REPLIGEN CORP Form 10-K June 09, 2006 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, 2006

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: 0-14656

REPLIGEN CORPORATION

(Exact name of Registrant as specified in its charter)

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: None

Securities registered pursuant to Section 12(g) of the Act

Common Stock, \$0.01 Par Value Per Share

Series A Junior Participating Preferred Stock Purchase Rights

(Title of 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 b.

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 b.

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 b 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.

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

Large accelerated filer " Accelerated filer b Non-accelerated filer "

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of September 30, 2005 the last business day of the registrant s most recently completed second fiscal quarter, was approximately \$93,925,837.

The number of shares of outstanding of the registrant s common stock as of June 6, 2006 was 30,377,635.

DOCUMENTS INCORPORATED BY REFERENCE

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 Certain Factors that May Affect Future Results and elsewhere in this Annual Report on Form 10-K.

We are developing novel therapeutics for the treatment of diseases of the central nervous system. We also own intellectual property on two biological therapies which may provide future revenues to support our product development efforts in neurological diseases. We also are a leading manufacturer of Protein A which is used in the production of many therapeutic monoclonal antibodies.

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. We partially fund the development of our proprietary therapeutic product candidates with the profits derived from the sales of our commercial products. This will enable us to independently advance our product candidates while at the same time minimize our operating losses.

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 two products: 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. In February 2005 we announced an amended and expanded Supply Agreement (the Agreement) with GE Healthcare (GEHC), the leading supplier of purification products to the biopharmaceutical industry and the largest consumer of Protein A. The Agreement calls for Repligen to be the primary supplier of Protein A to GEHC through 2010. We are also collaborating with GEHC to scale-up the production of a modified form of Protein A which may provide additional value to the producers of monoclonal antibodies. 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 \$15 billion in 2005. This growth is based on the increasing use of therapeutic antibodies, including Erbitux® 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 October 1999, we licensed exclusive commercial rights to a diagnostic product based on a synthetic form of porcine (pig-derived) secretin, which we market as SecreFlo®, from ChiRhoClin, Inc. (ChiRhoClin), a private company. ChiRhoClin is our sole supplier of SecreFlo 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. In 2004 we terminated our agreement with ChiRhoClin for breach and filed an arbitration proceeding against ChiRhoClin for their alleged failure to meet certain obligations related to product and clinical development. In May 2005 we announced the settlement of the arbitration proceeding through an agreement by which we will continue to sell SecreFlo® for the next few years.

Intellectual Property on Monoclonal Antibody and Antibody Fusion Products

Erbitux®

Erbitux® is a monoclonal antibody developed by ImClone Systems (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. We believe that Erbitux® is manufactured with a cell line created by a company whose assets were subsequently acquired by Repligen. This cell line contains certain patented genetic technologies (DNA enhancers) which increase the productivity of a cell line. This patent is assigned to MIT and exclusively licensed to Repligen. Imclone previously announced that it had manufactured approximately \$1 billion of Erbitux® as of February 2004. Imclone recently reported that nearly all of this pre-approval stockpile of Erbitux® was exhausted by the end of December 2005. In May 2004, Repligen and MIT filed a lawsuit against Imclone alleging that Imclone has infringed our patent rights in its production of Erbitux®. Our patent expired in May 2004 and we have applied for a 5 year term extension for the patent, or until May 2009.

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 block organ transplant rejection and to treat certain autoimmune diseases. Additional animal and human studies by many other groups have confirmed that CTLA4-Ig may be useful in treating diseases such as rheumatoid arthritis, multiple sclerosis, lupus, psoriasis and organ transplant rejection. 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 February 2004, we were issued a U.S. patent covering the use of CTLA4-Ig for the treatment of rheumatoid arthritis, multiple sclerosis and lupus. This patent is in force until 2021. In August 2004 we were issued a European patent covering the use of CTLA4-Ig for the treatment of autoimmune disease including rheumatoid arthritis as well as organ transplant rejection. This patent is in force until 2013.

In December 2005, the FDA approved Bristol-Myers Squibb Corporation s (Bristol) application to market CTLA4-Ig, under the brand name Orencia®, for treatment of rheumatoid arthritis. Bristol started commercial sales of Orencia® in February 2006.

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

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.

Development Stage Products for Neuropsychiatric Disorders

Secretin

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. More recently, secretin and its receptor have been found in the central nervous system, suggesting a possible role as a neurotransmitter. We are evaluating secretin as a treatment for schizophrenia and for improvement of MRI imaging of the pancreas.

Schizophrenia is a serious, disabling and chronic mental disorder that affects 2 million people in the United States. Schizophrenia is characterized by thought disorders such as delusions or hallucinations, as well as social withdrawal, lack of initiative, and cognitive deficits. Current antipsychotic drugs are effective in reducing thought disorders in some patients but have limited effects on the social withdrawal or cognitive symptoms. The total cost for the care and treatment of patients with schizophrenia in the United States in 2002 was over \$60 billion.

We have completed enrollment in a follow-on study to assess the impact of RG1068, synthetic human secretin, on a surrogate marker for a cognitive deficit characteristic of patients with schizophrenia. This study was conducted to determine if the preliminary finding that secretin may have had an impact on a cognitive deficit in schizophrenia is reproducible and related to drug treatment. This was an investigator initiated study conducted by Indiana University Hospital School of Medicine. Twenty-eight patients were assigned to one of two double blind treatment groups, and received either subcutaneous saline or subcutaneous RG1068. Additional assessments were made on the patients to investigate the effects of RG1068 on information processing and affect modulation. A preliminary review of the blinded data suggests that while there may be an effect of drug treatment, further analysis of the data will be necessary to understand the potential impact of secretin on this patient population.

Secretin has gained acceptance especially in Europe for use with abdominal MRI imaging to improve visualization of pancreaticobiliary structures and to increase diagnostic sensitivity relative to unenhanced abdominal MRI. MRI technology images stationary 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 procedures.

In June, we initiated a clinical trial to evaluate the use of RG1068 as an agent to improve the detection of structural abnormalities of the pancreatic ducts during MRI imaging of the pancreas. This is a multi-center, baseline controlled, single dose study in which 80 patients with a history of pancreatitis will receive a secretin-enhanced MRI and an unenhanced MRI of the pancreas. This study will assess the sensitivity and specificity of secretin-enhanced MRI to improve the ability to detect pancreatic duct abnormalities relative to unenhanced MRI as well as the safety of secretin in combination with MRI. This study is being initiated at approximately 8-10 clinical sites. Discussions with the FDA have resulted in a consensus on the design of a clinical study to support this indication including patient selection, study operations and endpoints.

Uridine

Uridine is a biological compound essential for 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 CNS disorders is supported by pre-clinical and clinical research. Researchers at McLean Hospital previously demonstrated that

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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 new 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-depressants. However side effects are frequent and troublesome, and patients do not respond fully, leading to frequent recurrences of mania and depression.

In March 2006 we initiated a Phase 2 clinical trial of RG2417, an oral formulation of uridine, in patients with bipolar depression. This Phase 2 study is a multi-center, dose escalating study in which 80 patients will receive either RG2417 or a placebo for 6 weeks. Patients will be evaluated for the safety and effectiveness of RG2417 on the symptoms of bipolar depression. This study is being conducted under a development agreement with the Stanley Medical Research Institute, under which Repligen will receive approximately \$1,200,000 in funding. The Stanley Medical Research Institute is the largest nonprofit provider of funding for research on schizophrenia and bipolar disorder in the United States.

Repligen previously completed a 6-week Phase 1 clinical trial of a prodrug of uridine (RG2133) in patients with bipolar disorder or major depression. The results demonstrated that administration of RG2133 in this patient population appeared to be safe, did not induce mania, and provided early evidence of a clinical effect of the drug. The trial evaluated 19 patients and was carried out by investigators at McLean Hospital, the largest psychiatric clinical care, teaching and research affiliate of Harvard Medical School.

Repligen s Business Strategy

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. We partially fund the development of our proprietary therapeutic product candidates with the profits derived from the sales of our commercial products. This will enable us to independently advance our product candidates while at the same time minimize our operating losses.

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 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 year 2006, the customers that accounted for more than 10% of our total revenue were GEHC and Applied Biosystems, Inc. During fiscal year 2005, the customers that accounted for more than 10% of our total revenue were GEHC, Applied Biosystems, Inc. and Cardinal Healthcare. During fiscal 2004, the customers that accounted for more than 10% of our total revenue were GEHC and Cardinal Healthcare.

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. Of our fiscal 2005 revenue, 43% is attributable to U.S. customers and 56% is attributable to foreign customers, of which 77% is attributable to three customers. Of our fiscal 2004 revenue, 50% is attributable to U.S. customers and 50% is attributable to foreign customers, of which 54% is attributable to two customers.

Employees

As of June 6, 2006 we had 43 employees. Of those employees, 30 were engaged in research, development and manufacturing and 13 in administrative and marketing functions. Fifteen 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, may also be 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.

Secretin

We are currently prosecuting patent applications for the use of secretin for the treatment of anxiety disorders and schizophrenia in the United States and key foreign markets. In March 2003, the University of North Carolina (UNC) filed patent applications claiming the use of secretin for the treatment of certain behavioral disorders, including schizophrenia. In March 2004, we exclusively licensed UNC s rights in this area, which is unrelated to SecreFlo[®].

CTLA4-Ig

We are the exclusive licensee of all CTLA4-Ig patent rights owned by the University of Michigan (Michigan). In February 2004, U.S. Patent No. 6,685,941 (the 941 patent) issued, to which we own the exclusive rights through license agreements with 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. The 941 patent expires in 2021. In August 2004, we were granted a European patent which claims the use of CTLA4-Ig in the treatment of autoimmune disease including rheumatoid arthritis as well as organ transplant. This patent will remain in force until 2013. Under the European system third parties can file oppositions to patents during the nine months following grant of a European patent. On May 4, 2005, Bristol filed an opposition to our European patent which initiates the opposition process and we have answered Bristol s opposition papers. The European Patent Office (EPO) will next schedule a hearing to allow both sides to orally present their case, following which a ruling will be made. The ruling will either uphold the patent claims as granted, modify the claims, or rescind the claims.

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Any ruling may be appealed, in whole or in part. Regardless of an opposition or any outcome during the opposition process, a granted European patent is held to be in effect and valid for its natural term or until such time as all final appeals are exhausted or waived. We intend to vigorously defend our granted European patent through the opposition process.

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 University of California, 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 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.

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 the University of California, San Diego to a United States 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 substantially all of our resources to the research and development of therapeutic product candidates and our commercial products and product candidates discussed herein. We spent \$5,163,000 in fiscal 2006, \$5,037,000 in fiscal 2005, and \$6,484,000 in fiscal 2004 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 ten-year supply agreement which was initiated in December 1998. In February 2005, we announced an amended and expanded Supply Agreement with GEHC, the leading supplier of purification products to the biopharmaceutical industry and the largest consumer of Protein A. While third parties carry out certain fermentation and certain recovery operations, 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.

SecreFlo® (synthetic porcine secretin)

SecreFlo® our diagnostic secretin product, is purchased from ChiRhoClin who contracts with third parties for the synthesis of the drug substance and the drug product. This company is our sole supplier for this product. Under the terms of a settlement agreement, ChiRhoClin is obligated to deliver a certain amount of SecreFlo® to Repligen over the next few years. After depletion of all supplies of SecreFlo®, including those to be delivered under the settlement agreement, Repligen will cease marketing and selling SecreFlo®. (For more information about the settlement agreement with ChiRhoClin, please see Item 3 Legal Proceedings.)

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 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.

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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.

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 a New Drug Application (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.

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Item 1A. RISK FACTORS CERTAIN FACTORS THAT MAY AFFECT FUTURE RESULTS

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

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

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

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

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

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 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.

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;

operate without infringing the proprietary rights of third parties; and

secure licenses from others on acceptable terms.

preserve our trade secrets;

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;

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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 and 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 are currently 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.

There has been substantial litigation and other proceedings regarding the complex patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We are a party to, and in the future may become a party to, patent litigation or other proceedings regarding intellectual property rights.

Other types of situations in which we may become involved in patent litigation or other intellectual property proceedings include:

We may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or services do not infringe such third parties patents.

We may initiate litigation or other proceedings against third parties to seek to enforce our patents against infringement.

If our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention.

If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such claims.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably to us, we or our collaborative partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. 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.

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For more information about the legal proceeding in which we are involved, 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 our 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 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;

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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

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.

We rely on a single supplier (ChiRhoClin) for our SecreFlo® product

We rely on a single supplier (ChiRhoClin) for our SecreFlo® product. Under the terms of our settlement agreement, ChiRhoClin is obligated to deliver a certain amount of SecreFlo® to Repligen over the next few years. After depletion of all supplies of SecreFlo®, including those to be delivered under the settlement agreement, Repligen will cease marketing and selling SecreFlo®. In the event that we are unable to acquire additional products, our revenues may be negatively impacted. (For more information about the settlement agreement regarding SecreFlo®, please see Legal Proceedings.)

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:

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

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

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

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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 expect to continue to incur operating losses and we will not be successful until we reverse this trend.

We have incurred operating losses in each year since our founding in 1981. We expect to continue to incur operating losses for the foreseeable future.

While we generate revenue from product sales, this revenue is not 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.

If we do not obtain additional capital for our drug development programs, we will be unable to develop or discover new drugs.

We 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 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 will 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.

Changes in the securities laws and regulations have increased, and are likely to continue to increase our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the Nasdaq have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards have increased our legal costs and financial and accounting costs, and we expect these increased costs to continue. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors.

Item 1B. NONE

Item 2. PROPERTIES.

We lease approximately 25,000 square feet of space in Waltham, Massachusetts, of which approximately 10,000 square feet is manufacturing and laboratory space. The remaining space is used as office space. Our lease expires in January 2013, with options to extend for two five-year periods. During fiscal 2006, we incurred aggregate rental costs for our facility, excluding maintenance, taxes and utilities, of approximately \$394,000. Our space is adequate for our current use and for the foreseeable future.

Item 3. LEGAL PROCEEDINGS. Bristol-Myers Squibb Company

In January 2006, Repligen Corporation 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 OrencThe 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, 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.

ImClone Systems, Inc.

In May 2004, Repligen Corporation and The Massachusetts Institute of Technology (MIT) filed an action for patent infringement in the United States District Court for the District of Massachusetts against ImClone Systems, Inc. (Imclone) for infringement of U.S. Patent No. 4,663,281 (the 281 patent) based on Imclone s manufacture and sale of the cancer drug Efbilihe technology claimed by the 281 patent, which was invented by researchers at MIT, covers certain genetic elements (DNA enhancers) that increase protein production in a mammalian cell. Repligen is the exclusive licensee of the 281 patent from MIT. Damon Biotech, a predecessor of Repligen, developed the cell line which is used to manufacture Erbitux® in 1990 for the National Cancer Institute and incorporated the DNA enhancer technology which is the basis of the 281 patent. Repligen seeks relief, including compensation in the form of royalties for the material Imclone manufactured prior to the expiration of the 281 patent in May of 2004.

In February 2006, the Court heard oral arguments on summary judgment motions brought by plaintiffs Repligen and MIT and defendant Imclone on the issue of exhaustion of patent rights. The Court may: 1) rule in plaintiffs favor, dispose of Imclone s patent exhaustion defense and set the case for trial; 2) deny both parties motions and set the case for trial; or 3) rule in Imclone s favor and enter judgment against plaintiffs in the case, subject to appeal.

Repligen and MIT have also filed an application for patent term extension for the 281 patent, which if granted will extend the term of the patent to May 2009.

ChiRhoClin, Inc.

In February 2004, Repligen terminated the September 1999 Licensing Agreement with ChiRhoClin, its supplier of SecreFlo[®], based on ChiRhoClin s alleged failure to meet its obligations under the Licensing Agreement.

On April 9, 2004, Repligen filed an arbitration demand against ChiRhoClin with the American Arbitration Association in New York seeking to recover payments made to ChiRhoClin and additional damages. In this arbitration demand, Repligen alleged that ChiRhoClin breached several of its obligations under the September 1999 Licensing Agreement including failure to use best efforts to obtain various FDA approvals and to manufacture and supply SecreFlo®, in a timely manner. In June 2004, ChiRhoClin filed a counterclaim alleging that Repligen had wrongfully terminated the Licensing Agreement.

On May 9, 2005, Repligen entered into a Settlement Agreement (the Agreement) with ChiRhoClin, Inc., in full settlement of the arbitration proceedings described above. Under the terms of the Agreement, Repligen received a payment of \$750,000 and will be entitled to continue to market SecreFlo®, for the next several years under a royalty structure more favorable to Repligen than under the Licensing Agreement. ChiRhoClin is obligated to deliver a certain amount of SecreFlo®, to Repligen over the next few years. This payment of \$750,000 was recorded as Accrued Liabilities as of June 30, 2005. The adoption of EITF 02-16 Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor has resulted in the reduction of cost of goods sold as future inventory purchased from ChiRhoClin is sold. After depletion of all supplies of SecreFlo® provided by ChiRhoClin, including those to be delivered under the Agreement, Repligen will cease marketing and selling a secretin product supplied by ChiRhoClin. ChiRhoClin will pay Repligen a per unit royalty on all sales by ChiRhoClin of its secretin products subject to certain time and/or volume limits. Repligen is not required to pay approximately \$1,170,000 of unremitted royalties to ChiRhoClin related to sales from February 2004 to March 2005. This amount which was accrued at March 31, 2005 was recorded as other income in the quarter ended June 30, 2005. Repligen has received security for ChiRhoClin s performance under the Agreement.

Other

From time to time, the Company may be subject to other legal proceedings and claims in the ordinary course of business. Repligen is not currently aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on the 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, 2006.

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PART II

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is traded over-the-counter on the Nasdaq National Market under the symbol RGEN. The following table sets forth for the periods indicated the high and low bid information for the common stock as reported by Nasdaq. These quotations reflect inter-dealer prices, without retail markup, markdown or commission and may not necessarily reflect actual transactions.

	Fiscal	Fiscal Year 2006		Fiscal Year 2005	
	High	Low	High	Low	
First Quarter	\$ 2.45	\$ 1.67	\$ 3.44	\$ 2.33	
Second Quarter	\$ 4.00	\$ 1.99	\$ 2.44	\$ 1.32	
Third Quarter	\$ 4.00	\$ 2.80	\$ 2.88	\$ 1.70	
Fourth Quarter	\$ 4.99	\$ 3.43	\$ 2.90	\$ 1.68	

Stockholders and Dividends

As of June 7, 2006 there were approximately 811 stockholders of record of our common stock. We have not paid any dividends since our inception and do not intend to pay any dividends on our common stock in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Any future determination as to the payment of dividends will be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Equity Compensation Plan Information

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

Recent Sales of Unregistered Securities

On March 1, 2006, we engaged CEOcast, Inc. to render investor relations services. In exchange and as consideration for CEOcast Inc. s investor relations services, we issued 25,000 restricted shares of common stock to CEOcast Inc. We recorded the value of these shares as determined using Black-Scholes option pricing model as selling, general and administrative expense in fiscal year 2006 in the accompanying statements of operations. No underwriters were involved in the issuance of this restricted common stock. The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended since the shares were issued to a single entity and based on other facts. The restrictions on the shares will lapse on March 1, 2007.

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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, 2005, 2004, 2003 and 2002.

Years ended March 31, 2006 2005 2004