

REPLIGEN CORP
Form 10-Q
November 05, 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 September 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)

Edgar Filing: REPLIGEN CORP - Form 10-Q

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

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (do not check if smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 November 2, 2009.

Class	Number of Shares
Common Stock, par value \$.01 per share	30,758,207

Table of Contents

Table of Contents

	PAGE
PART I FINANCIAL INFORMATION	
Item 1. Unaudited Condensed Financial Statements	
<u>Balance Sheets as of September 30, 2009 and March 31, 2009</u>	3
<u>Statements of Operations for the Three and Six-Month Periods Ended September 30, 2009 and 2008</u>	4
<u>Statements of Cash Flows for the Six-Month Periods Ended September 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>	19
Item 4. <u>Controls and Procedures</u>	19
PART II OTHER INFORMATION	
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>	20
Item 5. <u>Other Information</u>	20
Item 6. <u>Exhibits</u>	21
<u>Signatures</u>	22
<u>Exhibit Index</u>	23

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

	September 30, 2009	March 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,085,530	\$ 5,041,410
Marketable securities	35,753,851	43,817,915
Accounts receivable, less reserve for doubtful accounts of \$10,000	2,467,392	540,779
Royalties receivable	2,556,300	2,036,800
Inventories	2,274,475	2,413,227
Prepaid expenses and other current assets	555,486	933,585
Total current assets	50,693,034	54,783,716
Property, plant and equipment, at cost:		
Leasehold improvements	3,852,243	3,845,247
Equipment	3,828,908	3,527,469
Furniture and fixtures	554,995	513,501
	8,236,146	7,886,217
Less: Accumulated depreciation	(4,869,575)	(4,216,430)
	3,366,571	3,669,787
Long-term marketable securities	17,384,153	15,101,239
Restricted cash	200,000	200,000
Total assets	\$ 71,643,758	\$ 73,754,742
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,480,245	\$ 1,922,572
Accrued liabilities	2,540,283	2,626,341
Total current liabilities	4,020,528	4,548,913
Long-term liabilities	64,100	82,398
Total liabilities	4,084,628	4,631,311
Commitments and contingencies		
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 30,758,207 shares at September 30, 2009 and 30,741,707 shares at March 31, 2009	307,582	307,417
Additional paid-in capital	183,194,492	182,673,275
Accumulated deficit	(115,942,944)	(113,857,261)
Total stockholders' equity	67,559,130	69,123,431

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 71,643,758	\$ 73,754,742
--	---------------	---------------

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30,		Six months ended September 30,	
	2009	2008	2009	2008
Revenue:				
Product revenue	\$ 2,741,578	\$ 2,984,304	\$ 5,214,168	\$ 8,677,647
Royalty and other revenue	2,679,016	2,105,620	5,267,279	10,072,522
Total revenue	5,420,594	5,089,924	10,481,447	18,750,169
Operating expenses: (1)				
Cost of product revenue	918,464	1,210,644	2,188,938	3,057,045
Cost of royalty and other revenue	341,057	210,612	658,803	535,612
Research and development	3,478,845	2,463,419	6,861,845	4,547,544
Selling, general and administrative	1,888,619	1,529,767	3,405,975	2,976,338
Total operating expenses	6,626,985	5,414,442	13,115,561	11,116,539
(Loss) income from operations	(1,206,391)	(324,518)	(2,634,114)	7,633,630
Investment income	227,364	515,235	549,783	1,047,820
Interest income (expense)	(676)	884	(1,352)	(1,021)
(Loss) income before taxes	(979,703)	191,601	(2,085,683)	8,680,429
Income tax provision		49,545		259,545
Net (loss) income	\$ (979,703)	\$ 142,056	\$ (2,085,683)	\$ 8,420,884
Earnings per share:				
Basic	\$ (0.03)	\$	\$ (0.07)	\$ 0.27
Diluted	\$ (0.03)	\$	\$ (0.07)	\$ 0.27
Weighted average shares outstanding:				
Basic	30,745,691	31,172,706	30,743,961	31,160,555
Diluted	30,745,691	31,555,896	30,743,961	31,568,948

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

Cost of product revenue	\$ 10,733	\$ 11,482	\$ 24,106	\$ 22,309
Research and development	48,353	45,291	97,811	76,967
Selling, general and administrative	175,672	141,631	349,796	259,560

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended September 30,	
	2009	2008
Cash flows from operating activities:		
Net (loss) income	\$ (2,085,683)	\$ 8,420,884
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	653,145	502,538
Stock-based compensation expense	471,713	358,836
Loss on disposal of assets		890
Changes in assets and liabilities:		
Accounts receivable	(1,926,613)	(546,188)
Royalties receivable	(519,500)	(1,874,850)
Inventories	138,752	209,606
Prepaid expenses and other current assets	378,099	7,048
Accounts payable	(442,327)	(2,057,058)
Accrued liabilities	(82,500)	503,670
Long-term liabilities	(18,298)	(12,678)
Net cash (used in) provided by operating activities	(3,433,212)	5,512,698
Cash flows from investing activities:		
Purchases of marketable securities	(29,965,657)	(25,066,911)
Redemptions of marketable securities	35,746,807	14,610,639
Purchases of property, plant and equipment	(349,929)	(463,279)
Net cash provided by (used in) investing activities	5,431,221	(10,919,551)
Cash flows from financing activities:		
Exercise of stock options	49,669	258,212
Repurchase of common stock		(289,102)
Principal payments under capital lease obligations	(3,558)	(1,634)
Net cash provided by (used in) financing activities	46,111	(32,524)
Net increase (decrease) in cash and cash equivalents	2,044,120	(5,439,377)
Cash and cash equivalents, beginning of period	5,041,410	32,562,138
Cash and cash equivalents, end of period	\$ 7,085,530	\$ 27,122,761
Supplemental disclosure of noncash activities:		
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 generally accepted accounting principles in the United States (U.S. GAAP) 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 U.S. GAAP. 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 U.S. GAAP 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.

During the period ended September 30, 2009, the Company adopted the new Accounting Standards Codification (ASC) as issued by the Financial Accounting Standards Board (FASB). The ASC has become the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The ASC is not intended to change or alter existing U.S. GAAP. The adoption of the ASC did not have a material impact on the Company s consolidated financial statements.

2. Revenue Recognition

The Company generates product revenues from the sale of Protein A products to customers in the pharmaceutical and process chromatography industries. The Company recognizes revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been met 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 began recognizing royalty revenue in fiscal year 2009 for Bristol s net sales in the United States of Orencia[®] which is used in the treatment of rheumatoid arthritis. Pursuant to the Bristol settlement (as defined in Note 13), the Company recognized royalty revenue of approximately \$2,274,000 and \$1,780,000 for the three months ended September 30, 2009 and 2008, respectively. For the six months ended September 30, 2009 and 2008, the Company recognized Bristol royalty revenue of approximately \$4,391,000 and \$9,677,000, respectively. The \$9,677,000 recognized in the first half of fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia[®] from January 1, 2008 to March 31, 2008, and \$3.4 million in royalties for sales of Orencia[®] from April 1, 2008 to September 30, 2008. Revenue earned from Bristol royalties is recorded in the periods when it is earned based on royalty reports sent by Bristol to the Company. The Company has no continuing obligations to Bristol as a result of this settlement.

Additionally, for the three months ended September 30, 2009 and 2008, the Company earned and recognized approximately \$280,000 and \$215,000, respectively, in royalty revenue from ChiRhoClin for their sales of secretin. For the six months ended September 30, 2009 and 2008, the Company earned and recognized ChiRhoClin royalties of approximately \$544,000 and \$285,000, respectively. Revenue earned from

Edgar Filing: REPLIGEN CORP - Form 10-Q

ChiRhoClin royalties is recorded in the periods when it is earned based on royalty reports sent by ChiRhoClin to the Company.

Table of Contents

For the three months ended September 30, 2009, the Company recognized approximately \$125,000 of revenue from a sponsored research and development project under an agreement with the Friedrich's Ataxia Research Alliance and the National Ataxia Foundation. For the three months ended September 30, 2008, the Company recognized approximately \$110,000 of revenue from a sponsored research and development project under an agreement with GoFar. For the six months ended September 30, 2009 and 2008, the Company recognized approximately \$332,000 and \$110,000, respectively, under sponsored research and development projects.

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

Basic earnings per share for the three and six-month periods ended September 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. Dilutive potential common shares include outstanding stock options, restricted stock and warrants.

Basic and diluted weighted average shares outstanding were as follows:

	Three months ended September 30,		Six months ended September 30,	
	2009	2008	2009	2008
Weighted average common shares	30,745,691	31,172,706	30,743,961	31,160,555
Dilutive common stock options		383,190		408,393
Weighted average common shares, assuming dilution	30,745,691	31,555,896	30,743,961	31,568,948

For the three and six-month periods ended September 30, 2008, respectively, 733,500 and 715,500 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 September 30, 2009, there were outstanding options to purchase 2,314,850 shares of the Company's common stock at a weighted average exercise price of \$4.37 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 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 September 30, 2009 and 2008, the Company recorded stock-based compensation expense of approximately \$234,758 and \$198,404, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan). The Company recorded stock-based compensation expense of approximately \$471,713 and \$358,836 for the six months ended September 30, 2009 and 2008, respectively, for stock options granted under 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

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 September 30, 2009, options to purchase 2,148,050 shares were outstanding under the 2001 Plan and options to purchase 166,800 shares were outstanding under the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the Plans). At September 30, 2009, 582,609 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. Forfeitures are 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 six months ended September 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	193,000	\$ 4.62		
Exercised	(16,500)	\$ 3.01		
Forfeited/Cancelled	(73,600)	\$ 5.27		
Options outstanding at September 30, 2009	2,314,850	\$ 4.37	6.61	\$ 2,354,277
Options exercisable at September 30, 2009	1,279,150	\$ 4.08	4.85	\$ 1,770,002
Vested and expected to vest at September 30, 2009 (1)	2,223,867	\$ 4.38	6.60	\$ 2,257,640

(1) This represents the number of vested options as of September 30, 2009 plus the number of unvested options expected to vest as of September 30, 2009 based on the unvested outstanding options at September 30, 2009 adjusted for the estimated forfeiture rates 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 September 30, 2009 of \$5.01 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 September 30, 2009.

The weighted average grant date fair value of options granted during the six months ended September 30, 2009 and 2008 was \$2.74 and \$3.64, respectively. The total fair value of stock options that vested during the six months ended September 30, 2009 and 2008 was approximately \$765,000 and \$235,000, respectively.

As of September 30, 2009, there was approximately \$2,354,247 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 3.00 years. The Company expects approximately 945,000 in unvested options to vest over the next five years.

5. Cash, Cash Equivalents and Marketable Securities

At September 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:

September 30, 2009	March 31, 2009
-------------------------------	---------------------------

Edgar Filing: REPLIGEN CORP - Form 10-Q

Cash and cash equivalents	\$ 7,085,530	\$ 5,041,410
Marketable securities:		
U.S. Government and agency securities	25,981,402	20,871,059
Corporate and other debt securities	9,772,449	22,946,856
	\$ 35,753,851	\$ 43,817,915
Long-term marketable securities:		
U.S. Government and agency securities	6,505,534	5,032,385
Corporate and other debt securities	10,878,618	10,068,854
	\$ 17,384,153	\$ 15,101,239
Total	\$ 60,223,534	\$ 63,960,564

The average remaining contractual maturity of marketable securities at September 30, 2009 is approximately 9.15 months.

Table of Contents

Management reviewed the Company's investments as of September 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 September 30, 2009 and March 31, 2009.

Investments in held-to-maturity debt securities consist of the following at September 30, 2009:

	Amortized Cost	September 30, 2009		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
Marketable securities:				
U.S. Government and agency securities	\$ 25,981,402	\$ 76,821	\$	\$ 26,058,223
Corporate and other debt securities	9,772,449	64,535		9,836,984
	35,753,851	141,356		35,895,207
Long-term marketable securities:				
U.S. Government and agency securities	6,505,535	26,860	(3,155)	6,529,240
Corporate and other debt securities	10,878,618	93,053		10,971,671
	17,384,153	119,913	(3,155)	17,500,911
Total	\$ 53,138,004	\$ 261,269	\$ (3,155)	\$ 53,396,118

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

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	
Marketable securities:				
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
Long-term marketable securities:				
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
Total	\$ 58,919,154	\$ 269,647	\$ (103,854)	\$ 59,084,947

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

Fair Value

Edgar Filing: REPLIGEN CORP - Form 10-Q

	Amortized Cost	
Due in 1 year or less	\$ 35,753,851	\$ 35,895,207
Due in 1 to 2 years	17,384,153	17,500,911
	\$ 53,138,004	\$ 53,396,118

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

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

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

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

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 September 30, 2009:

	Fair value measurement at reporting date using:			Balance as of September 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	\$ 6,019,097			\$ 6,019,097

There were no remeasurements to fair value during the three months ended September 30, 2009 of financial 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:

	September 30, 2009	March 31, 2009
Raw materials	\$ 1,153,185	\$ 1,400,408
Work in process	862,381	791,465
Finished goods	258,909	221,354
Total	\$ 2,274,475	\$ 2,413,227

8. Accrued Expenses and Other Current Liabilities

The Company estimates accrued liabilities by identifying services performed on the Company's behalf, estimating the level of service performed and determining the associated cost incurred for such service as of each balance sheet date. Examples of estimated accrued expenses include: 1) Fees paid to contract manufacturers in conjunction with the production of clinical materials. These expenses are normally determined through a contract or purchase order issued by the Company; 2) Service fees paid to organizations for their performance in conducting clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs which have been incurred as of each reporting date; 3) Professional and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred, or tracking costs incurred by service providers under fixed fee arrangements.

The Company has processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that the Company does not identify certain costs which have begun to be incurred or the Company under or over-estimates the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often judgmental. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

Accrued liabilities consist of the following:

	September 30, 2009	March 31, 2009
Employee compensation	\$ 847,275	\$ 1,040,529
Royalty and license fees	391,400	269,850
Research and development	735,991	769,793
Professional fees	264,000	94,572
Other accrued expenses	85,528	110,059
Other current liabilities	216,089	216,538
Unearned revenue		125,000
	\$ 2,540,283	\$ 2,626,341

9. Income Taxes

For the three and six-month periods ended September 30, 2009, the Company did not record a tax provision as no taxable income was generated.

For the three and six-month periods ended September 30, 2008, the Company had income before taxes of approximately \$192,000 and \$8,680,000, respectively. The Company had income tax provisions of approximately \$50,000 and \$260,000 for the three and six-month periods ended September 30, 2008, respectively. For the six months ended September 30, 2008, the effective income tax rate was approximately 2.99%. 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 September 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. As of September 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

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 views its operations, makes decisions regarding how to allocate resources and manages the business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

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

	Three months ended		Six months ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Sweden	41%	43%	34%	36%
U.S.	56%	48%	57%	60%
Other	3%	9%	9%	4%
	100%	100%	100%	100%

Royalty revenue from Bristol represented 42% and 35% of the Company's total revenue for the three months ended September 30, 2009 and 2008, respectively. For the six months ended September 30, 2009 and 2008, royalty revenue from Bristol represented 42% and 52% of the Company's total revenue, respectively.

The Company's largest Protein A customer accounted for 41% and 43% of total revenues for the three months ended September 30, 2009 and 2008, respectively. For the six months ended September 30, 2009 and 2008, the Company's largest Protein A customer represented 34% and 36%, respectively.

At September 30, 2009, Bristol's royalty represented 45% of accounts receivable while the Company's largest Protein A customer accounted for 44% of accounts receivable. Bristol's royalty represented 70% of accounts receivable as of March 31, 2009.

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

Pursuant to the License Agreement, the Company agreed to pay Scripps an initial license fee of \$300,000, certain royalty and sublicense fees and, in the event that the Company achieves specified developmental and commercial milestones, certain additional milestone payments. Total future milestone payments, were all milestones achieved, would be approximately \$4.3 million. In addition, the Company issued Scripps and certain of its designees 87,464 shares of the Company's common stock (the Shares) representing \$300,000 as of the Effective Date. The

Edgar Filing: REPLIGEN CORP - Form 10-Q

Company recorded the initial license payment and the value of the shares issued as research and development costs in the statements of operations in fiscal 2008.

In connection with the License Agreement, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. The warrants have a 7-year term and are exercisable based on performance criteria as detailed in the warrant agreement. No expense has been recorded related to these warrants through September 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.

Table of Contents

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

Research Funding and Option Agreement

On October 26, 2007, the Company entered into a research funding and option agreement (*Funding Agreement*) with Scripps to fund a research program for the research and development of compounds that may have utility in the treatment of Friedreich's ataxia. Pursuant to the *Funding Agreement*, the Company is required to fund approximately \$35,000 per quarter which is recorded as research and development expenses. In exchange for funding the research, Scripps will grant an exclusive option to the Company to acquire a sole, worldwide license, including the right to sublicense, manufacture and sell products, and services that result from the research program. There are no guaranties or warranties that products or services may result from the research program and the Company has therefore ascribed no value to the license. The *Funding Agreement* expires or may be terminated (i) when all of the royalty obligations under the *Funding Agreement* expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the *Funding Agreement*, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the *Funding Agreement*; or (iv) by the Company upon 90 days written notice. This agreement terminates in October 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®. 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® for any clinical indication at a rate of 1.8% for the first \$500 million of annual net sales, 2.0% for the next \$500 million of annual net sales and 4% of annual net sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013. The *Bristol Settlement* served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against Bristol and for Repligen and the University of Michigan to grant to Bristol an exclusive worldwide license to the 941 patent and certain other intellectual property.

Pursuant to the *Bristol Settlement*, the Company recognized royalty revenue of approximately \$2,274,000 and \$1,780,000 for the three months ended September 30, 2009 and 2008, respectively. For the six months ended September 30, 2009 and 2008, the Company recognized Bristol royalty revenue of approximately \$4,391,000 and \$9,677,000, respectively. The \$9,677,000 recognized in the first half of fiscal 2009 included an initial \$5.0 million royalty payment, \$1.3 million in royalties for sales of Orencia® from January 1, 2008 to March 31, 2008, and \$3.4 million in royalties for sales of Orencia® from April 1, 2008 to September 30, 2008 (see Note 2).

Repligen must also remit to the University of Michigan 15% of all royalty revenue received from Bristol, after deducting certain legal and other costs incurred related to the *Bristol Settlement*. Royalty expense for the three and six month periods ended September 30, 2009 was approximately \$341,000 and \$659,000, respectively. For the three and six-month periods ended September 30, 2008, the royalty expense was approximately \$211,000 and \$536,000, respectively. The Company incurred approximately \$6.1 million in such legal costs, which when deducted from the \$9.7 million in royalty revenue earned through September 30, 2008, resulted in a net amount due to the University of Michigan of \$536,000. This operating expense has been included on the statements of operations under the line item *Cost of royalty and other revenue* .

14. Share Repurchase

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million of the Company's common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. For the three and six-month periods ended September 30, 2008, the

Edgar Filing: REPLIGEN CORP - Form 10-Q

Company repurchased 75,441 shares of common stock, for an aggregate purchase price of \$360,757, leaving 1,174,559 shares remaining under this authorization. No shares were repurchased for the three and six-month periods ended September 30, 2009.

Table of Contents

15. Subsequent Events

The Company has evaluated subsequent events through November 5, 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 Orenzia®. 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 September 30, 2009 vs. September 30, 2008

Total revenue

Total revenues for the three-month periods ended September 30, 2009 and 2008 were approximately \$5,421,000 and \$5,090,000, respectively, an increase of \$331,000 or 6%.

Sales of Protein A for the three-month periods ended September 30, 2009 and 2008 were approximately \$2,742,000 and \$2,984,000, respectively. This decrease of \$242,000, or 8%, was largely due to reduced demand from certain key customers. We sell 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.

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 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.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$2,274,000 and \$1,780,000 for the three months ended September 30, 2009 and 2008, respectively. Additionally, for the three months ended September 30, 2009 and 2008, we earned and recognized approximately \$280,000 and \$215,000, respectively, in royalty revenue from ChiRhoClin for their sales of secretin.

For the three months ended September 30, 2009, we recognized approximately \$125,000 of revenue from a sponsored research and development project under an agreement with the Friedreich's Ataxia Research Alliance and the National Ataxia Foundation. For the three months ended September 30, 2008, we recognized approximately \$110,000 of revenue from a sponsored research and development project under an agreement with GoFar.

Table of Contents

Costs and operating expenses

Total costs and operating expenses were approximately \$6,627,000 and \$5,414,000 for the three-month periods ended September 30, 2009 and 2008, respectively, an increase of \$1,213,000 or 22%.

Cost of product revenue was approximately \$918,000 and \$1,211,000 for the three-month periods ended September 30, 2009 and 2008, respectively, a decrease of \$293,000 or 24%. This decrease is primarily due to the decrease in Protein A sales noted above and the timing of certain manufacturing expenditures as well as favorable manufacturing variances during the three-month period ended September 30, 2009.

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 September 30, 2009 and 2008, the cost of royalty revenue was \$341,000 and \$211,000, respectively.

Research and development expenses were approximately \$3,479,000 and \$2,463,000 for the three-month periods ended September 30, 2009 and September 30, 2008, respectively, an increase of \$1,016,000 or 41%. The increase is due to increased overall activity, in comparison to the prior period, in our two clinical trials as well as ongoing research and development costs incurred identifying a drug target and investigating potential clinical candidates to be used in the treatment of Friedreich's Ataxia. Specifically, as patient enrollment continues to progress in our phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging, we have increased spending versus the prior period by \$369,000. In addition, we have engaged a clinical research organization to assist in the deployment of our phase 2b clinical trial for RG2417, evaluating the use of uridine to treat bi-polar depression, and otherwise increased overall clinical trial efforts, adding an incremental \$244,000 of spending compared to the prior period. Finally, our Friedreich's ataxia spending has also increased by \$350,000 as we continue our research efforts. 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 \$1,889,000 and \$1,529,000 for the three-month periods ended September 30, 2009 and September 30, 2008, respectively, an increase of \$360,000 or 24%. This increase is largely attributable to increased headcount and other costs as we expand our business development and other functions to support the business.

Investment income

Investment income was approximately \$227,000 and \$515,000 for the three-month periods ended September 30, 2009 and 2008, respectively. This decrease of \$288,000, or 56%, is primarily due to lower interest rates resulting from overall economic conditions.

Income tax provision

For the three-month period ended September 30, 2009, we did not record a tax provision as no taxable income was generated in the period and it is uncertain whether we will be able to utilize the tax benefit created by this loss before income taxes.

For the three months ended September 30, 2008, we had income before taxes of approximately \$192,000 and an income tax provision of \$50,000 for an effective income tax rate of 2.99%. 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.

We have 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, we also have business tax credit carryforwards of approximately \$2,613,000 available to reduce future state income taxes, if any. We have 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 September 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 we will realize the benefits of such deferred tax assets.

Table of Contents

Six months ended September 30, 2009 vs. September 30, 2008

Total revenue

Total revenues for the six-month periods ended September 30, 2009 and September 30, 2008 were approximately \$10,841,000 and \$18,750,000 respectively, a decrease of \$7,909,000 or 42%.

Sales of Protein A for the six-month periods ended September 30, 2009 and September 30, 2008 were \$5,214,000 and \$8,481,000, respectively. The decrease of \$3,267,000, or 39%, was largely the result of decreased demand from certain key customers. 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.

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 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.

In April 2008, we settled our outstanding litigation with Bristol. We have therefore begun recognizing royalty revenue in fiscal year 2009 for Bristol's net sales in the United States of Ocrevus[®] which is used in the treatment of rheumatoid arthritis. Pursuant to the Bristol Settlement, we have recognized \$9,677,000 in royalty revenue in the six-month period ended September 30, 2008, of which, \$6,330,000 represented royalties for Bristol's sales of Ocrevus[®] prior to our fiscal year 2009 that were recognized upon settlement of our litigation. Additionally, during the six-month periods ended September 30, 2009 and September 30, 2008, we earned and recognized approximately \$544,000 and \$285,000, respectively, in royalty revenue from ChiRhoClin.

During the six-month periods ended September 30, 2009, and September 30, 2008, we recognized approximately \$332,000 and \$110,000, respectively, of revenue from various sponsored research and development projects. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred.

As previously disclosed, we have ceased sales of SecreFlo[®] in the prior year due to the expiration of our agreement with our sole supplier, ChiRhoClin. Sales of SecreFlo[®] for the six-month period ended September 30, 2008 were \$168,000.

Costs and operating expenses

Total operating expenses were approximately \$13,116,000 and \$11,117,000 for the six-month periods ended September 30, 2009 and September 30, 2008, respectively, an increase of \$1,999,000 or 18%.

Cost of product revenue was approximately \$2,189,000 and \$3,057,000 for the six-month periods ended September 30, 2009 and September 30, 2008, respectively, a decrease of \$868,000 or 28%. This decrease is primarily due to the decrease in Protein A sales noted above, offset by increased depreciation and occupancy expenses related to expansion of our manufacturing capacity and investments in product quality.

In connection with 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. Total cost of royalty revenue was \$659,000 and \$536,000 for the six-month periods ended September 30, 2009 and September 30, 2008, respectively.

Research and development expenses were approximately \$6,862,000 and \$4,548,000 for the six-month periods ended September 30, 2009 and September 30, 2008, respectively, an increase of \$2,314,000 or 51%. The increase is due to increased overall activity, in comparison to the prior period, in our two clinical trials as well as ongoing research and development costs incurred identifying a drug target and investigating potential clinical candidates to be used in the treatment of Friedreich's Ataxia. Specifically, as patient enrollment continues to progress in our phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging, we have increased spending versus the prior period by \$463,000. In addition, we have engaged a clinical research organization to assist in the deployment of our phase 2b clinical trial for RG2417, evaluating the use of uridine to treat bi-polar depression, and otherwise increased overall clinical trial efforts, adding an incremental \$1,018,000 of spending compared to the prior period. Finally, our Friedreich's ataxia spending has also increased by \$779,000 as we continue our research efforts in advance of entering a phase 1 clinical trial. 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.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Selling, general and administrative expenses were approximately \$3,406,000 and \$2,976,000 for the six-month periods ended September 30, 2009 and September 30, 2008, respectively, an increase of \$430,000 or 14%. This increase is largely attributable to increased headcount and other costs as we expand our business development and other functions to support the business.

Table of Contents

Investment income

Investment income was approximately \$550,000 and \$1,048,000 for the six-month periods ended September 30, 2009 and 2008, respectively. This decrease of \$498,000, or 46%, is primarily due to lower interest rates resulting from overall economic conditions.

Income tax provision

For the six-month period ended September 30, 2009, we did not record a tax provision as no taxable income was generated in the period and it is uncertain whether we will be able to utilize the tax benefit created by this loss before income taxes.

For the six-month period ended September 30, 2008, we generated income before taxes of \$8,680,000 and had an income tax provision of \$260,000, for an effective tax rate of 2.99%. The effective tax rate differs from the statutory tax rate due to the continued utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax (AMT) on income derived during the fiscal year.

We have 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, we also have business tax credit carryforwards of approximately \$2,613,000 available to reduce future state income taxes, if any. We have 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 September 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 we 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 research 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 September 30, 2009 were approximately \$60,224,000, a decrease of \$3,737,000 from \$63,961,000 at March 31, 2009.

Operating activities

Our operating activities consumed cash of approximately \$3,433,000 for the six months ended September 30, 2009. Cash used in operating activities is primarily attributable to a net loss of \$2,086,000, a \$1,927,000 increase in accounts receivable, a \$520,000 increase in royalties receivable, and a \$442,000 decrease in accounts payable, offset by certain non-cash expenses such as \$653,000 for depreciation and \$472,000 in stock-based compensation expense.

Investing activities

Our investing activities provided approximately \$5,431,000 for the six-month period ended September 30, 2009 as we had \$5,781,000 in net redemptions of marketable securities. In addition, we invested approximately \$350,000 in equipment purchases and improvements to our facility.

Financing activities

Stock option exercises provided cash proceeds of approximately \$50,000 for the six months ended September 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 decreased approximately \$3,562,000 to \$46,673,000 at September 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 September 30, 2009, we did not have any off-balance sheet arrangements.

Commitments

As of September 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	\$ 1,347	\$ 638	\$ 696	\$ 13	\$
Capital lease obligations (1)	42	42			
Purchase obligations (2)	529	529			
Contractual obligations (3)	2,007	1,189	818		
Total	\$ 3,925	\$ 2,398	\$ 1,514	\$ 13	\$

- (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 clinical trials.
- (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, 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

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

Table of Contents

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 DISCLOSURE 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 \$440,000 decrease in the fair value of our investments as of September 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.

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

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 for the year ended March 31, 2009.

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

Edgar Filing: REPLIGEN CORP - Form 10-Q

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. The Company did not repurchase any securities under this program for the six months ended September 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.

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

The Company's Annual Meeting of Stockholders (the Annual Meeting) was held on September 11, 2009. At the Annual Meeting, the stockholders of the Company considered and acted upon a proposal to elect a Board of Directors for the ensuing year.

The stockholders elected all of the Company's nominees for directors:

Directors	Shares Voting in	
	Favor	Withhold
Karen Dawes*	23,984,793	602,103
Alfred L. Goldberg, Ph.D.*	24,001,959	584,937
Walter C. Herlihy, Ph.D.*	24,134,189	452,707
Alexander Rich, M.D.*	21,460,147	3,126,749
Thomas F. Ryan, Jr.*	21,643,377	2,943,519
Earl Webb Henry, M.D.*	24,005,926	580,970

* Incumbent

ITEM 5. OTHER INFORMATION

None.

Table of Contents

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). (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: November 5, 2009

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

Date: November 5, 2009

By: */s/* WILLIAM J. KELLY
William J. Kelly
Chief Financial Officer
(Principal financial and accounting officer)
Repligen Corporation

Table of Contents

EXHIBIT INDEX

Exhibit

Number Document Description

- 3.1 Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (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.