due to net purchases of marketable equity securities of \$13,126,000. We also spent \$1,103,000 in capital expenditures as we continue to upgrade both our research and development and manufacturing capabilities. In fiscal 2007, investing activities included capital spending of \$1,327,000 mainly related to the new fermentation facility in Waltham, Massachusetts. We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines.

Financing Activities

In fiscal 2008, exercises of stock options provided cash receipts of \$638,000. In fiscal 2007, exercises of stock options provided cash proceeds of \$158,000.

Off-Balance Sheet Arrangements

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

Contractual Obligations

As of March 31, 2008, we had the following fixed obligations and commitments:

	Total	Payments Due By Period			
		Less than 1 Year	1 3 Years (In thousands)	3 5 Years	More than 5 Years
Operating lease obligations	\$ 2,015	\$ 523	\$ 1,083	\$ 409	\$
Capital lease obligations	94	49	45		
Purchase obligations (1)	784	784			
Contractual obligations (2)	329	138	96	72	23

Edgar Filing: REPLIGEN CORP - Form 10-K

Total	\$ 3,222	\$ 1,494	\$ 1,224	\$ 481	\$ 23
-------	----------	----------	----------	--------	-------

- (1) This amount represents minimum commitments due under a third-party manufacturing agreement.
- (2) These amounts include payments for license, supply and consulting agreements.

Table of Contents

Capital Requirements

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

the success of our clinical studies;

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

our ability to acquire additional product candidates;

the success of any proposed financing efforts; and

the ability to sustain sales and profits of our commercial products.

Absent an acquisition of another product candidate, 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 an increased level of expense in fiscal 2009 compared to those incurred in fiscal 2008. This is due to anticipated increases in clinical study expenses as well as increased personnel expenses, offset by decreased legal fees as we have successfully concluded our litigation activities. Our future capital requirements include, but are not limited to, continued investment in our research and development programs, 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 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, 2008, we had net operating loss carryforwards of approximately \$63,517,000, research and development credit carryforwards of approximately \$2,205,000, and other tax credits of \$733,000 available to reduce future federal income taxes, if any. The net operating loss and tax credit carryforwards will begin to and will continue to expire at various dates, beginning in fiscal 2009, if not used. 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. We did not record a tax provision in fiscal 2007 and 2006 statement of operations as we did not generate taxable income. In fiscal 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.

Recent Accounting Pronouncements

Edgar Filing: REPLIGEN CORP - Form 10-K

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)) and SFAS No. 160, *Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in financial statements, including capitalizing at the acquisition date the fair value of acquired in process research and development projects, and remeasuring and writing down these assets, if necessary, in subsequent periods during their development. The new standards will be applied prospectively for business combinations that occur for the Company on or after April 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding minority interests shall be applied retrospectively.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Agreements* (EITF 07-1). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products. EITF 07-1 is effective for the Company as of April 1, 2009. The Company has not yet completed its evaluation of EITF 07-1, 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 June 2007, the FASB ratified EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF No. 07-3 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of EITF 07-3, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In February 2007, the FASB issued FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS No. 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. SFAS No. 159 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of SFAS No. 159, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* (SFAS 157). SFAS 157 defines fair value, provides guidance for measuring fair value in U.S. generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of SFAS 157, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

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 \$209,000 decrease in the fair value of our investments as of March 31, 2008. However, 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. treasury obligations) and type of instrument. We do not expect any material loss from our marketable security investments due to interest rate fluctuations and therefore believe that our potential interest rate exposure is limited. We intend to hold these investments to maturity, in accordance with our business plans.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL 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

Edgar Filing: REPLIGEN CORP - Form 10-K

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.

Table of Contents

(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;

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, 2008. 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, 2008, 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, 2008. Please see Item 9A of this Form 10-K.

/s/ REPLIGEN CORPORATION

June 11, 2008

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

Table of Contents

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, 2008, 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, 2008, 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, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2008 of Repligen Corporation and our report dated June 11, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

June 11, 2008

(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, 2008 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 Annual Meeting of Stockholders to be held on September 12, 2008.

PART IV

Item 15. EXHIBITS, 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 35 of this Report, as follows:

<u>Report of Independent Registered Public Accounting Firm</u>	Page 36
<u>Balance Sheets as of March 31, 2008 and 2007</u>	37
<u>Statements of Operations for the Years Ended March 31, 2008, 2007 and 2006</u>	38
<u>Statements of Stockholders' Equity for the Years Ended March 31, 2008, 2007 and 2006</u>	39
<u>Statements of Cash Flows for the Years Ended March 31, 2008, 2007 and 2006</u>	40
<u>Notes to Financial Statements</u>	41
(a) (2) <i>Financial Statement Schedules:</i>	

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.

Table of Contents

EXHIBIT INDEX

Exhibit Number	Document Description
3.1	Restated Certificate of Incorporation dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
3.2	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*	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).
4.3	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).
4.5*	The Amended and Restated 2001 Repligen Corporation Stock Option Plan, adopted by the Stockholders on September 10, 2003 (filed as Appendix B to Repligen Corporation's Definitive Proxy Statement on Schedule 14A dated July 22, 2003 and incorporated herein by reference).
4.6	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).
10.1*	Consulting Agreement, dated October 1, 1981, between Dr. Paul Schimmel and Repligen Corporation. (filed as Exhibit 10.1 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
10.2*	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).
10.3*	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).
10.4*	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).
10.5*	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).
#10.6	Patent Purchase Agreement dated as of March 9, 1999 among the Company and Autism Research Institute and Victoria Beck (filed as Exhibit 2.1 to Repligen Corporation's Current Report on Form 8-K/A filed June 15, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
#10.7	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).

Table of Contents

Exhibit Number	Document Description
#10.8	Supply Agreement dated as of May 26, 1999 by and between Repligen Corporation and Amersham Pharmacia Biotech AB (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
#10.9	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).
10.10	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).
#10.11	Wellstat/Repligen Settlement Agreement by and among The Regents of The University of California, Robert Naviaux and Repligen Corporation and dated as of November 16, 2004 (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 and incorporated herein by reference).
#10.12	Regents/Repligen Settlement Agreement by and between Wellstat Therapeutics Corporation (formerly Pro-Neuron, Inc.) and Repligen Corporation and dated as of November 16, 2004 (as Exhibit 10.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 and incorporated herein by reference).
#10.13	Amendment No. 1 to Supply Agreement between Amersham Biosciences and Repligen Corporation dated May 26, 1999, dated February 3, 2005, (SEC File No. 000-14656), (filed as Exhibit 10.13 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2005 and incorporated herein by reference).
10.14*	The 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).
10.15*	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).
10.16*	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).
#10.17	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).
#10.18	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).
#10.19	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).
10.20*+	Employment Offer Letter dated February 29, 2008 by and between Repligen Corporation and William Kelly.
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

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 2008 annual meeting, the Registrant will furnish that person without charge a copy of any exhibits listed above. Requests should be addressed to Repligen Corporation, 41 Seyon Street, Waltham, MA 02453.

Table of Contents**SIGNATURES**

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

REPLIGEN CORPORATION

By: */s/ WALTER C. HERLIHY*
Walter C. Herlihy
Chief Executive Officer and President
(Principal executive officer)

Date: June 13, 2008

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.

Signature	Title	Date
<i>/s/ ALEXANDER RICH</i> Alexander Rich, M.D.	Chairman of the Board of Directors	June 13, 2008
<i>/s/ WALTER HERLIHY</i> Walter C. Herlihy, Ph.D.	President, Chief Executive Officer and Director (Principal executive officer)	June 13, 2008
<i>/s/ WILLIAM J. KELLY</i> William J. Kelly	Vice President, Finance and Administration (Principal accounting and financial officer)	June 13, 2008
<i>/s/ KAREN DAWES</i> Karen Dawes	Director	June 13, 2008
<i>/s/ THOMAS F. RYAN, JR.</i> Thomas F. Ryan, Jr.	Director	June 13, 2008
<i>/s/ EARL W. HENRY</i> Earl W. Henry, M.D.	Director	June 13, 2008

Table of Contents

EXHIBIT INDEX

Exhibit Number	Document Description
3.1	Restated Certificate of Incorporation dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
3.2	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*	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).
4.3	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).
4.5*	The Amended and Restated 2001 Repligen Corporation Stock Option Plan, adopted by the Stockholders on September 10, 2003 (filed as Appendix B to Repligen Corporation's Definitive Proxy Statement on Schedule 14A dated July 22, 2003 and incorporated herein by reference).
4.6	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).
10.1*	Consulting Agreement, dated October 1, 1981, between Dr. Paul Schimmel and Repligen Corporation. (filed as Exhibit 10.1 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference) (SEC File No. 000-14656).
10.2*	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).
10.3*	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).
10.4*	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).
10.5*	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).
#10.6	Patent Purchase Agreement dated as of March 9, 1999 among the Company and Autism Research Institute and Victoria Beck (filed as Exhibit 2.1 to Repligen Corporation's Current Report on Form 8-K/A filed June 15, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
#10.7	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).

Table of Contents

Exhibit Number	Document Description
#10.8	Supply Agreement dated as of May 26, 1999 by and between Repligen Corporation and Amersham Pharmacia Biotech AB (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 and incorporated herein by reference) (SEC File No. 000-14656).
#10.9	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).
10.10	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).
#10.11	Wellstat/Repligen Settlement Agreement by and among The Regents of The University of California, Robert Naviaux and Repligen Corporation and dated as of November 16, 2004 (filed as Exhibit 10.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 and incorporated herein by reference).
#10.12	Regents/Repligen Settlement Agreement by and between Wellstat Therapeutics Corporation (formerly Pro-Neuron, Inc.) and Repligen Corporation and dated as of November 16, 2004 (as Exhibit 10.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 and incorporated herein by reference).
#10.13	Amendment No. 1 to Supply Agreement between Amersham Biosciences and Repligen Corporation dated May 26, 1999, dated February 3, 2005, (SEC File No. 000-14656), (filed as Exhibit 10.13 to Repligen Corporation's Annual Report on Form 10-K for the year ended March 31, 2005 and incorporated herein by reference).
10.14*	The 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).
10.15*	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).
10.16*	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).
#10.17	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).
#10.18	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).
#10.19	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).
10.20*+	Employment Offer Letter dated February 29, 2008 by and between Repligen Corporation and William Kelly
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

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	36
<u>Balance Sheets as of March 31, 2008 and 2007</u>	37
<u>Statements of Operations for the Years Ended March 31, 2008, 2007 and 2006</u>	38
<u>Statements of Stockholders' Equity for the Years Ended March 31, 2008, 2007 and 2006</u>	39
<u>Statements of Cash Flows for the Years Ended March 31, 2008, 2007 and 2006</u>	40
<u>Notes to Financial Statements</u>	41

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, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2008. 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, 2008 and 2007, and the results of its operations, and its cash flows for each of the three years in the period ended March 31, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, on April 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

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, 2008, 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 11, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

June 11, 2008

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

	March 31, 2008	March 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,562,138	\$ 7,726,505
Marketable securities	17,221,653	14,900,840
Accounts receivable, less reserve of \$10,000	1,125,801	1,143,694
Inventories	2,804,247	1,514,571
Prepaid expenses and other current assets	707,347	445,415
Total current assets	54,421,186	25,731,025
Property and equipment, at cost:		
Leasehold improvements	3,333,098	3,212,916
Equipment	3,271,446	2,353,667
Furniture and fixtures	226,655	191,356
Total property and equipment	6,831,199	5,757,939
Less: accumulated depreciation	(3,417,941)	(2,613,081)
Property, plant and equipment, net	3,413,258	3,144,858
Long-term marketable securities	10,805,263	
Restricted cash	200,000	200,000
Total assets	\$ 68,839,707	\$ 29,075,883
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,721,909	\$ 1,161,504
Accrued liabilities	1,867,901	2,175,739
Total current liabilities	4,589,810	3,337,243
Long-term liabilities	143,043	200,342
Total liabilities	4,732,853	3,537,585
Commitments and contingencies (Notes 5, 10 and 11)		
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 31,072,934 shares at March 31, 2008 and 30,477,635 shares at March 31, 2007	310,729	304,776
Additional paid-in capital	184,372,945	182,916,856
Accumulated deficit	(120,576,820)	(157,683,334)
Total stockholders' equity	64,106,854	25,538,298
Total liabilities and stockholders' equity	\$ 68,839,707	\$ 29,075,883

See accompanying notes.

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF OPERATIONS

	Years ended March 31,		
	2008	2007	2006
Revenue:			
Product revenue	\$ 18,587,376	\$ 13,073,894	\$ 12,529,404
Other revenue	708,905	1,000,345	382,000
Total revenue	19,296,281	14,074,239	12,911,404
Operating expenses: (1)			
Cost of product revenue	6,160,245	3,614,837	3,550,861
Research and development	7,240,812	5,924,439	5,163,098
Selling, general and administrative	10,173,400	6,360,292	5,417,339
Net gain from litigation settlement	(40,170,000)		
Total operating expenses	(16,595,543)	15,899,568	14,131,298
Income / (loss) from operations	35,891,824	(1,825,329)	(1,219,894)
Investment income	2,051,258	947,547	750,156
Interest expense	(9,097)	(11,481)	(3,010)
Other income			1,169,608
Income / (loss) before income taxes	37,933,985	(889,263)	696,860
Provision for income taxes	827,471		
Net income (loss)	\$ 37,106,514	\$ (889,263)	\$ 696,860
Basic earnings (loss) per share	\$ 1.20	\$ (0.03)	\$ 0.02
Diluted earnings (loss) per share	\$ 1.18	\$ (0.03)	\$ 0.02
Weighted average shares outstanding:			
Basic	30,834,491	30,379,350	30,125,041
Diluted	31,320,997	30,379,350	30,690,941
(1) Includes non-cash stock-based compensation as follows:			
Cost of product revenue	\$ 28,134	\$ 25,655	\$
Research and development	106,870	228,597	20,650
Selling, general and administrative	389,383	582,280	

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Stockholders' Equity
	Number of Shares	Amount				
Balance at March 31, 2005	30,094,435	\$ 300,944	\$ 181,479,645	\$	\$ (157,490,931)	\$ 24,289,658
Issuance of common stock for services	25,000	250	85,500			85,750
Deferred compensation related to employee stock options	20,000	200	82,600	(82,600)		200
Amortization of deferred compensation				20,650		20,650
Exercise of stock options	238,200	2,382	337,529			339,911
Net income					696,860	696,860
Balance at March 31, 2006	30,377,635	303,776	181,985,274	(61,950)	(156,794,071)	25,433,029
Reclassification of deferred compensation			(61,950)	61,950		
Share-based compensation expense			836,532			836,532
Repurchase and retirement of treasury stock	(10,000)	(100)	100			
Exercise of stock options	110,000	1,100	156,900			158,000
Net loss					(889,263)	(889,263)
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

See accompanying notes.

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF CASH FLOWS

	2008	Years ended March 31, 2007	2006
Cash flows from operating activities:			
Net (loss) income:	\$ 37,106,514	\$ (889,263)	\$ 696,860
Adjustments to reconcile net income to net cash provided by (used in) operating activities			
Issuance of common stock for license	300,000		
Issuance of common stock for services			85,750
Depreciation	824,626	539,032	398,434
Stock-based compensation expense	524,387	836,532	20,650
Loss on disposal of assets	9,559		18,369
Bad debt reserve			(5,000)
Changes in assets and liabilities:			
Accounts receivable	17,893	(549,969)	175,507
Inventories	(1,289,676)	(48,979)	(832,278)
Prepaid expenses and other current assets	(261,932)	106,827	133,906
Accounts payable	1,560,405	95,059	49,487
Accrued liabilities	(267,876)	346,419	(327,805)
Long-term liabilities	(57,299)	(30,176)	1,504
Net cash provided by operating activities	38,466,601	405,482	415,384
Cash flows from investing activities:			
Purchases of marketable securities	(54,797,953)	(13,973,896)	(11,383,595)
Redemptions of marketable securities	41,671,877	17,075,000	13,583,000
Purchases of property and equipment	(1,102,585)	(1,326,529)	(735,495)
Net cash provided by (used in) investing activities	(14,228,661)	1,774,575	1,463,910
Cash flows from financing activities:			
Exercise of stock options	637,655	158,000	340,111
Principal payments under capital lease obligation	(39,962)	(40,029)	(7,609)
Net cash provided by financing activities	597,693	117,971	332,502
Net increase in cash and cash equivalents	24,835,633	2,298,028	2,211,796
Cash and cash equivalents, beginning of period	7,726,505	5,428,477	3,216,681
Cash and cash equivalents, end of period	\$ 32,562,138	\$ 7,726,505	\$ 5,428,477
Supplemental disclosure of non-cash activities			
Purchase of capital lease equipment	\$	\$	\$ 133,261
Non-cash tender of common stock to exercise stock options	\$ 564,003	\$	\$
Reclassification of deferred compensation	\$	\$ 61,950	\$
Recording of deferred compensation	\$	\$	\$ 82,600

Edgar Filing: REPLIGEN CORP - Form 10-K

Disposal of fully depreciated equipment	\$	\$	\$	109,339
---	----	----	----	---------

See accompanying notes.

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 of novel therapeutics primarily for the treatment of diseases of the central nervous system. A number of drug development programs are currently being conducted to evaluate the Company's drug candidates in diseases such as pancreatitis, bipolar disorder and neurodegeneration. In addition, Repligen sells two commercial products, Protein A, for monoclonal antibody purification, and SecreFlo®, for assessment of pancreatic disorders.

The Company's business strategy is to deploy the profits from its commercial products and any revenue that it may receive from its patents to enable the Company to invest in the development of product candidates in the treatment area of neuropsychiatric diseases.

The Company is subject to a number of risks typically associated with companies in the biotechnology industry. Principally those risks are associated with 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 applies Staff Accounting Bulletin No. 104, Revenue Recognition (SAB No. 104) to its revenue arrangements.

The Company generates product revenues from the sale of Protein A products to customers in the pharmaceutical and process chromatography industries and from the sale of SecreFlo® to hospital-based gastroenterologists. In accordance with SAB No. 104, 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 are based on management's judgments primarily regarding the fixed nature of the fee charged for product delivered, and the collectibility of those fees. The Company has a few longstanding customers who comprise the majority of product revenue and have excellent payment history. The Company has had no significant write-offs of uncollectible invoices in the periods presented. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and related purchase orders identify the terms and conditions of each sale and the price of the goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales return, warranty or other issues is largely diminished. Sales returns and warranty issues are infrequent and have had nominal impact on the Company's historical financial statements. Should changes in conditions cause management to determine that warranty, returns or other sale-related reserves are necessary for certain future transactions, revenue recognized for any reporting period could be adversely affected.

During the fiscal years ended March 31, 2008 and 2007, the Company recognized \$365,000 and \$825,000, respectively, of revenue from a sponsored research and development project under an agreement with the Stanley Medical Research Institute (SMRI). In fiscal 2008, the

Edgar Filing: REPLIGEN CORP - Form 10-K

Company recognized \$100,000 under an agreement with the Freidrieich s Ataxia Research Alliance. Research revenue is recognized on a cost plus fixed-fee basis when the expense has been incurred and services have been performed. Determination of which costs incurred qualify for reimbursement under the terms of the contractual agreement and the timing of when such costs were incurred involves the judgment of management. The Company

Table of Contents

believes its calculations are based upon the agreed-upon terms as stated in the contracts. However, should the estimated calculations change or be challenged, 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.

Additionally, during fiscal 2008 and 2007, the Company earned and recognized approximately \$244,000 and \$175,000 in royalty revenue, respectively, from ChiRhoClin, Inc. (ChiRhoClin) based on their sales of secretin. Revenues earned from ChiRhoClin royalties are recorded in the periods when they are earned based on royalty reports sent by ChiRhoClin to the Company.

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)

The Company applies the standards established in Statement of Financial Accounting Standards (SFAS) No. 130, Reporting Comprehensive Income. SFAS No. 130 requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources. The Company's comprehensive income (loss) is equal to its reported net income (loss) for all periods presented.

Cash Equivalents & Marketable Securities

The Company applies the standards established in SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At March 31, 2008, the majority of the Company's cash equivalents and marketable securities are classified as held-to-maturity investments as the Company has the positive intent and ability to hold to maturity. As a result, these investments are recorded at amortized cost. Marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are investment grade securities with maturities of greater than one year.

At March 31, 2008 and 2007, marketable securities also include investment grade auction rate securities, which provide higher yields than money market and other cash equivalent investments. Auction rate securities have long-term underlying maturities, but have interest rates that are reset every 90 days or less, at which time the securities can typically be purchased or sold. The Company does not intend to hold these securities to maturity, but rather to use the securities to provide liquidity as necessary. Auction rate securities are classified as available-for-sale and reported at fair value. Due to the reset feature and their carrying value equaling their fair value, there are no unrealized gains or losses from these short-term investments. Subsequent to March 31, 2008, the Company successfully sold \$825,000 of our auction rate securities without incurring a loss, leaving only \$75,000 remaining in our portfolio.

Table of Contents

Cash and cash equivalents and marketable securities consist of the following at March 31, 2008 and 2007:

Type of Security	As of March 31,		Unrealized Gain (Loss)	
	2008	2007	As of March 31, 2008	As of March 31, 2007
Cash and cash equivalents	\$ 32,562,138	\$ 7,726,505	\$	\$
Marketable securities:				
Auction rate securities	900,000	475,000		
U.S. Government and agency securities		3,460,665		(8,273)
Corporate and other debt securities	16,321,653	10,965,175	106,137	(9,877)
	17,221,653	14,900,840	106,137	(18,150)
Long-term marketable securities:				
Corporate and other debt securities	10,805,263		140,761	
Total	\$ 60,589,054	\$ 22,627,345	\$ 246,898	\$ (18,150)

The average of remaining maturity of long-term marketable securities at March 31, 2008 is approximately one and one half years.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments which represent cash, cash equivalents, marketable securities, and accounts receivable generally approximate fair value due to the short-term nature of these instruments.

Concentrations of Credit Risk and Significant Customers

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and accounts receivable. The Company's cash equivalents and marketable securities are invested in financial instruments with high credit ratings and by policy limits the amount of its credit exposure to any one issue, issuer, (with the exception of U.S. treasury obligations) and type of instrument. At March 31, 2008, the Company has no investments such as those 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. The Company maintains reserves for the potential write-off of accounts receivable. To date, the Company has not written off any significant accounts. 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,		
	2008	2007	2006
Customer A	61%	49%	49%
Customer B	14%	23%	26%

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

	As of March 31,	
	2008	2007
Customer A	20%	47%

Customer B	24%	15%
Inventories		

Inventories relate to the Company's Protein A business. The Company values inventory at cost or, if lower, fair market value. Repligen determines cost 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

Table of Contents

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 Protein A 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.

Work-in-process and finished products inventories consist of material, labor, outside processing costs and manufacturing overhead. Inventories at March 31, 2008 and 2007 consist of the following:

Classification	As of March 31,	
	2008	2007
Raw Materials	\$ 1,676,402	\$ 733,112
Work-in-process	676,769	616,519
Finished products	451,076	164,940
Total	\$ 2,804,247	\$ 1,514,571

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	Five years

The Company recorded a charge to operations for depreciation of property and equipment in the amount of \$824,626, \$539,032 and \$398,434 in 2008, 2007 and 2006, respectively. Depreciation includes the depreciation of assets recorded under capitalized lease agreements which aggregated \$42,762, \$41,850, and \$16,268 in 2008, 2007 and 2006, respectively.

Earnings (Loss) Per Share

The Company applies the standards established in Statement of Financial Accounting Standard (SFAS) No. 128, Presenting Earnings Per Share. Basic earnings (loss) per share for the years ended March 31, 2008, 2007 and 2006 were computed on the basis of the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share were 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 in accordance with SFAS No. 128. Dilutive potential common shares include outstanding stock options.

Basic and diluted weighted average shares outstanding were as follows:

	Twelve Months Ended March 31,		
	2008	2007	2006
Basic weighted average common shares outstanding	30,834,491	30,379,350	30,125,041
Dilutive effect of common stock options	486,506		565,900
Diluted weighted average common shares outstanding	31,320,997	30,379,350	30,690,941

Edgar Filing: REPLIGEN CORP - Form 10-K

Diluted weighted average shares outstanding for the year ended March 31, 2007 does not include 2,292,750 potential common shares for stock options because to do so would be antidilutive. Accordingly, for the year ended March 31, 2007, basic and diluted net loss per share is the same.

Table of Contents

For the years ended March 31, 2008 and 2006, options to purchase 443,000 and 955,400 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 applies the standards established in SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. The chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance, identifies operating segments as components of an enterprise about which separate discrete financial information is available for evaluation. To date, the Company has viewed its operations and manages its business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

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

	Year Ended March 31,		
	2008	2007	2006
Sweden	61%	45%	51%
United States	36%	47%	48%
Other	3%	8%	1%
Total	100%	100%	100%

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

	Year Ended March 31,		
	2008	2007	2006
Protein A	\$ 16,321	\$ 11,127	\$ 10,540
SecreFlo®	2,266	1,947	1,989
Total	\$ 18,587	\$ 13,074	\$ 12,529

As of March 31, 2008 and 2007 all of the Company's assets are located in the United States.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)) and SFAS No. 160, *Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in financial statements, including capitalizing at the acquisition date the fair value of acquired in process research and development projects, and remeasuring and writing down these assets, if necessary, in subsequent periods during their development. The new standards will be applied prospectively for business combinations that occur for the Company on or after April 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding minority interests shall be applied retrospectively.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Agreements* (EITF 07-1). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products. EITF 07-1 is effective for the Company as of April 1, 2009. The Company has not yet completed its evaluation of EITF 07-1, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

Edgar Filing: REPLIGEN CORP - Form 10-K

In June 2007, the FASB ratified EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF No. 07-3 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of EITF 07-3, 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 February 2007, the FASB issued FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS No. 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. SFAS No. 159 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of SFAS No. 159, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* (SFAS 157). SFAS 157 defines fair value, provides guidance for measuring fair value in U.S. generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for the Company as of April 1, 2008. The Company has not yet completed its evaluation of SFAS 157, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

Stock Based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123R, *Share-Based Payment: An Amendment of FASB Statements No. 123 and 95*, (SFAS No. 123R), which requires all companies to measure compensation cost for all share-based payments, including employee stock options, at fair value. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123, *Accounting for Stock-Based Compensation*, (SFAS No. 123). However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value over the requisite service period. Pro forma disclosure is no longer an alternative. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) No. 107 (SAB No. 107), which expressed the views of the SEC regarding the interaction between SFAS No. 123(R) and certain rules and regulations of the SEC. SAB No. 107 provides guidance related to the valuation of share-based payment arrangements for public companies, including assumptions such as expected volatility and expected term.

Prior to the adoption of SFAS No. 123R, the Company applied SFAS No. 123, *Accounting for Stock-Based Compensation*, amended by SFAS No. 148, *Accounting for Stock-based Compensation: Transition and Disclosure*, which allowed companies to apply the existing accounting rules under APB Opinion No. 25. Pursuant to APB Opinion No. 25, the Company accounted for its stock-based awards to employees using the intrinsic-value method, under which compensation expense was measured on the date of grant as the difference between the fair value of the Company's common stock and the option exercise price multiplied by the number of options granted. Generally, the Company granted stock options with exercise prices equal to the fair value of its common stock; however, to the extent that the fair value of the common stock exceeded the exercise price of stock options granted to employees on the date of grant, the Company recorded deferred stock-based compensation and amortized the expense over the vesting schedule of the options, generally four years. During the year ended March 31, 2006, in accordance with APB Opinion No. 25, the Company recorded deferred stock-based compensation resulting from the grant of employee stock options with an exercise price less than the fair value of common stock. As of March 31, 2006, the Company had \$61,950 of deferred stock-based compensation remaining to be amortized. Upon the adoption of SFAS No. 123R on April 1, 2006, the deferred stock-based compensation balance was netted against additional paid-in capital on the balance sheet and statement of stockholders' equity.

The following table illustrates the effect on net income (loss) and net income (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Plans for the fiscal year ended March 31, 2006. Since stock-based compensation expense for the fiscal years ended March 31, 2008 and 2007 was calculated under the provisions of SFAS No. 123R, there is no disclosure of pro forma net income (loss) and net income (loss) per share for those periods. For purposes of the pro forma disclosure for the fiscal year ended March 31, 2006 set forth in the table below, the value of the options is estimated using a Black-Scholes option pricing model and amortized on a straight-line basis to expense over the options' vesting periods.

Table of Contents

	Year ended March 31, 2006
Net income as reported	\$ 696,860
Add: Stock-based employee compensation cost included in reported net income	20,650
Deduct: Stock-based employee compensation cost that would have been included in the determination of net loss as reported if the fair value method had been applied to all awards	(745,043)
Pro forma net (loss)	\$ (27,533)
Basic and diluted net income per common share, as reported	\$ 0.02
Basic and diluted net (loss) per common share, pro forma	\$

Effective April 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123R, using the modified prospective transition method. Under this transition method, compensation cost recognized in the statement of operations for the fiscal year ended March 31, 2007 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123 adjusted for estimated forfeitures and (b) compensation cost for all share-based payments granted, modified or settled subsequent to April 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated.

For the fiscal years ended March 31, 2008 and 2007, the Company recorded stock-based compensation expense of approximately \$524,000 and \$837,000, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan. Basic and diluted earnings per share amounts for the fiscal year ended March 31, 2007 were decreased by \$0.03 as a result of the adoption of SFAS No. 123R.

The Company currently has the following stock-based employee compensation plans which are subject to the provisions of SFAS No. 123R: the 1992 Repligen Corporation Stock Option Plan, as amended, and the Amended and Restated 2001 Repligen Corporation Stock Plan (collectively, the Plans). The 1992 Repligen Corporation Stock Option Plan expired on September 14, 2001, though this had no impact on outstanding option grants. Options granted prior to the date of termination remain outstanding and may be exercised in accordance with their terms.

The Plans allow for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of common stock. Historically, incentive options granted to employees under the Plans generally vested over a four to five-year period, with 20%-25% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At March 31, 2008, options to purchase 1,266,250 shares of common stock were outstanding under the Amended and Restated 2001 Repligen Corporation Plan and options to purchase 356,500 shares of common stock were outstanding under the 1992 Repligen Corporation Stock Option Plan. At March 31, 2008, 442,809 shares were available for future grant under the Amended and Restated 2001 Repligen Corporation Stock Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value on the grant date of stock-based compensation for stock options granted under the Plans. The fair value of stock options granted during the fiscal years ended March 31, 2008, 2007 and 2006 were calculated using the following estimated weighted-average assumptions:

	March 31, 2008	Year ended March 31, 2007	March 31, 2006
Expected term (years)	6.5	6.5	7
Volatility	64.46%-76.85%	77.24%-91.86%	90.79%-94.41%
Risk-free interest rate	2.81%-4.97%	4.44%-5.07%	3.83%-4.58%
Expected dividend yield			

Table of Contents

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. For option grants made subsequent to the adoption of SFAS No. 123R, the expected life of stock options granted is based on the simplified method allowable under SAB No. 107. 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, 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 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.

The Company recognizes 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. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS No. 123R, the Company accounted for forfeitures upon occurrence as permitted under SFAS No. 123. Based on an analysis of historical data, the Company has calculated an 8% annual forfeiture rate for non-director level employees, a 3% annual forfeiture rate for director-level employees, and a 0% forfeiture rate for non-employee members of the Board of Directors, which it believes 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 the Company's current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

Information regarding option activity for the year ended March 31, 2008 under the Plans is summarized below:

	Options Outstanding (in thousands)	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2007	2,293	\$ 3.25		
Granted	327	4.50		
Exercised	(647)	1.86		
Forfeited/Cancelled	(350)	4.26		
Options outstanding at March 31, 2008	1,623	\$ 3.85	5.87	\$ 2,364
Options exercisable at March 31, 2008	1,031	\$ 3.93	4.45	\$ 1,626
Vested and expected to vest at March 31, 2008 (1)	1,570	\$ 3.78	5.99	\$ 2,259

- (1) This represents the number of vested options as of March 31, 2008 plus the number of unvested options expected to vest as of March 31, 2008 based on the unvested outstanding options at March 31, 2008 adjusted for the estimated forfeiture rate of 8% for awards granted to non-director level employees and 3% for awards granted to director level employees.

Edgar Filing: REPLIGEN CORP - Form 10-K

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, 2008 of \$4.82 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, 2008.

Table of Contents

The weighted average grant date fair value of options granted during the fiscal year ended March 31, 2008 was \$3.04. The total fair value of stock options that vested during the fiscal years ended March 31, 2008 and 2007 was approximately \$494,000 and \$869,000, respectively. The total intrinsic value of options exercised during the years ended March 31, 2008, 2007 and 2006 was \$1,672,260, \$189,800, and \$852,152, respectively, determined as of the date of exercise. The Company received \$637,655, \$158,000 and \$339,911 from stock option exercises during the years ended March 31, 2008, 2007 and 2006, respectively.

As of March 31, 2008, there was \$1,030,022 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.39 years. The Company expects approximately 539,000 shares of common stock subject to unvested outstanding options to vest over the next five years.

3. Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, Accounting for Income Taxes.

The Company's tax provision for the year ended March 31, 2008, \$827,471, is comprised of a current provision for federal income taxes in the amount of \$736,805 and a current provision for state income taxes in the amount of \$90,666. The Company did not record a federal or state tax provision for the years ended March 31, 2007 and 2006 since the Company did not generate taxable income in such years.

At March 31, 2008, the Company had net operating loss carryforwards of approximately \$63,517,000, business tax credits carryforwards of approximately \$2,205,000, and other tax credits of approximately \$733,000 available to reduce future federal income taxes, if any. Additionally, at March 31, 2008 the Company also had business tax credits carryforwards of approximately \$2,665,000 available to reduce future state income taxes, if any. At March 31, 2008, the Company had utilized all available state net operating loss carryforwards. Federal net operating loss carryforwards of approximately \$8,482,000 and \$7,533,000 expired in fiscal 2007 and 2006, respectively. The net operating loss and business tax credits carryforwards will continue to expire at various dates through March 2026. 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.

The deferred tax assets consist of the following:

	As of March 31,	
	2008	2007
Temporary timing differences	\$ 5,621,000	\$ 6,580,000
Net operating loss carryforwards	21,596,000	40,060,000
Tax business credits carryforwards	4,697,000	5,270,000
Total deferred tax assets	31,914,000	51,910,000
Valuation allowance	(31,914,000)	(51,910,000)
Net deferred tax asset	\$	\$

At March 31, 2008 and 2007, 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.

Table of Contents

The reconciliation of the federal statutory rate to the effective income tax rate for the years ended March 31, 2008, 2007 and 2006, respectively, is as follows:

	Years Ended March 31,					
	2008		2007		2006	
Income (loss) before income taxes	\$ 37,933,985	%	\$ (889,263)	%	\$ 686,860	%
Expected tax (recovery) at statutory rate	12,897,555	34.0%	(302,349)	34.0%	233,532	34.0%
Adjustments due to:						
State income taxes	1,620,725	4.3%	(53,356)	6.0%	41,212	6.0%
Utilization of loss carryforwards and business tax credits	(13,987,955)	(36.9)%				
Alternative minimum tax	732,817	1.9%				
Permanent differences	191,459	0.5%	152,887	(17.2)%	(5,000)	(0.7)%
Change in valuation allowance	(627,130)	(1.6)%	202,818	(22.8)%	(269,744)	(39.3)%
Provision for income taxes	\$ 827,471	2.2%	\$ 0.0%		\$ 0.0%	

The Company adopted the provisions of FIN 48, an interpretation of SFAS No. 109, *Accounting for Income Taxes*, on April 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At the adoption date and as of March 31, 2008, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required.

The Company may from time to time be assessed interest or penalties by major tax jurisdictions. 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 2005 through 2008 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, 2008, the Company has reserved 2,065,559 shares of common stock pursuant to the Plans. As discussed in Note 11, 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.

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, 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.

Table of Contents**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, 2008 and 2007. In 2007, the Company entered into a five-year lease agreement for 2,500 square feet of space in Waltham, Massachusetts to provide for expanded manufacturing operations.

In fiscal 2006, the Company entered into a capital lease agreement to provide the Company with manufacturing equipment. Repligen received approximately \$171,000 in equipment financing over a five-year period. In fiscal 2005, the Company entered into two capital lease agreements to provide the Company with two pieces of office equipment. Repligen received approximately \$33,000 in equipment financing. The lease terms are three and five years beginning in June and October of 2004, respectively. Capital lease obligations are recorded in accrued liabilities and long-term liabilities in the Company's balance sheets.

Obligations under non-cancelable operating leases, including the facility leases discussed above, and capital equipment leases as of March 31, 2008 are as follows:

Years Ending	Operating Leases	Capitalized Leases
March 31, 2009	\$ 523,251	\$ 48,871
March 31, 2010	541,602	45,211
March 31, 2011	541,602	
March 31, 2012	408,782	
Minimum lease payments	\$ 2,015,237	94,082
Less amount representing interest		(6,995)
Present value of future lease payments		87,087
Less current obligations under capitalized leases		(44,682)
Noncurrent obligations under capitalized leases		\$ 42,405

Rent expense charged to operations under operating leases was approximately \$512,000 for the year ended March 31, 2008 and, \$452,000 for the years ended March 31, 2007 and 2006, respectively. As of March 31, 2008 and 2007, the Company had deferred rent liability of \$118,900 and \$119,000, respectively related to the escalating rent provisions for our 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. As more fully discussed in Note 11 to these financial statements, in April 2007 the Company entered into an exclusive license agreement with the Scripps Research Institute. 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 the year ended March 31, 2008. The Company has recorded as research and development expenses the payments associated with license agreements in the amount of \$681,000, \$87,000, and \$114,000 for the years ended March 31, 2008, 2007 and 2006, 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, 2008 aggregated approximately \$1,113,000 and are expected to be substantially completed within one

year.

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

Prepaid expenses and other current assets consist of the following:

Description	As of March 31,	
	2008	2007
Interest receivable	\$ 422,678	\$ 167,483
Prepaid insurance	137,837	124,376
Equipment and services	108,832	71,656
Clinical and research expenses	35,000	47,636
Other	3,000	34,264
Total	\$ 707,347	\$ 445,415

7. Accrued Liabilities

The Company prepares its financial statements in accordance with accounting principles generally accepted in the United States. These principles require that the Company estimate accrued liabilities. This process involves identifying services, which have been performed on the company's behalf, and estimating the level of service performed and 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.

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 has been no material adjustments to our accrued liabilities in any of the periods presented in the accompanying financial statements.

Accrued liabilities consist of the following:

Description	As of March 31,	
	2008	2007
Employee compensation	\$ 621,982	\$ 557,100
Professional fees	451,287	400,474
Other accrued expenses	217,874	122,836
Other current liabilities	217,162	309,015
Research & development	201,825	602,615
Royalty and license fees	87,806	56,529
Unearned revenue	59,965	127,170
Total	\$ 1,857,901	\$ 2,175,739

In February 2004, the Company terminated its Licensing Agreement with ChiRhoClin, Inc. (ChiRhoClin). On May 9, 2005, Repligen entered into a Settlement Agreement with ChiRhoClin, in full settlement of their arbitration proceedings described below. Repligen determined that it

Edgar Filing: REPLIGEN CORP - Form 10-K

was not required to pay approximately \$1,170,000 of unremitted and accrued royalties to ChiRhoClin. This was recorded as other income in the quarter ended June 30, 2005. Under the terms of the Settlement Agreement, Repligen also received a payment of \$750,000 and is entitled to continue to market SecreFlo® under a royalty structure more favorable to Repligen than under the Licensing Agreement. ChiRhoClin was obligated to deliver a certain amount of SecreFlo® to Repligen and no further deliveries will be made. This payment of \$750,000

Table of Contents

was recorded as *Accrued Liabilities* at the time of settlement. The adoption of EITF 02-16 *Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor* (EITF 02-16) in fiscal 2006 has resulted in the Company reducing cost of goods sold as inventory purchased from ChiRhoClin is sold. Other current liabilities as of March 31, 2008 include \$10,650 related to ChiRhoClin settlement which will be relieved as a reduction to cost of good sold as inventory purchased from ChiRhoClin is sold.

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 who have completed four months of service 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 \$56,647, \$31,353, and \$27,278 for the fiscal years ended March 31, 2008, 2007, and 2006 respectively. Forfeitures of previous participants partially funded contributions for fiscal year 2007. Forfeitures of previous participants completely funded contributions for fiscal year 2006 and as a result had no impact on the Company's operations.

9. Related Party Transaction

The Company paid Drs. Schimmel and Rich, the Co-Chairmen of the Board of Directors prior to Dr. Schimmel's retirement in fiscal 2008, \$32,800 and \$43,200, respectively, during the fiscal year ended March 31, 2008, and \$49,200 and \$43,200, respectively, during each of the fiscal years ended March 31, 2007 and 2006 pursuant to consulting agreements. Pursuant to their terms, these agreements are automatically extended for successive one-year terms unless terminated by either party to the agreement at least 90 days prior to the 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. Dr. Rich's agreement continues until October 31, 2008. Dr. Rich has advised the Company that he has no present intention of terminating his agreement. Drs. Schimmel and Rich received no separate cash compensation for attendance at meetings of the Board of Directors or otherwise as directors.

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®. 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 has been recorded as a separate component of operating expenses in the Company's statement of operations in fiscal 2008.

Table of Contents

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. 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. See Note 12 below for further discussion of events subsequent to year end.

11. Scripps Agreements

License Agreement

On April 6, 2007 (the Effective Date), 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.

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 the Company achieves specified developmental and commercial milestones, certain additional milestone payments. In addition, the Company issued Scripps and certain of its designees 87,464 shares of the Company's common stock (the Shares) representing \$300,000 as of the Effective Date. The Company recorded the initial license payment and the value of the shares issued as research and development costs in the Company's statement of operations in fiscal 2008.

If the value of the Shares does not equal at least \$300,000 on the one-year anniversary of the Effective Date, the Company shall make a cash payment to Scripps equal to the difference. At March 31, 2008 as well as on April 6, 2008, the one-year anniversary of the Effective Date, the fair value of the shares exceeded \$300,000; therefore, no liability has been recorded. The Company issued the Shares in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. The Shares were issued to Scripps, or to designees of Scripps on its behalf, as an accredited investor (as such term is defined in Rule 501(a) of Regulation D) without general solicitation or advertising and did not involve a public offering.

Furthermore, 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 in fiscal 2008, 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 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 and Funding 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 \$140,000 annually, payable quarterly, which are 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 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

Edgar Filing: REPLIGEN CORP - Form 10-K

licensed technology, or (e) defaults in its performance under the Funding Agreement; or (iv) by the Company upon 90 days written notice. The Company made payments to Scripps of \$105,000 during the year ended March 31, 2008 in connection with the Funding Agreement.

Table of Contents**12. Subsequent Event**

On April 7, 2008, Repligen and the University of Michigan entered into a settlement agreement (the Bristol Settlement) with Bristol-Myers Squibb relating to the lawsuit against Bristol-Myers Squibb for infringement of the 941 patent. Pursuant to the Bristol Settlement, Bristol-Myers Squibb made an initial payment of \$5 million to Repligen. The settlement further provides for Bristol-Myers Squibb to pay royalties on the United States net sales of Orencia® for any clinical indication at a rate of 1.8% for the first \$500 million of annual net sales, 2.0% for the next \$500 million of annual net sales and 4% of annual net sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013. The Bristol Settlement served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against Bristol-Myers Squibb and for Repligen and the University of Michigan to grant to Bristol Myers-Squibb an exclusive worldwide license to the 941 patent and certain other intellectual property.

13. Selected Quarterly Financial Data (Unaudited)

The following table contains statements of operations information for each quarter of fiscal 2008 and 2007. 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 FY08	Q3 FY08	Q2 FY08	Q1 FY08	Q4 FY07	Q3 FY07	Q2 FY07	Q1 FY07
	(in thousands, except per share amounts)							
Revenue:								
Product revenue	\$ 3,137	\$ 4,563	\$ 5,156	\$ 5,731	\$ 3,397	\$ 3,633	\$ 2,680	\$ 3,364
Research revenue	164	101	196	248	302	249	185	264
Total revenue	3,301	4,664	5,352	5,979	3,699	3,882	2,865	3,628
Operating expenses:								
Cost of revenue	1,304	1,730	1,412	1,714	902	805	915	993
Research and development	2,357	1,592	1,154	2,138	1,452	1,674	1,583	1,215
Selling, general and administrative	3,504	2,341	2,186	2,142	1,696	1,660	1,463	1,541
Net gain from litigation settlement (1)			(40,170)					
Total operating expenses	7,165	5,663	(35,418)	5,994	4,050	4,139	3,961	3,749
Income (loss) from operations	(3,864)	(999)	40,770	(15)	(351)	(257)	(1,096)	(121)
Investment income	669	759	366	257	247	240	236	225
Interest expense	(2)	(2)	(3)	(2)	(3)	(3)	(3)	(3)
Income (loss) before taxes	(3,197)	(242)	41,133	240	(107)	(20)	(863)	101
Income tax provision			(827)					
Net income (loss)	\$ (3,197)	\$ (242)	\$ 40,306	\$ 240	\$ (107)	\$ (20)	\$ (863)	\$ 101
Earning per share:								
Basic	\$ (0.10)	\$ (0.01)	\$ 1.31	\$ 0.01	\$ (0.00)	\$ (0.00)	\$ (0.03)	\$ (0.00)
Diluted	\$ (0.10)	\$ (0.01)	\$ 1.29	\$ 0.01	\$ (0.00)	\$ (0.00)	\$ (0.03)	\$ (0.00)
Weighted average shares outstanding:								
Basic	31,064	30,954	30,767	30,564	30,420	30,376	30,364	30,358
Diluted	31,064	30,954	31,224	31,127	30,420	30,376	30,364	30,828

Edgar Filing: REPLIGEN CORP - Form 10-K

- (1) Second quarter in fiscal 2008 includes \$40,170 net gain from litigation settlement (see Note 10).

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:				
2006	\$ 15,000		\$ 5,000	\$ 10,000
2007	\$ 10,000			\$ 10,000
2008	\$ 10,000	\$ 5,000	\$ 5,000	\$ 10,000