

REPLIGEN CORP
Form 10-Q
May 07, 2013
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, 2013

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 19, 2013.

Class	Number of Shares
Common Stock, par value \$.01 per share	31,442,868

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, 2013 and December 31, 2012</u>	3
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three-Month Periods Ended March 31, 2013 and 2012</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Three-Month Periods Ended March 31, 2013 and 2012</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>	15
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>	22
<u>Signatures</u>	23
<u>Exhibit Index</u>	24

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

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,570,015	\$ 29,209,821
Marketable securities	19,337,124	10,845,195
Accounts receivable, less reserve for doubtful accounts of \$10,000	6,912,751	4,158,758
Royalties and other receivables	3,845,715	9,130,515
Inventories, net	10,264,232	11,143,695
Deferred tax asset, net	416,580	416,580
Prepaid expenses and other current assets	1,352,523	1,304,887
Total current assets	70,698,940	66,209,451
Property, plant and equipment, at cost:		
Leasehold improvements	5,246,962	5,200,271
Equipment	12,963,808	12,802,978
Furniture and fixtures	1,978,138	1,937,238
Construction in progress	383,353	338,814
Total property, plant and equipment, at cost	20,572,261	20,279,301
Less: Accumulated depreciation	(10,879,103)	(10,326,840)
Property, plant and equipment, net	9,693,158	9,952,461
Long-term deferred tax asset, net	2,669,762	2,557,384
Long-term marketable securities	6,148,089	9,914,855
Intangible assets, net	6,910,819	7,182,012
Goodwill	994,000	994,000
Restricted cash	200,000	200,000
Total assets	\$ 97,314,768	\$ 97,010,163
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,900,861	\$2,454,238
Accrued liabilities	6,993,805	8,297,990
Total current liabilities	8,894,666	10,752,228
Other long-term liabilities	1,009,068	2,133,339
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, 31,425,368 shares at March 31, 2013 and 31,195,041 shares at December 31, 2012 issued and outstanding	314,254	311,950
Additional paid-in capital	188,255,742	187,051,253
Accumulated other comprehensive income	1,653,379	1,911,970
Accumulated deficit	(102,812,341)	(105,150,577)

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total stockholders' equity	87,411,034	84,124,596
Total liabilities and stockholders' equity	\$ 97,314,768	\$ 97,010,163

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,	
	2013	2012
Revenue:		
Product revenue	\$ 11,934,269	\$ 9,342,601
Royalty and other revenue	4,521,724	3,481,860
Total revenue	16,455,993	12,824,461
Operating expenses:		
Cost of product revenue	6,896,608	5,272,543
Cost of royalty revenue	576,857	462,088
Research and development	2,183,404	2,808,463
Selling, general and administrative	3,308,099	3,428,536
Contingent consideration fair value adjustments	(53,974)	
Gain on bargain purchase		(314,244)
Total operating expenses	12,910,994	11,657,386
Income from operations	3,544,999	1,167,075
Investment income	61,519	31,424
Interest expense	(13,531)	(22,381)
Other (expense) income	29,081	109,261
Income before income taxes	3,622,068	1,285,379
Income tax provision	1,283,832	58,907
Net income	\$ 2,338,236	\$ 1,226,472
Earnings per share:		
Basic	\$ 0.07	\$ 0.04
Diluted	\$ 0.07	\$ 0.04
Weighted average shares outstanding:		
Basic	31,240,606	30,729,660
Diluted	31,855,428	31,009,833
Other comprehensive income:		
Unrealized gain (loss) on investments	(1,983)	8,099
Foreign currency translation gain (loss)	(256,608)	1,079,726
Comprehensive income	\$ 2,079,645	\$ 2,314,297

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,	
	2013	2012
Cash flows from operating activities:		
Net income:	\$ 2,338,236	\$ 1,226,472
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	818,920	824,409
Stock-based compensation expense	250,071	240,873
Deferred tax expense	(112,403)	
Provision for bad debts		8,036
Gain on bargain purchase		(314,244)
(Gain) loss on revaluation of contingent consideration	(53,974)	24,629
Changes in assets and liabilities:		
Accounts receivable	(2,772,175)	(1,362,078)
Royalties and other receivables	5,284,800	126,252
Inventories	872,260	(54,782)
Prepaid expenses and other current assets	(51,472)	(293,908)
Accounts payable	(548,648)	276,225
Accrued liabilities	(1,301,152)	960,971
Long-term liabilities	(1,129,760)	70,967
Net cash provided by operating activities	3,594,703	1,733,822
Cash flows from investing activities:		
Purchases of marketable securities	(10,538,701)	(14,612,493)
Redemptions of marketable securities	5,811,555	14,383,333
Purchases of property, plant and equipment	(322,099)	(156,742)
Net cash used in investing activities	(5,049,245)	(385,902)
Cash flows from financing activities:		
Exercise of stock options	956,721	113,540
Net cash provided by financing activities	956,721	113,540
Effect of exchange rate changes on cash and cash equivalents	(141,985)	163,694
Net (decrease) increase in cash and cash equivalents	(639,806)	1,625,154
Cash and cash equivalents, beginning of period	29,209,821	11,167,745
Cash and cash equivalents, end of period	\$ 28,570,015	\$ 12,792,899

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 Annual Report on Form 10-K for the year ended December 31, 2012.

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 (the Company made this 1,000,000 Euro payment in March 2013); (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 Company made a 1,000,000 Euro milestone payment in March 2013 in connection with the achievement of the milestone discussed in clause (i) above. The probability-weighted fair value of the remaining contingent consideration was \$1,013,000 and \$2,353,000 at March 31, 2013 and at December 31, 2012, 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

price of approximately \$427,000 as a gain on bargain purchase. In the three months ended March 31, 2012, the Company recognized an 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.

Table of Contents*Goodwill*

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at March 31, 2013. There were no goodwill impairment charges during the three-month period ended March 31, 2013.

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. 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, 2013.

Other intangible assets consisted of the following at March 31, 2013:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,450,743	\$ (404,503)	8
Patents	240,000	(95,000)	8
Customer relationships	6,853,905	(1,134,326)	8
Total other intangible assets	\$ 8,544,648	\$ (1,633,829)	8

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

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,452,729	\$ (360,748)	8
Patents	240,000	(87,500)	8
Customer relationships	6,872,383	(934,852)	8
Total other intangible assets	\$ 8,565,112	\$ (1,383,100)	8

Amortization expense for amortized intangible assets was approximately \$251,000 for the three months ended March 31, 2013. The Company expects to record amortization expense of approximately \$1,000,000 in each of the next five years.

3. Revenue Recognition*Product Sales*

The Company generates revenue from the sale of products, licensing transactions and research and development collaborations. The Company's product revenues are from the sale of bioprocessing products to customers in the life science and biopharmaceutical industries. Revenue related

Edgar Filing: REPLIGEN CORP - Form 10-Q

to product sales is recognized upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been met are based on management's judgments primarily regarding the fixed nature of the fee charged for 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.

Table of Contents*Orencia Royalty*

In April 2008, the Company settled its outstanding litigation with Bristol-Myers Squibb Company (Bristol) and began recognizing royalty revenue in fiscal year 2009 for Bristol's net sales in the United States of Orencia[®] which is used in the treatment of rheumatoid arthritis. Pursuant to the settlement with Bristol (Bristol Settlement), the Company recognized royalty revenue of approximately \$3,846,000 and \$3,081,000 for the three months ended March 31, 2013 and 2012, 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, 2013 and 2012 was approximately \$577,000 and \$462,000, respectively. This operating expense has been included in the Company's Statements of Operations under the line item Cost of royalty revenue.

Pfizer License Agreement

In December 2012, the Company entered into an exclusive worldwide licensing agreement (the License Agreement) with Pfizer Inc. (Pfizer) to advance the SMA program, which is led by RG3039 and also includes backup compounds and enabling technologies. Under the terms of the License Agreement, the Company received \$5 million from Pfizer as an upfront payment on January 22, 2013 and is entitled to receive up to \$65 million in potential future milestone payments, a portion of which may be owed to third parties. These potential payments are approximately equally divided between milestones related to clinical development and initial commercial sales in specific geographies. In addition, the Company is entitled to receive royalties on any future sales of RG3039 or any SMA compounds developed under the License Agreement. The royalty rates are tiered and begin in the high single-digits for RG3039 or lesser amounts for any backup compounds developed under the License Agreement. Repligen's receipt of these royalties is subject to an obligation under an existing in-license agreement and other customary offsets and deductions. There are no refund provisions in this agreement. The Company recognized \$4,876,000 of revenue related to the value of the license in the year ended December 31, 2012. The Company recognized \$55,000 of revenue in the three months ended March 31, 2013 and expects to recognize the remaining \$69,000 of revenue from the upfront payment under the License Agreement in the fiscal quarter ending June 30, 2013 as the Company performs clinical and transition services under the agreement.

Research and Development Agreements

For the three months ended March 31, 2013 and 2012, the Company recognized approximately \$621,000 and \$401,000 of revenue, respectively, from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute and Go Friedrich's Ataxia Research (GoFar).

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.

4. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss) by component:

(In thousands)	Unrealized gain (loss) on investments	Foreign currency translation gain (loss)	Total
Balance at December 31, 2012	\$ 14,130	\$ 1,897,840	\$ 1,911,970
Other comprehensive income (loss) before reclassifications	(1,983)	(256,608)	(258,591)

Edgar Filing: REPLIGEN CORP - Form 10-Q

Amounts reclassified from accumulated other
comprehensive income (loss)

Net current period other comprehensive income (loss)	(1,983)	(256,608)	(258,591)
Balance at March 31, 2013	\$ 12,147	\$ 1,641,232	\$ 1,653,379

Table of Contents**5. Earnings Per Share**

The Company reports earnings 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 per share is computed by dividing net income 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 and warrants 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 considered in the calculation of basic and diluted earnings per share.

Basic and diluted weighted average shares outstanding were as follows:

	Three Months Ended March 31,	
	2013	2012
Weighted average common shares	31,240,606	30,729,660
Dilutive common stock options	614,822	280,173
Weighted average common shares, assuming dilution	31,855,428	31,009,833

At March 31, 2013, there were outstanding options to purchase 2,231,590 shares of the Company's common stock at a weighted average exercise price of \$4.40 per share. For the three-month period ended March 31, 2013, 516,500 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At 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.

6. Stock-Based Compensation

For the three months ended March 31, 2013 and 2012, the Company recorded stock-based compensation expense of approximately \$250,000 and \$241,000, 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 following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Three Months Ended March 31,	
	2013	2012
Cost of product revenue	\$ 12,000	\$ 10,000
Research and development	8,000	52,000
Selling, general and administrative	230,000	179,000
Total	\$ 250,000	\$ 241,000

Edgar Filing: REPLIGEN CORP - Form 10-Q

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 March 31, 2013, options to purchase 2,231,590 shares were outstanding under the Plans. At March 31, 2013, 1,253,120 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

Table of Contents

as expense over the employee's requisite service period on a straight-line basis. 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 three months ended March 31, 2013 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, 2013	2,315,090	\$ 4.20		
Granted	325,000	6.23		
Exercised	(310,300)	4.86		
Forfeited/Cancelled	(98,200)	4.32		
Options outstanding at March 31, 2013	2,231,590	\$ 4.40	6.70	\$ 5,618,691
Options exercisable at March 31, 2013	1,223,100	\$ 4.28	5.01	\$ 3,241,959
Vested and expected to vest at March 31, 2013 (1)	2,121,159	\$ 4.37	6.63	\$ 5,417,308

- (1) This represents the number of vested options as of March 31, 2013 plus the number of unvested options expected to vest as of March 31, 2013 based on the unvested outstanding options at March 31, 2013 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, 2013 of \$6.91 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, 2013.

The weighted average grant date fair value of options granted during the three months ended March 31, 2013 and 2012 was \$3.26 and \$2.30, respectively. The total fair value of stock options that vested during the three months ended March 31, 2013 and 2012 was approximately \$232,617 and \$256,000, respectively.

As of March 31, 2013, there was \$2,144,889 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 3.29 years. The Company expects 898,059 unvested options to vest over the next five years.

7. Cash, Cash Equivalents and Marketable Securities

At March 31, 2013 and December 31, 2012, the Company's investments included money market funds as well as short-term and long-term marketable securities. These marketable securities are classified as available-for-sale. 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, 2013 is approximately 9.21 months.

Management reviewed the Company's investments as of March 31, 2013 and December 31, 2012 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.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Investments in debt securities consisted of the following at March 31, 2013:

	Amortized Cost	March 31, 2013		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
Marketable securities:				
U.S. Government and agency securities	\$ 2,084,913	\$ 208	\$	\$ 2,085,121
Corporate and other debt securities	17,242,580	11,159	(1,736)	17,252,003
	19,327,493	11,367	(1,736)	19,337,124

Table of Contents

	Amortized Cost	March 31, 2013		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
Long-term marketable securities:				
U.S. Government and agency securities	5,324,930	2,457	(209)	5,327,178
Corporate and other debt securities	820,643	306	(38)	820,911
	6,145,573	2,763	(247)	6,148,089
Total	\$ 25,473,066	\$ 14,130	\$ (1,983)	\$ 25,485,213

At March 31, 2013, the Company's investments included twelve debt securities in unrealized loss positions with a total unrealized loss of approximately \$2,000 and a total fair market value of approximately \$9,305,000. 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, 2013 or the year ended December 31, 2012.

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

	Amortized Cost	December 31, 2012		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
Marketable securities:				
U.S. Government and agency securities	\$ 2,000,897	\$ 353	\$ (7)	\$ 2,001,243
Corporate and other debt securities	8,835,098	8,854		8,843,952
	10,835,995	9,207	(7)	10,845,195
Long-term marketable securities:				
U.S. Government and agency securities	5,198,264	2,747		5,201,011
Corporate and other debt securities	4,711,679	3,525	(1,360)	4,713,844
	9,909,943	6,272	(1,360)	9,914,855
Total	\$ 20,745,938	\$ 15,479	\$ (1,367)	\$ 20,760,050

The contractual maturities of debt securities at March 31, 2013 were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 19,327,493	\$ 19,337,124
Due in 1 to 2 years	6,145,573	6,148,089
	\$ 25,473,066	\$ 25,485,213

8. 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

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

Table of Contents

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, 2013.

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, 2013:

	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	\$ 3,112,314	\$	\$	\$ 3,112,314
U.S. Government and agency securities	2,085,121	5,327,178		7,412,299
Corporate and other debt securities		18,072,914		18,072,914
Total	\$ 5,197,435	\$ 23,400,092	\$	\$ 28,597,527

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. Changes in the fair value of contingent consideration in the three-month period ended March 31, 2013 are primarily attributable to a 1,000,000 Euro milestone payment made to Novozymes Denmark in March 2013 and a \$55,000 minimum royalty payment made to BioFlash, which were previously accrued. The following table provides a roll forward of the fair value of the contingent consideration:

Balance at December 31, 2012	\$ 2,899,076
Additions	
Payments	(1,332,005)
Changes in fair value	(53,974)
Balance at March 31, 2013	\$ 1,513,097

There were no remeasurements to fair value during the three months ended March 31, 2013 of financial assets and liabilities that are not measured at fair value on a recurring basis.

9. 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 12 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. Reserves for excess and obsolete inventory were \$154,000 at both March 31, 2013 and December 31, 2012.

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 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, 2013	December 31, 2012
Raw materials	\$ 4,661,940	\$ 4,064,317
Work-in-process	2,635,479	4,112,478
Finished products	2,966,813	2,966,900
Total	\$ 10,264,232	\$ 11,143,695

10. 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. For example, the Company would accrue for 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, 2013	December 31, 2012
Employee compensation	\$ 2,559,183	\$ 3,634,839
Royalty and license fees	968,716	1,459,680
Contingent consideration	1,092,821	1,376,877
Unearned revenue	550,498	599,120
Professional fees	332,792	418,800
VAT liabilities	186,180	98,162
Research and development	32,585	18,300
Other accrued expenses	1,271,030	692,212
Total	6,993,805	8,297,990

11. Income Taxes

Edgar Filing: REPLIGEN CORP - Form 10-Q

For the three months ended March 31, 2013, the Company had income before taxes of approximately \$3,622,000 and recorded a tax provision of \$1,284,000 for an effective tax rate of approximately 35.45%. This is based on an expected effective tax rate of 28.21% for the year ending December 31, 2013 plus approximately \$298,000 of discrete items recognized in the quarter ended March 31, 2013. 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. Effective January 1, 2013, Sweden's statutory tax rate decreased from 26.3% to 22.0%. The effective tax rate differs from the statutory tax rates primarily due to the utilization of prior year net operating loss carryforwards and credits.

The Company has net operating loss carryforwards of approximately \$44,678,000 and business tax credits carryforwards of approximately \$2,160,000 available to reduce future federal income taxes, if any. The net operating loss and business tax credit carryforwards will continue to expire at various dates through December 2032. The net operating loss and business tax credits carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

Table of Contents

In the fourth quarter of 2012, we entered into a cumulative pre-tax income position and concluded that it was more likely than not that we will generate sufficient taxable income in 2013 based on our 2013 projections to realize the tax benefit of a portion of our deferred tax assets. As a result, we recorded a tax benefit in the fourth quarter of 2012 that included the reversal of \$3,021,000 of the valuation allowance on our deferred tax assets. We reversed an additional \$767,000 of the valuation allowance on our deferred tax assets in the quarter ended March 31, 2013.

12. Segment Reporting

The Company views its operations, makes decisions regarding how to allocate resources and manages its 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,	
	2013	2012
United States	47%	36%
Sweden	39%	43%
United Kingdom	12%	14%
Other	2%	7%
	100%	100%

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

	Three months ended March 31,	
	2013	2012
Orencia® Royalties from Bristol	24%	24%
Bioprocessing Customer A	38%	43%
Bioprocessing Customer B	12%	14%
Bioprocessing Customer C	15%	

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

	March 31, 2013	December 31, 2012
Orencia® Royalties from Bristol	36%	31%
Bioprocessing Customer A	36%	21%
Pfizer		38%

13. New Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to

Edgar Filing: REPLIGEN CORP - Form 10-Q

be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. This ASU is effective for reporting periods beginning after December 15, 2012. We adopted this standard in the first quarter of 2013 and presented this information in Note 4, Accumulated Other Comprehensive Income (Loss) to these condensed consolidated financial statements. The adoption of this standard did not have an impact on our financial position or results of operations.

Table of Contents**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 high-value, consumable bioprocessing products for life sciences companies and biopharmaceutical manufacturing companies worldwide. We are a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in biomanufacturing to separate and purify 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 use in clinical-scale manufacturing. These pre-packed, plug-and-play columns are uniquely flexible and customizable to our customers' media and size requirements. We generally manufacture and sell Protein A and growth factors to life sciences companies under long-term supply agreements and sell our chromatography columns, as well as media and quality test kits, directly to biopharmaceutical companies or contract manufacturing organizations. We refer to these activities as our bioprocessing business.

On December, 20, 2011, we significantly increased the size of our bioprocessing business through a strategic acquisition. We acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB (Novozymes) in Lund, Sweden, 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) and the acquisition of the Novozymes Biopharma Business, the Novozymes Acquisition) for a total upfront cash payment of 20.65 million Euros (~\$26.9 million). As a result of the Novozymes Acquisition, we nearly doubled the size of our bioprocessing business.

Historically, Repligen also conducted activities aimed at developing proprietary therapeutic drug candidates, often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. In addition, we have out-licensed certain intellectual property to Bristol-Myers Squibb Company, or Bristol, from which we receive royalties on Bristol's net sales in the United States of their product Orenicia®. As part of our strategic decision in 2012 to focus our efforts on our core bioprocessing business, we scaled back our efforts on our clinical development programs and increased our efforts to find collaboration partners to pursue the development and, if successful, the commercialization of these drug programs. The current status of our development portfolio is:

On December 28, 2012, we out-licensed our SMA program, led by RG3039, to Pfizer Inc., or Pfizer. Pursuant to the license agreement, Pfizer will assume the majority of the costs associated with completing the required clinical trials for this program as well as obtaining U.S. Food and Drug Administration (FDA) approval of the respective new drug application (NDA). Under the license agreement, we are obligated to conduct additional activities in support of this program, which includes completing the second cohort of the current Phase I trial for RG3039 and supporting the transition of the program to Pfizer. We completed this second cohort during the quarter ended March 31, 2013 and expect to complete these transition activities in the first half of 2013.

The most advanced product candidate in our development portfolio is RG1068, a synthetic human hormone being developed as a novel imaging agent for the improved detection of pancreatic duct abnormalities in combination with magnetic resonance imaging in patients with pancreatitis and potentially other pancreatic diseases. We submitted an NDA to the FDA and a marketing authorization application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2012. In the second quarter of 2012, we received a complete response letter from the FDA, indicating the need for additional clinical efficacy and safety trial data. We are currently working with the FDA on the details of an additional registration study. We believe providing certainty as to the requirements of this additional registration study may be an important factor in the decision by third-parties that may wish to pursue a development or commercialization agreement with us for RG1068. We expect that any additional development activities that we may pursue in the future will be largely supported by sponsors or collaborators.

Our third clinical development program was targeted at Friedrich's Ataxia and led by RG2833, a class I histone deacetylase (HDAC) inhibitor. RG2833 has received Orphan Drug designation from the FDA and European Commission. We initiated a single, ascending dose Phase I study of RG2833 in Friedrich's Ataxia patients in Italy in the fourth quarter of 2012 and completed the patient dosing in the quarter ended March 31, 2013. We believe the results of this trial, which we are currently analyzing, may be an important consideration for any third-party that may wish to pursue a development or commercialization agreement with us for RG2833. We expect that any additional development activities that we may pursue in the future will be largely supported by sponsors or collaborators.

On April 7, 2008, we entered into a settlement agreement with Bristol in connection with a patent infringement lawsuit we filed against Bristol. Under the terms of the agreement, Bristol is obligated to pay us royalties on its U.S. net sales of

Table of Contents

Orencia® for any clinical indication at a rate of 1.8% for the first \$500,000,000 of annual sales, 2.0% for the next \$500,000,000 of annual sales and 4% of annual sales in excess of \$1 billion. Under the terms of the agreement, we will not receive any future royalties on Bristol's sales of Orencia made after December 31, 2013.

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 Annual Report on Form 10-K for the year ended December 31, 2012. There have been no changes to our critical accounting policies since December 31, 2012.

Results of Operations

Three months ended March 31, 2013 vs. March 31, 2012

Revenues

Total revenues for the three-month periods ended March 31, 2013 and 2012 were comprised of the following:

	Three months ended March 31,		% Change
	2013	2012	2013 vs. 2012
	(in thousands, except percentages)		
Bioprocessing product revenue	\$ 11,934	\$ 9,343	28%
Royalty and other revenue	4,522	3,482	30%
Total revenue	\$ 16,456	\$ 12,824	28%

Sales of bioprocessing products for the three months ended March 31, 2013 and 2012 were \$11,934,000 and \$9,343,000, respectively, an increase of \$2,591,000, or 28%. This increase was primarily due to increases in orders from our key bioprocessing customers. Sales of our bioprocessing products can be impacted by the timing of orders, development efforts at our customers or end-users and regulatory approvals for biologics that incorporate our products, 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 settlement with Bristol, we recognized royalty revenue of \$3,846,000 and \$3,081,000 for the three months ended March 31, 2013 and 2012, respectively. We expect to receive these royalty payments for Bristol's sales through December 31, 2013.

For the three months ended March 31, 2013 and 2012, we recognized \$621,000 and \$401,000, respectively, of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute and Go Friedrich's Ataxia Research (GoFar).

We recognized \$55,000 of revenue from the upfront payment under the Pfizer License Agreement in the three months ended March 31, 2013.

Costs and operating expenses

Total costs and operating expenses for the three-month periods ended March 31, 2013 and 2012 were comprised of the following:

	Three months ended March 31,		% Change
	2013	2012	2013 vs. 2012

Edgar Filing: REPLIGEN CORP - Form 10-Q

	(in thousands, except percentages)		
Cost of product revenue	\$ 6,897	\$ 5,273	31%
Cost of royalty revenue	577	462	25%
Research and development	2,183	2,808	22%
Selling, general and administrative	3,308	3,429	4%
Contingent consideration fair value adjustments	(54)		-100%
Gain on bargain purchase		(314)	100%
Total costs and operating expenses	\$ 12,911	\$ 11,658	11%

Table of Contents

Cost of product revenue was approximately \$6,897,000 and \$5,273,000 for the three-month periods ended March 31, 2013 and 2012, respectively, an increase of \$1,624,000 or 31%. This increase is primarily due to the increase in bioprocessing product sales noted above, the sale of higher cost bioprocessing material manufactured in 2012 at our facility in Sweden, the mix of products sold, normal variations in manufacturing yield and other individually insignificant manufacturing variances. We anticipate that, among other factors, the efficiencies we have implemented at our Swedish manufacturing facility will lead to an overall improvement in our gross margin for the remainder of 2013.

Pursuant to the settlement with Bristol, 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, 2013 and 2012, the cost of royalty revenue was approximately \$577,000 and \$462,000, respectively. This increase is directly related to the increase in Bristol royalty revenues noted above.

Research and development expenses were approximately \$2,183,000 and \$2,808,000 for the three-month periods ended March 31, 2013 and 2012, respectively, a decrease of \$625,000 or 22%. This decrease is primarily attributable to a \$658,000 reduction in costs related to RG1068 which was undergoing an FDA review during the first quarter of last year, a \$563,000 decrease related to our Friedreich's ataxia program as we incurred higher costs in the prior period from clinical trial and related costs, and a \$110,000 increase in costs related to RG3039 due an ongoing clinical trial and expenses related to transitioning the program to Pfizer, partially offset by an increase of \$112,000 related to bioprocessing R&D.

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. In August 2012, we announced a strategic focus on our Bioprocessing business and a simultaneous effort to find partners, out-licensing opportunities or other funding arrangements with external parties to reduce or eliminate the net expenditures on research and development activities for our therapeutic programs. For each of the remaining quarters in 2013, we expect total research and development expenses to be lower than the quarter ended March 31, 2013. We expect that any research and development activities that we undertake in the future with respect to our therapeutic drug candidates will be limited to those which could support the transition of development and commercialization activities for these programs to potential collaborators. We intend to focus the majority of our future research and development efforts on developing new bioprocessing products.

Selling, general and administrative expenses were approximately \$3,308,000 and \$3,429,000 for the three-month periods ended March 31, 2013 and 2012, respectively, a decrease of \$121,000, or 4%. This decrease is primarily attributable to a \$372,000 decrease in external audit and legal fees and a \$182,000 reduction in sales and marketing expenses for Secretin, a product which we are no longer actively commercializing. These reductions were partially offset by an increase in \$377,000 in compensation and consulting costs related to our bioprocessing business. For each of the remaining quarters in 2013, we expect selling, general and administrative expenses to be moderately lower than the quarter ended March 31, 2013.

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 \$62,000 and \$31,000 for the three-month periods ended March 31, 2013 and 2012, respectively. This increase of \$31,000, or 100%, is primarily attributable to slightly higher interest rates.

Provision for income taxes

For the three months ended March 31, 2013, we had income before taxes of approximately \$3,622,000 and a tax provision of \$1,284,000 for an effective tax rate of approximately 35.45%. This is based on an expected effective tax rate of 28.21% for the year ending December 31, 2013 plus approximately \$298,000 of discrete items recognized in the quarter ended March 31, 2013. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different tax jurisdictions. Effective January 1, 2013, Sweden's statutory tax rate decreased from 26.3% to 22.0%. The effective tax rate differs from the statutory tax rate primarily due to the utilization of prior year net operating loss carryforwards and credits.

Table of Contents

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 license arrangements and a litigation settlement. 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. Our revenue for the foreseeable future will be limited to our bioprocessing product revenue, royalties from Bristol's sales of Orencia through December 31, 2013, and research and development grants. We will not receive royalty payments for Bristol's sales of Orencia after December 31, 2013 and, as a result, we may need to use our existing capital resources to fund a portion of our operating activities.

At March 31, 2013, we had cash and marketable securities of \$54,055,000 compared to \$49,970,000 at December 31, 2012. A deposit for leased office space of \$200,000 is classified as restricted cash and is not included in cash and marketable securities totals for March 31, 2013 or December 31, 2012.

Operating activities

For the three-month period ended March 31, 2013, our operating activities provided cash of \$3,595,000 reflecting net income of \$2,338,000 and non-cash charges totaling \$957,000 including depreciation, amortization, stock-based compensation charges and deferred tax expense. The remaining cash flow used in operations resulted from favorable changes in various working capital accounts.

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.

Investing activities

We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines. Our investing activities consumed \$5,049,000 for the three-month period ended March 31, 2013, primarily due to net purchases of marketable debt securities and \$322,000 used for fixed asset additions. For the three-month period ended March 31, 2012, our investing activities consumed \$386,000, primarily due to net purchases of marketable debt securities and \$157,000 used for fixed asset additions.

Financing activities

Exercises of stock options provided cash receipts of \$957,000 and \$114,000 in the three-month periods ended March 31, 2013 and 2012, respectively.

We do not currently use derivative financial instruments.

Working capital increased by approximately \$6,347,000 to \$61,804,000 at March 31, 2013 from \$55,457,000 at December 31, 2012 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 continue the integration of the Novozymes Biopharma Business and recognize expected synergies;

our ability to establish one or more partnerships for development and commercialization of RG1068 or RG2833;

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

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 operating expenses in the year ending December 31, 2013 to decrease as we invest less in therapeutic drug development and simultaneously improve gross margins through greater optimization

Table of Contents

of our two production facilities and other process improvements we have developed internally. 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, expansion of our Waltham facility and other purchases of property, plant and equipment, the acquisition of additional bioprocessing products and technologies to complement our existing manufacturing capabilities, 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 do not have any special purpose entities or off-balance sheet financing arrangements as of March 31, 2013.

Contractual obligations

As of March 31, 2013, 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	\$ 15,583	\$ 2,219	\$ 4,438	\$ 3,590	\$ 5,336
Purchase obligations (1)	4,406	4,406			
Contingent consideration (2)	1,513	1,088	197	228	
Total	\$ 21,502	\$ 7,713	\$ 4,635	\$ 3,818	\$ 5,336

- (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, express or implied statements regarding current or future financial performance and position, our strategic decision to focus on the growth of our bioprocessing business, 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 or supply relationships, including our agreement with Pfizer, 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, including as a result of acquisition, commercialization or partnership opportunities, the success of our clinical

Edgar Filing: REPLIGEN CORP - Form 10-Q

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,

Table of Contents

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 successfully integrate Repligen Sweden, including achieving manufacturing efficiencies at 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 Annual Report on Form 10-K for the year ended December 31, 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 \$196,000 decrease in the fair value of our investments as of March 31, 2013. 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. We currently do not seek to hedge this exposure to fluctuations in exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

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

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

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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 Annual Report on Form 10-K for the year ended December 31, 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-month period ended March 31, 2013. As of March 31, 2013, 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).
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).
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, 2013, 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 7, 2013

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

Date: May 7, 2013

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).
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).
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, 2013, 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.