

REPLIGEN CORP
Form 10-Q
February 07, 2008
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended December 31, 2007

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, Bldg. 1, Suite 100

Waltham, MA
(Address of principal executive offices)

02453
(Zip Code)

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

Edgar Filing: REPLIGEN CORP - Form 10-Q

(Former name, former address and former fiscal year, if changed since last report.)

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

Indicate by check mark whether the registrant 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 ☒ Non-accelerated filer ☐

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of February 5, 2008.

Class	Number of Shares
Common Stock, par value \$.01 per share	31,056,434

Table of Contents

REPLIGEN CORPORATION

INDEX

	PAGE
PART I. FINANCIAL INFORMATION	
Item 1. <u>Unaudited Financial Statements</u>	
<u>Balance Sheets as of December 31, 2007 and March 31, 2007</u>	3
<u>Statements of Operations for the Three and Nine-Month Periods Ended December 31, 2007 and 2006</u>	4
<u>Statements of Cash Flows for the Nine Months Ended December 31, 2007 and 2006</u>	5
<u>Notes to Unaudited Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	18
Item 1A. <u>Risk Factors</u>	20
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 3. <u>Defaults Upon Senior Securities</u>	20
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	20
Item 5. <u>Other Information</u>	20
Item 6. <u>Exhibits</u>	20
<u>Signatures</u>	21
<u>Exhibit Index</u>	22

Table of Contents**REPLIGEN CORPORATION****BALANCE SHEETS****(Unaudited)**

	December 31, 2007	March 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,920,255	\$ 7,726,505
Marketable securities	35,824,587	14,900,840
Accounts receivable, less reserve of \$ 25,000	3,448,355	1,143,694
Inventories	1,524,688	1,514,571
Prepaid expenses and other current assets	783,978	445,415
Total current assets	57,501,863	25,731,025
Property, plant and equipment, at cost:		
Leasehold improvements	3,270,193	3,212,916
Equipment	2,893,320	2,353,667
Furniture and fixtures	205,517	191,356
	6,369,030	5,757,939
Less: Accumulated depreciation and amortization	(3,210,100)	(2,613,081)
	3,158,930	3,144,858
Long-term marketable securities	9,597,903	
Restricted cash	200,000	200,000
TOTAL ASSETS	\$ 70,458,696	\$ 29,075,883
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 874,594	\$ 1,161,504
Accrued liabilities	2,324,466	2,175,739
Total current liabilities	3,199,060	3,337,243
Long-term liabilities	137,100	200,342
Total liabilities	3,336,160	3,537,585
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; authorized: 5,000,000 shares, issued or outstanding: none		
Common stock, \$.01 par value; authorized: 40,000,000 shares, issued and outstanding: 31,055,434 shares at December 31, 2007 and 30,477,635 shares at March 31, 2007	310,524	304,776
Additional paid-in capital	184,191,233	182,916,856
Accumulated deficit	(117,379,221)	(157,683,334)
Total stockholders' equity	67,122,536	25,538,298
Total liabilities and stockholders' equity	\$ 70,458,696	\$ 29,075,883

Edgar Filing: REPLIGEN CORP - Form 10-Q

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended December 31,		Nine months ended December 31,	
	2007	2006	2007	2006
Revenue:				
Product revenue	\$ 4,562,976	\$ 3,633,683	\$ 15,450,799	\$ 9,677,157
Other revenue	101,390	248,756	544,705	698,270
Total revenue	4,664,366	3,882,439	15,995,504	10,375,427
Operating expenses: (1)				
Cost of product revenue	1,730,464	804,913	4,857,191	2,712,885
Research and development	1,591,796	1,674,584	4,883,116	4,472,224
Selling, general and administrative	2,341,108	1,659,931	6,669,038	4,664,347
Net gain from litigation settlement (see Note 13)			(40,170,000)	
Total operating expenses	5,663,368	4,139,428	(23,760,655)	11,849,456
Income (loss) from operations	(999,002)	(256,989)	39,756,159	(1,474,029)
Investment income	759,511	240,290	1,382,778	700,765
Interest expense	(2,451)	(3,010)	(7,353)	(9,030)
Income (loss) before taxes	(241,932)	(19,709)	41,131,584	(782,294)
Income tax provision			(827,471)	
Net income (loss)	\$ (241,932)	\$ (19,709)	\$ 40,304,113	\$ (782,294)
Earnings (loss) per share:				
Basic	\$ (0.01)	\$	\$ 1.31	\$ (0.03)
Diluted	\$ (0.01)	\$	\$ 1.29	\$ (0.03)
Weighted average shares outstanding:				
Basic	30,953,608	30,375,635	30,763,049	30,365,840
Diluted	30,953,608	30,375,635	31,238,013	30,365,840
(1) Includes non-cash stock-based compensation as follows:				
Cost of product revenue	\$ 6,876	\$ 6,497	\$ 19,242	\$ 19,058
Research and development	27,814	59,335	81,123	170,158
Selling, general and administrative	97,254	70,811	289,735	451,438

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended December 31,	
	2007	2006
Cash flows from operating activities:		
Net income (loss)	\$ 40,304,113	\$ (782,294)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Issuance of common stock for license	300,000	
Depreciation and amortization	597,020	384,935
Stock-based compensation expense	390,100	640,654
Changes in assets and liabilities:		
Accounts receivable	(2,304,661)	(1,383,883)
Inventories	(10,117)	375,992
Prepaid expenses and other current assets	(338,563)	45,049
Accounts payable	(286,910)	(579,960)
Accrued liabilities	148,727	1,064,662
Long-term liabilities	(63,242)	(31,064)
Net cash provided by (used in) operating activities	38,736,467	(265,909)
Cash flows from investing activities:		
Purchases of marketable securities	(44,440,120)	(10,194,849)
Redemptions of marketable securities	14,125,000	11,550,000
Purchases of property, plant and equipment	(611,091)	(1,210,379)
Net cash (used in) provided by investing activities	(30,926,211)	144,772
Cash flows from financing activities:		
Exercise of stock options	421,899	18,800
Principal payments under capital lease obligations	(38,405)	(37,892)
Net cash provided by financing activities	383,494	(19,092)
Net increase in cash and cash equivalents	8,193,750	(140,229)
Cash and cash equivalents, beginning of period	7,726,505	5,428,477
Cash and cash equivalents, end of period	\$ 15,920,255	\$ 5,288,248
Supplemental disclosure of noncash activities:		
Non-cash tender of common stock to exercise stock options	\$ 725,861	\$

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

Table of Contents

REPLIGEN CORPORATION

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. Basis of Presentation

The financial statements included herein have been prepared by Repligen Corporation (the Company, Repligen or we) in accordance with accounting principles generally accepted in the United States and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC), for quarterly reports on Form 10-Q and Article 10 of Regulation S-X and do not include all of the information and footnote disclosures required by accounting principles generally accepted in the United States. These financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in our annual report on Form 10-K for the year ended March 31, 2007.

In the opinion of management, the accompanying unaudited financial statements include all adjustments, consisting of only normal, recurring adjustments necessary for a fair presentation of the financial position, results of operations and cash flows. The results of operations for the interim periods presented are not necessarily indicative of results to be expected for the entire year.

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.

2. Revenue Recognition

The Company applies Staff Accounting Bulletin No. 104, Revenue Recognition, (SAB 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 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 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 nine-month period ended December 31, 2007, the Company recognized approximately \$365,000 of revenue from a sponsored research and development project with the Stanley Medical 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 the contractual agreement and the timing of when such costs were incurred involves the judgment of management. The Company believes its calculations are consistent with the agreed-upon terms as stated in the arrangement. However, should the estimated calculations change or be challenged by SMRI, 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 this sponsored research and development project.

Table of Contents

Additionally, during the nine-month period ended December 31, 2007, the Company earned and recognized approximately \$179,000 in royalty revenue from ChiRhoClin. 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.

3. Earnings (Loss) Per Share

We follow the provisions of Statement of Financial Accounting Standard or SFAS No. 128, Earnings Per Share, (SFAS 128). Basic earnings per share for the three and nine-month periods ended December 31, 2007 and 2006 were computed on the basis of the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed on the basis of the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period using the treasury stock method in accordance with SFAS 128. Dilutive potential common shares include outstanding stock options.

Basic and diluted weighted average shares outstanding were as follows:

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2007	2006	2007	2006
Weighted average common shares	30,953,608	30,375,635	30,763,049	30,365,840
Dilutive common stock options			474,964	
Weighted average common shares, assuming dilution	30,953,608	30,375,635	31,238,013	30,365,840

Options to purchase 1,556,000 shares of common stock were excluded from the calculation of diluted earnings per share for the three-month period ended December 31, 2007, as the Company incurred a net loss during the period, and the effect of these options would be anti-dilutive. Options to purchase 348,193 shares of our common stock were excluded from the calculation of diluted earnings per share for the nine-month period ended December 31, 2007, because the exercise prices of the stock options were greater than or equal to the average price of the common shares.

Options to purchase 2,410,750 shares of our common stock were excluded from the calculation of diluted earnings per share for the three and nine-month periods ended December 31, 2006, as the Company incurred a net loss during the period, and the effect of these options would be anti-dilutive.

At December 31, 2007, there were exercisable options to purchase 1,076,849 shares of our common stock at a weighted average exercise price of \$3.90 per share.

4. Stock-Based Compensation

The Company follows the fair value recognition provisions of SFAS No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95, (SFAS 123R), using the modified prospective transition method.

For the three and nine-month periods ended December 31, 2007, the Company recorded stock-based compensation expense of approximately \$132,000 and approximately \$390,000, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan.

For the three and nine-month periods ended December 31, 2006, the Company recorded stock-based compensation expense of approximately \$137,000 and \$641,000, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan.

The 1992 Repligen Corporation Stock Option Plan and the Amended and Restated 2001 Repligen Corporation Stock Plan (collectively, the Plans) allow for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of Common Stock. Incentive options granted to employees under the Plans generally vest over a five-year period, with 20% vesting on the first anniversary

Edgar Filing: REPLIGEN CORP - Form 10-Q

of the date of grant and the remainder vesting in equal annual 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. The total authorized shares of our common stock by the Plans are 3,989,083. Total shares exercised since the inception of the Plans through December 31, 2007 were 1,260,218, and total shares outstanding at December 31, 2007, were 1,556,050 shares, which was comprised of 1,076,849 shares that were vested and exercisable and 479,201 shares that were unvested and not exercisable under the Plans. There were 1,172,815 shares of our common stock available for future grant at December 31, 2007.

Table of Contents

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 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. 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 nine months ended December 31, 2007 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 April 1, 2007	2,293	\$ 3.25		
Granted	204	4.40		
Exercised	(630)	1.85		
Forfeited/Cancelled	(311)	4.27		
Options outstanding at December 31, 2007	1,556	\$ 3.76	5.77	\$ 4,608
Options exercisable at December 31, 2007	1,077	\$ 3.90	4.67	\$ 3,122
Vested and expected to vest at December 31, 2007 (1)	1,518	\$ 3.77	5.76	\$ 4,489

(1) Represents the number of vested options as of December 31, 2007 plus the number of unvested options expected to vest as of December 31, 2007 based on the unvested outstanding options at December 31, 2007 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 as described above.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the Common Stock on December 31, 2007 of \$6.55 and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on December 31, 2007.

The weighted average grant date fair value of options granted during the nine months ended December 31, 2007 and 2006 was \$2.98 and \$2.31, respectively. The total fair value of stock options that vested during the nine months ended December 31, 2007 and 2006 was approximately \$652,000 and \$9,000, respectively.

As of December 31, 2007, there was approximately \$2,120,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over the remaining requisite service period of 4.7 years. The Company expects approximately 407,000 in unvested options to vest over the next five years.

5. Cash, Cash Equivalents and Marketable Securities

We follow the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At December 31, 2007, our investments included short-term marketable securities, the majority of which are classified as held-to-maturity investments as we have 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.

Table of Contents

At December 31, 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, which creates a highly liquid market for these securities. We do 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 gross unrealized gains or losses from these short-term investments.

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

	December 31, 2007	March 31, 2007
Cash and cash equivalents	\$ 15,920,255	\$ 7,726,505
Marketable securities:		
U.S. Government and agency securities	\$ 464,490	\$ 3,460,664
Auction rate securities	1,375,000	475,000
Corporate and other debt securities	33,985,097	10,965,176
	\$ 35,824,587	\$ 14,900,840
Long-term marketable securities:		
Corporate and other debt securities	\$ 9,597,903	\$

Marketable securities held by the Company have an average remaining maturity of 5.6 months at December 31, 2007, assuming that the maturity of auction rate securities is set as of the date of the next auction. Long-term marketable securities have an average remaining maturity of 17.4 months at December 31, 2007.

Restricted cash of \$200,000 is related to our facility lease obligation.

6. Inventories

Inventories relate to the Company's Protein A business. The Company values inventory at the lower of cost or market on a first-in, first-out basis. Cost includes material, labor and applicable manufacturing overhead costs. 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 goods. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to twelve months. The Company writes down inventory that has become obsolete, has a cost basis in excess of its expected net realizable value, or is in excess of expected requirements to cost of goods sold. 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 inventory and reported operating results. During all periods presented in the accompanying financial statements, there have been no material adjustments related to a revised estimate of inventory valuations.

Inventories consist of the following:

	December 31, 2007	March 31, 2007
Raw materials	\$ 959,179	\$ 733,112
Work in process	464,326	616,519
Finished goods	101,183	164,940

\$	1,524,688	\$	1,514,571
----	-----------	----	-----------

Table of Contents**7. Accrued Expenses and Other Current 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 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 expenses and other current liabilities consist of the following:

	December 31, 2007	March 31, 2007
Income taxes payable	\$ 178,973	\$
Professional and consulting costs	655,936	400,474
Research & development costs	616,637	602,615
Payroll & payroll related costs	500,790	557,100
Other accrued expenses	152,882	122,836
Royalty expenses	75,947	56,529
Other current liabilities	36,816	309,015
Unearned revenue	106,485	127,170
	\$ 2,324,466	\$ 2,175,739

8. Income Taxes

The Company had a pretax loss of approximately \$242,000 for the three months ended December 31, 2007. The Company had pretax income of approximately \$41.1 million for the nine months ended December 31, 2007. The Company had no income tax provision for the three months ended December 31, 2007. The Company had an income tax provision of \$827,000 for the nine months ended December 31, 2007. For the nine months ended December 31, 2007, the effective income tax rate was 2%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rate due to the utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax on income derived during the fiscal year.

9. Comprehensive Income/Loss

We follow the provisions of SFAS No. 130, Reporting Comprehensive Income (SFAS 130). SFAS 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 resulting from transactions and other events and circumstances from non-owner sources. Our comprehensive income is equal to our reported net income for all periods presented.

Table of Contents**10. Segment Reporting**

We follow the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131). SFAS 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 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, we view our operations and manage our business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to our principal operating segment.

The following table represents percentage of total revenue, exclusive of licensing revenue, classified by geographic area:

	Three months ended December 31,		Nine months ended December 31,	
	2007	2006	2007	2006
Europe	79%	36%	68%	53%
US	20%	64%	32%	46%
Other	1%	0%	0%	1%
	100%	100%	100%	100%

The Company's two largest customers accounted for 76% and 4% of product revenues for the three months ended December 31, 2007 and 65% and 14% of product revenues for the nine months ended December 31, 2007. The Company's two largest customers accounted for 42% and 33% of product revenues for the three months ended December 31, 2006 and 43% and 37% of product revenues for the nine months ended December 31, 2006. At December 31, 2007, the Company's two largest customers accounted for 80% and 1% of our accounts receivable. At March 31, 2007, two customers accounted for 47% and 15% of accounts receivable, respectively.

11. New Accounting Pronouncements*Fair Value Option for Financial Assets and Financial Liabilities*

In February 2007, the FASB issued FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. FASB has indicated it believes that SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. For example, SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), and FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments* (SFAS 107). SFAS 159 is effective as of the beginning of a company's first fiscal year beginning after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided that the company makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of SFAS 157. The Company has not yet completed its evaluation of SFAS 159, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal

Edgar Filing: REPLIGEN CORP - Form 10-Q

years beginning after December 15, 2007. The Company is currently analyzing the effect, if any, EITF 07-3 will have on its financial position and results of operations.

Table of Contents

12. Scripps Agreements

License Agreement. On April 6, 2007, the Company entered into an exclusive worldwide commercial license agreement (License Agreement) with The Scripps Research Institute (Scripps). Pursuant to the 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 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 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 accompanying Statement of Operations for the nine-month period ended December 31, 2007.

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 between the actual total value of the Shares on the one-year anniversary of the Effective Date. At each reporting date during the one-year period beginning on the Effective Date, the Company records a liability to the extent the fair value of the Shares, as calculated using the closing price of the common stock, is below \$300,000. At December 31, 2007, 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 exclusively to Scripps 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 certain individuals 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 for the three and nine-month periods ended December 31, 2007, 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 agreement with Scripps expires or may be terminated (i) when all of the royalty obligations under the agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the 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 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 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 agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the 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 agreement; or (iv) by the Company upon 90 days written notice.

13. Litigation Settlement

In May 2004, the Company 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 Erbitux®. 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 the Company.

Table of Contents

On September 10, 2007, the Company and MIT entered into a settlement agreement (the Settlement Agreement) with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the Settlement Agreement, ImClone made a payment of \$65 million to the Company and MIT that resulted in net proceeds to the Company 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 Settlement Agreement served as the basis for the Company and MIT to dismiss the lawsuit against ImClone and for the Company to grant ImClone a non-exclusive sublicense to the 281 patent and certain other intellectual property. There are no further obligations to the Company with respect to the sublicenses. The net gain on litigation settlement was recorded as a separate component of operating expenses on the Company's Statement of Operations for the nine-month period ended December 31, 2007.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company focused on the development of novel therapeutics for the treatment of diseases of the central nervous system. A number of drug development programs are currently being conducted to evaluate our naturally occurring 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.

Our business strategy is to deploy the profits from our current commercial products and any revenue that we may receive from our patents to enable us to invest in the development of our product candidates in the treatment area of neurological and psychiatric diseases while reducing our financial risk.

We are subject to a number of risks typically associated with similar companies in the biotechnology industry. Principally, those risks are associated with our dependence on collaborative arrangements, development by us or our competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, results of clinical trials, compliance with the U.S. Food and Drug Administration and other governmental regulations and approval requirements, as well as the ability to grow our business and to obtain adequate capital to fund this growth, as well as other potential risk factors included in the filings made by us from time to time with the SEC, including under the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended March 31, 2007.

Critical Accounting Policies and Estimates

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our critical accounting policies in Note 2 to the Financial Statements included in our Annual Report on Form 10-K dated March 31, 2007.

Results of Operations

Three months ended December 31, 2007 vs. December 31, 2006

Total revenue

Total revenues for the three-month periods ended December 31, 2007 and December 31, 2006 were approximately \$4,664,000 and \$3,882,000 respectively, an increase of \$782,000 or 20.1%.

Table of Contents

Sales of Protein A for the quarter ended December 31, 2007 and December 31, 2006 was \$3,920,000 and \$3,059,000, respectively. The increase of \$861,000, or 28.1%, was due to a 63% increase in the volume partially offset by a 21% decrease in average selling price of Protein A. The increased volume shipped was in response to an increase in customer orders in the third quarter of the 2008 fiscal year as compared to the same period in the 2007 fiscal year. The Company sells different Protein A products at different price points. The mix of products sold varies and impacts the fluctuations in total sales revenue and cost of product revenues from quarter to quarter. 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.

Sales of SecreFlo® for the quarter ended December 31, 2007 and December 31, 2006 was \$643,000 and \$574,000, respectively, which represents an increase of \$69,000 or 11.8% due to a higher number of vials sold.

The settlement in fiscal 2005 with our sole supplier of SecreFlo® provides for a certain amount of vials of product that we can ultimately sell. The last shipment of SecreFlo® to the Company from ChiRhoClin was received in July 2007 and is expected to allow us to fill sales orders through the second quarter in fiscal year 2009.

During the three-month periods ended December 31, 2007 and December 31, 2006, we recognized approximately \$25,000 and \$213,000, respectively, of revenue from a sponsored research and development project under an agreement with SMRI. The decrease in revenue is due to the completion of the project and the wrap up of the final milestone in the third quarter of fiscal year 2008 as compared to the same period in the 2007 fiscal year. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Additionally, during the three-month periods ended December 31, 2007 and December 31, 2006, we earned and recognized approximately \$76,000 and \$36,000, respectively in royalty revenue from ChiRhoClin.

Operating expenses

Total operating expenses were approximately \$5,663,000 and \$4,139,000 for the three-month periods ended December 31, 2007 and December 31, 2006, respectively, an increase of \$1,524,000 or 36.8%.

Cost of product revenues was approximately \$1,730,000 and \$805,000 for the three-month periods ended December 31, 2007 and December 31, 2006, respectively, an increase of \$926,000 or 115%. The increase in cost of product revenue is primarily due to increased material costs of \$683,000, and increased personnel and occupancy costs of \$228,000 in the three-month period ended December 31, 2007.

Research and development expenses were approximately \$1,592,000 and \$1,675,000 for the three-month periods ended December 31, 2007 and December 31, 2006, respectively, a decrease of \$84,000 or 5%. The decrease is largely attributable to decreased clinical trial expenses of \$779,000, as the Company's Phase 2 clinical trial to evaluate the use of RG1068, synthetic human secretin, was completed in the first quarter of the 2008 fiscal year. The lower clinical trials expenses were partially offset by \$696,000 higher research expenses for the development of new therapeutic drugs for central nervous system disorders. Significant fluctuations in research and development expenses may occur from period to period depending on the nature, timing, and extent of development activities over any given period of time.

Selling, general and administrative expenses were approximately \$2,341,000 and \$1,660,000 for the three-month periods ended December 31, 2007 and December 31, 2006, respectively, an increase of \$681,000 or 41%. This increase is largely attributable to litigation expenses incurred in conjunction with our continuing patent infringement lawsuit against Bristol-Myers Squibb, partially offset primarily by lower salaries and benefits expenses.

Interest income

Interest income was approximately \$760,000 and \$240,000 for the three-month periods ended December 31, 2007 and December 31, 2006, respectively. The increase in the three months ended December 31, 2007 is a result of higher interest rates and increased cash and marketable securities as a result of the funds received from the Settlement Agreement with ImClone.

Income Tax Provision

The Company had pretax losses of approximately \$242,000 and \$20,000 in the three-month periods ended December 31, 2007, and December 31, 2006, respectively. The Company had no income tax provisions in the three-month periods ended December 31, 2007 and December 31, 2006, respectively.

Table of Contents

Nine months ended December 31, 2007 vs. December 31, 2006

Total revenue

Total revenues for the nine-month periods ended December 31, 2007 and December 31, 2006 were approximately \$15,994,000 and \$10,375,000 respectively, an increase of \$5,619,000 or 54.2%. Protein A sales for the nine-month periods ended December 31, 2007 and December 31, 2006 were approximately \$13,665,000 and \$8,228,000 respectively, an increase of \$5,437,000 or 66.1%. The increase in Protein A sales is due to an 82% increase in the volume, partially offset by a 7% decrease in the price of Protein A. The increase in volume of Protein A shipped was due to an increase in customer orders in the 2008 fiscal year, as compared to the same period in fiscal year 2007. The Company sells different Protein A products at different price points. The mix of products sold varies and impacts the fluctuations in total sales revenue from period to period.

Sales of SecreFlo® for the nine-month period ended December 31, 2007 and December 31, 2006 were approximately \$1,785,000 and \$1,449,000 respectively, an increase of \$336,000 or 23.2%, primarily due to a higher number of vials sold.

The settlement in fiscal 2005 with our sole supplier of SecreFlo® provides for a certain amount of vials of product that we can ultimately sell. The last shipment of SecreFlo® to the Company from ChiRhoClin was received in July 2007 and is expected to allow us to fill sales orders through the second quarter in fiscal year 2009.

During the nine-month periods ended December 31, 2007 and December 31, 2006, we recognized \$365,000 and \$581,000, respectively, of revenue from a sponsored research and development project under an agreement with SMRI. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Additionally, during the nine-month periods ended December 31, 2007 and December 31, 2006, we earned and recognized approximately \$179,000 and \$117,000, respectively, in royalty revenue from ChiRhoClin, Inc.

Operating expenses

Total operating expenses, not including the net gain on litigation settlement, were approximately \$16,409,000 and \$11,849,000 for the nine-month periods ended December 31, 2007 and December 31, 2006, respectively, an increase of \$4,560,000 or 38.5%.

Cost of product revenues for the nine-month periods ended December 31, 2007 and December 31, 2006 were approximately \$4,857,000 and \$2,713,000, respectively, an increase of \$2,144,000 or 79%. Material costs increased by \$1,521,000, and personnel costs increased by \$696,000 in support of the increased product revenues.

Research and development expenses for the nine-month periods ended December 31, 2007 and December 31, 2006 were approximately \$4,883,000 and \$4,472,000, respectively, an increase of \$411,000 or 9.2%. This increase is largely attributable to increased licensing expense of approximately \$625,000 attributable to the payment of milestones associated with the signing of the License Agreement with Scripps (the Scripps License Agreement), as well as external research of approximately \$878,000 associated with our Friedreich's ataxia project, offset mainly by decreases in clinical trial expenses of approximately \$948,000 primarily due to the wrapup of the Phase 2 programs for bipolar and magnetic resonance cholangiopancreatography (MRCP) and lower stock compensation expenses of \$88,000. Significant fluctuations in research and development expenses may occur from period to period depending on the nature, timing, and extent of development activities over any given period of time.

Selling, general and administrative expenses were approximately \$6,669,000 and \$4,664,000 for the nine-month periods ended December 31, 2007 and December 31, 2006 respectively, an increase of \$2,005,000 or 43%. This increase is largely attributable to increased litigation expenses of \$1,473,000 incurred in conjunction with the patent infringement lawsuit against Bristol-Myers Squibb.

Net gain from litigation settlement

On September 10, 2007, Repligen and MIT entered into the Settlement Agreement with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the Settlement Agreement, ImClone made a payment of \$65 million to Repligen and MIT that resulted in net proceeds to Repligen of \$40,170,000. The Settlement Agreement 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.

Table of Contents

Interest income

Interest income for the nine-month periods ended December 31, 2007 and December 31, 2006 was approximately \$1,383,000 and \$701,000 respectively. The increase in the nine months ended December 31, 2007 is a result of higher interest rates and increased cash and marketable securities as a result of the funds received from the Settlement Agreement with ImClone.

Income Tax Provision

The Company had pretax income of \$41.1 million in the nine-month period ended December 31, 2007, and an income tax provision of approximately \$827,000 in the nine-month period ended December 31, 2007. The effective income tax rate for the nine months ended December 31, 2007 was 2%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rate due to the utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax on income derived during the fiscal year. No income taxes were provided in the nine months ended December 31, 2006 due to pre-tax losses being incurred.

Liquidity and capital resources

We have financed our operations primarily through sales of equity securities and revenues derived from product sales and grant and research agreements and more recently from consideration received as a result of the successful settlement of litigation. Our revenue for the foreseeable future will be primarily limited to our product revenue related to Protein A. Revenues derived from the sales of SecreFlo® vials are expected only through the second quarter of fiscal year 2009. Given the uncertainties related to pharmaceutical product development, we are currently unable to reliably estimate when, if ever, our therapeutic product candidates will generate revenue and cash flows. Total cash and marketable securities at December 31, 2007 totaled approximately \$61,343,000, an increase of \$38,716,000 from \$22,627,000 at March 31, 2007.

Operating activities

Our operating activities provided cash of approximately \$38,736,000 for the nine-month period ended December 31, 2007. Cash received is primarily driven from our settlement with ImClone in September 2007, for which the Company received \$40,170,000 (see Note 13), which contributed to net income of \$40,304,000. Other factors affecting cash from operating activities included non-cash charges of approximately \$597,000 for depreciation and amortization, \$390,000 in stock based compensation expense and \$300,000 for issuance of common stock for the Scripps License Agreement, partially offset by changes in changes in operating assets and liabilities.

Investing activities

Cash spending of approximately \$30,926,000 for the nine-month period ended December 31, 2007 was primarily driven by increased purchases of marketable securities, as the Company began to invest the funds received from the Settlement Agreement with ImClone. In addition, the Company continues to make investments in equipment purchases and improvements to the Company's facility.

Financing activities

Stock option exercises provided cash proceeds of approximately \$422,000 for the nine months ended December 31, 2007.

We do not currently use derivative financial instruments. We generally place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines.

Working capital increased to approximately \$54,303,000 at December 31, 2007 from \$22,394,000 at March 31, 2007. This increase is primarily driven by net gain of \$40,170,000 from our Settlement Agreement with ImClone.

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

the success of our clinical studies;

Edgar Filing: REPLIGEN CORP - Form 10-Q

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;

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

the funding requirements and status of outstanding legal matters.

Table of Contents

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash and investment balances are adequate to meet our needs. 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 facilities and continued investment in our intellectual property portfolio.

We plan to continue to invest in key research and development activities. We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. We continue to seek to acquire such potential assets that may offer us the best opportunity to create value for our shareholders. In order to acquire such assets, we may need to seek additional financing to fund these investments. This may require the issuance or sale of additional equity or debt securities. The sale of additional equity may result in 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.

Off-Balance Sheet Arrangements

As of December 31, 2007, we did not have any off-balance sheet arrangements.

Commitments

As of December 31, 2007, we had the following fixed obligations and commitments:

(In thousands)

	Total	Payments Due by Period			
		Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating lease obligations	\$ 1,874	\$ 340	\$ 937	\$ 597	\$
Capital lease obligations (1)	95	31	64		
Purchase obligations (2)	921	921			
Contractual obligations (3)	484	182	149	129	24
Total	\$ 3,374	\$ 1,474	\$ 1,150	\$ 726	\$ 24

(1) Represents principal payments only; principal and interest are payable through a fixed annual payment of approximately \$48,000.

(2) Represents a minimum commitment due under a third-party manufacturing agreement.

(3) Includes payments for license, supply and consulting agreements.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this Quarterly Report on Form 10-Q, as well as oral statements that may be made by Repligen or by officers, directors or employees of Repligen acting on its behalf, that are not historical facts constitute 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 forward-looking statements in this Quarterly Report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements in this Quarterly Report on Form 10-Q which are not strictly historical statements, including, without limitation, statements regarding current or future financial performance, management's strategy, litigation strategy, costs of legal proceedings, disputes with suppliers, plans and objectives for future operations, clinical trials and results, marketing plans, revenue potential of therapeutic product candidates, product research, intellectual property and development, manufacturing plans and performance, delays in manufacturing by us or our partners, timing of customer orders, the anticipated growth in our target markets, including, without limitation, the market for neuropsychiatric disorders treatment, the market for pancreatic disease treatment, the monoclonal antibody market and the process chromatography industry and

Edgar Filing: REPLIGEN CORP - Form 10-Q

projected growth in product sales, costs of operations, sufficiency of funds to meet management objectives and availability of financing and effects of accounting pronouncements constitute forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from the historical results or from any results expressed or implied by such forward-looking statements, including, without limitation, risks associated with: the success of current and future collaborative relationships, the success of our clinical trials and our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug

Table of Contents

Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of current and future litigation regarding our patent and other intellectual property rights, the risk of litigation with collaborative partners, our limited sales and marketing experience and capabilities, our limited manufacturing capabilities and our dependence on third-party manufacturers and value-added resellers, our ability to hire and retain skilled personnel, the market acceptance of our products, our ability to compete with larger, better financed pharmaceutical and biotechnology companies that may develop new approaches to the treatment of our targeted diseases, our history of losses and expectation of incurring continued losses, our ability to generate future revenues, our ability to raise additional capital to continue our drug development programs, our volatile stock price, and the effects of our anti-takeover provisions. Further information on potential risk factors that could affect our financial results are included in the filings made by us from time to time with the Securities and Exchange Commission including under the section entitled "Certain Factors That May Affect Future Results" in our Annual Report on Form 10-K for the year ended March 31, 2007.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk

We have investments in commercial paper, U.S. Government and agency securities, 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 increase in interest rates would result in an approximate \$204,000 decrease in the fair value of our investments as of December 31, 2007. We believe, however, that the conservative nature of our investments mitigates our interest rate exposure, and our investment policy limits the amount of our credit exposure to any one issue, issuer (with the exception of U.S. agency obligations) and type of instrument. We do not expect any material loss from our marketable security investments and therefore believe that our potential interest rate exposure is limited. We intend to hold the majority of our investments to maturity, in accordance with our business plans.

ITEM 4. CONTROLS AND PROCEDURES

The Company's management, with the participation of our chief executive officer (principal executive, financial and accounting 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 Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on such evaluation, our chief executive officer has concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer, as appropriate to allow timely decisions regarding required disclosure.

There was no change in the Company's internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

ImClone Systems

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 the 281 patent based on ImClone's manufacture and sale of Erbitux. 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 the Settlement Agreement with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the Settlement Agreement, 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 Settlement Agreement

Edgar Filing: REPLIGEN CORP - Form 10-Q

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.

Table of Contents

Bristol-Myers Squibb

In January 2006, Repligen and the University of Michigan jointly filed a complaint against Bristol-Myers Squibb 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-Myers Squibb answered the complaint and counterclaimed seeking a declaratory judgment that the 941 patent is invalid and unenforceable and that Bristol-Myers Squibb does not infringe the patent. The outcome of this case is undeterminable at this time. In December 2007, Bristol-Myers Squibb filed two motions for summary judgment alleging that the 941 patent is invalid based on anticipation and lack of enablement of the subject invention. On January 29, 2008, Repligen and the University of Michigan filed oppositions to Bristol-Myers Squibb's motions. Jury selection for the trial in this matter is scheduled to commence on April 7, 2008. Information regarding this matter has also been disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007.

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.

Table of Contents

ITEM 1A. RISK FACTORS

None.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits

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). (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).
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).
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive, Financial and Accounting Officer.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Filed herewith.

Table of Contents

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REPLIGEN CORPORATION

Date: February 7, 2008

By: /s/ Walter C. Herlihy
Walter C. Herlihy
Chief Executive Officer and President
(Principal Executive, Financial and Accounting Officer)
Repligen Corporation

Table of Contents

EXHIBIT INDEX

EXHIBIT	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). (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).
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).
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive, Financial and Accounting Officer.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Filed herewith.