

REPLIGEN CORP
Form 10-Q
November 08, 2012
[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, 2012

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)
41 Seyon Street, Bldg. 1, Suite 100

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

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 the 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 (Do not check if a smaller reporting company) 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 30, 2012.

Class	Number of Shares
Common Stock, par value \$.01 per share	31,111,765

Table of Contents**Table of Contents**

	PAGE	
PART I	FINANCIAL INFORMATION	
Item 1.	Unaudited Condensed Consolidated Financial Statements	
	<u>Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011</u>	3
	<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine-Month Periods Ended September 30, 2012 and 2011</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Nine-Month Periods Ended September 30, 2012 and 2011</u>	5
	<u>Notes to Unaudited Condensed Consolidated 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>	20
Item 4.	<u>Controls and Procedures</u>	20
PART II.	<u>OTHER INFORMATION</u>	21
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>Mine Safety Disclosures</u>	21
Item 5.	<u>Other Information</u>	21
Item 6.	<u>Exhibits</u>	21
	<u>Signatures</u>	23
	<u>Exhibit Index</u>	24

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

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,389,977	\$ 11,167,745
Marketable securities	11,918,020	15,421,436
Accounts receivable, less reserve for doubtful accounts of \$10,000	7,636,346	2,825,414
Royalties receivable	3,962,704	3,206,840
Inventories, net	10,768,322	13,363,073
Prepaid expenses and other current assets	1,117,341	910,298
Total current assets	53,792,710	46,894,806
Property, plant and equipment, at cost:		
Leasehold improvements	5,179,119	5,083,852
Equipment	12,648,183	12,011,154
Furniture and fixtures	1,763,973	1,244,451
Construction in progress	294,982	275,258
Total property, plant and equipment, at cost	19,886,257	18,614,715
Less: Accumulated depreciation	(9,769,919)	(7,877,296)
Property, plant and equipment, net	10,116,338	10,737,419
Long-term marketable securities	12,417,051	9,435,350
Intangible assets, net	7,376,533	7,795,239
Goodwill	994,000	994,000
Restricted cash	200,000	200,000
Total assets	\$ 84,896,632	\$ 76,056,814
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,766,699	\$ 1,422,483
Accrued liabilities	7,269,086	6,041,038
Total current liabilities	9,035,785	7,463,521
Other long-term liabilities	1,900,102	2,469,412
Deferred tax liability	256,765	136,881
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, 31,054,765 shares at September 30, 2012 and 30,714,757 shares at December 31, 2011 issued and outstanding	310,548	307,148
Additional paid-in capital	186,500,090	184,872,839
Accumulated other comprehensive income	1,579,403	113,627
Accumulated deficit	(114,686,061)	(119,306,614)
Total stockholders' equity	73,703,980	65,987,000

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 84,896,632	\$ 76,056,814
--	---------------	---------------

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

Table of Contents**REPLIGEN CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)****(Unaudited)**

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Revenue:				
Product revenue	\$ 11,123,236	\$ 5,741,920	\$ 32,125,076	\$ 13,250,840
Royalty and other revenue	3,981,059	2,889,458	11,327,500	8,940,648
Total revenue	15,104,295	8,631,378	43,452,576	22,191,488
Operating expenses:				
Cost of product revenue	6,418,962	2,092,815	19,036,762	5,038,713
Cost of royalty and other revenue	594,406	418,419	1,593,427	1,211,180
Research and development	2,433,043	3,074,625	8,147,164	10,376,357
Selling, general and administrative	3,126,244	2,493,093	9,973,013	7,220,847
Contingent consideration fair value adjustments	343,932		343,932	
Gain on bargain purchase			(314,244)	
Total operating expenses	12,916,587	8,078,952	38,780,054	23,847,097
Income (loss) from operations	2,187,708	552,426	4,672,522	(1,655,609)
Investment income	95,807	52,247	156,747	187,482
Interest expense	7,205		(42,536)	(13,484)
Other income (expense)	(500,414)		67,145	
Income (loss) before income taxes	1,790,306	604,673	4,853,878	(1,481,611)
Income tax provision (benefit)	(16,183)		250,954	
Net income (loss)	\$ 1,806,489	\$ 604,673	\$ 4,602,924	\$ (1,481,611)
Earnings (loss) per share:				
Basic	\$ 0.06	\$ 0.02	\$ 0.15	\$ (0.05)
Diluted	\$ 0.06	\$ 0.02	\$ 0.15	\$ (0.05)
Weighted average shares outstanding:				
Basic	30,948,062	30,796,797	30,841,344	30,800,510
Diluted	31,256,273	30,933,832	31,131,749	30,800,510
Comprehensive income (loss)	\$ 3,913,569	\$ 607,360	\$ 6,068,700	\$ (1,478,924)

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

Table of Contents**REPLIGEN CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	Nine months ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	\$ 4,602,924	\$ (1,481,611)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,592,824	1,212,489
Stock-based compensation expense	743,947	781,645
Fair value adjustments to contingent consideration	339,433	
Gain on bargain purchase	(314,244)	
Loss on disposal of assets		5,597
Changes in assets and liabilities:		
Accounts receivable	(4,672,351)	(2,849,296)
Royalties receivable	(755,864)	(42,858)
Inventories	3,036,051	(522,515)
Prepaid expenses and other current assets	247,093	1,262,077
Accounts payable	309,710	(118,734)
Accrued liabilities	1,087,295	671,455
Long-term liabilities	(1,006,654)	(36,674)
Net cash provided by (used in) operating activities	6,210,164	(1,118,425)
Cash flows from investing activities:		
Purchases of marketable securities	(36,337,643)	(65,381,613)
Redemptions of marketable securities	36,863,333	68,100,987
Purchases of property, plant and equipment	(825,061)	(545,318)
Net cash (used in) provided by investing activities	(299,371)	2,174,056
Cash flows from financing activities:		
Exercise of stock options	886,704	69,239
Repurchase of common stock		(419,267)
Net cash provided by (used in) financing activities	886,704	(350,028)
Effect of exchange rate changes on cash and cash equivalents	424,735	
Net increase in cash and cash equivalents	7,222,232	705,603
Cash and cash equivalents, beginning of period	11,167,745	9,794,509
Cash and cash equivalents, end of period	\$ 18,389,977	\$ 10,500,112

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

Table of Contents**REPLIGEN CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(Unaudited)****1. Basis of Presentation**

The consolidated 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 consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes thereto included in the Company s Transition Report on Form 10-K for the nine months ended December 31, 2011.

In the opinion of management, the accompanying unaudited consolidated 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. Acquisitions, Goodwill and Other Intangible Assets*Acquisitions**Novozymes Biopharma Sweden AB*

On December 20, 2011, pursuant to the terms of the Asset Transfer Agreement, dated as of October 27, 2011 (the Asset Transfer Agreement), by and among the Company, Repligen Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of the Company (Repligen Sweden), Novozymes Biopharma DK A/S, a company organized under the laws of Denmark (Novozymes Denmark), and Novozymes Biopharma Sweden AB, a company organized under the laws of Sweden and a wholly-owned subsidiary of Novozymes Denmark (Novozymes Sweden and, together with Novozymes Denmark, Novozymes), the Company acquired Novozymes business headquartered at Novozymes Sweden s facility in Lund, Sweden and all related operations, including the manufacture and supply of cell culture ingredients and Protein A affinity ligands for use in industrial cell culture, stem and therapeutic cell culture and biopharmaceutical manufacturing (the Novozymes Biopharma Business). Pursuant to the Asset Transfer Agreement, Repligen Sweden (a) purchased all of the assets related to the Novozymes Biopharma Business and assumed certain specified liabilities related to the Novozymes Biopharma Business from Novozymes Sweden and (b) purchased contract rights and licenses used in the Novozymes Biopharma Business and other specified assets from Novozymes Denmark (collectively, the Transferred Business and the acquisition of the Transferred Business, the Novozymes Acquisition). The Novozymes Biopharma Business now operates as Repligen Sweden. The Company paid a total purchase price of 20,310,000 (~\$26,400,000) to Novozymes for the Transferred Business. In addition, Novozymes has the right to contingent payments of up to 4,000,000 (~\$5,200,000) consisting of: (i) an earn-out of 1,000,000 (~\$1,300,000) if the Transferred Business achieves sales of a minimum quantity of a Novozymes product between January 1, 2012 and December 31, 2012; (ii) two milestone payments of 1,000,000 (~\$1,300,000) each if sales of certain Novozymes products achieve agreed levels for the combined calendar years 2012 and 2013 and for calendar year 2014, respectively; and (iii) technology transfer payments totaling 1,000,000 (~\$1,300,000) following the successful transfer of certain Novozymes manufacturing technology. The probability-weighted fair value of the 4,000,000 contingent consideration was \$2,019,000 and \$1,611,000 at September 30, 2012 and December 31, 2011, respectively.

The Company accounted for the Novozymes Acquisition as the purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of the Novozymes Biopharma Business were recorded as of the acquisition date, at their respective fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was approximately \$28,922,000, which exceeded the total consideration transferred of \$28,495,000. Accordingly, the Company recognized the excess of the fair value of the net assets over the purchase price of approximately \$427,000 as a gain on bargain purchase. In the nine months ended September 30, 2012, the Company recognized an

Edgar Filing: REPLIGEN CORP - Form 10-Q

additional gain on bargain purchase of \$314,000 due to net working capital adjustments. The Company finalized its fixed asset valuation analysis in the quarter ended September 30, 2012 and the purchase price allocation is now considered final.

Goodwill

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at September 30, 2012. There were no goodwill impairment charges during the three or nine-month periods ended September 30, 2012.

Table of Contents*Other Intangible Assets*

Intangible assets are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within selling, general and administrative expense in the statements of operations. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for our products or changes in the size of the market for our products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset based on the sum of the future undiscounted cash flows expected to result from the use and disposition of the asset. If the estimate of an intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at September 30, 2012.

Other intangible assets consisted of the following at September 30, 2012:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,446,395	\$ (316,117)	8
Patents	240,000	(80,000)	8
Customer relationships	6,813,471	(727,216)	8
Total other intangible assets	\$ 8,499,866	\$ (1,123,333)	8

Other intangible assets consisted of the following at December 31, 2011:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,413,564	\$ (184,402)	8
Patents	240,000	(57,500)	8
Customer relationships	6,508,147	(124,570)	8
Total other intangible assets	\$ 8,161,711	\$ (366,472)	8

Amortization expense for amortized intangible assets was approximately \$757,000 for the nine months ended September 30, 2012. The Company expects to record amortization expense of approximately \$978,000 in each of the next five years.

3. Revenue Recognition

The Company generates product revenues from the sale of bioprocessing products to customers in the life science and biopharmaceutical 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 is based on management's judgments primarily regarding the fixed nature of the fee charged for the 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 histories and therefore the Company does not require collateral. The Company has had no significant write-offs of uncollectible invoices in the periods presented.

Edgar Filing: REPLIGEN CORP - Form 10-Q

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 the 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 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 settlement with Bristol (Bristol Settlement), the Company recognized royalty revenue of approximately \$3,963,000 and \$2,789,000 for the three months ended September 30, 2012 and 2011, respectively. For the nine months ended September 30, 2012 and 2011, the Company recognized Bristol royalty revenue of approximately \$10,623,000 and \$8,075,000,

Table of Contents

respectively. 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. The royalty agreement with Bristol provides that the Company will receive such royalty payments on sales of Orencia® by Bristol through December 31, 2013.

Pursuant to the Bristol Settlement, Repligen must remit to the University of Michigan 15% of all royalty revenue received from Bristol. Royalty expense for the three months ended September 30, 2012 and 2011 was approximately \$594,000 and \$418,000, respectively. For the nine months ended September 30, 2012 and 2011, the Company incurred royalty expense of approximately \$1,593,000 and \$1,211,000, respectively. This operating expense has been included in the Company's Statements of Operations under the line item Cost of royalty and other revenue.

For the three months ended September 30, 2012 and 2011, the Company recognized approximately \$18,000 and \$100,000 of revenue, respectively, from sponsored research and development projects under agreements with the European Friedrich's Ataxia Consortium for Translational Studies and Go Friedreich's Ataxia Research. For the nine months ended September 30, 2012 and 2011, the Company recognized approximately \$704,000 and \$866,000 of revenue, respectively, from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the European Friedrich's Ataxia Consortium for Translational Studies, the National Institutes of Health / Scripps Research Institute, Go Friedreich's Ataxia Research, and the Friedreich's Ataxia Research Alliance.

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 on 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 significant 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 consolidated financial statements.

4. Earnings (Loss) Per Share

The Company reports earnings (loss) per share in accordance with Accounting Standards Codification Topic 260, Earnings Per Share, which establishes standards for computing and presenting earnings per share. Basic earnings (loss) per share is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common share equivalents consist of restricted stock awards and the incremental common shares issuable upon the exercise of stock options and warrants. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are included in the calculation of basic and diluted earnings per share. Common share equivalents were not included in the net loss per share computation for the nine-month period ended September 30, 2011 because their effect is anti-dilutive.

Basic and diluted weighted average shares outstanding were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Weighted average common shares	30,948,062	30,796,797	30,841,344	30,800,510
Dilutive common stock options	308,211	137,035	290,405	
Weighted average common shares, assuming dilution	31,256,273	30,933,832	31,131,749	30,800,510

At September 30, 2012, there were outstanding options to purchase 2,625,690 shares of the Company's common stock at a weighted average exercise price of \$4.11 per share. For the three and nine-month periods ended September 30, 2012, 1,431,600 and 1,602,000 options to purchase shares of the Company's common stock, respectively, 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.

Edgar Filing: REPLIGEN CORP - Form 10-Q

At September 30, 2011, there were outstanding options to purchase 2,719,100 shares of the Company's common stock at a weighted average exercise price of \$4.09 per share. For the three-month period ended September 30, 2011, 2,046,700 options to purchase 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

Table of Contents

greater than or equal to the average price of the common shares, and were therefore anti-dilutive. For the nine-month period ended September 30, 2011, all such outstanding options have been excluded from the calculation of diluted earnings per share because their effect would be anti-dilutive.

5. Stock-Based Compensation

For the three months ended September 30, 2012 and 2011, the Company recorded stock-based compensation expense of approximately \$288,000 and \$245,000, respectively, for share-based awards granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan) and the Repligen Corporation 2012 Stock Option and Incentive Plan (the 2012 Plan, and collectively with the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan, the Plans). The Company recorded stock-based compensation expense of approximately \$744,000 and \$782,000 for the nine-month periods ended September 30, 2012 and 2011, respectively, for share-based awards granted under the Plans.

The 2012 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock and other equity awards. Incentive options granted to employees under the Plans 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 Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At September 30, 2012, options to purchase 2,625,690 shares were outstanding under the Plans. At September 30, 2012, 1,567,620 shares were available for future grant under the 2012 Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognizes it as expense over the employee's requisite service period on a straight-line basis. The Company records the expense for share-based awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates whether the achievement of a performance-based milestone is probable as of the reporting date. The Company has no awards that are subject to market conditions. The Company recognizes stock-based compensation expense based upon options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted by an amount of estimated forfeitures.

Information regarding option activity for the nine months ended September 30, 2012 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 January 1, 2012	2,823,400	\$ 4.05		
Granted	357,190	3.57		
Exercised	(426,100)	3.12		
Forfeited/Cancelled	(128,800)	4.72		
Options outstanding at September 30, 2012	2,625,690	\$ 4.11	6.21	\$ 4,960,713
Options exercisable at September 30, 2012	1,549,700	\$ 4.32	4.69	\$ 2,632,460
Vested and expected to vest at September 30, 2012 (1)	2,479,847	\$ 4.11	6.09	\$ 4,678,761

- (1) This represents the number of vested options as of September 30, 2012 plus the number of unvested options expected to vest as of September 30, 2012 based on the unvested outstanding options at September 30, 2012 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

Edgar Filing: REPLIGEN CORP - Form 10-Q

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, 2012 of \$5.96 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, 2012.

The weighted average grant date fair value of share-based awards granted during the nine months ended September 30, 2012 and 2011 was \$3.63 and \$2.21, respectively. The total fair value of stock options that vested during the nine months ended September 30, 2012 and 2011 was approximately \$756,444 and \$953,330, respectively.

Table of Contents

As of September 30, 2012, there was \$2,070,353 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 2.87 years. The Company expects 930,147 unvested options to vest over the next five years.

6. Cash, Cash Equivalents and Marketable Securities

At September 30, 2012 and December 31, 2011, the Company's investments included money market funds as well as short-term and long-term marketable securities. 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. The average remaining contractual maturity of marketable securities at September 30, 2012 is approximately 11.9 months.

Management reviewed the Company's investments as of September 30, 2012 and December 31, 2011 and concluded that there were no securities with other than temporary impairments in the investment portfolio. The Company does not intend to sell any investments in an unrealized loss position 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.

Investments in debt securities consisted of the following at September 30, 2012:

	Amortized Cost	September 30, 2012 Gross Unrealized		Fair Value
		Gain	Loss	
Marketable securities:				
U.S. Government and agency securities	\$ 2,454,733	\$ 444	\$	\$ 2,455,177
Corporate and other debt securities	9,452,831	10,012		9,462,843
	11,907,564	10,456		11,918,020
Long-term marketable securities:				
U.S. Government and agency securities	6,199,772	2,103	(1,374)	6,200,501
Corporate and other debt securities	6,217,685	1,682	(2,817)	6,216,550
	12,417,457	3,785	(4,191)	12,417,051
Total	\$ 24,325,021	\$ 14,241	\$ (4,191)	\$ 24,335,071

At September 30, 2012, the Company's investments included eight debt securities in unrealized loss positions with a total unrealized loss of approximately \$4,000 and a total fair market value of approximately \$4,676,000. All investments with gross unrealized losses have been in unrealized loss positions for less than 12 months. The unrealized losses were caused primarily by current economic and market conditions. There was no change in the credit risk of the securities. There were no realized gains or losses on the investments for the nine-month periods ended September 30, 2012 or December 31, 2011.

Investments in debt securities consisted of the following at December 31, 2011:

	Amortized Cost	December 31, 2011 Gross Unrealized		Fair Value
		Gain	Loss	
Marketable securities:				
U.S. Government and agency securities	\$ 8,373,355	\$ 3,126	\$ (233)	\$ 8,376,248
Corporate and other debt securities	7,046,222	3,336	(4,370)	7,045,188

Edgar Filing: REPLIGEN CORP - Form 10-Q

	15,419,577	6,462	(4,603)	15,421,436
Long-term marketable securities:				
U.S. Government and agency securities	8,399,428	2,223	(91)	8,401,560
Corporate and other debt securities	1,031,443	2,347		1,033,790
	9,430,871	4,570	(91)	9,435,350
Total	\$ 24,850,448	\$ 11,032	\$ (4,694)	\$ 24,856,786

Table of Contents

The contractual maturities of debt securities at September 30, 2012 were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 11,907,564	\$ 11,918,020
Due in 1 to 2 years	12,417,457	12,417,051
	\$ 24,325,021	\$ 24,335,071

7. 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 fixed income investments are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2012.

The following fair value hierarchy table presents information about each major category of the Company's assets measured at fair value on a recurring basis as of September 30, 2012:

Fair value measurement at reporting date using:			
Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total

Edgar Filing: REPLIGEN CORP - Form 10-Q

Assets:				
Money market funds	\$ 3,598,743	\$	\$	\$ 3,598,743
U.S. Government and agency securities	1,202,219	7,453,459		8,655,678
Corporate and other debt securities		15,679,393		15,679,393
Total	\$ 4,800,962	\$ 23,132,852	\$	\$ 27,993,814

Table of Contents

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 liabilities for contingent consideration recorded in connection with the Novozymes Acquisition and the acquisition of the assets of BioFlash Partners, LLC (BioFlash). The contingent consideration related to Novozymes is valued using management's estimates of expected future milestone payments based upon a probability weighted analysis of amounts to be paid to Novozymes Denmark. The contingent consideration related to BioFlash is valued using management's estimates of royalties to be paid to the former shareholders of BioFlash based on sales of the acquired assets. These valuations are Level 3 valuations as the primary inputs are unobservable. The following table provides a roll forward of the fair value of the contingent consideration:

Balance at December 31, 2011	\$ 2,197,226
Payments	(35,000)
Changes in fair value	339,434
Effect of exchange rate changes	103,330
 Balance at September 30, 2012	 \$ 2,604,990

There were no remeasurements to fair value during the three or nine months ended September 30, 2012 of financial assets and liabilities that are not measured at fair value on a recurring basis.

8. 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 consolidated 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 consisted of the following:

	September 30, 2012	December 31, 2011
Raw materials	\$ 3,206,689	\$ 3,563,395
Work-in-process	5,968,423	5,936,578
Finished products	1,593,210	3,863,100
 Total	 \$ 10,768,322	 \$ 13,363,073

9. 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

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); and 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 that 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 often require the exercise of judgment. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

Table of Contents

Accrued liabilities consisted of the following:

	September 30, 2012	December 31, 2011
Employee compensation	\$ 3,302,618	\$ 2,741,738
Contingent consideration	1,317,217	35,000
Royalty and license fees	1,078,661	499,776
Unearned revenue	476,827	469,046
VAT liabilities	228,353	566,542
Professional fees	225,351	871,086
Research and development	9,000	142,695
Other accrued expenses	631,059	715,155
	\$ 7,269,086	\$ 6,041,038

10. Income Taxes

For the three and nine-month periods ended September 30, 2012, the Company had income before taxes of approximately \$1,790,000 and \$4,854,000, respectively. The Company recorded an income tax benefit of \$16,000 for the three-month period ended September 30, 2012 and a provision of \$251,000 for the nine-month period ended September 30, 2012 based on an effective tax rate of approximately 5.17%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rates primarily due to the utilization of prior year net operating losses and credits earned in the U.S.

For the three-month period ended September 30, 2011, we did not record a tax provision as the effective income tax rate was 0%. For the nine-month period ended September 30, 2011, we did not record a tax provision as no taxable income was generated in the period.

The Company has net operating loss carryforwards of approximately \$53,972,000 and business tax credit carryforwards of approximately \$2,312,000 available to reduce future federal income taxes, if any. Additionally, the Company has net operating loss carryforwards of approximately \$4,361,000 and business tax credit carryforwards of approximately \$2,934,000 available to reduce future state income taxes, if any. The net operating loss and business tax credit carryforwards will continue to expire at various dates through December 2031. 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.

At September 30, 2012 and December 31, 2011, a full valuation allowance has been provided against the U.S. deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

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,		Nine months ended September 30,	
	2012	2011	2012	2011
United States	41%	36%	41%	44%
Sweden	49%	58%	46%	48%

Edgar Filing: REPLIGEN CORP - Form 10-Q

United Kingdom	7%	2%	10%	3%
Other	3%	4%	3%	5%
Total	100%	100%	100%	100%

Table of Contents

Revenue from significant customers as a percentage of the Company's total revenue was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Orencia® Royalties from Bristol	26%	32%	24%	36%
Bioprocessing Customer A	49%	58%	46%	48%
Bioprocessing Customer B	8%	3%	11%	4%
Bioprocessing Customer C	12%		12%	

Significant accounts receivable balances as a percentage of the Company's total trade accounts receivable and royalties receivable balances were as follows:

	September 30, 2012	December 31, 2011
Orencia® Royalties from Bristol	34%	53%
Bioprocessing Customer A	44%	31%
Bioprocessing Customer B	9%	7%

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

We are a life sciences company that develops, manufactures and markets bioprocessing products for life sciences and biopharmaceutical manufacturing customers worldwide. In December 2011, we acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB thereby diversifying and expanding our bioprocessing product offering and customer base, as well as doubling our manufacturing capacity. We are a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in the manufacture of monoclonal antibodies, a type of biologic drug. We also supply several growth factor products used to increase cell culture productivity during the biomanufacturing process. In the burgeoning area of disposable biomanufacturing technologies, we have developed and currently market a series of OPUS (Open-Platform, User-Specified) chromatography columns for clinical-stage manufacturing. These pre-packed plug-and-play columns are uniquely flexible and customizable to our customers' media and size requirements.

We also applied our expertise in biologic product development to RG1068, a synthetic version of the human hormone secretin that was being developed by the Company as a novel imaging agent for use in combination with magnetic resonance imaging (MRI) to improve the detection of pancreatic duct abnormalities in patients with pancreatitis. We previously submitted a new drug application (NDA) for RG1068 to the U.S. Food and Drug Administration (FDA) and a marketing authorization application (MAA) to the European Medicines Agency (EMA). We received a complete response letter (CRL) in June 2012 from the FDA requesting additional clinical efficacy and safety trial data to support potential approval of the NDA. While we believe RG1068 addresses an area of significant unmet medical need in the detection of pancreatic abnormalities, consistent with our decision to focus our internal efforts on our core bioprocessing business, the Company is currently seeking development and commercialization partners for RG1068. In conjunction with this decision, we are discontinuing active prosecution of our NDA and MAA for RG1068.

We also have two early stage central nervous system (CNS) rare disease programs that are advancing through Phase 1 clinical trials in Friedreich's ataxia and spinal muscular atrophy. As a result of our decision to focus on the growth of the Company's core bioprocessing business, we are seeking development and commercialization partnerships for these programs.

In addition, we have out-licensed certain intellectual property from which we receive royalties from Bristol-Myers Squibb Company (Bristol) on their net sales in the U.S. of their product Orencia®. We expect to receive these royalty payments for Bristol's sales through December 31, 2013.

Total revenue for the nine months ended September 30, 2012 increased by 96% as compared to the nine months ended September 30, 2011 and is primarily due to the addition of the Novozymes Biopharma Business, an increase in bioprocessing product sales orders from a large customer and increased royalty revenue from Bristol as their product Orencia® continues to penetrate the market. In connection with our decision to focus on the growth of the Company's core bioprocessing business, our research and development expenses will likely decline in the future.

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

Table of Contents

effect of matters that are inherently uncertain. For additional information, please see the discussion of our critical accounting policies in Management's Discussion and Analysis and our significant accounting policies in Note 2 to the Financial Statements included in our Transition Report on Form 10-K for the nine months ended December 31, 2011. There have been no changes to our critical accounting policies since December 31, 2011.

Results of Operations

Three months ended September 30, 2012 vs. September 30, 2011

Total revenue

Total revenues for the three-month periods ended September 30, 2012 and 2011 were approximately \$15,104,000 and \$8,631,000, respectively, an increase of \$6,473,000 or 75%.

Sales of bioprocessing products for the three months ended September 30, 2012 and 2011 were \$11,123,000 and \$5,742,000, respectively, an increase of \$5,381,000, or 94%. This increase is primarily due to the addition of the Novozymes Biopharma Business. A majority of the bioprocessing products that we manufacture are based on recombinant Protein A and are sold to customers who incorporate these 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 the bioprocessing products we manufacture 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. Such quarterly fluctuations are expected but they may not be predictive of future revenue or otherwise indicate a trend.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$3,963,000 and \$2,789,000 for the three months ended September 30, 2012 and 2011, respectively. We expect to receive these royalty payments for Bristol's sales through December 31, 2013.

For the three months ended September 30, 2012 and 2011, we recognized approximately \$18,000 and \$100,000, respectively, of revenue from sponsored research and development projects under agreements with the European Friedrich's Ataxia Consortium for Translational Studies and Go Friedrich's Ataxia Research.

Costs and operating expenses

Total costs and operating expenses were approximately \$12,917,000 and \$8,079,000 for the three-month periods ended September 30, 2012 and 2011, respectively, an increase of \$4,838,000 or 60%.

Cost of product revenue was approximately \$6,419,000 and \$2,093,000 for the three-month periods ended September 30, 2012 and 2011, respectively, an increase of \$4,326,000 or 207%. This increase is primarily due to the addition of the Novozymes Biopharma Business and related product mix and other individually insignificant manufacturing variances. While we have reduced headcount and related costs at Repligen Sweden, we anticipate that gross margins will be lower in the twelve-month period ending December 31, 2012 as compared to the same period in 2011 because a significant percentage of our bioprocessing products are now manufactured in our facility in Sweden which has a higher cost of product revenue.

Pursuant to the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the settlement agreement in December 2013 to the University of Michigan. For the three-month periods ended September 30, 2012 and 2011, the cost of royalty revenue was approximately \$594,000 and \$418,000, respectively. This increase is due to the increase in Bristol royalty revenue noted above.

Research and development expenses were approximately \$2,433,000 and \$3,075,000 for the three-month periods ended September 30, 2012 and 2011, respectively, a decrease of \$642,000 or 21%. This decrease is attributable to reduced spending on our drug development programs as we focus our efforts on our core bioprocessing business.

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 of 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. We expect that future research and development costs related to our therapeutic programs will be limited to those intended to most directly add value to potential development and commercialization partnering opportunities. These costs may vary depending on the timing of when each program can be partnered to an outside party, if at all, and any

Edgar Filing: REPLIGEN CORP - Form 10-Q

development work that we continue under any such arrangement. In the future, we expect research and development expenses to be lower as we primarily focus on product development to support our bioprocessing business.

Table of Contents

Selling, general and administrative expenses were approximately \$3,126,000 and \$2,493,000 for the three-month periods ended September 30, 2012 and 2011, respectively, an increase of \$633,000 or 25%. This increase is primarily attributable to a \$312,000 increase related to the addition of the Novozymes Biopharma Business, a \$185,000 increase in professional fees as a result of the acquisition and a \$104,000 increase in recruiting fees related to the hiring of our new Chief Financial Officer. For the remaining quarter in 2012, we expect selling, general and administrative expenses to be consistent with the quarter ended September 30, 2012 as we reduce certain RG1068 pre-commercialization activities and focus on finding a development or commercialization partner for the program.

In connection with the addition of the Novozymes Biopharma Business and the acquisition of the assets of BioFlash, we may be required to pay future consideration that is contingent on achieving certain revenue and technology transfer based milestones. As of each respective acquisition date, we recorded contingent consideration liabilities for the estimated fair value of the amount we expect to pay to the former shareholders of each acquired business. This liability is based on future revenue projections of the respective businesses under various potential scenarios and weighted probability assumptions of these outcomes. At each reporting period, we re-measure the fair value of these liabilities and record the changes in fair value through a separate line item, contingent consideration fair value adjustments, within our Condensed Consolidated Statements of Comprehensive Income (Loss). Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability in connection with the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. For the three-month period ended September 30, 2012, we recorded a charge of approximately \$344,000 primarily reflecting an increase in the fair value of the liability related to the addition of the Novozymes Biopharma Business.

Investment income

Investment income includes income earned on invested cash balances. Investment income was approximately \$96,000 and \$52,000 for the three-month periods ended September 30, 2012 and 2011, respectively. This increase of \$44,000, or 85%, is primarily attributable to higher interest income on cash balances in Sweden partially offset by lower interest earned on our investment portfolio due to lower interest rates and a lower average investment balance during the period.

Other income (expense)

Other expense was approximately \$500,000 for the three-month period ended September 30, 2012 and is primarily attributable to the impact of movements in exchange rates on foreign currency denominated revenues and expenses.

Provision for income taxes

For the three-month period ended September 30, 2012, we had income before taxes of approximately \$1,790,000 and a tax benefit of \$16,000 based on an effective tax rate of 5.17%. For the three-month period ended September 30, 2011, we did not record a tax provision as the effective income tax rate was 0%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rate primarily due to the utilization of prior year net operating loss carryforwards and credits.

Nine months ended September 30, 2012 vs. September 30, 2011

Total revenue

Total revenues for the nine-month periods ended September 30, 2012 and 2011 were approximately \$43,453,000 and \$22,191,000 respectively, an increase of \$21,262,000 or 96%.

Sales of bioprocessing products for the nine-month periods ended September 30, 2012 and 2011 were approximately \$32,125,000 and \$13,251,000, respectively, an increase of \$18,874,000, or 142%. This increase is primarily due to the addition of the Novozymes Biopharma Business and an increase in bioprocessing product sales orders from a large customer. A majority of the bioprocessing products that we manufacture are based on recombinant Protein A and are sold to customers who incorporate these 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. Such quarterly fluctuations are expected but they may not be predictive of future revenue or otherwise indicate a trend.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$10,623,000 and \$8,075,000 for the nine-month periods ended September 30, 2012 and 2011, respectively. We expect to receive these royalty payments for Bristol's sales through December 31, 2013.

Edgar Filing: REPLIGEN CORP - Form 10-Q

For the nine months ended September 30, 2012 and 2011, we recognized approximately \$704,000 and \$866,000, respectively, of revenue from sponsored research and development projects under agreements with the Muscular Dystrophy Association, the European Friedrich s Ataxia Consortium for Translational Studies, the National Institutes of Health / Scripps Research Institute, Go Friedreich s Ataxia Research, and the Friedreich s Ataxia Research Alliance.

Table of Contents***Costs and operating expenses***

Total costs and operating expenses were approximately \$38,780,000 and \$23,847,000 for the nine-month periods ended September 30, 2012 and 2011, respectively, an increase of \$14,933,000 or 63%.

Cost of product revenue was approximately \$19,037,000 and \$5,039,000 for the nine-month periods ended September 30, 2012 and 2011, respectively, an increase of \$13,998,000 or 278%. This increase is primarily due to the addition of the Novozymes Biopharma Business and related product mix, the increase in bioprocessing product sales noted above and other individually insignificant manufacturing variances. While we have reduced headcount and related costs in Sweden, we anticipate that gross margins will be lower in the twelve-month period ending December 31, 2012 as compared to the same period in 2011 because a significant percentage of our bioprocessing products are now manufactured in our facility in Sweden which has a higher cost of product revenue.

Pursuant to the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the settlement agreement in December 2013 to the University of Michigan. For the nine-month periods ended September 30, 2012 and 2011, the cost of royalty revenue was approximately \$1,593,000 and \$1,211,000, respectively.

Research and development expenses were approximately \$8,147,000 and \$10,376,000 for the nine-month periods ended September 30, 2012 and 2011, respectively, a decrease of \$2,229,000 or 21%. This decrease is attributable to reduced spending on our drug development programs as we focus our efforts on our core bioprocessing business.

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 of 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. We expect that future research and development costs will be limited to those intended to most directly add value to potential development and commercialization partnering opportunities. These costs may vary depending on the timing of when each program can be partnered to an outside party, if at all, and any development work that we continue under any such arrangement. In connection with our decision to focus on the growth of the Company's core bioprocessing business, our research and development expenses will likely decline in the future.

Selling, general and administrative expenses were approximately \$9,973,000 and \$7,221,000 for the nine-month periods ended September 30, 2012 and 2011, respectively, an increase of \$2,752,000 or 38%. This increase is largely attributable to increased headcount and transaction costs associated with the addition of the Novozymes Biopharma Business, as well as increased commercialization expenditures prior to receipt of the CRL from the FDA for RG1068 and increased sales and marketing activities related to our decision to focus our internal efforts on our bioprocessing business.

In connection with the addition of the Novozymes Biopharma Business and the acquisition of the assets of BioFlash, we may be required to pay future consideration that is contingent on achieving certain revenue and technology transfer based milestones. As of each respective acquisition date, we recorded contingent consideration liabilities for the estimated fair value of the amount we expect to pay to the former shareholders of each acquired business. This liability is based on future revenue projections of the respective businesses under various potential scenarios and weighted probability assumptions of these outcomes. At each reporting period, we re-measure the fair value of these liabilities and record the changes in fair value through a separate line item, contingent consideration fair value adjustments, within our Condensed Consolidated Statements of Comprehensive Income (Loss). Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability in connection with the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. For the nine-month period ended September 30, 2012, we recorded a charge of approximately \$344,000 primarily reflecting an increase in the fair value of the Novozymes liability.

For the nine months ended September 30, 2012, we recorded a \$314,000 gain on bargain purchase associated with a working capital adjustment related to the Novozymes Acquisition.

Investment income

Investment income includes income earned on invested cash balances. Investment income was approximately \$157,000 and \$187,000 for the nine-month periods ended September 30, 2012 and 2011, respectively. This decrease of \$30,000, or 16%, is primarily attributable to lower interest earned on our investment portfolio due to lower interest rates and a lower average investment balance during the period partially offset by higher interest income on cash balances in Sweden.

Table of Contents

Other income (expense)

Other income was approximately \$67,000 for the nine-month period ended September 30, 2012 and is primarily attributable to the impact of movements in exchange rates on foreign currency denominated revenues and expenses.

Provision for income taxes

For the nine-month period ended September 30, 2012, we had income before taxes of approximately \$4,854,000 and a tax provision of \$251,000, based on an effective tax rate of 5.17%. For the nine-month period ended September 30, 2011, we did not record a tax provision as no taxable income was generated in the period. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rate primarily due to the utilization of prior year net operating loss carryforwards and credits.

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's sales of Orenicia® through December 31, 2013, and research and development grants. We are currently seeking development and commercialization partners for RG1068 and our two early stage CNS programs. However, given the uncertainties related to our ability to negotiate and consummate development and commercialization partnerships for our portfolio of therapeutic and diagnostic assets on acceptable terms, if at all, and the delayed or contingent nature of most or all payments in typical partnership arrangements, we are currently unable to reliably estimate when, if ever, our therapeutic product candidates will generate revenue and cash flows.

Total cash and marketable securities at September 30, 2012 were approximately \$42,725,000, an increase of \$6,700,000 from \$36,025,000 at December 31, 2011. A deposit for leased office space of \$200,000 is classified as restricted cash and is not included in the cash and marketable securities totals for September 30, 2012 or December 31, 2011.

Operating activities

For the nine-month period ended September 30, 2012, our operating activities provided cash of \$6,210,000 reflecting net income of \$4,603,000 and non-cash charges totaling \$3,362,000 including depreciation, amortization, stock-based compensation charges, fair value adjustments to contingent consideration and the gain on bargain purchase. The remaining cash flow used in operations resulted from net unfavorable changes in various working capital accounts.

For the nine-month period ended September 30, 2011, our operating activities consumed cash of \$1,118,000 reflecting a net loss of \$1,482,000 and non-cash charges totaling \$1,994,000 including depreciation, amortization, and stock-based compensation charges. The remaining cash flow used in operations resulted from net unfavorable changes in various working capital accounts.

Investing activities

We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines. Our investing activities consumed \$299,000 for the nine-month period ended September 30, 2012, primarily due to \$825,000 used for fixed asset additions partially offset by net redemptions of marketable debt securities. For the nine-month period ended September 30, 2011, our investing activities provided \$2,174,000, primarily due to net redemptions of marketable debt securities and \$545,000 used for fixed asset additions.

Financing activities

Exercises of stock options provided cash proceeds of \$887,000 in the nine-month period ended September 30, 2012. In the nine months ended September 30, 2011, exercises of stock options provided \$69,000 of cash and we used \$419,000 to repurchase shares of our common stock.

We do not currently use derivative financial instruments.

Working capital increased by approximately \$5,326,000 to \$44,757,000 at September 30, 2012 from \$39,431,000 at December 31, 2011 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 expansion of our bioprocessing business;

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

the resources required to successfully integrate the Novozymes Biopharma Business and recognize expected synergies;

Table of Contents

our ability to establish one or more partnerships for development and commercialization of RG1068 or our early stage CNS programs;

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

the success of our clinical studies;

FDA requirements for additional clinical efficacy and safety trial data to support the NDA for RG1068 and the impact of any additional clinical trials on the timeline for commercialization of RG1068;

our ability to acquire additional bioprocessing products or product candidates;

the extent of any share repurchase activity;

the success of any proposed financing efforts; and

the amount of royalty revenues we receive from Bristol through December 31, 2013.

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash balances are adequate to meet our cash needs for at least the next 24 months. We expect to incur moderately lower expenses in the year ending December 31, 2012 as compared to our annualized spending in the nine months ended December 31, 2011, as we reduce certain RG1068 pre-commercialization activities and focus on finding development or commercialization partners for RG1068 and our early stage CNS programs. We expect to incur continued spending related to the development and expansion of our bioprocessing product lines for the foreseeable future. Our future capital requirements may include, but are not limited to, continued investment in our research and development programs, the acquisition of additional bioprocessing products and technologies to complement our existing manufacturing capabilities, capital expenditures primarily associated with purchases of equipment and continued investment in our intellectual property portfolio.

We plan to continue to invest in our bioprocessing business and in key research and development activities associated with our efforts to identify and consummate development and commercialization partnerships. We actively evaluate various strategic transactions on an ongoing basis, including monetizing existing assets and 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 additional 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 special purpose entities or off-balance sheet financing arrangements as of September 30, 2012.

Contractual obligations

As of September 30, 2012, we had the following fixed obligations and commitments:

Edgar Filing: REPLIGEN CORP - Form 10-Q

(In thousands)	Total	Payments Due by Period			
		Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating lease obligations	\$ 16,655	\$ 2,211	\$ 4,423	\$ 4,142	\$ 5,879
Purchase obligations (1)	3,713	3,713			
Contingent consideration (2)	705	55	190	280	180
Total	\$ 21,073	\$ 5,979	\$ 4,613	\$ 4,422	\$ 6,059

- (1) Represents purchase orders for the procurement of raw material for manufacturing as well as other operating expenses.
(2) These minimum contingent consideration amounts relating to acquisitions are recorded in accrued expenses and long term liabilities on our consolidated balance sheets.

Cautionary Statement Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains 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 Exchange Act). 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

Table of Contents

statements, including, without limitation, express or implied statements regarding current or future financial performance and position, our strategic decision to focus on the growth of our bioprocessing business, the FDA and EMA review of our NDA and MAA for RG1068 and additional clinical data that may be required in connection therewith, management's strategy, plans and objectives for future operations or acquisitions, clinical trials and results, litigation strategy, product candidate research, development and regulatory approval, selling, general and administrative expenditures, intellectual property, development and manufacturing plans, availability of materials and product and adequacy of capital resources and financing plans constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the success of current and future collaborative relationships, our ability to successfully negotiate and consummate development and commercialization partnerships for our portfolio of therapeutic and diagnostic assets on acceptable terms, if at all, our ability to successfully grow our bioprocessing business, 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, reduced demand for our products that adversely impacts our future revenues, cash flows, results of operations and financial condition, 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 ability to generate future revenues, our ability to successfully integrate Repligen Sweden, 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 Transition Report on Form 10-K for the nine months ended December 31, 2011 and in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2012 and June 30, 2012.

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 decrease in interest rates would result in an approximate \$241,000 decrease in the fair value of our investments as of September 30, 2012. 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.

Foreign Exchange Risk

Transactions by our subsidiary, Repligen Sweden, may be denominated in Swedish kronor, British pound sterling, U.S. dollars, or in Euros while the entity's functional currency is the Swedish krona. Exchange gains or losses resulting from the translation between the transactional currency and the functional currency of Repligen Sweden are included in our consolidated statements of operations. The functional currency of the Company is U.S. dollars. Fluctuations in exchange rates may adversely affect our results of operations, financial position and cash flows.

ITEM 4. CONTROLS AND PROCEDURES

The Company's management, with the participation of the principal executive officer and the principal financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on such evaluation, the principal executive officer and principal financial officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to the Company's management, including the Company's principal executive officer and the Company's principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Edgar Filing: REPLIGEN CORP - Form 10-Q

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

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

The matters discussed in this Form 10-Q include forward-looking statements that involve risks or uncertainties. These statements are neither promises nor guarantees, but are based on various assumptions by management regarding future circumstances, over many of which Repligen has little or no control. A number of important risks and uncertainties, including those identified under the caption **Risk Factors** in Item 1A in our Transition Report on Form 10-K for the nine months ended December 31, 2011, Item 1A in our Quarterly Report on Form 10-Q for the three months ended March 31, 2012 and Item 1A in our Quarterly Report on Form 10-Q for the three months ended June 20, 2012, and subsequent filings as well as risks and uncertainties discussed elsewhere in this Form 10-Q, could cause our actual results to differ materially from those in the forward-looking statements.

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

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million shares of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We did not repurchase any shares of common stock during the three or nine-month periods ended September 30, 2012. As of September 30, 2012, there are 657,173 shares remaining under this authorization.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit

Number

Document Description

Edgar Filing: REPLIGEN CORP - Form 10-Q

- 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 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)
- 3.3 Amendment No. 1 to the Amended and Restated By-Laws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on December 20, 2011 and incorporated herein by reference).
- 3.4 Amendment No. 2 to the Amended and Restated By-Laws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on May 25, 2012 and incorporated herein by reference).
- 10.1 Letter Agreement, dated as of September 20, 2012, by and between Repligen Corporation and Jonathan I. Lieber (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on September 21, 2012 and incorporated herein by reference). (File No. 000-14656)
- 31.1+ Rule 13a-14(a)/15d-14(a) Certification.
- 31.2+ Rule 13a-14(a)/15d-14(a) Certification.

Table of Contents

Exhibit

Number	Document Description
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101^	The following materials from Repligen Corporation on Form 10-Q for the quarterly period ended September 30, 2012, formatted in Extensible Business Reporting Language (xBRL): (i) Consolidated Statements of Comprehensive Income (Loss), (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

+ Filed herewith.

* Furnished herewith.

^ As provided in Rule 406T of Regulation S-T, the xBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

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 8, 2012

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

Date: November 8, 2012

By: /s/ Jonathan I. Lieber
Jonathan I. Lieber
Chief Financial Officer
(Principal financial 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	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)
3.3	Amendment No. 1 to the Amended and Restated By-Laws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on December 20, 2011 and incorporated herein by reference). (File No. 000-14656)
3.4	Amendment No. 2 to the Amended and Restated By-Laws (filed as Exhibit 3.1 to Repligen Corporation's Current Report on Form 8-K filed on May 25, 2012 and incorporated herein by reference). (File No. 000-14656)
10.1	Letter Agreement, dated as of September 20, 2012, by and between Repligen Corporation and Jonathan I. Lieber (filed as Exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed on September 21, 2012 and incorporated herein by reference). (File No. 000-14656)
31.1+	Rule 13a-14(a)/15d-14(a) Certification.
31.2+	Rule 13a-14(a)/15d-14(a) Certification.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101^	The following materials from Repligen Corporation on Form 10-Q for the quarterly period ended September 30, 2012, formatted in Extensible Business Reporting Language (xBRL): (i) Consolidated Statements of Comprehensive Income (Loss), (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

+ Filed herewith.

* Furnished herewith.

^ As provided in Rule 406T of Regulation S-T, the xBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.