REPLIGEN CORP Form 10-Q November 08, 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 September 30, 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)

Delaware (State or other jurisdiction of

04-2729386 (I.R.S. Employer

incorporation or organization)

Identification No.)

41 Seyon Street, Bldg. 1, Suite 100

Waltham, MA (Address of principal executive offices)

02453 (Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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

X

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 x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of October 23, 2013.

Class Common Stock, par value \$.01 per share **Number of Shares** 31,908,441

Table of Contents

		PAGE
PART I	FINANCIAL INFORMATION	
Item 1.	Unaudited Condensed Consolidated Financial Statements	
	Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012	3
	Condensed Consolidated Statements of Comprehensive Income for the Three and Nine-Month Periods Ended September 30, 2013 and 2012	4
	Condensed Consolidated Statements of Cash Flows for the Nine-Month Periods Ended September 30, 2013 and 2012	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	22
Item 4.	Controls and Procedures	22
PART II.	OTHER INFORMATION	23
Item 1.	Legal Proceedings	23
Item 1A.	Risk Factors	23
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3.	Defaults Upon Senior Securities	23
Item 4.	Mine Safety Disclosures	23
Item 5.	Other Information	23
Item 6.	<u>Exhibits</u>	24
<u>Signatures</u>		25
Evhibit Ind	dev	26

REPLIGEN CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	S	eptember 30, 2013	D	ecember 31, 2012
Assets				
Current assets:				
Cash and cash equivalents	\$	42,244,420	\$	29,209,821
Marketable securities		20,746,490		10,845,195
Accounts receivable, less reserve for doubtful accounts of \$10,000		6,323,537		4,158,758
Royalties and other receivables		6,595,017		9,130,515
Inventories, net		10,063,695		11,143,695
Deferred tax asset, net		416,580		416,580
Prepaid expenses and other current assets		1,051,379		1,304,887
Total current assets		87,441,118		66,209,451
Property, plant and equipment, at cost:				
Leasehold improvements		5,258,050		5,200,271
Equipment		13,485,039		12,802,978
Furniture and fixtures		2,035,224		1,937,238
Construction in progress		3,383,870		338,814
Total property, plant and equipment, at cost		24,162,183		20,279,301
Less: Accumulated depreciation		(11,871,114)		(10,326,840)
Property, plant and equipment, net		12,291,069		9,952,461
Long-term deferred tax asset, net		114,788		2,557,384
Long-term marketable securities		4,114,450		9,914,855
Intangible assets, net		6,481,532		7,182,012
Goodwill		994,000		994,000
Restricted cash		200,000		200,000
Total assets	\$	111,636,957	\$	97,010,163
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	\$	929,586	\$	2,454,238
Accrued liabilities		7,854,729		8,297,990
Total current liabilities		8,784,315		10,752,228
Other long-term liabilities		2,695,521		2,133,339
Commitments and contingencies		, ,		

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Stockholders equity:

318,830	311,950
190,048,182	187,051,253
2,174,989	1,911,970
(92,384,880)	(105,150,577)
100,157,121	84,124,596
\$ 111,636,957	\$ 97,010,163
	190,048,182 2,174,989 (92,384,880) 100,157,121

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

REPLIGEN CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

	Three months ended September 30, 2013 2012		Nine mon Septem 2013	
Revenue:	2010	2012	2010	2012
Product revenue	\$ 12,184,215	\$11,123,236	\$ 37,132,094	\$ 32,125,076
Royalty and other revenue	6,637,838	3,981,059	15,654,919	11,327,500
.,	-,,	- , ,	- , ,	, ,
Total revenue	18,822,053	15,104,295	52,787,013	43,452,576
Operating expenses:		, ,	, ,	
Cost of product revenue	5,659,832	6,418,962	17,854,249	19,036,762
Cost of royalty revenue	723,777	594,406	1,943,370	1,593,427
Research and development	1,429,529	2,433,043	5,919,265	8,147,164
Selling, general and administrative	2,902,048	3,126,244	9,334,087	9,973,013
Contingent consideration fair value adjustments	65,108	343,932	46,521	343,932
Gain on bargain purchase				(314,244)
Total operating expenses	10,780,294	12,916,587	35,097,492	38,780,054
Income from operations	8,041,759	2,187,708	17,689,521	4,672,522
Investment income	76,046	95,807	203,170	156,747
Interest (expense) income	(11,704)	7,205	(37,637)	(42,536)
Other (expense) income	36,678	(500,414)	(56,504)	67,145
Income before income taxes	8,142,779	1,790,306	17,798,550	4,853,878
Income tax provision (benefit)	2,254,505	(16,183)	5,032,853	250,954
Net income	\$ 5,888,274	\$ 1,806,489	\$12,765,697	\$ 4,602,924
Earnings per share:				
Basic	\$ 0.18	\$ 0.06	\$ 0.40	\$ 0.15
Diluted	\$ 0.18	\$ 0.06	\$ 0.40	\$ 0.15
Weighted average shares outstanding: Basic	31,858,103	30,948,062	31,583,063	30,841,344
Diluted	32,551,586	31,256,273	32,282,702	31,131,749

Other comprehensive income:

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Unrealized gain (loss) on investments	2,276	2,006	(4,345)	3,975
Foreign currency translation gain (loss)	1,407,860	2,105,074	267,364	1,461,801
Comprehensive income	\$ 7,298,410	\$ 3,913,569	\$ 13,028,716	\$ 6,068,700

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

REPLIGEN CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 12,765,697	\$ 4,602,924
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,271,181	2,592,824
Stock-based compensation expense	768,534	743,947
Deferred tax expense	2,442,596	
Gain on bargain purchase		(314,244)
Loss on revaluation of contingent consideration	46,521	339,433
Changes in assets and liabilities:		
Accounts receivable	(2,118,953)	(4,672,351)
Royalties and other receivables	2,535,498	(755,864)
Inventories	1,149,997	3,036,051
Prepaid expenses and other current assets	264,690	247,093
Accounts payable	(1,529,213)	309,710
Accrued liabilities	(495,056)	1,087,295
Long-term liabilities	490,267	(1,006,654)
Net cash provided by operating activities	18,591,759	6,210,164
Cash flows from investing activities:		
Purchases of marketable securities	(23,998,430)	(36,337,643)
Redemptions of marketable securities	19,893,195	36,863,333
Purchases of property, plant and equipment	(3,774,847)	(825,061)
Net cash used in investing activities	(7,880,082)	(299,371)
Cash flows from financing activities:		
Exercise of stock options	2,235,274	886,704
Net cash provided by financing activities	2,235,274	886,704
Effect of exchange rate changes on cash and cash equivalents	87,648	424,735
Net increase in cash and cash equivalents	13,034,599	7,222,232
Cash and cash equivalents, beginning of period	29,209,821	11,167,745

Cash and cash equivalents, end of period

\$ 42,244,420

\$ 18,389,977

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

5

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. Goodwill and Intangible Assets

Goodwill

Goodwill is not amortized and is reviewed for impairment at least annually. There was no evidence of impairment to goodwill at September 30, 2013. There were no goodwill impairment charges during the three or nine-month periods ended September 30, 2013.

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 Company s statements of comprehensive income (loss). 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 September 30, 2013.

Intangible assets consisted of the following at September 30, 2013:

	Gross Carrying Amount	Accumulated Amortization	Weighted Average Useful Life (in years)
Technology developed	\$ 1,460,204	\$ (494,465)	8
Patents	240,000	(110,000)	8
Customer relationships	6,941,895	(1,556,102)	8
Total intangible assets	\$ 8,642,099	\$ (2,160,567)	8

Intangible assets consisted of the following at December 31, 2012:

			Weighted Average
	Gross		Useful Life
	Carrying Amount	Accumulated Amortization	(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 intangible assets	\$8,565,112	\$ (1,383,100)	8

6

Amortization expense for amortized intangible assets was approximately \$777,000 for the nine months ended September 30, 2013. The Company expects to record amortization expense of approximately \$1,000,000 in each of the next five years related to these intangible assets.

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 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.

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 \$4,825,000 and \$3,963,000 for the three months ended September 30, 2013 and 2012, respectively. For the nine months ended September 30, 2013 and 2012, the Company recognized Bristol royalty revenue of approximately \$12,956,000 and \$10,623,000, respectively. Revenue earned from Bristol royalties is recorded in the periods when it is earned based on royalty reports sent by Bristol to the Company. The Company has no continuing obligations to Bristol as a result of this settlement. The royalty agreement with Bristol provides that the Company will receive such royalty payments on sales of Orencia® by Bristol through December 31, 2013.

Pursuant to the Bristol Settlement, Repligen must remit to the University of Michigan 15% of all royalty revenue received from Bristol. Royalty expense for the three months ended September 30, 2013 and 2012 was approximately \$724,000 and \$594,000, respectively. For the nine months ended September 30, 2013 and 2012, the Company incurred royalty expense of approximately \$1,943,000 and \$1,593,000, respectively. This operating expense has been included in the Company s statements of comprehensive income 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 spinal muscular atrophy program, or SMA program, which is led by RG3039, a small molecule drug candidate in clinical development for SMA, 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 a \$1 million milestone payment on September 4, 2013. The Company is eligible to receive up to \$64 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 eligible 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. For the three and nine-month periods ended September 30, 2013, the Company recognized \$1,093,000 and \$1,217,000 of revenue, respectively, under the License Agreement, including a \$1,000,000 milestone payment that was triggered by successful completion of specific clinical development activities as well as other fees associated with the transition.

Research and Development Agreements

For the three months ended September 30, 2013 and 2012, the Company recognized approximately \$719,000 and \$18,000 of revenue, respectively, from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, Go Friedreich s Ataxia Research and the European Friedrich s Ataxia Consortium for Translational Studies. For the nine months ended September 30, 2013 and 2012, the Company recognized approximately \$1,481,000 and \$704,000 of revenue, respectively, from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, Go Friedreich s Ataxia Research, and the European Friedrich s Ataxia Consortium for Translational Studies.

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

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

	Unrealized gain Foreign currency					
(In thousands)	(loss) on	investm enta sl	ation gain (los	s) Total		
Balance at December 31, 2012	\$	14,130 \$	1,897,840	\$1,911,970		
Other comprehensive income (loss) before						
reclassifications		(4,345)	267,364	263,019		
Amounts reclassified from accumulated othe	r					
comprehensive income (loss)						
Net current period other comprehensive inco (loss)	me	(4,345)	267,364	263,019		
Balance at September 30, 2013	\$	9,785 \$	2,165,204	\$ 2,174,989		

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. Performance based option awards have been excluded from this calculation as they would not be issuable as of September 30, 2013 if that were the end of the contingency period.

Basic and diluted weighted average shares outstanding were as follows:

	Three months ended September 30,		Nine mon Septem	
	2013	2012	2013	2012
Weighted average common shares	31,858,103	30,948,062	31,583,063	30,841,344
Dilutive common stock options	693,483	308,211	699,639	290,405
Weighted average common shares, assuming				
dilution	32,551,586	31,256,273	32,282,702	31,131,749

At September 30, 2013, there were outstanding options to purchase 1,670,688 shares of the Company s common stock at a weighted average exercise price of \$4.87 per share. For the three and nine-month periods ended September 30, 2013, 161,000 and 469,500

8

shares of the Company s common stock, respectively, were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At September 30, 2012, there were outstanding options to purchase 2,625,690 shares of the Company s common stock at a weighted average exercise price of \$4.11 per share. For the three and nine-month periods ended September 30, 2012, 1,431,600 and 1,602,000 options to purchase shares of the Company s common stock, respectively, were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

6. Stock-Based Compensation

For the three months ended September 30, 2013 and 2012, the Company recorded stock-based compensation expense of \$205,772 and \$288,279, respectively, for share-based awards granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan) and the Repligen Corporation 2012 Stock Option and Incentive Plan (the 2012 Plan, and collectively with the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan, the Plans). The Company recorded stock-based compensation expense of \$768,535 and \$743,948 for the nine-month periods ended September 30, 2013 and 2012, respectively, for share-based awards granted under the Plans.

The following table presents stock-based compensation expense included in the Company s consolidated statements of comprehensive income:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Cost of product revenue	\$ 24,059	\$ 10,646	\$ 47,151	\$ 33,420
Research and development	30,092	53,094	73,814	169,919
Selling, general and administrative	151,621	224,539	647,569	540,609
Total	\$ 205,772	\$ 288,279	\$768,534	\$743,948

The 2012 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock and other equity awards. Incentive options granted to employees under the Plans generally vest over a four to five-year period, with 20%-25% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company s common stock on the date of grant. At September 30, 2013, options to purchase 1,670,688 shares were outstanding under the Plans. At September 30, 2013, 1,155,216 shares were available for future grant under the Plans.

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 awards with service based vesting as expense over the employee s requisite service period on a straight-line basis. The Company records the expense for share-based awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone

is probable. Management evaluates whether the achievement of a performance-based milestone is probable as of the reporting date. The Company has no awards that are subject to market conditions. The Company recognizes stock-based compensation expense for options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted for estimated forfeitures.

Information regarding option activity for the nine months ended September 30, 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	541,052	6.97		
Exercised	(884,954)	4.36		
Forfeited/Cancelled	(300,500)	5.03		
Options outstanding at September 30, 2013	1,670,688	\$ 4.87	6.91	\$10,394,325
Options exercisable at September 30, 2013	866,136	\$ 4.19	5.16	\$ 5,972,968
Vested and expected to vest at September 30, 2013 (1)	1,576,516	\$ 4.77	6.82	\$ 9,970,772

(1) This represents the number of vested options as of September 30, 2013 plus the number of unvested options expected to vest as of September 30, 2013 based on the unvested outstanding options at September 30, 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 September 30, 2013 of \$11.09 and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on September 30, 2013.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2013 and 2012 was \$4.19 and \$3.63, respectively. The total fair value of stock options that vested during the nine months ended September 30, 2013 and 2012 was \$934,280 and \$756,444, respectively.

As of September 30, 2013, there was \$2,119,182 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 3.22 years. The Company expects 710,380 unvested options to vest over the next five years.

7. Cash, Cash Equivalents and Marketable Securities

At September 30, 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 September 30, 2013 is approximately 7.47 months.

Management reviewed the Company s investments as of September 30, 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.

Investments in debt securities consisted of the following at September 30, 2013:

	September 30, 2013				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	
Marketable securities:					
U.S. Government and agency securities	\$ 1,567,499	\$ 313	\$ (335)	\$ 1,567,477	
Corporate and other debt securities	19,171,567	9,977	(2,531)	19,179,013	
	20,739,066	10,290	(2,866)	20,746,490	
Long-term marketable securities:					
U.S. Government and agency securities	4,112,079	2,436	(65)	4,114,450	

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Corporate and other debt securities				
	4,112,079	2,436	(65)	4,114,450
Total	\$ 24,851,145	\$ 12,726	\$ (2,931)	\$ 24,860,940

At September 30, 2013, the Company s investments included nineteen debt securities in unrealized loss positions with a total unrealized loss of approximately \$3,000 and a total fair market value of approximately \$4,410,000. All investments with gross unrealized losses have been in unrealized loss positions for less than 12 months. The unrealized losses were caused primarily by current economic and market conditions. There was no change in the credit risk of the securities. There were no realized gains or losses on the investments for the nine months ended September 30, 2013 or the year ended December 31, 2012.

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

	December 31, 2012				
		Gross	Gross		
	Amortized	Unrealized	Unrealized		
	Cost	Gain	Loss	Fair Value	
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 September 30, 2013 were as follows:

	Amortized	
	Cost	Fair Value
Due in 1 year or less	\$ 20,739,066	\$ 20,746,490
Due in 1 to 2 years	4,112,079	4,114,450
	\$ 24,851,145	\$ 24,860,940

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 on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The Company s fixed income investments are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2013.

11

The following fair value hierarchy table presents information about each major category of the Company s assets measured at fair value on a recurring basis as of September 30, 2013:

	Fair value measurement at reporting date using:					
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total		
Assets:						
Money market funds	\$ 9,188,883	\$	\$	\$ 9,188,883		
U.S. Government and agency						
securities	2,547,978	3,133,949		5,681,927		
Corporate and other debt securities		19,179,013		19,179,013		
Total	\$11,736,861	\$ 22,312,962	\$	\$ 34,049,823		

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 Biopharma DK A/S, a company organized under the laws of Denmark (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 and nine-month periods ended September 30, 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 in January 2013, 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	(1,341,339)
Changes in fair value	46,521
Balance at September 30, 2013	\$ 1,604,258

There were no remeasurements to fair value during the three or nine months ended September 30, 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 \$156,000 at September 30, 2013 and \$154,000 at December 31, 2012.

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 consisted of the following:

	Se	ptember 30, 2013	De	ecember 31, 2012
Raw materials	\$	4,356,520	\$	4,064,317
Work-in-process		3,583,924		4,112,478
Finished products		2,123,251		2,966,900
Total	\$	10 063 695	\$	11 143 695

12

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:

	September 30, 2013	December 31, 2012
Employee compensation	\$ 2,680,016	\$ 3,634,839
Taxes	1,618,850	396,499
Contingent consideration	1,161,953	1,376,877
Royalty and license fees	1,153,469	1,459,680
Professional fees	394,563	418,800
Research and development	167,000	18,300
Unearned revenue	1,909	599,120
Other accrued expenses	676,969	393,875
Total	7,854,729	8,297,990

11. Income Taxes

For the three and nine-month periods ended September 30, 2013, the Company had income before taxes of \$8,142,779 and \$17,798,550, respectively. The Company recorded income tax provisions of \$2,254,505 and \$5,032,853, respectively, for the three and nine-month periods ended September 30, 2013. This is based on an expected effective tax rate of 26.6% 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 U.S. statutory tax rate primarily due to the expected utilization of prior year net operating loss carryforwards in excess of amounts previously recognized and the lower statutory tax rate in Sweden.

For the three and nine-month periods ended September 30, 2012, the Company had income before taxes of \$1,790,306 and \$4,853,878, respectively. The Company recorded an income tax benefit of \$16,183 for the three-month period

ended September 30, 2012 and a provision of \$250,954 for the nine-month period ended September 30, 2012 based on an effective tax rate of approximately 5.17%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rates primarily due to the utilization of prior year net operating loss carryforwards and credits earned in the U.S.

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.

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.

The Company is currently undergoing an audit in the Commonwealth of Massachusetts (the Commonwealth) for the tax years ended March 31, 2008 through December 31, 2011. At issue is the apportionment of certain license income to the Commonwealth, as well as the recoverability of certain research and development credits earned between 1993 and 2011. As of September 30, 2013 we do not have a reserve recorded for these matters as we believe it is more likely than not that we will prevail. On October 29, 2013, the Company met with the Commonwealth to attempt to mediate our differences of opinion. However, this did not result in successful resolution. The Company continues to believe in the validity of its tax positions on these matters. As a result, we anticipate receiving a tax assessment that we will appeal in a process that could take up to several years. Total exposure, including penalties, but not interest, were we to ultimately be unsuccessful, would be approximately \$2.5 million.

13

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 September 30,		ths ended iber 30,
	2013	2012	2013	2012
United States	56%	41%	51%	41%
Sweden	31%	49%	35%	46%
United Kingdom	9%	7%	11%	10%
Other	4%	3%	3%	3%
Total	100%	100%	100%	100%

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

		Three months ended September 30,		hs ended ber 30,
	2013	2012	2013	2012
Orencia® Royalties from Bristol	26%	26%	25%	24%
Bioprocessing Customer A	28%	49%	35%	46%
Bioprocessing Customer B	10%	8%	12%	11%
Bioprocessing Customer C	20%	12%	15%	12%

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

	September 30, 2013	December 31, 2012
Orencia® Royalties from Bristol	37%	31%
Bioprocessing Customer A	20%	21%
Bioprocessing Customer B	8%	4%
Bioprocessing Customer C	15%	5%
Tenant improvement allowance due from		
landlord	14%	
Pfizer	1%	38%

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 expanding area of flexible 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 purchase price of 20,310,000 Euros (~\$26,400,000). As a result of the Novozymes Acquisition, we doubled the size of our bioprocessing business.

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 Orencia. 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 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. We expect that the upcoming loss of these royalty payments will materially and adversely affect our revenue and operating results.

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. 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 spinal muscular atrophy program, or SMA program, led by RG3039, a small molecule drug candidate in clinical development for SMA, 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 substantially all of our remaining clinical obligations during the quarter ended June 30, 2013. As of September 30, 2013, we had completed all of our clinical obligations under the license agreement.

Our second clinical development program focused on a class I histone deacetylase (HDAC) inhibitor targeted at Friedrich s ataxia. We initiated a single, ascending dose Phase 1 study of RG2833 in Friedreich s ataxia patients in Italy in the fourth quarter of 2012 and completed the patient dosing in the quarter ended March 31, 2013. The results of the study support the use of an oral HDAC inhibitor in the treatment of Friedrich s ataxia, demonstrating a dose-dependent improvement in the expression of a disease biomarker. While RG2833 was shown to be well tolerated and no adverse events were reported, the generation of potentially toxic metabolites was observed. We believe that other compounds in our HDAC inhibitor portfolio may be more suitable than RG2833 for clinical development and, in alignment with our focus on bioprocessing, we continue to seek non-profit and biopharmaceutical development partners to support future development of this program.

Our clinical development portfolio also includes RG1068, a synthetic human hormone 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 to the European Medicines Agency 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 have also received from the FDA the requirements for an additional registration study. We believe this information

15

may be a 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 other third parties.

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 September 30, 2013 vs. September 30, 2012

Revenues

Total revenues for the three-month periods ended September 30, 2013 and 2012 were comprised of the following:

		Three months ended September 30,	
	2013	2012	2013 vs. 2012
	(in thou	ısands, except j	percentages)
Bioprocessing product revenue	\$ 12,184	\$ 11,123	10%
Royalty and other revenue	6,638	3,981	67%
Total revenue	\$ 18,822	\$ 15,104	25%

Sales of bioprocessing products for the three months ended September 30, 2013 and 2012 were \$12,184,000 and \$11,123,000, respectively, an increase of \$1,061,000, or 10%. 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 \$4,825,000 and \$3,963,000 for the three months ended September 30, 2013 and 2012, respectively. We expect to receive these royalty payments for Bristol s sales through December 31, 2013. We expect that the upcoming loss of these royalty payments will materially and adversely affect our revenue and operating results.

For the three months ended September 30, 2013 and 2012, we recognized \$719,000 and \$18,000 of revenue, respectively, from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, Go Friedreich s Ataxia Research and the European Friedrich s Ataxia Consortium for Translational Studies.

In the three months ended September 30, 2013, we recognized \$1,093,000 of revenue under the Pfizer License Agreement, including a \$1,000,000 milestone payment that was triggered by completion of specific clinical development activities as well as other fees associated with the transition. Depending on the development path chosen by Pfizer, we may receive the remaining \$1,000,000 of the first clinical milestone by the end of 2014.

Costs and operating expenses

Total costs and operating expenses for the three-month periods ended September 30, 2013 and 2012 were comprised of the following:

		Three mo	% Change			
		2013	2013 vs. 2012			
		(in thousands, except percentages)				
Cost of product revenue		\$ 5,660	\$ 6,419	-12%		
Cost of royalty revenue		724	595	22%		
Research and development		1,429	2,433	-41%		
Selling, general and administrative		2,902	3,126	-7%		
Contingent consideration fa	ir value adjustments	65	344	-81%		
Total costs and operating expenses		\$ 10,780	\$ 12,917	-17%		

Cost of product revenue was approximately \$5,660,000 and \$6,419,000 for the three-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$759,000 or 12%. This decrease is primarily due to operational efficiencies implemented during 2012 at our subsidiary, Repligen Sweden AB (Repligen Sweden), offset by higher overall costs associated with increased bioprocessing product revenue in the third quarter of 2013 as compared to the third quarter of 2012. Gross margins may decline over the remainder of the year based on expected production volume and shipments, product mix and the sale of higher cost inventory that was produced at a higher cost level in 2012.

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 September 30, 2013 and 2012, the cost of royalty revenue was approximately \$724,000 and \$595,000, respectively. This increase is directly related to the increase in Bristol royalty revenue noted above.

Research and development expenses were approximately \$1,429,000 and \$2,433,000 for the three-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$1,004,000 or 41%. This decrease is primarily attributed to a reduction in therapeutics related research and development expenses partially offset by an increase in bioprocessing research and development expense. For the three-month periods ended September 30, 2013 and 2012, approximately \$1,062,000 and \$994,000, respectively, of our total research and development expenses were incurred on bioprocessing research and development activities.

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 the remaining quarter in 2013, we expect similar levels of total research and development expenses to those incurred in the quarter ended September 30, 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 \$2,902,000 and \$3,126,000 for the three-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$224,000 or 7%. This decrease is primarily attributable to a reduction in outside professional and consulting services expenses of approximately \$372,000 offset by higher employee related expenses of approximately \$163,000. For the remaining quarter in 2013, we expect similar levels of selling, general and administrative expenses to those incurred in the quarter ended September 30, 2013.

Investment income

Investment income includes income earned on invested cash balances. Investment income was approximately \$76,000 and \$96,000 for the three-month periods ended September 30, 2013 and 2012, respectively. This decrease of \$20,000, or 21%, is primarily attributable to slightly lower average invested cash balances.

Other (expense) income

Other (expense) income was approximately \$37,000 and (\$500,000) for the three-month periods ended September 30, 2013 and 2012, respectively, and are primarily attributable to foreign currency gains (losses) related to our Sweden operations.

17

Provision (benefit) for income taxes

For the three months ended September 30, 2013, we had income before taxes of \$8,142,776 and a tax provision of \$2,254,504 based on an effective tax rate of 26.6%. 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 U.S. statutory tax rate primarily due to the expected utilization of prior year net operating loss carryforwards in excess of amounts previously benefitted and the lower statutory tax rate in Sweden.

We are currently undergoing an audit in the Commonwealth of Massachusetts, or the Commonwealth, for the tax years ended March 31, 2008 through December 31, 2011. At issue is the apportionment of certain license income to the Commonwealth, as well as the recoverability of certain research and development credits earned between 1993 and 2011. As of September 30, 2013 we do not have a reserve recorded for these matters as we believe it is more likely than not that we will prevail. On October 29, 2013, we met with the Commonwealth to attempt to mediate our differences of opinion. However, this did not result in successful resolution. We continue to believe in the validity of our tax positions on these matters. As a result, we anticipate receiving a tax assessment that we will appeal in a process that could take up to several years. Total exposure, including penalties, but not interest, were we to ultimately be unsuccessful, would be approximately \$2.5 million.

For the three months ended September 30, 2012, we had income before taxes of \$1,790,306 and a tax benefit of \$16,183 based on an effective tax rate of 5.17%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different tax jurisdictions. The effective tax rate differs from the U.S. statutory tax rate primarily due to the utilization of prior year net operating loss carryforwards and credits.

Nine months ended September 30, 2013 vs. September 30, 2012

Revenues

Total revenues for the nine-month periods ended September 30, 2013 and 2012 were comprised of the following:

	Nine mon Septem	% Change				
	2013	2012	2013 vs. 2012			
	(in thousands, except percentages)					
Bioprocessing product revenue	\$ 37,132	\$ 32,125	16%			
Royalty and other revenue	15,655	11,328	38%			
Total revenue	\$ 52,787	\$ 43,453	21%			

Sales of bioprocessing products for the nine-month periods ended September 30, 2013 and 2012 were \$37,132,000 and \$32,125,000, respectively, an increase of \$5,007,000, or 16%. 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 approximately \$12,956,000 and \$10,623,000 for the nine-month periods ended September 30, 2013 and 2012, respectively. We expect to receive these royalty payments for Bristol s sales through December 31, 2013. We expect that the upcoming loss of these royalty payments will materially and adversely affect our revenue and operating results.

For the nine months ended September 30, 2013 and 2012, we recognized \$1,481,000 and \$704,000, respectively, of revenue from sponsored research and development projects under agreements with the National Institutes of Health / Scripps Research Institute, the Muscular Dystrophy Association, Go Friedreich s Ataxia Research, the Friedreich s Ataxia Research Alliance and the European Friedrich s Ataxia Consortium for Translational Studies.

In the nine months ended September 30, 2013, we recognized \$1,217,000 of revenue under the Pfizer License Agreement, including a \$1,000,000 milestone payment that was triggered by completion of specific clinical development activities as well as other fees associated with the transition.

Costs and operating expenses

Total costs and operating expenses for the nine-month periods ended September 30, 2013 and 2012 were comprised of the following:

	Nine mon Septem	% Change			
	2013	2012	2013 vs. 2012		
	(in thousands, except percentages)				
Cost of product revenue	\$ 17,854	\$ 19,037	-6%		
Cost of royalty revenue	1,943	1,593	22%		
Research and development	5,919	8,147	-27%		
Selling, general and administrative	9,334	9,973	-6%		
Contingent consideration fair value adjustments	47	344	-86%		
Gain on bargain purchase		(314)	100%		
Total costs and operating expenses	\$ 35,097	\$38,780	-9%		

18

Cost of product revenue was approximately \$17,854,000 and \$19,037,000 for the nine-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$1,183,000 or 6%. This decrease is primarily due to operational efficiencies implemented during 2012 at Repligen Sweden offset by higher overall costs associated with increased bioprocessing product revenue in the first nine months of 2013 as compared to the first nine months of 2012. Gross margins may decline slightly in the fourth quarter based on expected production volume and shipments, product mix and the sale of higher cost inventory that was produced in 2012.

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 nine-month periods ended September 30, 2013 and 2012, the cost of royalty revenue was approximately \$1,943,000 and \$1,593,000, respectively. This increase is directly related to the increase in Bristol royalty revenue noted above.

Research and development expenses were approximately \$5,919,000 and \$8,147,000 for the nine-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$2,228,000 or 27%. This decrease is primarily attributed to a reduction in therapeutics related research and development expenses partially offset by an increase in bioprocessing research and development expense. For the nine-month periods ended September 30, 2013 and 2012, approximately \$3,363,000 and \$3,025,000, respectively, of our total research and development expenses was incurred in connection with bioprocessing research and development activities.

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 the remaining quarter in 2013, we expect levels of total research and development expenses similar to those incurred in the quarter ended September 30, 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 \$9,334,000 and \$9,973,000 for the nine-month periods ended September 30, 2013 and 2012, respectively, a decrease of \$639,000 or 6%. This decrease is primarily attributable to a reduction in outside professional and consulting services expenses of approximately \$835,000, a reduction in spending on sales and marketing related to therapeutics programs of approximately \$472,000 offset in part by higher employee related expenses of approximately \$866,000. Selling, general and administrative expenses in 2012 included non-recurring legal and accounting costs related to complying with reporting requirements with respect to the combined entity after the completion of the Novozymes acquisition, and other business development and corporate activities. For the remaining quarter in 2013, we expect similar levels of selling, general and administrative expenses to those incurred in the quarter ended September 30, 2013.

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

Investment income

Investment income includes income earned on invested cash balances. Investment income was approximately \$203,000 and \$157,000 for the nine-month periods ended September 30, 2013 and 2012, respectively. This increase of \$46,000, or 29%, is primarily attributable to slightly higher interest rates and slightly higher average invested cash balances.

Other (expense) income

Other (expense) income was approximately (\$57,000) and \$67,000 for the nine-month periods ended September 30, 2013 and 2012, respectively, and are primarily attributable to foreign currency gains (losses) related to our Sweden operations.

Provision (benefit) for income taxes

For the nine months ended September 30, 2013, we had income before taxes of \$17,798,550 and a tax provision of \$5,032,853 for an effective tax rate of approximately 28.28%. This is based on an expected effective tax rate of 26.6% 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 in excess of amounts previously recognized and the lower statutory rate in Sweden.

We are currently undergoing an audit in the Commonwealth of Massachusetts, or the Commonwealth, for the tax years ended March 31, 2008 through December 31, 2011. At issue is the apportionment of certain license income to the Commonwealth, as well as the recoverability of certain research and development credits earned between 1993 and 2011. As of September 30, 2013 we do not have a reserve recorded for these matters as we believe it is more likely than not that we will prevail. On October 29, 2013, we met with the Commonwealth to attempt to mediate our differences of opinion. However, this did not result in successful resolution. We continue to believe in the validity of our tax positions on these matters. As a result, we anticipate receiving a tax assessment that we will appeal in a process that could take up to several years. Total exposure, including penalties, but not interest, were we to ultimately be unsuccessful, would be approximately \$2.5 million.

19

For the nine-month period ended September 30, 2012, we had income before taxes of \$4,853,878 and a tax provision of \$250,954, based on an effective tax rate of 5.17%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different tax jurisdictions. The effective tax rate differs from the statutory tax rate primarily due to the utilization of prior year net operating loss carryforwards and credits.

Liquidity and capital resources

We have financed our operations primarily through sales of equity securities, revenues derived from product sales, and research grants, as well as proceeds and royalties from 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, research and development grants, and potential milestones earned under our collaboration agreement with Pfizer or under other potential out-licensing arrangements that may occur. 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. If we are unable to replace these royalty payments with an alternative source of revenue and related income, our revenue and operating results will be materially and adversely affected.

At September 30, 2013, we had cash and marketable securities of \$67,105,000 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 September 30, 2013 or December 31, 2012.

Operating activities

For the nine-month period ended September 30, 2013, our operating activities provided cash of \$18,592,000 reflecting net income of \$12,766,000 and non-cash charges totaling \$5,529,000 including depreciation, amortization, stock-based compensation, deferred tax expense and fair value adjustments to contingent consideration. The remaining cash flow provided by operations resulted from favorable changes in various working capital accounts, in particular the collection of \$5 million due from Pfizer pursuant to our collaboration agreement.

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

Investing activities

We place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines. Our investing activities consumed \$7,880,000 for the nine-month period ended September 30, 2013, primarily due to net purchases of marketable debt securities as well as \$3,775,000 used for fixed asset additions. For the nine-month period ended September 30, 2012, our investing activities consumed \$299,000, primarily due to \$825,000 used for fixed asset additions partially offset by net redemptions of marketable debt securities.

Financing activities

Exercises of stock options provided cash proceeds of \$2,235,000 in the nine-month-period ended September 30, 2013. In the nine months ended September 30, 2012, exercises of stock options provided \$887,000 of cash.

We do not currently use derivative financial instruments.

Working capital increased by approximately \$23,200,000 to \$78,657,000 at September 30, 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;

20

the extent of any share repurchase activity;

the success of any proposed financing efforts; and

the amount of royalty revenues we receive from Bristol for their sales of Orencia through December 31, 2013.

Absent acquisitions of additional products 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 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 September 30, 2013.

Contractual obligations

As of September 30, 2013, we have the following fixed obligations and commitments:

	Payments Due by Period						
		Less	than 1	1 - 3	3 - 5	Moı	re than 5
(In thousands)	Total	Y	'ear	Years	Years	3	Years
Operating lease obligations	\$ 14,537	\$	2,235	\$4,471	\$3,057	\$	4,774
Purchase obligations (1)	2,978		2,978				
Contingent consideration (2)	1,593		1,159	201	233		
Total	\$ 19,108	\$	6,372	\$4,672	\$3,290	\$	4,774

- (1) Primarily represents purchase orders for the procurement of raw material for manufacturing.
- (2) Represents the current estimated fair value of contingent consideration amounts relating to acquisitions. These amounts 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 or guidance 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

21

success of our clinical trials and our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of litigation regarding our patent and other intellectual property rights, the risk of litigation with collaborative partners, our limited sales and marketing experience and capabilities, our limited manufacturing capabilities and our dependence on third-party manufacturers and value-added resellers, our ability to hire and retain skilled personnel, the market acceptance of our products, reduced demand for our products that adversely impacts our future revenues, cash flows, results of operations and financial condition, our ability to compete with larger, better financed pharmaceutical and biotechnology companies that may develop new approaches to the treatment of our targeted diseases, our 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, the effects of our anti-takeover provisions, and the impact of the expiration on December 31, 2013 of Bristol-Meyers Squibb royalty payments based on its U.S. sales of Orencia[®]. 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 \$155,000 decrease in the fair value of our investments as of September 30, 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 comprehensive income. 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.

22

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 Quarterly Report on 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 and below, could cause our actual results to differ materially from those in the forward-looking statements.

Pursuant to the settlement with Bristol, we received royalty revenue from Bristol on its sales of Orencia that represented 25%, 24% and 37% of total revenues for the nine-month period ended September 30, 2013, the fiscal year ended December 31, 2012 and the nine-month fiscal year ended December 31, 2011, respectively. We will receive royalty payments from Bristol s sales of Orencia through December 31, 2013. We will not receive royalty payments from Bristol on sales of Orencia after December 31, 2013. The expiration of the royalty payments under the Bristol Settlement is expected to have a material and adverse effect on our revenue and operating results. If we are unable to replace the royalty revenues with alternative sources of revenue, we may need to use our existing cash on hand to finance our operating activities, which will have a material and adverse effect on the liquidity of our operations.

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

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million shares of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We did not repurchase any shares of common stock during the three or nine-month periods ended September 30, 2013. As of September 30, 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.

23

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 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 Current Report on Form 8-K filed on May 25, 2012 and incorporated herein by reference).
10.1	Separation Agreement, dated September 10, 2013, by and between the Company and Jonathan Lieber (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on September 13, 2013 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 September 30, 2013, formatted in Extensible Business Reporting Language (xBRL): (i) Consolidated Statements of Comprehensive Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

S

24

⁺ Filed herewith.

^{*} Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REPLIGEN CORPORATION

Date: November 8, 2013 By: /s/ Walter C. Herlihy

Walter C. Herlihy nt and Chief Executive Off

President and Chief Executive Officer
(Principal executive officer)
Repligen Corporation

Date: November 8, 2013 By: /s/ WILLIAM J. KELLY

William J. Kelly Chief Accounting Officer (Principal financial officer) Repligen Corporation

25

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