

REPLIGEN CORP
Form 10-Q
May 10, 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 March 31, 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 April 30, 2012.

Class	Number of Shares
Common Stock, par value \$.01 per share	30,846,165

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 March 31, 2012 and December 31, 2011</u>
	3
	<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three-Month Periods Ended March 31, 2012 and 2011</u>
	4
	<u>Condensed Consolidated Statements of Cash Flows for the Three-Month Periods Ended March 31, 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>
	17
Item 4.	<u>Controls and Procedures</u>
	18
PART II	<u>OTHER INFORMATION</u>
	18
Item 1.	<u>Legal Proceedings</u>
	18
Item 1A.	<u>Risk Factors</u>
	18
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	18
Item 3.	<u>Defaults Upon Senior Securities</u>
	18
Item 4.	<u>Mine Safety Disclosures</u>
	18
Item 5.	<u>Other Information</u>
	18
Item 6.	<u>Exhibits</u>
	19
	<u>Signatures</u>
	20
	<u>Exhibit Index</u>
	21

Table of Contents

REPLIGEN CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,792,899	\$ 11,167,745
Marketable securities	15,108,360	15,421,436
Accounts receivable, less reserve for doubtful accounts of \$18,183 at March 31, 2012 and \$10,000 at December 31, 2011	4,253,891	2,825,414
Royalties receivable	3,080,588	3,206,840
Inventories, net	13,845,705	13,363,073
Prepaid expenses and other current assets	1,660,146	910,298
Total current assets	50,741,589	46,894,806
Property, plant and equipment, at cost:		
Leasehold improvements	5,148,334	5,083,852
Equipment	12,301,405	12,011,154
Furniture and fixtures	1,292,055	1,244,451
Construction in progress	367,424	275,258
Total property, plant and equipment, at cost	19,109,218	18,614,715
Less: Accumulated depreciation	(8,445,025)	(7,877,296)
Property, plant and equipment, net	10,664,193	10,737,419
Long-term marketable securities	9,985,685	9,435,350
Intangible assets, net	7,808,130	7,795,239
Goodwill	994,000	994,000
Restricted cash	200,000	200,000
Total assets	\$ 80,393,597	\$ 76,056,814
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,721,334	\$ 1,422,483
Accrued liabilities	7,069,413	6,041,038
Total current liabilities	8,790,747	7,463,521
Other long-term liabilities	2,678,079	2,469,412
Long-term deferred tax liability	254,557	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, 30,836,206 shares at March 31, 2012 and 30,714,757 shares at December 31, 2011 issued and outstanding	308,362	307,148
Additional paid-in capital	185,226,038	184,872,839
Accumulated other comprehensive income	1,201,452	113,627
Accumulated deficit	(118,065,638)	(119,306,614)

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total stockholders' equity	68,670,214	65,987,000
Total liabilities and stockholders' equity	\$ 80,393,597	\$ 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 March 31,	
	2012	2011
Revenue:		
Product revenue	\$ 9,342,601	\$ 3,150,529
Royalty and other revenue	3,481,860	2,755,856
Total revenue	12,824,461	5,906,385
Operating expenses:		
Cost of product revenue	5,026,320	1,393,089
Cost of royalty and other revenue	462,088	376,890
Research and development	2,808,463	3,784,271
Selling, general and administrative	3,674,759	2,438,636
Gain on bargain purchase	(314,244)	
Total operating expenses	11,657,386	7,992,886
Income (loss) from operations	1,167,075	(2,086,501)
Investment income	31,424	69,298
Interest expense	(22,381)	(13,484)
Other income	109,261	
Income (loss) before income taxes	1,285,379	(2,030,687)
Income tax provision	58,907	
Net income (loss)	\$ 1,226,472	\$ (2,030,687)
Earnings (loss) per share:		
Basic	\$ 0.04	\$ (0.07)
Diluted	\$ 0.04	\$ (0.07)
Weighted average shares outstanding:		
Basic	30,729,660	30,792,428
Diluted	31,009,833	30,792,428
Comprehensive income (loss)	\$ 2,314,297	\$ (2,030,687)

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)

	Three months ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	\$ 1,226,472	\$ (2,030,687)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	824,409	400,281
Stock-based compensation expense	240,873	255,031
Provision for bad debts	8,036	
Gain on bargain purchase	(314,244)	
Loss on revaluation of contingent consideration	24,629	
Loss on disposal of assets		5,597
Changes in assets and liabilities:		
Accounts receivable	(1,362,078)	(88,428)
Royalties receivable	126,252	233,998
Inventories	(54,782)	(16,406)
Prepaid expenses and other current assets	(293,908)	1,694,651
Accounts payable	276,225	231,420
Accrued liabilities	960,971	791,461
Long-term liabilities	70,967	(32,838)
Net cash provided by operating activities	1,733,822	1,444,080
Cash flows from investing activities:		
Purchases of marketable securities	(14,612,493)	(26,234,591)
Redemptions of marketable securities	14,383,333	29,425,417
Purchases of property, plant and equipment	(156,742)	(206,684)
Net cash (used in) provided by investing activities	(385,902)	2,984,142
Cash flows from financing activities:		
Exercise of stock options	113,540	69,214
Repurchase of common stock		(88,401)
Net cash provided by (used in) financing activities	113,540	(19,187)
Effect of exchange rate changes on cash and cash equivalents	163,694	
Net increase in cash and cash equivalents	1,625,154	4,409,035
Cash and cash equivalents, beginning of period	11,167,745	9,794,509
Cash and cash equivalents, end of period	\$ 12,792,899	\$ 14,203,544

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 Euros (~\$26,400,000) to Novozymes for the Transferred Business. In addition, Novozymes has the right to contingent payments of up to 4,000,000 Euros (~\$5,200,000) consisting of: (i) an earn-out of 1,000,000 Euros (~\$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 Euros (~\$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 Euros (~\$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 \$1,698,000 and \$1,611,000 at March 31, 2012 and at December 31, 2011, respectively.

The Company accounted for the Novozymes Acquisition as the purchase of a business under 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 three months ended March 31, 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 purchase price allocation is preliminary as the Company has not yet finalized its fixed asset valuation analysis.

Goodwill

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at March 31, 2012. There were no goodwill impairment charges during the three-month period ended March 31, 2012.

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

Table of Contents

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 March 31, 2012.

Other intangible assets consisted of the following at March 31, 2012:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,439,149	\$ (228,146)	8
Patents	240,000	(65,000)	8
Customer relationships	6,746,088	(323,961)	8
Total other intangible assets	\$ 8,425,237	\$ (617,107)	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 \$251,000 for the three months ended March 31, 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.

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.

Edgar Filing: REPLIGEN CORP - Form 10-Q

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 \$3,081,000 and \$2,512,000 for the three months ended March 31, 2012 and 2011, 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 March 31, 2012 and 2011 was approximately \$462,000 and \$376,000, respectively. This operating expense has been included in the Company's Statements of Operations under the line item Cost of royalty and other revenue.

Table of Contents

For the three months ended March 31, 2012 and 2011, the Company recognized approximately \$401,000 and \$244,000 of revenue, respectively, from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, Go Friedrich's Ataxia Research (GoFar), and the Friedrich'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 have not been included in the net loss per share computation for the three-month period ended March 31, 2011 because their effect is anti-dilutive.

Basic and diluted weighted average shares outstanding were as follows:

	Three Months Ended	
	March 31,	
	2012	2011
Weighted average common shares	30,729,660	30,792,428
Dilutive common stock options		280,173
Weighted average common shares, assuming dilution	31,009,833	30,792,428

At March 31, 2012, there were outstanding options to purchase 2,622,400 shares of the Company's common stock at a weighted average exercise price of \$4.17 per share. For the three-month period ended March 31, 2012, 1,917,900 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 March 31, 2011, there were outstanding options to purchase 2,580,600 shares of the Company's common stock at a weighted average exercise price of \$4.15 per share.

5. Stock-Based Compensation

For the three months ended March 31, 2012 and 2011, the Company recorded stock-based compensation expense of approximately \$241,000 and \$255,000, respectively, for stock options granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan).

Edgar Filing: REPLIGEN CORP - Form 10-Q

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,

Table of Contents

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 March 31, 2012, options to purchase 2,622,400 shares were outstanding under the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan (collectively with the 2001 Plan, the Plans). At March 31, 2012, 15,509 shares were available for future grant under the 2001 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 has no awards with market or performance 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 three months ended March 31, 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	15,000	4.63		
Exercised	(203,000)	2.59		
Forfeited/Cancelled	(13,000)	4.05		
Options outstanding at March 31, 2012	2,622,400	\$ 4.17	6.28	\$ 4,634,129
Options exercisable at March 31, 2012	1,622,600	\$ 4.28	5.10	\$ 2,730,691
Vested and expected to vest at March 31, 2012 (1)	2,480,545	\$ 4.17	6.18	\$ 4,382,363

(1) This represents the number of vested options as of March 31, 2012 plus the number of unvested options expected to vest as of March 31, 2012 based on the unvested outstanding options at March 31, 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.

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 March 31, 2012 of \$5.90 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 March 31, 2012.

The weighted average grant date fair value of options granted during the three months ended March 31, 2012 and 2011 was \$2.30 and \$2.68, respectively. The total fair value of stock options that vested during the three months ended March 31, 2012 and 2011 was approximately \$256,000 and \$174,787, respectively.

As of March 31, 2012, there was \$1,552,464 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 2.75 years. The Company expects 857,945 unvested options to vest over the next five years.

6. Cash, Cash Equivalents and Marketable Securities

Edgar Filing: REPLIGEN CORP - Form 10-Q

At March 31, 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 March 31, 2012 is approximately 11.92 months.

Management reviewed the Company's investments as of March 31, 2012 and December 31, 2011 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 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.

Table of Contents

Investments in debt securities consisted of the following at March 31, 2012:

	March 31, 2012			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	\$ 5,279,804	\$ 1,159	\$ (363)	\$ 5,280,600
Corporate and other debt securities	9,811,251	17,099	(590)	9,827,760
	15,091,055	18,258	(953)	15,108,360
Long-term marketable securities:				
U.S. Government and agency securities	7,600,546	1,386	(2,575)	7,599,357
Corporate and other debt securities	2,388,736		(2,408)	2,386,328
	9,989,282	1,386	(4,983)	9,985,685
Total	\$ 25,080,337	\$ 19,644	\$ (5,936)	\$ 25,094,045

At March 31, 2012, the Company's investments included eleven debt securities in unrealized loss positions with a total unrealized loss of approximately \$6,000 and a total fair market value of approximately \$9,205,000. 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 three months ended March 31, 2012 or the nine-month period ended December 31, 2011.

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

	December 31, 2011			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
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
	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

The contractual maturities of debt securities at March 31, 2012 were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 15,091,055	\$ 15,108,360

Edgar Filing: REPLIGEN CORP - Form 10-Q

Due in 1 to 2 years	9,989,282	9,985,685
	\$ 25,080,337	\$ 25,094,045

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

Table of Contents

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 March 31, 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 March 31, 2012:

	Fair value measurement at reporting date using:			Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 3,850,782	\$	\$	\$ 3,850,782
U.S. Government and agency securities	2,510,293	10,369,665		12,879,958
Corporate and other debt securities		12,214,087		12,214,087
Total	\$ 6,361,075	\$ 22,583,752	\$	\$ 28,944,827

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	24,629
Effect of exchange rate changes	73,973
Balance at March 31, 2012	\$ 2,260,828

There were no remeasurements to fair value during the three months ended March 31, 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.

Table of Contents

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 consist of the following:

	March 31, 2012	December 31, 2011
Raw materials	\$ 3,513,942	\$ 3,563,395
Work-in-process	7,601,400	5,936,578
Finished products	2,730,363	3,863,100
Total	\$ 13,845,705	\$ 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 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.

Accrued liabilities consist of the following:

	March 31, 2012	December 31, 2011
Employee compensation	\$ 2,659,748	\$ 2,741,738
Professional fees	1,031,171	871,086
Unearned revenue	576,794	469,046
Royalty and license fees	487,088	499,776
Research and development	332,700	142,695
VAT liabilities	297,409	566,542
Other accrued expenses	1,684,503	750,155
	\$ 7,069,413	\$ 6,041,038

10. Income Taxes

For the three months ended March 31, 2012, the Company had income before taxes of approximately \$1,285,000 and recorded a tax provision of \$59,000 based on an effective tax rate of approximately 4.58%. 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.

For the three months ended March 31, 2011, the Company did not record a tax provision as no taxable income was generated in the period.

The Company has net operating loss carryforwards of approximately \$58,243,000 and business tax credit carryforwards of approximately \$2,196,000 available to reduce future federal income taxes, if any. Additionally, the Company has net operating loss

Table of Contents

carryforwards of approximately \$4,816,000 and business tax credit carryforwards of approximately \$2,986,000 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 March 31, 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 March 31,	
	2012	2011
Sweden	43%	39%
United States	36%	52%
United Kingdom	14%	
Other	7%	9%
	100%	100%

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

	Three months ended March 31,	
	2012	2011
Orencia® Royalties from Bristol	24%	43%
Bioprocessing Customer A	43%	39%
Bioprocessing Customer B	14%	1%

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

	March 31,	December
	2012	31, 2011
Orencia® Royalties from Bristol	42%	53%
Bioprocessing Customer A	18%	31%
Bioprocessing Customer B	22%	7%

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

We are a world-leading supplier of critical biologic products used to manufacture biologic drugs. 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 also apply our expertise in biologic product development to RG1068, for which our first new drug application (NDA) has been submitted and accepted for priority review by the U.S. Food and Drug Administration (FDA) and for which we have submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA). RG1068 is a synthetic version of the human hormone secretin 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 expect to receive a complete response letter on the previously announced June 21, 2012 PDUFA date requesting additional clinical trial data to support the NDA. 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. 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 Ocrencia®. Total revenue in the three months ended March 31, 2012 increased by 117% as compared to the three months ended March 31, 2011 and is primarily due to the addition of the Novozymes Biopharma Business, an increase in bioprocessing product sales orders from our single largest customer and increased royalty revenue from Bristol as their product Ocrencia® continues to penetrate the market.

Critical Accounting Policies and Estimates

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our critical accounting policies in 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 March 31, 2012 vs. March 31, 2011******Total revenue***

Total revenues for the three-month periods ended March 31, 2012 and 2011 were approximately \$12,824,000 and \$5,906,000, respectively, an increase of \$6,918,000 or 117%.

Sales of bioprocessing products for the three months ended March 31, 2012 and 2011 were \$9,343,000 and \$3,151,000, respectively, an increase of \$6,192,000, or 197%. This increase is primarily due to the addition of the Novozymes Biopharma Business and an increase in bioprocessing product sales orders from our single largest customer. Substantially all of the bioprocessing products 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.

Pursuant to the Bristol Settlement, we recognized royalty revenue of approximately \$3,081,000 and \$2,512,000 for the three months ended March 31, 2012 and 2011, respectively.

For the three months ended March 31, 2012 and 2011, we recognized approximately \$401,000 and \$243,000, respectively, of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, Go Friedreich's Ataxia Research (GoFar), and the Friedreich's Ataxia Research Alliance.

Costs and operating expenses

Total costs and operating expenses were approximately \$11,657,000 and \$7,993,000 for the three-month periods ended March 31, 2012 and 2011, respectively, an increase of \$3,664,000 or 46%.

Table of Contents

Cost of product revenue was approximately \$5,026,000 and \$1,393,000 for the three-month periods ended March 31, 2012 and 2011, respectively, an increase of \$3,633,000 or 261%. This increase is primarily due to the addition of the Novozymes Biopharma Business, the increase in bioprocessing product sales noted above and other individually insignificant manufacturing variances. We anticipate that gross margins may be lower in the year ending December 31, 2012 as a significant percentage of our bioprocessing products are 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 March 31, 2012 and 2011, the cost of royalty revenue was approximately \$462,000 and \$377,000, respectively. This increase is directly related to the increase in Bristol royalty revenue noted above.

Research and development expenses were approximately \$2,808,000 and \$3,784,000 for the three-month periods ended March 31, 2012 and 2011, respectively, a decrease of \$976,000 or 26%. This decrease is primarily attributable to a \$493,000 decrease in costs related to RG2417 for the treatment of patients with bipolar disorder as we discontinued this program in March 2011, a \$392,000 decrease related to our Friedreich's ataxia program as we incurred higher costs in the prior period related to testing and drug substance manufacture in preparation for our ongoing Phase 1 study of RG2833 in adult patients with Friedreich's ataxia in Europe, and a \$232,000 decrease in costs related to our secretin program for MRI imaging of the pancreas as the re-analysis of the images obtained from our Phase 3 clinical trial was completed in March 2011.

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. For each of the remaining quarters in 2012, we expect total research and development expenses to be consistent with the quarter ended March 31, 2012.

Selling, general and administrative expenses were approximately \$3,675,000 and \$2,439,000 for the three-month periods ended March 31, 2012 and 2011, respectively, an increase of \$1,236,000 or 51%. This increase is primarily attributable to a \$585,000 increase related to the addition of the Novozymes Biopharma Business, a one-time \$380,000 increase in legal and audit fees related to this acquisition and a \$97,000 increase in marketing activities related to our bioprocessing business. For each of the remaining quarters in 2012, we expect selling, general and administrative expenses to be moderately lower than the quarter ended March 31, 2012 as we delay certain RG1068 pre-commercialization activities pending our expected receipt of a complete response letter from the FDA on the June 21, 2012 PDUFA date requesting additional clinical trial data to support the NDA.

For the three months ended March 31, 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 \$31,000 and \$69,000 for the three-month periods ended March 31, 2012 and 2011, respectively. This decrease of \$38,000, or 55%, is primarily attributable to lower interest rates.

Provision for income taxes

For the three months ended March 31, 2011, we had income before taxes of approximately \$1,285,000 and a tax provision of \$59,000 based on an effective tax rate of 4.58%. 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 losses and credits.

For the three months ended March 31, 2011, 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's sales of Orenicia® through December 31, 2013, and research and development grants. Given the uncertainties related to pharmaceutical product development, we are currently unable to reliably estimate when, if ever, our therapeutic product candidates will generate revenue and cash flows.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total cash and marketable securities at March 31, 2012 were approximately \$37,887,000, an increase of \$1,862,000 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 March 31, 2012 or December 31, 2011.

Operating activities

For the three-month period ended March 31, 2012, our operating activities provided cash of \$1,734,000 reflecting net income of \$1,226,000 and non-cash charges totaling \$770,000 including depreciation, amortization, stock-based compensation charges and the gain on bargain purchase. The remaining cash flow used in operations resulted from unfavorable changes in various working capital accounts.

Table of Contents

For the three-month period ended March 31, 2011, our operating activities provided cash of \$1,444,000 reflecting a net loss of \$2,031,000 and non-cash charges totaling \$661,000 including depreciation, amortization, and stock-based compensation charges. The remaining cash flow provided in operations resulted from favorable 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 \$386,000 for the three-month period ended March 31, 2012, primarily due to net purchases of marketable debt securities and \$157,000 used for fixed asset additions. For the three-month period ended March 31, 2011, our investing activities provided \$2,984,000, primarily due to net redemptions of marketable debt securities offset by \$207,000 used for fixed asset additions.

Financing activities

Exercises of stock options provided cash receipts of \$114,000 and \$69,000 in the three-periods ended March 31, 2012 and 2011, respectively. In the three months ended March 31, 2011, we used \$88,000 to repurchase shares of our common stock.

We do not currently use derivative financial instruments.

Working capital increased by approximately \$2,520,000 to \$41,951,000 at March 31, 2012 from \$39,431,000 at December 31, 2011 due to the various changes noted above.

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;

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

the success of our clinical studies;

FDA requirements for additional clinical 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 establish one or more partnerships for commercialization of RG1068;

our ability to acquire additional 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.

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. This moderate decrease is primarily due to the delay of certain pre-commercialization activities pending our expected receipt of a complete response letter from the FDA on the June 21, 2012 PDUFA date requesting additional clinical trial data to support our NDA for RG1068 for MRI imaging of the pancreas and includes continued spending related to the development and expansion of our OPUS product line and our ongoing development of RG2833 for Friedreich's ataxia and RG3039 for spinal muscular atrophy. Our future capital requirements include, but are not limited to, continued investment in our research and development programs, the acquisition of additional products and technologies to complement our 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. 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 do not have any special purpose entities or off-balance sheet financing arrangements as of March 31, 2012.

Table of Contents**Contractual obligations**

As of March 31, 2012, 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	\$ 17,763	\$ 2,174	\$ 4,400	\$ 4,400	\$ 6,789
Purchase obligations (1)	4,789	4,789			
Contingent consideration (2)	705	55	190	280	180
Total	\$ 23,257	\$ 7,018	\$ 4,590	\$ 4,680	\$ 6,969

- (1) Represents purchase orders for the procurement of raw material for manufacturing as well as clinical materials to support our clinical trials.
- (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 statements, including, without limitation, statements regarding current or future financial performance, 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, 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 Transition Report on Form 10-K for the nine months ended December 31, 2011 and in this Quarterly Report on Form 10-Q.

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.

Edgar Filing: REPLIGEN CORP - Form 10-Q

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 \$249,000 decrease in the fair value of our investments as of March 31, 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.

Table of Contents***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.

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

PART II. OTHER INFORMATION**ITEM 1. LEGAL PROCEEDINGS**

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

ITEM 1A. RISK FACTORS

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 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.

We believe the FDA will require additional clinical data in order to continue its review of the RG1068 NDA.

On December 21, 2011, we filed an NDA seeking approval to market RG1068, or SecreFlo, a synthetic version of the human hormone secretin we are developing as a novel imaging agent for use in combination with MRI to improve the detection of pancreatic duct abnormalities in patients with pancreatitis. The NDA was prepared based on positive outcomes from a re-read of our Phase 3 clinical study. On April 25, 2012, the FDA notified us that the FDA Advisory Committee meeting previously scheduled for May 31, 2012 to review RG1068 was cancelled by the FDA. The Company expects to receive a Complete Response letter on the previously announced June 21, 2012 PDUFA date requesting additional clinical trial data to support the NDA. At this time, we do not know what additional clinical trial data the FDA will seek and we cannot guarantee that the FDA will seek additional clinical trial data. If the FDA does seek additional clinical trial data, we do not know whether any such clinical trial will be cost effective or the outcome(s) of such clinical trial(s). Accordingly, we are unable at this time to determine if or how to continue the clinical development of RG1068 and the related potential costs of such continued clinical development.

If we are unable to finance any such continued clinical development of RG1068 from our operating cash flow, we may need to raise capital from outside sources. We may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your

ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we do not enter into a collaboration agreement to support the continued development of RG1068, or if adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, we may be required to terminate or delay our development efforts in support of RG1068, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize RG1068, in the event we obtain regulatory approval for RG1068.

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 month period ended March 31, 2012. As of March 31, 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.

Table of Contents

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit	
Number	Document Description
3.1	Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (File No. 000-14656)
3.2	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).
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 March 31, 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, tagged as blocks of text.

+ 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: May 10, 2012

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

Date: May 10, 2012

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Document Description
3.1	Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (File No. 000-14656)
3.2	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).
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 March 31, 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, tagged as blocks of text.

+ 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.