

REPLIGEN CORP  
Form 10-Q  
November 02, 2010  
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, 2010

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

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

**41 Seyon Street, Bldg. 1, Suite 100**

**Waltham, MA**  
(Address of principal executive offices)

**02453**  
(Zip Code)

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

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 (§232.405 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 a 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 October 26, 2010.

Class	Number of Shares
Common Stock, par value \$.01 per share	30,787,307

**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 September 30, 2010 and March 31, 2010</u>
	3
	<u>Statements of Operations for the Three and Six-Month Periods Ended September 30, 2010 and 2009</u>
	4
	<u>Statements of Cash Flows for the Six-Month Periods Ended September 30, 2010 and 2009</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>
	15
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	20
Item 4.	<u>Controls and Procedures</u>
	20
<b>PART II</b>	<b><u>OTHER INFORMATION</u></b>
Item 1.	<u>Legal Proceedings</u>
	21
Item 1A.	<u>Risk Factors</u>
	21
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	21
Item 3.	<u>Defaults Upon Senior Securities</u>
	21
Item 4.	<u>(Removed and Reserved)</u>
	21
Item 5.	<u>Other Information</u>
	21
Item 6.	<u>Exhibits</u>
	22
	<u>Signatures</u>
	23
	<u>Exhibit Index</u>
	24

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

	September 30, 2010	March 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,163,290	\$ 12,526,040
Marketable securities	41,269,809	40,608,710
Accounts receivable, less reserve for doubtful accounts of \$10,000	2,096,011	570,038
Royalties receivable	2,513,000	2,296,000
Inventories	2,036,863	2,201,140
Prepaid expenses and other current assets	1,218,064	1,479,107
<b>Total current assets</b>	<b>64,297,037</b>	<b>59,681,035</b>
Property, plant and equipment, at cost:		
Leasehold improvements	3,876,630	3,855,616
Equipment	4,290,059	4,176,281
Furniture and fixtures	587,437	567,480
<b>Total property, plant and equipment, at cost</b>	<b>8,754,126</b>	<b>8,599,377</b>
Less: Accumulated depreciation	(6,186,215)	(5,466,354)
Property, plant and equipment, net	2,567,911	3,133,023
Long-term marketable securities	3,258,084	6,011,697
Intangible assets, net	1,310,833	1,400,208
Goodwill	994,000	994,000
Restricted cash	200,000	200,000
<b>Total assets</b>	<b>\$ 72,627,865</b>	<b>\$ 71,419,963</b>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 898,630	\$ 991,005
Accrued liabilities	2,846,678	3,666,135
<b>Total current liabilities</b>	<b>3,745,308</b>	<b>4,657,140</b>
Long-term liabilities	620,149	642,447
<b>Total liabilities</b>	<b>4,365,457</b>	<b>5,299,587</b>
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 30,787,307 shares at September 30, 2010 and 30,761,807 shares at March 31, 2010	307,873	307,618
Additional paid-in capital	184,264,378	183,733,863
Accumulated deficit	(116,309,843)	(117,921,105)
<b>Total stockholders' equity</b>	<b>68,262,408</b>	<b>66,120,376</b>

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 72,627,865	\$ 71,419,963
--	---------------	---------------

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,	
	2010	2009	2010	2009
<b>Revenue:</b>				
Product revenue	\$ 4,415,786	\$ 2,741,578	\$ 8,684,598	\$ 5,214,168
Royalty and other revenue	2,891,192	2,679,016	5,632,252	5,267,279
<b>Total revenue</b>	<b>7,306,978</b>	<b>5,420,594</b>	<b>14,316,850</b>	<b>10,481,447</b>
<b>Operating expenses: <sup>(1)</sup></b>				
Cost of product revenue	1,471,561	918,464	2,737,311	2,188,938
Cost of royalty and other revenue	376,991	341,057	748,733	658,803
Research and development	3,119,279	3,478,845	5,814,327	6,861,845
Selling, general and administrative	1,812,617	1,888,619	3,600,854	3,405,975
<b>Total operating expenses</b>	<b>6,780,448</b>	<b>6,626,985</b>	<b>12,901,225</b>	<b>13,115,561</b>
<b>Income (loss) from operations</b>	<b>526,530</b>	<b>(1,206,391)</b>	<b>1,415,625</b>	<b>(2,634,114)</b>
Investment income	96,679	227,364	195,637	549,783
Interest expense		(676)		(1,352)
<b>Income (loss) before income taxes</b>	<b>623,209</b>	<b>(979,703)</b>	<b>1,611,262</b>	<b>(2,085,683)</b>
<b>Income tax (benefit) provision</b>				
<b>Net income (loss)</b>	<b>\$ 623,209</b>	<b>\$ (979,703)</b>	<b>\$ 1,611,262</b>	<b>\$ (2,085,683)</b>
<b>Earnings (loss) per share:</b>				
Basic	\$ 0.02	\$ (0.03)	\$ 0.05	\$ (0.07)
Diluted	\$ 0.02	\$ (0.03)	\$ 0.05	\$ (0.07)
<b>Weighted average shares outstanding:</b>				
Basic	30,780,279	30,745,691	30,773,967	30,743,961
Diluted	30,920,400	30,745,691	30,922,474	30,743,961
<b>(1) Includes non-cash stock-based compensation as follows:</b>				
Cost of product revenue	\$ 12,246	\$ 10,733	\$ 27,368	\$ 24,106
Research and development	51,926	48,353	112,747	97,811
Selling, general and administrative	177,957	175,672	364,897	349,796

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

**Table of Contents**

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

	<b>Six months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 1,611,262	\$ (2,085,683)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>		
Depreciation and amortization	809,236	653,145
Stock-based compensation expense	505,012	471,713
<b>Changes in assets and liabilities:</b>		
Accounts receivable	(1,525,973)	(1,926,613)
Royalties receivable	(217,000)	(519,500)
Inventories	164,277	138,752
Prepaid expenses and other current assets	261,043	378,099
Accounts payable	(92,375)	(442,327)
Accrued liabilities	(819,457)	(82,500)
Long-term liabilities	(22,298)	(18,298)
<b>Net cash provided by (used in) operating activities</b>	<b>673,727</b>	<b>(3,433,212)</b>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(33,407,486)	(29,965,657)
Redemptions of marketable securities	35,500,000	35,746,807
Purchases of property, plant and equipment	(154,749)	(349,929)
<b>Net cash provided by investing activities</b>	<b>1,937,765</b>	<b>5,431,221</b>
<b>Cash flows from financing activities:</b>		
Exercise of stock options	25,758	49,669
Principal payments under capital lease obligations		(3,558)
<b>Net cash provided by financing activities</b>	<b>25,758</b>	<b>46,111</b>
<b>Net increase in cash and cash equivalents</b>	<b>2,637,250</b>	<b>2,044,120</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>12,526,040</b>	<b>5,041,410</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 15,163,290</b>	<b>\$ 7,085,530</b>

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, 2010.

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.

**2. Revenue Recognition**

The Company generates product revenues from the sale of bioprocessing 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 and the University of Michigan settled their joint litigation against Bristol-Myers Squibb Company (Bristol) and the Company 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. The settlement 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 royalty revenue of approximately \$2,513,000 and \$2,274,000 for the three months ended September 30, 2010 and 2009, respectively. For the six months ended September 30, 2010 and 2009, the Company recognized Bristol royalty revenue of approximately \$4,992,000 and \$4,391,000, respectively. Revenue earned from Bristol royalties is recorded in the period 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.

Repligen must 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 September 30, 2010 and 2009 was approximately \$377,000 and \$341,000, respectively. For the six months ended September 30, 2010 and 2009, the Company incurred royalty expense of approximately \$749,000 and \$659,000, respectively. This operating expense has been included in the Company's Statements of Operations under the line item Cost of royalty and other revenue.



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

Additionally, for the three and six-month periods ended September 30, 2009, the Company earned and recognized approximately \$280,000 and \$544,000, respectively, in royalty revenue from ChiRhoClin for their sales of secretin. Revenue earned from ChiRhoClin royalties was recorded in the periods when it was earned based on royalty reports sent by ChiRhoClin to the Company. As of December 31, 2009, ChiRhoClin had fulfilled its royalty obligations to the Company for its sales of secretin. The Company does not expect to recognize any further royalty revenue from ChiRhoClin.

**Table of Contents**

For the three months ended September 30, 2010, the Company recognized approximately \$378,000 of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, Go Friedrich's Ataxia Research (GoFar), and the Friedrich's Ataxia Research Alliance. 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 six months ended September 30, 2010 and 2009, the Company recognized approximately \$641,000 and \$332,000, 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 incurred costs 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 (loss) per share for the three and six-month periods ended September 30, 2010 and 2009 were computed on the basis of the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) 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,	
	2010	2009	2010	2009
Weighted average common shares	30,780,279	30,745,691	30,773,967	30,743,961
Dilutive common stock options	140,121		148,507	
Weighted average common shares, assuming dilution	30,920,400	30,745,691	30,922,474	30,743,961

At September 30, 2010, there were outstanding options to purchase 2,579,750 shares of the Company's common stock at a weighted average exercise price of \$4.08 per share. For the three and six-month periods ended September 30, 2010, respectively, 1,928,700 and 1,857,200 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, 2010 and 2009, the Company recorded stock-based compensation expense of approximately \$242,000 and \$235,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan

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

(the 2001 Plan ). The Company recorded stock-based compensation expense of approximately \$505,000 and \$472,000 for the six months ended September 30, 2010 and 2009, 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 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, 2010, options to purchase 2,579,750 shares were outstanding under the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the Plans ). At September 30, 2010, 288,609 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, 2010 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, 2010	2,312,750	\$ 4.38		
Granted	437,000	3.30		
Exercised	(20,500)	1.25		
Forfeited/Cancelled	(149,500)	6.79		
Options outstanding at September 30, 2010	2,579,750	\$ 4.08	6.54	\$ 540,363
Options exercisable at September 30, 2010	1,488,150	\$ 3.96	4.95	\$ 494,812
Vested and expected to vest at September 30, 2010 <sup>(1)</sup>	2,440,328	\$ 4.06	6.42	\$ 535,194

(1) This represents the number of vested options as of September 30, 2010 plus the number of unvested options expected to vest as of September 30, 2010 based on the unvested outstanding options at September 30, 2010 adjusted for 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, 2010 of \$3.38 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, 2010.

The weighted average grant date fair value of options granted during the six months ended September 30, 2010 and 2009 was \$1.94 and \$2.74, respectively. The total fair value of stock options that vested during the six months ended September 30, 2010 and 2009 was approximately \$738,000 and \$765,000, respectively.

As of September 30, 2010, there was approximately \$2,150,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 3.09 years. The Company expects approximately 952,000 unvested options to vest over the next five years.

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

At September 30, 2010, 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 the investments to maturity. These investments are therefore recorded on an amortized cost basis. Marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are securities with maturities of greater than one year.

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

Edgar Filing: REPLIGEN CORP - Form 10-Q

	September 30, 2010	March 31, 2010
Cash and cash equivalents	\$ 15,163,290	\$ 12,526,040
Marketable securities:		
U.S. Government and agency securities	18,998,078	23,009,237
Corporate and other debt securities	22,271,731	17,599,473
	\$ 41,269,809	\$ 40,608,710
Long-term marketable securities:		
U.S. Government and agency securities	3,258,084	3,261,524
Corporate and other debt securities		2,750,173
	\$ 3,258,084	\$ 6,011,697
Total	\$ 59,691,183	\$ 59,146,447

**Table of Contents**

The average remaining contractual maturity of marketable securities at September 30, 2010 is approximately 4.56 months.

Management reviewed the Company's investments as of September 30, 2010 and concluded that there are no securities with other than temporary impairments 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, 2010 and March 31, 2010.

Investments in held-to-maturity debt securities consist of the following at September 30, 2010:

	Amortized Cost	September 30, 2010 Gross Unrealized		Fair Value
		Gain	Loss	
<b>Marketable securities:</b>				
U.S. Government and agency securities	\$ 18,998,078	\$ 19,892	\$ (1,325)	\$ 19,016,645
Corporate and other debt securities	22,271,731	58,594		22,330,325
	41,269,809	78,486	(1,325)	41,346,970
<b>Long-term marketable securities:</b>				
U.S. Government and agency securities	3,258,084	4,371	(1,710)	3,260,745
<b>Total</b>	<b>\$ 44,527,893</b>	<b>\$ 82,857</b>	<b>\$ (3,035)</b>	<b>\$ 44,607,715</b>

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, 2010:

	Amortized Cost	March 31, 2010 Gross Unrealized		Fair Value
		Gain	Loss	
<b>Marketable securities:</b>				
U.S. Government and agency securities	\$ 23,009,237	\$ 25,883	\$ (1,748)	\$ 23,033,372
Corporate and other debt securities	17,599,473	82,760		17,682,233
	40,608,710	108,643	(1,748)	40,715,605
<b>Long-term marketable securities:</b>				
U.S. Government and agency securities	3,261,524	10,849	(8,546)	3,263,827
Corporate and other debt securities	2,750,173	28,105		2,778,278
	6,011,697	38,954	(8,546)	6,042,105
<b>Total</b>	<b>\$ 46,620,407</b>	<b>\$ 147,597</b>	<b>\$ (10,294)</b>	<b>\$ 46,757,710</b>

The contractual maturities of held-to-maturity debt securities at September 30, 2010 were as follows:

Edgar Filing: REPLIGEN CORP - Form 10-Q

	<b>Amortized Cost</b>	<b>Fair Value</b>
Due in 1 year or less	\$ 41,269,809	\$ 41,346,970
Due in 1 to 2 years	3,258,084	3,260,745
	<b>\$ 44,527,893</b>	<b>\$ 44,607,715</b>

**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, other than the liability for contingent consideration recorded in connection with the acquisition of BioFlash Partners, LLC ( BioFlash ). The contingent consideration is valued using management's estimates of royalties to be paid to the former shareholders of BioFlash based on sales of the acquired assets. This valuation is a Level 3 valuation as the primary inputs are unobservable. The following table provides a roll forward of the fair value of the contingent consideration:

Balance at March 31, 2010	\$ 560,000
Additions	
Changes in Fair Value	
Balance at September 30, 2010	\$ 560,000

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, 2010:

	Fair value measurement at reporting date using:			Balance as of September 30, 2010
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				



Edgar Filing: REPLIGEN CORP - Form 10-Q

Money market funds	\$ 12,289,502	\$ 12,289,502
--------------------	---------------	---------------

There were no remeasurements to fair value during the three months ended September 30, 2010 of financial assets and liabilities that are not measured at fair value on a recurring basis.

**Table of Contents****7. Inventories**

Inventories relate to the Company's bioprocessing 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 bioprocessing finished goods is done to order and tested for quality specifications prior to shipment.

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

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

	September 30, 2010	March 31, 2010
Raw materials	\$ 872,966	\$ 1,067,823
Work in process	607,881	395,088
Finished goods	556,016	738,229
Total	\$ 2,036,863	\$ 2,201,140

**8. Accrued 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, 2010	March 31, 2010
Employee compensation	\$ 1,044,061	\$ 1,285,172
Royalty and license fees	689,450	881,900
Research and development	561,481	787,267

Edgar Filing: REPLIGEN CORP - Form 10-Q

Professional fees	72,000	216,086
Other accrued expenses	240,705	188,916
Unearned revenue	238,981	306,794
	\$ 2,846,678	\$ 3,666,135

**Table of Contents****9. Income Taxes**

For the three and six-month periods ended September 30, 2010, the Company had income before taxes of approximately \$623,000 and \$1,611,000, respectively. The Company did not record a tax provision as the effective income tax rate was 0%. The effective income tax rate was based upon the estimated loss 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.

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.

The Company has net operating loss carryforwards of approximately \$63,903,000 and business tax credits carryforwards of approximately \$2,118,000 available to reduce future federal income taxes, if any. Additionally, the Company also has net operating loss carryforwards of approximately \$3,061,000 and business tax credits carryforwards of approximately \$5,615,000 available to reduce future state income taxes, if any. The net operating loss and business tax credits carryforwards will continue to expire at various dates through March 2030. 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, 2010, 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.

**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 September 30,		Six months ended September 30,	
	2010	2009	2010	2009
Sweden	50%	41%	46%	34%
U.S.	46%	56%	45%	57%
Other	4%	3%	9%	9%
	100%	100%	100%	100%

Royalty revenue from Bristol represented 34% and 42% of the Company's total revenue for the three months ended September 30, 2010 and 2009, respectively. For the six months ended September 30, 2010 and 2009, royalty revenue from Bristol represented 35% and 42% of the Company's total revenue, respectively.

The Company's largest bioprocessing customer accounted for 50% and 41% of total revenues for the three months ended September 30, 2010 and 2009, respectively. For the six months ended September 30, 2010 and 2009, the Company's largest bioprocessing customer represented 46% and 34%, respectively.

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

At September 30, 2010, Bristol's royalty represented 55% of accounts receivable while the Company's largest Protein A customer accounted for 38% of accounts receivable. Bristol's royalty represented 80% of accounts receivable as of March 31, 2010.

### **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.

---

## **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 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 which had a value of \$300,000 on the date of issuance. The 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, 2010, 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 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 to 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.

### **13. FSMA License Agreement**

On October 22, 2009, the Company entered into an exclusive worldwide commercial license agreement ( *FSMA License Agreement* ) with Families of Spinal Muscular Atrophy ( *FSMA* ). Pursuant to the FSMA License Agreement, the Company obtained an exclusive license to develop and commercialize certain patented technology and improvements thereon, owned or licensed by FSMA, relating to compounds which may have utility in treating spinal muscular atrophy ( *SMA* ). SMA is an inherited neurodegenerative disease in which a defect in the survival motor neuron gene ( *SMN* ) results in low levels of the protein SMN and leads to progressive damage to motor neurons, loss of muscle function and, in many patients, early death.

Pursuant to the License Agreement, the Company paid FSMA an initial license fee of \$500,000 and a related sublicense fee of \$175,000 in fiscal 2010. These license fees have been recorded as research and development expense in the statements of operations. If all milestones are achieved, total financial obligations under this agreement, including milestone payments, sublicense fees, and other charges, could total approximately \$16,000,000. Given the uncertain nature of such a development program, the likelihood that products or services will result from the research program is not known at this time. The Company has therefore ascribed no value to the license or the related liability.

The License Agreement with FSMA expires or may be terminated (i) on the later of: (a) when all related patents have expired or been abandoned, or (b) 10 years following the first commercial sale of a licensed product; (ii) by FSMA if the Company (a) fails to make payments under the License Agreement, (b) fails to use commercially reasonable efforts towards development and commercial objectives, (c) fails to maintain the required insurance or becomes insolvent, or (d) defaults in its performance under the License Agreement; or (iii) by the Company upon 30 days written notice.



**Table of Contents****14. Goodwill, Other Intangible Assets and Acquisitions***Goodwill*

There was no change in the carrying value of goodwill during the six months ended September 30, 2010.

*Other Intangible Assets*

	Gross Carrying Amount	Accumulated Amortization	Useful Life (in years)
<b>As of September 30, 2010</b>			
Technology developed	\$ 760,000	\$ (63,334)	8
Patents	240,000	(20,000)	8
Customer relationships	430,000	(35,833)	8
	\$ 1,430,000	\$ (119,167)	
	Gross Carrying Amount	Accumulated Amortization	Useful Life (in years)
<b>As of March 31, 2010</b>			
Technology developed	\$ 760,000	\$ (15,834)	8
Patents	240,000	(5,000)	8
Customer relationships	430,000	(8,958)	8
	\$ 1,430,000	\$ (29,792)	

On January 29, 2010, the Company acquired the assets of BioFlash including a technology platform for the production of pre-packed, plug and play chromatography columns for total consideration transferred of \$2.6 million. This patented technology enables economical production of chromatography columns in a format that is ready for use in the production of a broad range of biopharmaceuticals including monoclonal antibodies, vaccines and recombinant proteins. The terms of the acquisition include an upfront payment of \$1.8 million, a milestone payment of \$300,000 payable on the earlier of (i) the date on which Repligen receives an acknowledgment executed by a specific customer or (ii) the second anniversary of the acquisition date, and future royalties based on product sales.

Amortization expense for amortized intangible assets was approximately \$89,000 for the six months ended September 30, 2010. The Company expects to record amortization expense of approximately \$179,000 in each of the next five years.

**15. Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2009-13, *Multiple-Deliverable Arrangements a consensus of the FASB Emerging Issues Task Force* ( ASU 2009-13 ). This ASU establishes the accounting and reporting guidance for arrangements under which a vendor will perform multiple revenue-generating activities. Specifically, the provisions of this update address how to separate deliverables and how to measure and allocate arrangement consideration to one or more units of accounting. This update is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of ASU-2009-13 to have a material impact on our results of operations, financial position or cash flows.

In April 2010, the FASB issued ASU No. 2010-17, *Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force* ( ASU 2010-17 ). This ASU provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company adopted ASU 2010-17 in



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

July 2010. The adoption of this update did not have a material impact on our results of operations, financial position or cash flows.

### **16. Subsequent Event**

On October 29, 2010, the Company was notified that it has received approximately \$733,000 in grants under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act. Amounts earned under these grants will be included in the Company's Statements of Operations under the line item Royalty and other revenue.

---

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**  
***Overview***

We are an integrated biopharmaceutical company focused on the development and commercialization of innovative therapies that deliver the benefits of protein therapies to patients and clinicians in the fields of neurology and gastroenterology. We are currently conducting a number of drug development programs for diseases such as pancreatitis, bipolar disorder, Friedreich's ataxia and spinal muscular atrophy. We have a core competency in the development and manufacturing of biologics which is the basis for our bioprocessing business. In addition, we have out-licensed certain biologics intellectual property from which we receive royalties from Bristol-Myers Squibb Company ( Bristol ) on 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 use our existing financial resources, to advance the development of our therapeutic product candidates and our bioprocessing business.

***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 for the year ended March 31, 2010. There have been no changes to our critical accounting policies since March 31, 2010.

***Results of Operations***

*Three months ended September 30, 2010 vs. September 30, 2009*

***Total revenue***

Total revenues for the three-month periods ended September 30, 2010 and 2009 were approximately \$7,307,000 and \$5,421,000, respectively, an increase of \$1,886,000 or 35%.

Sales of bioprocessing products for the three-month periods ended September 30, 2010 and 2009 were approximately \$4,416,000 and \$2,742,000, respectively. This increase of \$1,674,000, or 61%, was largely due to increased orders from our largest customer as they rebounded from relatively low levels of activity in the prior period. Substantially all of our bioprocessing products are based on recombinant Protein A and 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 our bioprocessing products are therefore impacted by the timing of large-scale production orders and the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations in product revenue. We expect such quarterly fluctuations but do not necessarily believe they are always predictive of future revenue or otherwise indicate a trend.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$2,513,000 and \$2,274,000 for the three-month periods ended September 30, 2010 and 2009, respectively. For the three-month periods ended September 30, 2009, we earned and recognized approximately \$280,000 in royalty revenue from ChiRhoClin for their sales of secretin. ChiRhoClin fulfilled its royalty obligations to us for their sales of secretin in December 2009 and, accordingly, we do not expect to recognize any further royalty revenue from ChiRhoClin.

For the three-month period ended September 30, 2010, we recognized approximately \$331,000 of revenue from a grant from the Muscular Dystrophy Association and approximately \$47,000 of revenue from a sponsored research and development project under agreements with the Friedreich's Ataxia Research Alliance and Go Friedreich's Ataxia Research (GoFAR). For the three-month period 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 (FARA) and the National Ataxia Foundation.

***Costs and operating expenses***

Total costs and operating expenses were approximately \$6,780,000 and \$6,627,000 for the three-month periods ended September 30, 2010 and 2009, respectively, an increase of \$153,000 or 2%.

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

Cost of product revenue was approximately \$1,472,000 and \$918,000 for the three-month periods ended September 30, 2010 and 2009, respectively, an increase of \$553,000 or 60%. This increase is primarily due to the 61% increase in bioprocessing product sales noted above.

---

**Table of Contents**

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-month periods ended September 30, 2010 and 2009, the cost of royalty revenue was \$377,000 and \$341,000, respectively.

Research and development expenses were approximately \$3,119,000 and \$3,479,000 for the three-month periods ended September 30, 2010 and 2009, respectively, a decrease of \$360,000 or 10%. The completion of our phase 3 clinical operations for RG1068 in fiscal year 2010 resulted in a \$233,000 reduction in spending in the current period as compared to the same period in fiscal year 2010. Similarly, lower drug development activity compared to the prior period and the completion of patient enrollment in September 2010 for our phase 2b trial for RG2417, evaluating the use of uridine in bipolar depression, further reduced spending by \$409,000. In addition, spending on our Friedreich's ataxia program and other miscellaneous costs were \$73,000 lower than the prior period, as costs were higher in the prior period as we prepared for our IND filing with the FDA. These decreases were offset partially by an increase of \$356,000 due to our Spinal Muscular Atrophy (SMA) program which was acquired in the third quarter last year.

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. Many resources including personnel, supplies and equipment are shared by all the development programs. As a result, and due to the significant risks and uncertainties in drug development, we are not able to provide cumulative spending to date or predict total development costs for any particular program.

Selling, general and administrative expenses were approximately \$1,813,000 and \$1,889,000 for the three-month periods ended September 30, 2010 and 2009, respectively, a decrease of \$76,000 or 4%. This decrease is largely attributable to the timing of certain legal and patent prosecution costs in the prior period.

***Investment income***

Investment income was approximately \$97,000 and \$227,000 for the three-month periods ended September 30, 2010 and 2009, respectively. This decrease of \$130,000, or 57%, is primarily due to lower interest rates resulting from overall economic conditions.

***Income tax provision***

For the three-month period ended September 30, 2010, we had income before taxes of approximately \$623,000. We did not record a tax provision as the effective income tax rate was 0%. 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.

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.

*Six months ended September 30, 2010 vs. September 30, 2009*

***Total revenue***

Total revenues for the six-month periods ended September 30, 2010 and 2009 were approximately \$14,317,000 and \$10,841,000 respectively, an increase of \$3,835,000 or 37%.

Sales of bioprocessing products for the six-month periods ended September 30, 2010 and September 30, 2009 were \$8,685,000 and \$5,214,000, respectively. This increase of \$3,470,000, or 67%, was largely due to increased orders from our largest customer as they rebounded from relatively low levels of activity in the prior period. Substantially all of our bioprocessing products are based on recombinant Protein A and 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 our bioprocessing products are therefore impacted by the timing of large-scale production orders and the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations in product revenue. We expect such quarterly fluctuations but do not necessarily believe they are always predictive of future revenue or otherwise indicate a trend.

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

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$4,992,000 and \$4,391,000 for the six-month periods ended September 30, 2010 and 2009, respectively. For the six-month period ended September 30, 2009, we also earned and recognized approximately \$544,000 in royalty revenue from ChiRhoClin for their sales of secretin. ChiRhoClin fulfilled its royalty obligations to us for their sales of secretin in December 2009 and, accordingly, we do not expect to recognize any further royalty revenue from ChiRhoClin.

For the six-month period ended September 30, 2010, we recognized approximately \$594,000 of revenue from a grant from the Muscular Dystrophy Association and approximately \$47,000 of revenue from a sponsored research and development project under

**Table of Contents**

agreements with the Friedrich s Ataxia Research Alliance and Go Friedrich s Ataxia Research (GoFAR). For the six-month period ended September 30, 2009, we recognized approximately \$207,000 of revenue from a grant from the Muscular Dystrophy Association and 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.

***Costs and operating expenses***

Total operating expenses were approximately \$12,901,000 and \$13,116,000 for the six-month periods ended September 30, 2010 and 2009, respectively, a decrease of \$215,000 or 2%.

Cost of product revenue was approximately \$2,737,000 and \$2,189,000 for the six-month periods ended September 30, 2010 and 2009, respectively, an increase of \$548,000 or 25%. This increase is primarily due to the increase in bioprocessing product sales noted above, offset by improved manufacturing efficiencies and greater absorption of fixed manufacturing costs.

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 \$749,000 and \$659,000 for the six-month periods ended September 30, 2010 and 2009, respectively.

Research and development expenses were approximately \$5,814,000 and \$6,862,000 for the six-month periods ended September 30, 2010 and 2009, respectively, a decrease of \$1,048,000 or 15%. The completion of our phase 3 clinical trial for RG1068 in fiscal year 2010 resulted in a \$1,066,000 reduction in spending in the current period. Similarly, lower drug development activity compared to the prior period and the completion of patient enrollment in September 2010 for our phase 2b trial for RG2417, evaluating the use of uridine in bipolar depression, further reduced spending by \$282,000, despite a \$250,000 milestone payment made to McLean Hospital during the current year. Spending on our Friedrich s ataxia program and other miscellaneous costs were approximately \$132,000 lower than the prior year, as costs incurred were higher in the prior year as we prepared for our IND filing with the FDA. These decreases were offset partially by an increase of \$432,000 due to our Spinal Muscular Atrophy (SMA) program which was newly acquired in the third quarter of fiscal 2010.

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. Many resources including personnel, supplies and equipment are shared by all the development programs. As a result, and due to the significant risks and uncertainties in drug development, we are not able to provide cumulative spending to date or predict total development costs for any particular program.

Selling, general and administrative expenses were approximately \$3,601,000 and \$3,406,000 for the six-month periods ended September 30, 2010 and 2009, respectively, an increase of \$195,000 or 6%. This increase is largely attributable to increased headcount, employee benefits, occupancy and other costs as we expand our business development and other functions to support the business.

***Investment income***

Investment income was approximately \$196,000 and \$550,000 for the six-month periods ended September 30, 2010 and 2009, respectively. This decrease of \$354,000, or 64%, is primarily due to lower interest rates resulting from overall economic conditions.

***Income tax provision***

For the six-month period ended September 30, 2010, we had income before taxes of approximately \$1,611,000. We did not record a tax provision as the effective income tax rate was 0%. 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.

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.

***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 bioprocessing product revenue, royalties from Bristol, and research and development grants. Given the uncertainties related to pharmaceutical product development, we are

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

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, 2010 were approximately \$59,691,000, an increase of \$545,000 from \$59,146,000 at March 31, 2010.

## **Table of Contents**

### *Operating activities*

Our operating activities provided approximately \$674,000 of cash for the six-month period ended September 30, 2010. Cash provided by operating activities is primarily attributable to net income of \$1,611,000, a decrease in inventory of \$164,000, a decrease in prepaid expenses of \$261,000, and certain non-cash expenses such as \$809,000 for depreciation and amortization and \$505,000 in stock-based compensation expense, offset by a \$1,526,000 increase in accounts receivable, a \$217,000 increase in royalties receivable, a \$912,000 decrease in accounts payable and accrued liabilities and a \$22,000 decrease in long term liabilities.

### *Investing activities*

Our investing activities provided approximately \$1,938,000 of cash for the six-month period ended September 30, 2010 as we had \$2,093,000 in net redemptions of marketable securities. In addition, we invested approximately \$155,000 in equipment purchases and improvements to our facility.

### *Financing activities*

Stock option exercises provided cash proceeds of approximately \$26,000 for the six-month period ended September 30, 2010.

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 \$5,528,000 to \$60,552,000 at September 30, 2010 from \$55,024,000 at March 31, 2010 due to the various changes noted above.

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;

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 for the foreseeable future. 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



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

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*

We did not have any off-balance sheet arrangements as of September 30, 2010.

### *Commitments*

As of September 30, 2010, 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	\$ 818	\$ 653	\$ 159	\$ 6	\$
Purchase obligations <sup>(1)</sup>	4,186	3,739	447		
Contractual obligations <sup>(2)</sup>	1,433	693	90	190	460
<b>Total</b>	<b>\$ 6,437</b>	<b>\$ 5,085</b>	<b>\$ 696</b>	<b>\$ 196</b>	<b>\$ 460</b>

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

(2) 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, milestone payments, tax payments and benefits, 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 markets for pancreatic disease treatment, bipolar disorder, Friedreich's ataxia and spinal muscular atrophy, as well as 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, 2010.

**Table of Contents**

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

***Interest Rate Risk***

We have investments in commercial paper, U.S. Government and agency securities as well as corporate bonds and other debt securities. As a result, we are exposed to potential loss from market risks that may occur as a result of changes in interest rates, changes in credit quality of the issuer or otherwise.

We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines. A hypothetical 100 basis point increase in interest rates would result in an approximate \$170,000 decrease in the fair value of our investments as of September 30, 2010. 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.

**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 for the year ended March 31, 2010.

**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. The Company did not repurchase any securities under this program for the six months ended September 30, 2010. Since June 2008, the Company has repurchased 492,827 shares of common stock, for an aggregate purchase price of approximately \$1,954,000, leaving 757,173 shares available for repurchase under this program.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. (REMOVED AND RESERVED)**

**ITEM 5. OTHER INFORMATION**

None.

---

**Table of Contents**

**ITEM 6. EXHIBITS**

*(a) Exhibits*

**Exhibit**

<b>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.

Date: November 2, 2010

REPLIGEN CORPORATION

By: /s/ Walter C. Herlihy

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

Date: November 2, 2010

By: /s/ William J. Kelly

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

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

<b>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.