

REPLIGEN CORP  
Form 10-Q  
August 06, 2009  
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 June 30, 2009

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-14656

**REPLIGEN CORPORATION**

(exact name of registrant as specified in its charter)

**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)

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

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

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 has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(do not check if smaller

reporting company)

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 July 27, 2009.

Class	Number of Shares
Common Stock, par value \$.01 per share	30,744,907

---

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

	<b>PAGE</b>
<b>PART I</b>	<b>FINANCIAL INFORMATION</b>
Item 1.	Unaudited Condensed Financial Statements
	<u>Balance Sheets as of June 30, 2009 and March 31, 2009</u>
	3
	<u>Statements of Operations for the Three-Month Periods Ended June 30, 2009 and 2008</u>
	4
	<u>Statements of Cash Flows for the Three-Month Periods Ended June 30, 2009 and 2008</u>
	5
	<u>Notes to Unaudited Condensed Financial Statements</u>
	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	14
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	18
Item 4.	<u>Controls and Procedures</u>
	18
<b>PART II</b>	<b><u>OTHER INFORMATION</u></b>
Item 1.	<u>Legal Proceedings</u>
	19
Item 1A.	<u>Risk Factors</u>
	19
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	19
Item 3.	<u>Defaults Upon Senior Securities</u>
	19
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>
	19
Item 5.	<u>Other Information</u>
	19
Item 6.	<u>Exhibits</u>
	20
	<u>Signatures</u>
	21
	<u>Exhibit Index</u>
	22

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

	<b>June 30, 2009</b>	<b>March 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,670,604	\$ 5,041,410
Marketable securities	43,967,298	43,817,915
Accounts receivable, less reserve for doubtful accounts of \$10,000	439,992	540,779
Royalties receivable	2,381,300	2,036,800
Inventories	2,179,918	2,413,227
Prepaid expenses and other current assets	812,448	933,585
<b>Total current assets</b>	<b>53,451,560</b>	<b>54,783,716</b>
Property, plant and equipment, at cost:		
Leasehold improvements	3,852,243	3,845,247
Equipment	3,638,016	3,527,469
Furniture and fixtures	521,388	513,501
	8,011,647	7,886,217
Less: Accumulated depreciation	(4,539,148)	(4,216,430)
	3,472,499	3,669,787
Long-term marketable securities	14,331,605	15,101,239
Restricted cash	200,000	200,000
<b>Total Assets</b>	<b>\$ 71,455,664</b>	<b>\$ 73,754,742</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,005,147	\$ 1,922,572
Accrued liabilities	2,119,106	2,626,341
<b>Total current liabilities</b>	<b>3,124,253</b>	<b>4,548,913</b>
Long-term liabilities	73,249	82,398
<b>Total liabilities</b>	<b>3,197,502</b>	<b>4,631,311</b>
<b>Commitments and contingencies</b>		
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, no shares issued or outstanding		
Common stock, \$.01 par value, 40,000,000 shares authorized, issued and outstanding 30,743,707 shares at June 30, 2009 and 30,741,707 shares at March 31, 2009	307,437	307,417
Additional paid-in capital	182,913,966	182,673,275
Accumulated deficit	(114,963,241)	(113,857,261)
<b>Total stockholders' equity</b>	<b>68,258,162</b>	<b>69,123,431</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 71,455,664</b>	<b>\$ 73,754,742</b>

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)**

	<b>Three months ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenue:</b>		
Product revenue	\$ 2,472,590	\$ 5,693,343
Royalty and other revenue	2,588,263	7,966,902
<b>Total revenue</b>	<b>5,060,853</b>	<b>13,660,245</b>
<b>Operating expenses: (1)</b>		
Cost of product revenue	1,270,474	1,846,401
Cost of royalty and other revenue	317,745	325,000
Research and development	3,383,000	2,084,125
Selling, general and administrative	1,517,357	1,446,571
<b>Total operating expenses</b>	<b>6,488,576</b>	<b>5,702,097</b>
<b>(Loss) income from operations</b>	<b>(1,427,723)</b>	<b>7,958,148</b>
Investment income	322,419	532,585
Interest expense	(676)	(1,905)
<b>(Loss) income before taxes</b>	<b>(1,105,980)</b>	<b>8,488,828</b>
Income tax provision		210,000
<b>Net (loss) income</b>	<b>\$ (1,105,980)</b>	<b>\$ 8,278,828</b>
<b>Earnings per share:</b>		
Basic	\$ (0.04)	\$ 0.27
Diluted	\$ (0.04)	\$ 0.26
<b>Weighted average shares outstanding:</b>		
Basic	30,742,212	31,152,556
Diluted	30,742,212	31,585,112
<b>(1) Includes non-cash stock-based compensation as follows:</b>		
Cost of product revenue	\$ 13,373	\$ 10,827
Research and development	49,458	31,676
Selling, general and administrative	174,124	117,929

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

**Table of Contents**

**REPLIGEN CORPORATION**  
**STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	<b>Three months ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net (loss) income	\$ (1,105,980)	\$ 8,278,828
<b>Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:</b>		
Depreciation and amortization	322,718	241,325
Stock-based compensation expense	236,955	160,432
<b>Changes in assets and liabilities:</b>		
Accounts receivable	100,787	298,368
Royalties receivable	(344,500)	(1,571,800)
Inventories	233,309	334,601
Prepaid expenses and other current assets	121,137	(202,280)
Accounts payable	(917,425)	(1,787,617)
Accrued liabilities	(505,478)	(108,571)
Long-term liabilities	(9,149)	(6,308)
<b>Net cash (used in) provided by operating activities</b>	<b>(1,867,626)</b>	<b>5,636,978</b>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(14,488,104)	(10,540,882)
Redemptions of marketable securities	15,108,355	5,900,000
Purchases of property, plant and equipment	(125,430)	(332,727)
<b>Net cash provided by (used in) investing activities</b>	<b>494,821</b>	<b>(4,973,609)</b>
<b>Cash flows from financing activities:</b>		
Exercise of stock options	3,756	234,455
Principal payments under capital lease obligations	(1,757)	(1,595)
<b>Net cash provided by financing activities</b>	<b>1,999</b>	<b>232,860</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(1,370,806)</b>	<b>896,229</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>5,041,410</b>	<b>32,562,138</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 3,670,604</b>	<b>\$ 33,458,367</b>
<b>Supplemental disclosure of noncash activities:</b>		
Disposal of fully depreciated equipment	\$	\$ 3,000

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

---

**Table of Contents**

**REPLIGEN CORPORATION**

**NOTES TO CONDENSED 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 the Company s annual report on Form 10-K for the year ended March 31, 2009.

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 No. 104 ) to all its revenue arrangements. The Company generates product revenues from the sale of Protein A products to customers in the pharmaceutical and process chromatography industries. In accordance with SAB No. 104, the Company recognizes revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been met are based on management s judgments primarily regarding the fixed nature of the fee charged for product delivered, and the collectability of those fees. The Company has a few longstanding customers who comprise the majority of revenue and have excellent payment history and therefore the Company does not require collateral. The Company has had no significant write-offs of uncollectible invoices in the periods presented.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and related purchase orders identify the terms and conditions of each sale and the price of the goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales return, warranty or other issues is largely diminished. Sales returns and warranty issues are infrequent and have had nominal impact on the Company s financial statements historically.

In April 2008, the Company settled its outstanding litigation with Bristol-Myers Squibb Company ( Bristol ) and therefore began recognizing royalty revenue in fiscal year 2009 for Bristol s net sales in the United States of Orencia<sup>®</sup> which is used in the treatment of rheumatoid arthritis. Pursuant to the Bristol settlement (as defined in Note 13), the Company recognized royalty revenue of approximately \$2,118,000 and \$7,899,000 for the three months ended June 30, 2009 and 2008, respectively. The \$7,899,000 recognized in the first quarter of fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia<sup>®</sup> from January 1, 2008 to March 31, 2008, and \$1.6 million in royalties for sales of Orencia<sup>®</sup> in from April 1, 2008 to June 30, 2008. Revenue earned from Bristol royalties are recorded in the periods when they are earned based on royalty reports sent by Bristol to the Company. The Company has no continuing obligations to Bristol as a result of this settlement.

Additionally, for the three months ended June 30, 2009 and 2008, the Company earned and recognized approximately \$263,000 and \$70,000, respectively, in royalty revenue from ChiRhoClin for their sales of secretin. Revenue earned from ChiRhoClin royalties are recorded in the periods when they are earned based on royalty reports sent by ChiRhoClin to the Company.

For the three months ended June 30, 2009, the Company recognized approximately \$207,000 of revenue from a sponsored research and development project under an agreement with the Muscular Dystrophy Association. No research revenue was earned or recognized for the three



months ended June 30, 2009.

**Table of Contents**

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

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

**3. Earnings (Loss) Per Share**

The Company follows the provisions of Statement of Financial Accounting Standard No. 128, Earnings Per Share, ( SFAS 128 ). Basic earnings per share for the three-month periods ended June 30, 2009 and 2008 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, restricted stock and warrants.

Basic and diluted weighted average shares outstanding were as follows:

	<b>Three Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
Weighted average common shares	30,742,212	31,152,556
Dilutive common stock options		432,556
Weighted average common shares, assuming dilution	30,742,212	31,585,112

For the three-month period ended June 30, 2008, 716,500 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At June 30, 2009, there were outstanding options to purchase 2,292,750 shares of the Company's common stock at a weighted average exercise price of \$4.36 per share. All such outstanding options have been excluded from the calculation of diluted earnings per share because their effect would be anti-dilutive.

**4. Stock-Based Compensation**

The Company applies the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95, or SFAS No. 123R. The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date.

For the three months ended June 30, 2009 and 2008, the Company recorded stock-based compensation expense of approximately \$237,000 and \$160,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan ).

The 2001 Plan allows for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of common stock. Incentive options granted to employees under the 2001 Plan generally vest over a four to five-year period, with 20%-25% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the 2001 Plan generally vest over one year. Options granted under the 2001 Plan have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At June 30, 2009, options to purchase 2,058,250 shares were outstanding under the 2001 Plan and options to purchase 234,500 shares were outstanding under the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the Plans ). At June 30, 2009, 619,209 shares were available for future grant under the 2001 Plan.



**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 No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Information regarding option activity for the three months ended June 30, 2009 under the Plans is summarized below:

	Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at April 1, 2009	2,211,950	\$ 4.37		
Granted	83,000	\$ 4.13		
Exercised	(2,000)	\$ 1.88		
Forfeited/Cancelled	(200)	\$ 3.30		
Options outstanding at June 30, 2009	2,292,750	\$ 4.36	6.68	\$ 3,186,650
Options exercisable at June 30, 2009	1,231,050	\$ 4.08	4.77	\$ 2,202,058
Vested and expected to vest at June 30, 2009 (1)	2,198,815	\$ 4.37	6.65	\$ 3,051,805

(1) This represents the number of vested options as of June 30, 2009 plus the number of unvested options expected to vest as of June 30, 2009 based on the unvested outstanding options at June 30, 2009 adjusted for the estimated forfeiture rate of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the common stock on June 30, 2009 of \$5.50 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 June 30, 2009.

The weighted average grant date fair value of options granted during the three months ended June 30, 2009 and 2008 was \$2.48 and \$3.70, respectively. The total fair value of stock options that vested during the three months ended June 30, 2009 and 2008 was approximately \$443,545 and \$261,230, respectively.

As of June 30, 2009, there was approximately \$2,319,279 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 3.18 years. The Company expects approximately 967,765 in unvested options to vest over the next five years.

**5. Cash, Cash Equivalents and Marketable Securities**

The Company follows the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At June 30, 2009, the Company's investments included money market funds as well as short-term and long-term marketable securities, which are classified as held-to-maturity investments as the Company has the positive intent and ability to hold 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.

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

	June 30, 2009	March 31, 2009
Cash and cash equivalents	\$ 3,670,604	\$ 5,041,410

Edgar Filing: REPLIGEN CORP - Form 10-Q

Marketable securities:

U.S. Government and agency securities	24,140,285	20,871,059
Corporate and other debt securities	19,827,013	22,946,856
	\$ 43,967,298	\$ 43,817,915

Long-term marketable securities:

U.S. Government and agency securities	3,991,024	5,032,385
Corporate and other debt securities	10,340,581	10,068,854
	\$ 14,331,605	\$ 15,101,239

Total	\$ 61,969,507	\$ 63,960,564
-------	---------------	---------------

**Table of Contents**

The average remaining contractual maturity of marketable securities at June 30, 2009 is approximately 8.37 months.

On April 9, 2009, the Financial Accounting Standards Board ( FASB ) released FASB Staff Position ( FSP ) FAS 115-2 Recognition and Presentation of Other-Than-Temporary Impairments ( FSP FAS 115-2 ) which provides new guidance on the recognition and presentation of Other-Than-Temporary Impairments ( OTTI ). FSP FAS 115-2 is effective for the Company for the period ended June 30, 2009. Management considered the new guidance of FSP FAS 115-2 while reviewing the Company's investments as of June 30, 2009 and concluded that there is no OTTI in the investment portfolio. The Company does not intend to sell any investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases at maturity. There were no realized gains or losses on the investments for the periods ended June 30, 2009 and March 31, 2009.

Our investments in held-to-maturity debt securities consist of the following at June 30, 2009:

	Amortized Cost	June 30, 2009		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
<b>Marketable securities:</b>				
U.S. Government and agency securities	\$ 24,140,285	\$ 108,550	\$ (212)	\$ 24,248,623
Corporate and other debt securities	19,827,013	91,907	(1,288)	19,917,632
	43,967,298	200,457	(1,500)	44,166,255
<b>Long-term marketable securities:</b>				
U.S. Government and agency securities	3,991,024	13,206	(310)	4,003,920
Corporate and other debt securities	10,340,581	60,796	(4,979)	10,396,398
	14,331,605	74,002	(5,289)	14,400,318
<b>Total</b>	<b>\$ 58,298,903</b>	<b>\$ 274,459</b>	<b>\$ (6,789)</b>	<b>\$ 58,566,573</b>

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

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

	Amortized Cost	March 31, 2009		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
<b>Marketable securities:</b>				
U.S. Government and agency securities	\$ 20,871,059	\$ 113,154	\$ (1,052)	\$ 20,983,161
Corporate and other debt securities	22,946,856	77,916	(82,087)	22,942,685
	43,817,915	191,070	(83,139)	43,925,846
<b>Long-term marketable securities:</b>				
U.S. Government and agency securities	5,032,385	21,835		5,054,220
Corporate and other debt securities	10,068,854	56,742	(20,715)	10,104,881
	15,101,239	78,577	(20,715)	15,159,101
<b>Total</b>	<b>\$ 58,919,154</b>	<b>\$ 269,647</b>	<b>\$ (103,854)</b>	<b>\$ 59,084,947</b>

The contractual maturities of held-to-maturity debt securities at June 30, 2009 were as follows:

Edgar Filing: REPLIGEN CORP - Form 10-Q

	<b>Amortized Cost</b>	<b>Fair Value</b>
Due in 1 year or less	\$ 43,967,298	\$ 44,166,255
Due in 1 to 2 years	14,331,605	14,400,318
	<b>\$ 58,298,903</b>	<b>\$ 58,566,573</b>

**Table of Contents****6. Fair Value Measurement**

In determining the fair value of its assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
- Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The Company's held-to-maturity securities, which are fixed income investments, are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These held-to-maturity securities are recorded at amortized cost and are therefore not included in the Company's market value measurement disclosure. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. The Company has no other assets or liabilities for which fair value measurement is either required or has been elected to be applied.

The following fair value hierarchy table presents information about each major category of the Company's assets and liabilities measured at fair value on a recurring basis as of June 30, 2009:

	Fair value measurement at reporting date using:			Balance as of June 30, 2009
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 2,963,610			\$ 2,963,610

There were no remeasurements to fair value during the three months ended June 30, 2009 of assets and liabilities that are not measured at fair value on a recurring basis.

**7. Inventories**

Inventories relate to the Company's Protein A business. The Company values inventory at cost or, if lower, fair market value using the first-in, first-out method. The Company reviews its inventories at least quarterly and records a provision for excess and obsolete inventory based on its estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in process and finished products. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to twelve months. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements to cost of product revenue. Manufacturing of Protein A finished goods is done to order and tested for quality specifications prior to shipment.



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

A change in the estimated timing or amount of demand for the Company's products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of inventory and reported operating results. During all periods presented in the accompanying financial statements, there has been no material adjustments related to a revised estimate of inventory valuations.

**Table of Contents**

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

	<b>June 30, 2009</b>	<b>March 31, 2009</b>
Raw materials	\$ 1,230,054	\$ 1,400,408
Work in process	596,712	791,465
Finished goods	353,152	221,354
Total	\$ 2,179,918	\$ 2,413,227

**8. 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.

Accrued liabilities consist of the following:

	<b>June 30, 2009</b>	<b>March 31, 2009</b>
Employee compensation	\$ 689,260	\$ 1,040,529
Royalty and license fees	380,200	269,850
Research and development	426,670	769,793
Professional fees	133,958	94,572
Other accrued expenses	147,357	110,059
Other current liabilities	216,661	216,538
Unearned revenue	125,000	125,000
	\$ 2,119,106	\$ 2,626,341

**9. Income Taxes**

For the three months ended June 30, 2009, the Company did not record a tax provision as no taxable income was generated in the period.

For the three months ended June 30, 2008, the Company had income before taxes of approximately \$8,489,000 and an income tax provision of \$210,000 based on an effective income tax rate of 2.47%. The effective income tax rate was 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.

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

The Company has net operating loss carryforwards of approximately \$58,696,000, research and development credit carryforwards of approximately \$2,089,000, and other tax credits of approximately \$833,000 available to reduce future federal income taxes, if any. Additionally, the Company also has business tax credit carryforwards of approximately \$2,613,000 available to reduce future state income taxes, if any. The Company has utilized all available state net operating loss carryforwards. The net operating loss and business tax credit carryforwards will continue to expire at various dates, if not used. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

**Table of Contents**

As of June 30, 2009, a full valuation allowance has been provided against the net operating losses, business tax credits and other deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

The Company applies the provisions of FIN 48, an interpretation of SFAS No. 109 Accounting for Income Taxes, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of June 30, 2009 and 2008, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required.

**10. Comprehensive Income/Loss**

The Company follows 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. The Company's comprehensive income/loss is equal to the reported net income/loss for all periods presented.

**11. Segment Reporting**

The Company follows 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 regarding how to allocate resources and assess performance, identifies operating segments as components of an enterprise about which separate discrete financial information is available for evaluation. To date, the Company views its operations and manages the business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

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

	Three months ended June 30,	
	2009	2008
Sweden	28%	33%
U.S.	57%	64%
Other	15%	3%
	100%	100%

Royalty revenue from Bristol represented 42% and 58% of the Company's total revenue for the three months ended June 30, 2009 and 2008, respectively. The Company's largest Protein A customer accounted for 28% and 33% of total revenues for the three months ended June 30, 2009 and 2008, respectively.

Bristol's royalty payment comprised 75% and 65% of the Company's accounts receivable at June 30, 2009 and 2008, respectively. One of the Company's largest Protein A customers accounted for 26% of accounts receivable as of June 30, 2008.

**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 License Agreement, the Company obtained a license to use, commercialize and sublicense certain patented technology and improvements thereon, owned or licensed by Scripps, relating to compounds which may have utility in treating Friedreich's ataxia, an inherited neurodegenerative disease. Research in tissues derived from patients, as well as, in mice, indicates that the

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

licensed compounds increase production of the protein frataxin, which suggests potential utility of these compounds in slowing or stopping progression of the disease. There are currently no approved treatments for Friedreich's ataxia in the U.S.

## **Table of Contents**

Pursuant to the License Agreement, the Company agreed to pay Scripps an initial license fee of \$300,000, certain royalty and sublicense fees and, in the event that we achieve specified developmental and commercial milestones, certain additional milestone payments. Total future milestone payments, were all milestones to be achieved, would be approximately \$4.3 million. In addition, the Company issued Scripps and certain of its designees 87,464 shares of the Company's common stock (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 our statement of operations in fiscal 2008.

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

In connection with the License Agreement, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. The warrants have a 7-year term and are exercisable based on performance criteria as detailed in the warrant agreement. No expense has been recorded related to these warrants through June 30, 2009, as none of the performance criteria have been achieved. At this time, the Company does not believe that the performance criteria are probable of being achieved in the near future.

The License Agreement with Scripps expires or may be terminated (i) when all of the royalty obligations under the License Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the License Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating to the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the License Agreement; or (iv) by the Company upon 90 days written notice.

### *Research and Funding Agreement*

On October 26, 2007, the Company entered into a research funding and option agreement ( "Funding Agreement") with Scripps to fund a research program for the research and development of compounds that may have utility in the treatment of Friedreich's ataxia. Pursuant to the Funding Agreement, the Company is required to fund approximately \$35,000 per quarter which is recorded as research and development expenses. In exchange for funding the research, Scripps will grant an exclusive option to the Company to acquire a sole, worldwide license, including the right to sublicense, manufacture and sell products, and services that result from the research program. There are no guaranties or warranties that products or services may result from the research program and the Company has therefore ascribed no value to the license. The Funding Agreement expires or may be terminated (i) when all of the royalty obligations under the Funding Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the Funding Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the Funding Agreement; or (iv) by the Company upon 90 days written notice. This agreement terminates in September 2009.

## **13. Legal Proceedings**

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

On April 7, 2008, Repligen and the University of Michigan entered into a settlement agreement (the "Bristol Settlement") with Bristol relating to the lawsuit against Bristol for infringement of the 941 patent. Pursuant to the Bristol Settlement, Bristol made an initial payment of \$5 million to Repligen. The settlement further provides for Bristol to pay royalties on the United States net sales of Orencia<sup>®</sup> for any clinical indication at a rate of 1.8% for the first \$500 million of annual net sales, 2.0% for the next \$500 million of annual net sales and 4% of annual net sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013. Pursuant to the Bristol Settlement, the Company recognized approximately \$2.1 million in royalty revenue for the three months ended June 30, 2009. The Company recognized \$7.9 million in royalty revenue for the three months ended June 30, 2008, which was comprised of the \$5 million initial royalty payment, \$1.3 million in royalties for sales of Orencia<sup>®</sup> from January 1, 2008 through March 31, 2008, and \$1.6 million in royalties for sales of Orencia<sup>®</sup> from April 1, 2008 through June 30, 2008 (see Note 2). The Bristol Settlement served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against

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

Bristol and for Repligen and the University of Michigan to grant to Bristol an exclusive worldwide license to the 941 patent and certain other intellectual property.

**Table of Contents**

Repligen must also remit to the University of Michigan 15% of all royalty revenue received from Bristol, after deducting certain legal and other costs incurred related to the Bristol Settlement. Royalty expense for the three months ended June 30, 2009 was approximately \$318,000. The Company incurred \$5.7 million in such legal costs, which when deducted from the \$7.9 million in royalty revenue earned during the three months ended June 30, 2008, resulted in a net amount due to the University of Michigan of \$325,000. This operating expense has been included in the Company's Statements of Operations under the line item Cost of royalty and other revenue.

**14. Subsequent Events**

In May 2009, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 165, Subsequent Events. The standard does not require significant changes regarding recognition or disclosure of subsequent events, but does require disclosure of the date through which subsequent events have been evaluated for disclosure and recognition. The standard is effective for financial statements issued after June 15, 2009. The implementation of this standard did not have a significant impact on the financial statements of the Company.

The Company has evaluated subsequent events through August 6, 2009, the date the financial statements were issued, and determined that there have been no subsequent events that would require recognition in the Financial Statements or disclosure in the Notes to Condensed Financial Statements.

**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 primarily for the treatment of diseases of the central nervous system. A number of drug development programs are currently being conducted to evaluate our drug candidates in diseases such as pancreatitis, bipolar disorder and neurodegeneration. We also have a bioprocessing business that both sells a line of products based on Protein A for monoclonal antibody purification and looks to acquire additional products and technologies to complement our manufacturing and quality capabilities. In addition, we receive royalties from Bristol for their net sales in the United States of their product Orencea®. We seek to invest the profits from our current commercial products and royalty and other revenues, as well as using our existing financial resources, to advance the development of our therapeutic and bioprocessing product candidates while also supporting our business development activities.

**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 significant accounting policies in Note 2 to the Financial Statements included in our Annual Report on Form 10-K dated March 31, 2009. There have been no changes to our critical accounting policies since March 31, 2009.

**Results of Operations**

*Three months ended June 30, 2009 vs. June 30, 2008*

**Total revenue**

Total revenues for the three-month periods ended June 30, 2009 and 2008 were approximately \$5,061,000 and \$13,660,000, respectively, a decrease of \$8,599,000 or 63%.

Sales of Protein A for the three months ended June 30, 2009 and 2008 were \$2,473,000 and \$5,525,000, respectively. This decrease of \$3,052,000, or 55%, was largely due to decreased demand from certain key customers in reaction to current economic conditions and other business events. The Company sells various Protein A products at various price points. The mix of products sold varies and impacts the fluctuations in total product revenue and cost of product revenues from period to period.



---

## Table of Contents

Our primary customers incorporate our Protein A products into their proprietary monoclonal antibody purification products that they sell directly to the biotechnology and pharmaceutical industry. Monoclonal antibodies are a well-established class of drug with applications in rheumatoid arthritis and other inflammatory disorders, and Non-Hodgkin's Lymphoma, among other therapeutic antibodies. Sales of Protein A are therefore impacted by the timing of large-scale production orders and by the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

There were no sales of SecreFlo® for the three months ended June 30, 2009 as we discontinued distribution of this product in the second quarter of fiscal year 2009 due to the expiration of our agreement with ChiRhoClin, Inc. Sales of SecreFlo® for the three months ended June 30, 2008 were \$168,000.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$2,118,000 and \$7,899,000 for the three months ended June 30, 2009 and 2008, respectively. The \$7,899,000 recognized in the first fiscal quarter of 2008 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia® from January 1, 2008 to March 31, 2008, and \$1.6 million in royalties for sales of Orencia® in from April 1, 2008 to June 30, 2008. Additionally, for the three months ended June 30, 2009 and 2008, the Company earned and recognized approximately \$263,000 and \$70,000, respectively, in royalty revenue from ChiRhoClin for their sales of secretin.

During the three-month period ended June 30, 2009, we recognized approximately \$207,000 of research revenue from a sponsored research and development project under an agreement with the Muscular Dystrophy Association. No research revenue was recognized in the three-month period ended June 30, 2008.

### Costs and operating expenses

Total costs and operating expenses were approximately \$6,489,000 and \$5,702,000 for the three-month periods ended June 30, 2009 and 2008, respectively, an increase of \$787,000 or 14%.

Cost of product revenue was approximately \$1,270,000 and \$1,846,000 for the three-month periods ended June 30, 2009 and 2008, respectively, a decrease of \$576,000 or 31%. This decrease is primarily due to the 55% decrease in Protein A revenue noted above, partially offset by increased depreciation expenses related to expansion of our manufacturing capacity and increased headcount.

Pursuant to the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the settlement agreement in December 2013, after deducting certain allowable legal and other costs, to the University of Michigan. For the three-months ended June 30, 2009 and 2008, the cost of royalty revenue was \$318,000 and \$325,000, respectively.

Research and development expenses were approximately \$3,383,000 and \$2,084,000 for the three-month periods ended June 30, 2009 and 2008, respectively, an increase of \$1,299,000 or 62%. The increase is largely due to a \$615,000 increase in our phase 2b clinical trial expenses for RG2417, evaluating the use of uridine to treat bipolar depression, and a \$295,000 increase related to the phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging. In addition, our research and development efforts increased by \$424,000 related to Friedreich's ataxia as we continue to search for a drug candidate. Research and development expenses are increasing as we continue to advance these three programs and look to expand our intellectual property portfolio, and we expect this trend to continue for the foreseeable future. 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. Due to the small size of the Company and the fact that these various programs share personnel and fixed costs such as facility costs, depreciation, and supplies, we do not track all our expenses by program.

Selling, general and administrative expenses were approximately \$1,517,000 and \$1,447,000 for the three-month periods ended June 30, 2009 and 2008, respectively, an increase of \$70,000 or 5%. This increase is largely attributable to a \$296,000 increase in payroll related expenses due to an increased headcount, partially offset by decreased litigation and patent costs as we entered into the Bristol Settlement in fiscal year 2009. We expect selling, general and administrative expenses to increase slightly in fiscal year 2010 as we prepare for the commercial launch of RG1068 for pancreatic imaging.

### Investment income

Investment income was approximately \$322,000 and \$532,000 for the three-month periods ended June 30, 2009 and 2008, respectively. The decrease of \$210,000, or 39%, is primarily due to lower interest rates resulting from overall economic conditions.



---

## **Table of Contents**

### **Income tax provision**

For the three months ended June 30, 2009, the Company did not record a tax provision as no taxable income was generated in the period.

For the three months ended June 30, 2008, the Company had income before taxes of approximately \$8,489,000 and an income tax provision of \$210,000 based on an effective income tax rate of 2.47%. The effective income tax rate was 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.

The Company has net operating loss carryforwards of approximately \$58,696,000, research and development credit carryforwards of approximately \$2,089,000, and other tax credits of approximately \$833,000 available to reduce future federal income taxes, if any. Additionally, the Company also has business tax credit carryforwards of approximately \$2,613,000 available to reduce future state income taxes, if any. The Company has utilized all available state net operating loss carryforwards. The net operating loss and business tax credit carryforwards will continue to expire at various dates, if not used. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

As of June 30, 2009, a full valuation allowance has been provided against the net operating losses, business tax credits and other deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

### **Liquidity and capital resources**

We have financed our operations primarily through sales of equity securities, revenues derived from product sales, and grants, as well as proceeds and royalties from litigation settlements. Our revenue for the foreseeable future will be limited to our Protein A product revenue, royalties from Bristol, and research and development grants. 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, cash equivalents and marketable securities at June 30, 2009 were approximately \$61,970,000, a decrease of \$1,991,000 from \$63,961,000 at March 31, 2009.

#### *Operating activities*

Our operating activities consumed cash of approximately \$1,868,000 for the three-month period ended June 30, 2009. Cash used in operating activities is primarily due to a net loss of \$1,106,000, a \$917,000 decrease in accounts payable, a \$505,000 decrease in accrued liabilities and a \$345,000 increase in royalties receivable, offset by certain non-cash expenses such as \$323,000 for depreciation and \$237,000 in stock-based compensation expense.

For the three months ended June 30, 2008, operating activities provided cash of approximately \$5,637,000. Cash provided by operations was primarily due to net income of \$8,279,000, offset by a \$1,273,000 increase in accounts receivable and a \$1,788,000 decrease in accounts payable.

#### *Investing activities*

Our investing activities provided approximately \$495,000 for the three-month period ended June 30, 2009 due the maturing of certain short term investments at the end of the period, offset by investing \$125,000 in equipment purchases and improvements to the Company's manufacturing facility.

#### *Financing activities*

Stock option exercises provided cash proceeds of approximately \$4,000 for the three months ended June 30, 2009.

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 approximately \$92,000 to \$50,327,000 at June 30, 2009 from \$50,235,000 at March 31, 2009 due to the various changes noted above.

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

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

the success of our clinical studies;

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

our ability to acquire additional product candidates;

the success of any proposed financing efforts;

**Table of Contents**

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

the amount of royalty revenues we receive from Bristol.

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash 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 June 30, 2009, we did not have any off-balance sheet arrangements.

**Commitments**

As of June 30, 2009, 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	\$ 1,476	\$ 661	\$ 815	\$	\$
Capital lease obligations (1)	32	32			
Purchase obligations (2)	704	704			
Contractual obligations (3)	2,890	2,215	650	10	15
<b>Total</b>	<b>\$ 5,102</b>	<b>\$ 3,612</b>	<b>\$ 1,465</b>	<b>\$ 10</b>	<b>\$ 15</b>

(1) Represents principal payments only.

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

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

---

**Table of Contents****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, 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 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 Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of 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 Risk Factors in our Annual Report on Form 10-K for the year ended March 31, 2009.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK****Interest Rate Risk**

We have investments in U.S. Government and agency securities, corporate debt securities and other interest bearing 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 \$413,000 decrease in the fair value of our investments as of June 30, 2009. 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 the principal executive officer and the principal financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the 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, the principal executive officer and principal financial officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to the Company's management, including the Company's principal executive officer and the Company's principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

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.

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

**ITEM 1A. RISK FACTORS**

For a discussion of risk factors, please see Item 1A in our Annual Report on Form 10-K dated March 31, 2009.

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

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million shares of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly announced the stock repurchase program on June 18, 2008. The Company did not repurchase any securities under this program for the three months ended June 30, 2009. Since June 2008, the Company has repurchased 492,827 shares of common stock, for an aggregate purchase price of \$1,969,240, leaving 757,173 shares available for repurchase under this program.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

None.



**Table of Contents**

**ITEM 6. EXHIBITS**

(a) Exhibits

<b>Exhibit Number</b>	<b>Document Description</b>
3.1	Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (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). (File No. 000-14656)
3.3	Amended and Restated By-laws (filed as Exhibit 3.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference). (File No. 000-14656)
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer.
31.2+	Rule 13a-14(a)/15d-14(a) Certification of Principal 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**

**SIGNATURES**

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

REPLIGEN CORPORATION

Date: August 6, 2009

By: /s/ Walter C. Herlihy

Walter C. Herlihy  
Chief Executive Officer and President  
(Principal executive officer)  
Repligen Corporation

Date: August 6, 2009

By: /s/ William J. Kelly

William J. Kelly  
Chief Financial Officer  
(Principal financial and accounting officer)  
Repligen Corporation

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Document Description</b>
3.1	Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (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). (File No. 000-14656)
3.3	Amended and Restated By-laws (filed as Exhibit 3.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference). (File No. 000-14656)
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer.
31.2+	Rule 13a-14(a)/15d-14(a) Certification of Principal 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.