

REPLIGEN CORP
Form 10-Q
November 07, 2008
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008

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 0-14656

REPLIGEN CORPORATION

(exact name of registrant as specified in its charter)

Edgar Filing: REPLIGEN CORP - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

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

41 Seyon Street, Bldg. 1, Suite 100

Waltham, MA
(Address of principal executive offices)

02453
(Zip Code)

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

(Former name, former address and former fiscal year, if changed since last report.)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of October 31, 2008.

Class	Number of Shares
Common Stock, par value \$.01 per share	31,184,534

Table of Contents

REPLIGEN CORPORATION

INDEX

	PAGE
PART I. FINANCIAL INFORMATION	
Item 1. Unaudited Financial Statements	
<u>Balance Sheets as of September 30, 2008 and March 31, 2008</u>	3
<u>Statements of Operations for the Three and Six-Month Periods Ended September 30, 2008 and 2007</u>	4
<u>Statements of Cash Flows for the Three and Six-Month Periods Ended September 30, 2008 and 2007</u>	5
<u>Notes to Unaudited Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	19
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	20
Item 1A. <u>Risk Factors</u>	20
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 3. <u>Defaults Upon Senior Securities</u>	20
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	20
Item 5. <u>Other Information</u>	21
Item 6. <u>Exhibits</u>	21
<u>Signatures</u>	22
<u>Exhibit Index</u>	23

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

	September 30, 2008	March 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,122,761	\$ 32,562,138
Marketable securities	22,904,803	17,221,653
Accounts receivable, less reserve of \$ 10,000	1,607,789	1,061,601
Royalties receivable	1,939,050	64,200
Inventories	2,594,641	2,804,247
Prepaid expenses and other current assets	700,299	707,348
Total current assets	56,869,343	54,421,187
Property, plant and equipment, at cost:		
Leasehold improvements	3,517,158	3,333,097
Equipment	3,475,313	3,271,446
Furniture and fixtures	294,868	226,655
	7,287,339	6,831,198
Less: Accumulated depreciation and amortization	(3,914,230)	(3,417,941)
	3,373,109	3,413,257
Long-term marketable securities	15,578,385	10,805,263
Restricted cash	200,000	200,000
TOTAL ASSETS	\$ 76,020,837	\$ 68,839,707
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 664,851	\$ 2,721,909
Accrued liabilities	2,441,592	1,867,900
Total current liabilities	3,106,443	4,589,809
Long-term liabilities	130,365	143,043
Total liabilities	3,236,808	4,732,852
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; authorized: 5,000,000 shares, issued or outstanding: none		
Common stock, \$.01 par value; authorized: 40,000,000 shares, issued and outstanding: 31,109,093 shares at September 30, 2008 and 31,072,934 shares at March 31, 2008		
	311,091	310,729
Additional paid-in capital	184,541,788	184,372,945
Accumulated deficit	(112,068,850)	(120,576,819)
Total stockholders' equity	72,784,029	64,106,855

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 76,020,837	\$ 68,839,707
--	---------------	---------------

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30,		Six months ended September 30,	
	2008	2007	2008	2007
Revenue:				
Product revenue	\$ 2,984,304	\$ 5,156,348	\$ 8,677,647	\$ 10,887,824
Royalty and other revenue	2,105,620	195,973	10,072,522	443,315
Total revenue	5,089,924	5,352,321	18,750,169	11,331,139
Operating expenses: (1)				
Cost of product revenue	1,210,644	1,412,428	3,057,045	3,126,727
Cost of royalty and other revenue	210,612		535,612	
Research and development	2,463,419	1,153,995	4,547,544	3,291,320
Selling, general and administrative	1,529,767	2,185,799	2,976,338	4,327,930
Net gain from litigation settlement		(40,170,000)		(40,170,000)
Total operating expenses	5,414,442	(35,417,778)	11,116,539	(29,424,023)
Income (loss) from operations	(324,518)	40,770,099	7,633,630	40,755,162
Investment income	515,235	365,900	1,047,820	623,267
Interest income (expense)	884	(2,451)	(1,021)	(4,902)
Income before taxes	191,601	41,133,548	8,680,429	41,373,527
Income tax provision	49,545	827,471	259,545	827,471
Net income	\$ 142,056	\$ 40,306,077	\$ 8,420,884	\$ 40,546,056
Earnings per share:				
Basic	\$	\$ 1.31	\$.27	\$ 1.32
Diluted	\$	\$ 1.29	\$.27	\$ 1.30
Weighted average shares outstanding:				
Basic	31,172,706	30,767,384	31,160,555	30,667,249
Diluted	31,555,896	31,224,386	31,568,948	31,150,073

(1) Includes non-cash stock-based compensation as follows:

Cost of product revenue	\$ 11,482	\$ 5,336	\$ 22,309	\$ 12,366
Research and development	45,291	(1,757)	76,967	53,309
Selling, general and administrative	141,631	68,003	259,560	192,481

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

Table of Contents

REPLIGEN CORPORATION
STATEMENTS OF CASH FLOWS
(Unaudited)

	Six months ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net income	\$ 8,420,884	\$ 40,546,056
Adjustments to reconcile net income to net cash provided by operating activities:		
Issuance of common stock for license		300,000
Depreciation and amortization	502,538	389,439
Stock-based compensation expense	358,836	258,156
Loss on disposal of assets	890	
Changes in assets and liabilities:		
Accounts receivable	(2,421,038)	(1,448,301)
Inventories	209,606	(152,619)
Prepaid expenses and other current assets	7,048	(130,336)
Accounts payable	(2,057,058)	22,561
Accrued liabilities	503,670	445,554
Long-term liabilities	(12,678)	(21,579)
Net cash provided by operating activities	5,512,698	40,208,931
Cash flows from investing activities:		
Purchases of marketable securities	(25,066,911)	(18,521,756)
Redemptions of marketable securities	14,610,639	9,200,000
Purchases of property, plant and equipment	(463,279)	(373,919)
Net cash (used in) investing activities	(10,919,551)	(9,695,675)
Cash flows from financing activities:		
Exercise of stock options	258,212	178,900
Repurchase of common stock	(289,102)	
Principal payments under capital lease obligations	(1,634)	(2,930)
Net cash provided by (used in) financing activities	(32,524)	175,970
Net increase (decrease) in cash and cash equivalents	(5,439,377)	30,689,226
Cash and cash equivalents, beginning of period	32,562,138	7,726,505
Cash and cash equivalents, end of period	\$ 27,122,761	\$ 38,415,731
Supplemental disclosure of noncash activities:		
Disposal of fully depreciated equipment	\$ 3,000	\$
Non-cash tender of common stock to exercise stock options	\$	\$ 564,003

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

Table of Contents

REPLIGEN CORPORATION

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. Basis of Presentation

The financial statements included herein have been prepared by Repligen Corporation (the Company, Repligen or we) in accordance with accounting principles generally accepted in the United States 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 accounting principles generally accepted in the United States. These financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in our annual report on Form 10-K for the year ended March 31, 2008.

In the opinion of management, the accompanying unaudited financial statements include all adjustments, consisting of only normal, recurring adjustments necessary for a fair presentation of the financial position, results of operations and cash flows. The results of operations for the interim periods presented are not necessarily indicative of results to be expected for the entire year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. Revenue Recognition

The Company applies Staff Accounting Bulletin No. 104, Revenue Recognition, (SAB 104), and Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21) to all its revenue arrangements.

The Company generates product revenues from the sale of Protein A products to customers in the pharmaceutical and process chromatography industries and from the sale of SecreFlo® to hospital-based gastroenterologists. In accordance with SAB 104, the Company recognizes revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is reasonably assured. Determination of whether these criteria have been met are based on management's judgments primarily regarding the fixed nature of the fee charged for product delivered, and the collectability of those fees. The Company has a few longstanding customers who comprise the majority of product revenue and have excellent payment history. The Company has had no significant write-offs of uncollectible invoices in the periods presented. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and related purchase orders identify the terms and conditions of each sale and the price of the goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales return, warranty or other issues is largely diminished. Sales returns and warranty issues are infrequent and have had nominal impact on the Company's financial statements historically. Should changes in conditions cause management to determine that warranty, returns or other sale-related reserves are necessary for certain future transactions, revenue recognized for any reporting period could be adversely affected.

The Company also recognizes royalty revenue in the period earned. Royalty revenue for the period was predominantly generated pursuant to an agreement with Bristol-Myers Squibb Company (Bristol) entered into on April 7, 2008 (see Note 14). The Company also recognized \$0.2 million from ChiRhoClin for their sales of secretin during the quarter. Bristol royalties are based on Bristol's net U.S. sales of Orencia® through 2013, and are payable quarterly. During the six months ended September 30, 2008, the Company recognized \$9.7 million in Bristol royalties, which included an initial \$5.0 million payment, \$1.3 million for sales of Orencia® from January 1, 2008 to March 31, 2008, and \$3.4 million for sales of Orencia® from April 1, 2008 to September 30, 2008. Bristol began selling Orencia® in February 2006. The initial \$5.0 million payment was considered payment for sales from February 2006 to December 31, 2007 and is consistent with the royalty rate applied to sales of Orencia® after December 31, 2007. This initial payment is non-refundable, there are no future delivery obligations on the part of the Company, and our rights to this revenue are not dependent on future sales of Orencia®, if any. Therefore, the Company has recognized this initial payment as royalty revenue upon receipt during the first quarter of fiscal 2009.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Research revenue is recognized on a cost plus fixed-fee basis when the expense has been incurred and services have been performed. Determination of which costs incurred qualify for reimbursement under the terms of the contractual agreement and the timing of when such costs were incurred involves the judgment of management. The Company believes its calculations are consistent with the agreed-upon terms as stated in the arrangement. However, should the estimated calculations change or be challenged by our research partners,

Table of Contents

research revenue may be adjusted in subsequent periods. The calculations have not historically changed or been challenged and the Company does not anticipate any subsequent change in its revenue related to sponsored research and development projects. During the six months ended September 30, 2008, the Company recognized \$0.1 million in research revenue. During the six months ended September 30, 2007, the Company recognized \$0.3 million in research revenue.

There have been no material changes to the Company's initial estimates related to revenue recognition in any periods presented in the accompanying financial statements.

3. Earnings (Loss) Per Share

We follow the provisions of Statement of Financial Accounting Standard or SFAS No. 128, Earnings Per Share, (SFAS 128). Basic earnings per share for the three and six-month periods ended September 30, 2008 and 2007 were computed on the basis of the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed on the basis of the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period using the treasury stock method in accordance with SFAS 128. Dilutive potential common shares include outstanding stock options.

Basic and diluted weighted average shares outstanding were as follows:

	Three months ended September 30,		Six months ended September 30,	
	2008	2007	2008	2007
Weighted average common shares	31,172,706	30,767,384	31,160,555	30,667,249
Dilutive common stock options	383,190	457,002	408,393	482,824
Weighted average common shares, assuming dilution	31,555,896	31,224,386	31,568,948	31,150,073

For the three-month periods ended September 30, 2008 and 2007, options to purchase 733,500 and 403,800 shares of our common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares. For the six-month periods ended September 30, 2008 and 2007, options to purchase 715,500 and 396,800 shares of our common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares.

At September 30, 2008, there were outstanding options to purchase 1,930,650 shares of our common stock at a weighted average exercise price of \$4.29 per share.

4. Stock-Based Compensation

The Company follows the fair value recognition provisions of SFAS No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95, or SFAS No. 123R, using the modified prospective transition method.

For the three and six-month periods ended September 30, 2008, the Company recorded stock-based compensation expense of approximately \$198,404 and \$358,836, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan.

For the three and six-month periods ended September 30, 2007, the Company recorded stock-based compensation expense of approximately \$71,582 and \$258,156, respectively, for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan.

The Plans allow for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of Common Stock. Incentive options granted to employees under the 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 the Company's Annual Meeting on September 12, 2008, shareholders voted to approve the Second Amended and Restated 2001 Repligen Corporation Stock Plan, increasing the number of available options to purchase common stock by 1,000,000 shares. At

Edgar Filing: REPLIGEN CORP - Form 10-Q

September 30, 2008, options to purchase 1,607,550 shares were outstanding under the Second Amended and Restated 2001 Repligen Corporation Plan and options to purchase 297,500 shares were outstanding under the 1992 Repligen Corporation Stock Option Plan. At September 30, 2008, 1,046,909 shares were available for future grant under the Second Amended and Restated 2001 Repligen Corporation Stock Plan.

Table of Contents

The Company recognizes compensation expense on a straight-line basis over the requisite service period based upon options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted by an amount of estimated forfeitures. Forfeitures represent only the unvested portion of a surrendered option. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical data, the Company has calculated an 8% annual forfeiture rate for non-director level employees, a 3% annual forfeiture rate for director level employees, and a 0% forfeiture rate for non-employee members of the Board of Directors, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

Information regarding option activity for the six months ended September 30, 2008 under the Plans is summarized below:

	Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at April 1, 2008	1,622,750	\$ 3.76		
Granted	424,500	\$ 5.79		
Exercised	(111,600)	\$ 2.36		
Forfeited/Cancelled	(30,600)	\$ 6.67		
Options outstanding at September 30, 2008	1,905,050	\$ 4.29	6.48	\$ 1,982,935
Options exercisable at September 30, 2008	1,113,700	\$ 3.92	4.64	\$ 1,525,297
Vested and expected to vest at September 30, 2008 (1)	1,837,131	\$ 4.26	6.52	\$ 1,867,361

(1) This represents the number of vested options as of September 30, 2008 plus the number of unvested options expected to vest as of September 30, 2008 based on the unvested outstanding options at September 30, 2008 adjusted for the estimated forfeiture rate of 8% for awards granted to non-director level employees and 3% for awards granted to director level employees as described above.

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, 2008 of \$4.71 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, 2008.

The weighted average grant date fair value of options granted during the six months ended September 30, 2008 and 2007 was \$3.64 and \$2.75, respectively. The total fair value of stock options that vested during the six months ended September 30, 2008 and 2007 was approximately \$235,000 and \$652,000, respectively.

As of September 30, 2008, there was approximately \$961,300 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 3.28 years. The Company expects approximately 726,000 in unvested options to vest over the next five years.

5. Cash, Cash Equivalents and Marketable Securities

We follow the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At September 30, 2008, our investments included money market funds as well as short-term and long-term marketable securities, which are classified as held-to-maturity investments as we have the positive intent and ability to hold to maturity. Accordingly, funds from investments designated as held to maturity are not available for immediate use. As a result, these investments are recorded at amortized cost. Marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are investment grade securities with maturities of greater than one year.

At March 31, 2008, marketable securities also included investment grade auction rate securities. Auction rate securities have long-term underlying maturities, but have interest rates that are reset every 90 days or less, at which time the securities can typically be purchased or sold.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Auction rate securities were classified as available-for-sale and reported at fair value. Due to the reset feature and their carrying value equaling their fair value, there were no gross unrealized gains or losses from these short-term investments. As of June 30, 2008, the Company had sold all remaining auction rate securities without incurring any losses. As of September 30, 2008, the Company holds no auction rate securities.

Table of Contents

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

	September 30, 2008	March 31, 2008
Cash and cash equivalents	\$ 27,122,761	\$ 32,562,138
Marketable securities:		
Auction rate securities	\$	\$ 900,000
Corporate and other debt securities	22,904,803	16,321,653
	\$ 14,931,652	\$ 17,221,653
Long-term marketable securities:		
U.S. Government and agency securities	\$ 10,560,851	\$
Corporate and other debt securities	5,017,534	10,805,263
	\$ 15,578,385	\$ 10,805,263

The average remaining maturity of long-term marketable securities at September 30, 2008 is approximately 8.25 months.

Restricted cash of \$200,000 is related to our facility lease obligation.

6. Fair Value Measurement

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an Amendment of FASB Statement No. 115 (SFAS 159), which allows an entity to choose to measure certain financial instruments and liabilities at fair value. Subsequent measurements for the financial instruments and liabilities an entity elects to fair value will be recognized in earnings. SFAS 159 also establishes additional disclosure requirements. SFAS 159 was effective for the Company beginning April 1, 2008. The adoption of SFAS 159 did not have a material impact on our condensed consolidated statement of financial position, results of operations or cash flows. We did not elect to remeasure any existing financial assets or liabilities under the provisions of SFAS 159.

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*, effective for financial statements issued for fiscal years beginning after November 15, 2007. SFAS No. 157 replaces multiple existing definitions of fair value with a single definition, establishes a consistent framework for measuring fair value and expands financial statement disclosures regarding fair value measurements. This Statement applies only to fair value measurements that already are required or permitted by other accounting standards and does not require any new fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, which delayed until January 1, 2009 the effective date of SFAS No. 157 for nonfinancial assets and liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis.

The adoption of SFAS No. 157 for our financial assets and liabilities in the first quarter of fiscal 2009 did not have a material impact on our financial position or results of operations. Our nonfinancial assets and liabilities that meet the deferral criteria set forth in FSP No. 157-2 include property, plant and equipment. We do not expect that the adoption of SFAS No. 157 for these nonfinancial assets and liabilities will have a material impact on our financial position or results of operations.

In determining the fair value of its financial assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes 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:

Edgar Filing: REPLIGEN CORP - Form 10-Q

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
- Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement

Table of Contents

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

The Company's held-to-maturity securities, which are fixed income investments, are comprised of obligations of U.S. government agencies, corporate debt securities and other interest bearing securities. These held-to-maturity securities are recorded at amortized cost and are therefore not included in our market value measurement disclosure. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1.

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2008:

	Fair value measurement at reporting date using:			Balance as of September 30, 2008
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 1,348,677			\$ 1,348,677

There were no remeasurements to fair value during the three months ended September 30, 2008 of financial assets and liabilities that are not measured at fair value on a recurring basis.

7. Inventories

Inventories relate to the Company's Protein A business. The Company values inventory at the lower of cost or market on a first-in, first-out basis. Cost includes material, labor and applicable manufacturing overhead costs. 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 goods. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to twelve months. The Company writes down inventory that has become obsolete, has a cost basis in excess of its expected net realizable value, or is in excess of expected requirements to cost of goods sold. Protein A finished goods are manufactured to order and tested for quality specifications prior to shipment.

A change in the estimated timing or amount of demand for our 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.

Inventories consist of the following:

	September 30, 2008	March 31, 2008
Raw materials	\$ 1,636,574	\$ 1,676,402
Work in process	869,080	676,769
Finished goods	88,987	451,076
	\$ 2,594,641	\$ 2,804,247

8. Accrued Expenses and Other Current Liabilities

Edgar Filing: REPLIGEN CORP - Form 10-Q

The Company prepares its financial statements in accordance with accounting principles generally accepted in the United States. These principles require that the Company estimate accrued liabilities. This process involves identifying services performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of estimated accrued expenses include: 1) Fees paid to contract manufacturers in conjunction with the production of clinical materials. These expenses are normally determined through a contract or purchase order issued by the Company; 2) Service fees paid to organizations for their performance in conducting clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs which have been incurred as of each reporting date; 3) Professional

Table of Contents

and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred, or tracking costs incurred by service providers under fixed fee arrangements. The Company has processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that the Company does not identify certain costs which have begun to be incurred or the Company under or over-estimates the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often judgmental. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

A change in the estimated cost or volume of services provided could result in additional accrued liabilities. Any significant unanticipated changes in such estimates could have a significant impact on our accrued liabilities and reported operating results. There has been no material adjustments to our accrued liabilities in any of the periods presented in the accompanying financial statements.

Accrued expenses and other current liabilities consist of the following:

	September 30, 2008	March 31, 2008
Employee compensation	\$ 502,004	\$ 621,982
Royalty and license fees	264,600	97,804
Research & development	290,139	201,825
Professional fees	233,135	451,287
Other accrued expenses	495,538	217,874
Other current liabilities	215,214	217,162
Unearned revenue	440,963	59,965
	\$ 2,441,593	\$ 1,867,899

9. Income Taxes

The Company had income before taxes of approximately \$8,680,000 and \$41,374,000 for the six month periods ended September 30, 2008 and 2007, respectively. The Company had income tax provisions of approximately \$260,000 and \$827,000 for the six month periods ended September 30, 2008 and 2007, respectively. For the six months ended September 30, 2008, the effective income tax rate was approximately 2.99%. The effective income tax rate is based upon the estimated income for the year and the composition of the income in different jurisdictions. The effective tax rate differs from the statutory tax rate due to the utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax on income derived during the fiscal year.

The Company has net operating loss carryforwards of approximately \$63,050,000, business tax credits carryforwards of approximately \$2,205,000, and other tax credits of approximately \$733,000 available to reduce future federal income taxes, if any. Additionally, the Company also has business tax credits carryforwards of approximately \$2,665,000 available to reduce future state income taxes, if any. The Company has utilized all available state net operating loss carryforwards. The net operating loss and business tax credits carryforwards will continue to expire at various dates through March 2026. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

As of September 30, 2008, a full valuation allowance has been provided against the net operating losses, business tax credits and other deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

10. Comprehensive Income/Loss

We follow the provisions of SFAS No. 130, Reporting Comprehensive Income (SFAS 130). SFAS 130 requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period resulting from transactions and other events and circumstances from non-owner sources. Our comprehensive income is equal to our reported net income for all periods presented.

11. Segment Reporting

Edgar Filing: REPLIGEN CORP - Form 10-Q

We follow the provisions of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information (SFAS 131). SFAS 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS 131 also establishes standards for related disclosures about products and services and geographic areas. The chief operating decision maker, or decision-making group, in making decisions regarding how to allocate resources and assess performance, identifies operating segments as

Table of Contents

components of an enterprise about which separate discrete financial information is available for evaluation. To date, we view our operations and manage our business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to our principal operating segment.

The following table represents the Company's revenue by geographic area (based on the location of the customer):

	Three months ended September 30,		Six months ended September 30,	
	2008	2007	2008	2007
Sweden	43%	50%	36%	59%
US	48%	46%	60%	36%
Other	9%	4%	4%	5%
	100%	100%	100%	100%

Royalty revenue from Bristol represented 35% of the Company's total revenue for the three months ended September 30, 2008 and 52% for the six months ended September 30, 2008. The Company's two largest Protein A customers accounted for 43% and 7% of total revenues for the three months ended September 30, 2008 and 36% and 3% of revenues for the six months ended September 30, 2008. The Company's two largest Protein A customers accounted for 50% and 28% of total revenues for the three months ended September 30, 2007 and 60% and 19% of revenues for the six months ended September 30, 2007.

At September 30, 2008, Bristol's royalty payment comprised 49% of our accounts receivable. One of the Company's largest Protein A customers accounted for 37% of our accounts receivable as of September 30, 2008. Two of the Company's largest Protein A customers accounted for 20% and 24% of accounts receivable as of March 31, 2008, respectively.

12. New Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141(R), Business Combinations (SFAS 141(R)) and SFAS No. 160, Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51 (SFAS 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in financial statements, including capitalizing at the acquisition date the fair value of acquired in process research and development projects, and remeasuring and writing down these assets, if necessary, in subsequent periods during their development. The new standards will be applied prospectively for business combinations that occur for the Company on or after April 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding minority interests shall be applied retrospectively. The Company does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In December 2007, the FASB ratified EITF No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products. EITF 07-1 is effective for the Company as of April 1, 2009. The Company has not yet completed its evaluation of EITF 07-1, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

13. Scripps Agreements*License Agreement*

On April 6, 2007 (the Effective Date), the Company entered into an exclusive worldwide commercial license agreement (License Agreement) with The Scripps Research Institute (Scripps). Pursuant to the License Agreement, the Company obtained a license to use, commercialize and sublicense certain patented technology and improvements thereon, owned or licensed by Scripps, relating to compounds which may have utility in treating Friedreich's Ataxia, an inherited neurodegenerative disease. Research in tissues derived from patients, as well as, in mice, indicates that the licensed compounds increase production of the protein frataxin, which suggests potential utility of these compounds in slowing or stopping progression of the disease. There are currently no approved treatments for Friedreich's Ataxia.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Pursuant to the License Agreement, the Company agreed to pay Scripps an initial license fee of \$300,000, certain royalty and sublicense fees and, in the event the Company achieves specified developmental and commercial milestones, certain additional milestone payments. In addition, the Company issued Scripps 87,464 shares of the Company's common stock (the Shares) representing \$300,000 as of the Effective Date. The Company recorded the initial license payment and the value of the shares issued as research and development costs in the Company's statement of operations in the first quarter of fiscal 2008.

Table of Contents

If the value of the Shares did not equal at least \$300,000 on the one-year anniversary of the Effective Date, the Company would have had to make a cash payment to Scripps equal to the difference. At April 6, 2008, the one-year anniversary of the Effective Date, the fair value of the shares exceeded \$300,000; therefore, no liability was recorded. Furthermore, the Company issued warrants to an individual at Scripps to purchase up to 150,000 shares of common stock. The warrants have a 7-year term and are exercisable based on performance criteria as detailed in the warrant agreement. No expense has been recorded related to these warrants in fiscal 2008 or for the six-month period ended September 30, 2008, as none of the performance criteria have been achieved. At this time, the Company does not believe that the performance criteria are probable of being achieved in the near future.

The License Agreement with Scripps expires or may be terminated (i) when all of the royalty obligations under the License Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the License Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating to the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the License Agreement; or (iv) by the Company upon 90 days written notice.

Research Funding and Option Agreement

On October 26, 2007, the Company entered into a research funding and option agreement (*Funding Agreement*) with Scripps to fund a research program for the research and development of compounds that may have utility in the treatment of Friedreich's Ataxia. Pursuant to the Funding Agreement, the Company is required to fund approximately \$140,000 annually, payable quarterly, which are recorded as research and development expenses. In exchange for funding the research, Scripps will grant an exclusive option to the Company to acquire a sole, worldwide license, including the right to sublicense, manufacture and sell products, and services that result from the research program. There are no guaranties or warranties that products or services may result from the research program, and the Company has ascribed no value to the license.

The Funding Agreement expires or may be terminated (i) when all of the royalty obligations under the Funding Agreement expire; (ii) at any time by mutual written consent; (iii) by Scripps if the Company (a) fails to make payments under the Funding Agreement, (b) fails to achieve certain developmental and commercial objectives, (c) becomes insolvent, (d) is convicted of a felony relating to the manufacture, use or sale of the licensed technology, or (e) defaults in its performance under the Funding Agreement; or (iv) by the Company upon 90 days written notice.

14. Legal Proceedings*ImClone Systems*

In May 2004, the Company and the Massachusetts Institute of Technology (*MIT*) filed an action in the United States District Court for the District of Massachusetts against ImClone Systems, Incorporated (*ImClone*) for infringement of U.S. Patent No. 4,663,281 (*the 281 patent*) based on ImClone's manufacture and sale of Erbitu[®]. The 281 patent, which covers the use of certain genetic elements that increase protein production in a mammalian cell, is assigned to MIT and exclusively licensed to Repligen.

On September 10, 2007, the Company and MIT entered into a settlement agreement (*the ImClone Settlement*) with ImClone relating to the lawsuit against ImClone for infringement of the 281 patent. Pursuant to the ImClone Settlement, ImClone made a payment of \$65 million to Repligen and MIT that resulted in net proceeds to Repligen of \$40.17 million, as follows:

Gross proceeds from ImClone Settlement agreement	\$ 65,000,000
Less: Amounts paid to MIT	(11,000,000)
Less: Legal fees and other costs	(13,830,000)
Net gain on litigation settlement	\$ 40,170,000

The ImClone Settlement served as the basis for the Company and MIT to dismiss the lawsuit against ImClone and for the Company to grant ImClone a non-exclusive sublicense to the 281 patent and certain other intellectual property. There are no further obligations to the Company with respect to the sublicenses. The net gain on litigation settlement was recorded as a separate component of operating expenses in the Company's statement of operations in fiscal 2008.

Bristol-Myers Squibb Company

Edgar Filing: REPLIGEN CORP - Form 10-Q

In January 2006, Repligen and the University of Michigan jointly filed a complaint against Bristol in the United States District Court for the Eastern District of Texas for infringement of U.S. Patent No. 6,685,941 (the 941 patent) for the commercial sale of Orencia®. The 941 patent, entitled Methods of Treating Autoimmune Disease via CTLA4-Ig, covers methods of using CTLA4-Ig to treat rheumatoid arthritis, as well as other therapeutic methods. Repligen has exclusive rights to this patent from its owners, the University of Michigan and the U.S. Navy. In February 2006, Bristol answered the complaint and counterclaimed seeking a declaratory judgment that the 941 patent is invalid and unenforceable and that Bristol does not infringe the patent.

Table of Contents

On April 7, 2008, Repligen and the University of Michigan entered into a settlement agreement (the Bristol Settlement) with Bristol relating to the lawsuit against Bristol for infringement of the 941 patent. Pursuant to the Bristol Settlement, Bristol made an initial payment of \$5 million to Repligen. The settlement further provides for Bristol to pay royalties on the United States net sales of Orencia® for any clinical indication at a rate of 1.8% for the first \$500 million of annual net sales, 2.0% for the next \$500 million of annual net sales and 4% of annual net sales in excess of \$1 billion for each year from January 1, 2008 until December 31, 2013. Pursuant to the Bristol Settlement agreement, the Company has recognized \$9.7 million in royalty revenue in the six month period ended September 30, 2008, including a \$5 million initial payment, \$1.3 million for sales of Orencia® from January 1, 2008 through March 31, 2008, as well as \$3.4 million for sales in the first two quarters of fiscal year 2009 (see Note 2). The Bristol Settlement served as the basis for Repligen and the University of Michigan to dismiss the lawsuit against Bristol and for Repligen and the University of Michigan to grant to Bristol an exclusive worldwide license to the 941 patent and certain other intellectual property.

Repligen must also remit to the University of Michigan 15% of all royalty revenue received from Bristol, after first deducting certain legal and other costs incurred related to the settlement. The Company has incurred approximately \$6.1 million in such legal costs, which when deducted from the \$9.7 million in royalty revenue earned to date, results in a net amount due to the University of Michigan of \$536,000. This operating expense has been included on our Statements of Operations under the line item Cost of royalty and other revenue.

15. Share Repurchase

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million 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 publicly announced the stock repurchase program on June 18, 2008. For the three and six-month periods ended September 30, 2008, the Company repurchased 75,441 shares of common stock, for an aggregate purchase price of \$360,757, leaving 1,174,559 shares remaining under this authorization.

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

We are a biopharmaceutical company focused primarily on the development of novel therapeutics for diseases that affect the central nervous system. A number of drug development programs are currently being conducted to evaluate our drug candidates in diseases such as bipolar disorder and neurodegeneration. In addition, we sell Protein A for monoclonal antibody purification and receive royalties on intellectual property that we license to third parties. Our business strategy is to deploy the profits from our current commercial products and patents licensing revenues to enable us to invest in the development of our therapeutic product candidates while reducing our financial risk.

Critical Accounting Policies and Estimates

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Financial Statements included in our Annual Report on Form 10-K dated March 31, 2008.

Results of Operations

Three month period ended September 30, 2008 vs. September 30, 2007

Total revenue

Total revenues for the three-month periods ended September 30, 2008 and September 30, 2007 were approximately \$5,090,000 and \$5,352,000 respectively, a decrease of \$262,000 or 5%.

Sales of Protein A for the three-month periods ended September 30, 2008 and September 30, 2007 were \$2,984,000 and \$4,516,000, respectively. The decrease of \$1,532,000, or 34%, was largely the result of lower overall sales volume as the prior quarter was unusually high as a result of the timing of customer orders.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Substantially all of our products based on recombinant Protein A are sold to customers who incorporate our manufactured products into their proprietary antibody purification systems to be sold directly to the pharmaceutical industry. Monoclonal antibodies are a well-established class of drug with applications in rheumatoid arthritis, asthma, Crohn's disease and a variety of cancers. Sales of Protein A are therefore impacted by the timing of large-scale production orders and on the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

Table of Contents

In April 2008, we settled our outstanding litigation with Bristol. We have therefore begun 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 Bristol Settlement, we have recognized \$1,780,000 in royalty revenue in the three months ended September 30, 2008. Additionally, during the three-month periods ended September 30, 2008 and September 30, 2007, we earned and recognized approximately \$215,000 and \$56,000, respectively, in royalty revenue from ChiRhoClin.

During the three-month periods ended September 30, 2008, and September 30, 2007, we recognized approximately \$110,000 and \$139,000, respectively, of revenue from various sponsored research and development projects. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred.

As previously disclosed, we have ceased sales of SecreFlo[®] in the current year due to the expiration of our agreement with our sole supplier, ChiRhoClin. There were no sales of SecreFlo[®] in the current quarter and we will no longer sell the product going forward. Sales of SecreFlo[®] for the quarter ended September 30, 2007 were \$640,000.

Operating expenses

Total operating expenses, exclusive of the net gain from litigation settlement, were approximately \$5,414,000 and \$4,752,000 for the three-month periods ended September 30, 2008 and September 30, 2007, respectively, an increase of \$662,000 or 14%.

Cost of product revenue was approximately \$1,211,000 and \$1,412,000 for the three-month periods ended September 30, 2008 and September 30, 2007, respectively, a decrease of \$201,000 or 14%. This decrease is primarily due to the decrease in Protein A sales noted above, as well as increased depreciation and occupancy expenses related to expansion of our manufacturing capacity and increased headcount in the three-month period ended September 30, 2008.

In connection with the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the settlement agreement in December 2013, after deducting certain allowable legal and other costs, to the University of Michigan. For the three-month period ended September 30, 2008, this cost of royalty revenue was \$211,000.

Research and development expenses were approximately \$2,463,000 and \$1,154,000 for the three-month periods ended September 30, 2008 and September 30, 2007, respectively, an increase of \$1,309,000 or 113%. The increase is due to increased overall activity, in comparison to the prior period, in our two clinical trials as well as ongoing research and development costs incurred investigating potential clinical candidates to be used in the treatment of Friedreich's Ataxia. Specifically, as patient enrollment continues to progress in our phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging, we have increased spending versus the prior period by \$150,000. In addition, we have engaged a clinical research organization to assist in the deployment of our phase 2b clinical trial for RG2417, evaluating the use of uridine to treat bi-polar depression, and otherwise increased overall clinical trial efforts, adding an incremental \$439,000 of spending compared to the prior period. Finally, our Friedreich's Ataxia spending has also increased by \$431,000 as we continue our research efforts. 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.

Selling, general and administrative expenses were approximately \$1,529,000 and \$2,186,000 for the three-month periods ended September 30, 2008 and September 30, 2007, respectively, a decrease of \$657,000 or 30%. This decrease is largely attributable to a \$1,030,000 decrease in litigation expenses related to our patent infringement settlements with both ImClone and Bristol, partially offset by increased headcount and recruiting costs as we expand our business development and other functions to support the business.

Interest income

Interest income was approximately \$515,000 and \$366,000 for the three-month periods ended September 30, 2008 and September 30, 2007, respectively. The increase is primarily due to a significantly higher average investment balance during the three month period ended September 30, 2008.

Income Tax Provision

The Company had income before taxes of approximately \$193,000 and \$41,134,000 for the three month periods ended September 30, 2008 and 2007, respectively. The Company had an income tax provision of \$50,000 and \$827,000 for the three month periods ended September 30, 2008 and 2007, respectively. Prior to the \$40.2 million litigation gain from in the second quarter of fiscal 2008, the company had net operating losses and other research credits that reduced our effective tax rate to zero. For fiscal year 2009, we anticipate an effective tax rate of approximately

Edgar Filing: REPLIGEN CORP - Form 10-Q

2.99%. The effective tax rate differs from the statutory tax rate due to the continued utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax (AMT) on income derived during the fiscal year.

The Company has net operating loss carryforwards of approximately \$63,050,000, business tax credits carryforwards of approximately \$2,205,000, and other tax credits of approximately \$733,000 available to reduce future federal income taxes, if any.

Table of Contents

Additionally, the Company also has business tax credits carryforwards of approximately \$2,665,000 available to reduce future state income taxes, if any. The Company has utilized all available state net operating loss carryforwards. The net operating loss and business tax credits carryforwards will continue to expire at various dates through March 2026. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

As of September 30, 2008, a full valuation allowance has been provided against the net operating losses, business tax credits and other deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

Six month period ended September 30, 2008 vs. September 30, 2007

Total revenue

Total revenues for the six-month periods ended September 30, 2008 and September 30, 2007 were approximately \$18,750,000 and \$11,331,000 respectively, an increase of \$7,419,000 or 65%.

Sales of Protein A for the six-month periods ended September 30, 2008 and September 30, 2007 were \$8,481,000 and \$9,710,000, respectively. The decrease of \$1,229,000, or 13%, was largely the result of lower overall sales volume as the prior period was unusually high as a result of the timing of customer orders.

Substantially all of our products based on recombinant Protein A are sold to customers who incorporate our manufactured products into their proprietary antibody purification systems to be sold directly to the pharmaceutical industry. Monoclonal antibodies are a well-established class of drug with applications in rheumatoid arthritis, asthma, Crohn's disease and a variety of cancers. Sales of Protein A are therefore impacted by the timing of large-scale production orders and on the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

In April 2008, we settled our outstanding litigation with Bristol. We have therefore begun 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 Bristol Settlement, we have recognized \$9,677,000 in royalty revenue in the six-month period ended September 30, 2008. Additionally, during the six-month periods ended September 30, 2008 and September 30, 2007, we earned and recognized approximately \$285,000 and \$103,000, respectively, in royalty revenue from ChiRhoClin.

During the three-month periods ended September 30, 2008, and September 30, 2007, we recognized approximately \$110,000 and \$340,000, respectively, of revenue from various sponsored research and development projects. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred.

As previously disclosed, we have ceased sales of SecreFlo[®] in the current year due to the expiration of our agreement with our sole supplier, ChiRhoClin. Sales of SecreFlo[®] for the six-month periods ended September 30, 2008 and September 30, 2007 were \$168,000 and \$640,000, respectively.

Operating expenses

Total operating expenses, exclusive of the net gain from litigation settlement, were approximately \$11,117,000 and \$10,746,000 for the six-month periods ended September 30, 2008 and September 30, 2007, respectively, an increase of \$371,000 or 3%.

Cost of product revenue was approximately \$3,057,000 and \$3,127,000 for the six-month periods ended September 30, 2008 and September 30, 2007, respectively, a decrease of \$70,000 or 2%. This decrease is primarily due to the decrease in Protein A sales noted above, as well as increased depreciation and occupancy expenses related to expansion of our manufacturing capacity and increased headcount in the six-month period ended September 30, 2008.

In connection with the Bristol Settlement, we must remit 15% of royalty revenue received through the expiration of the settlement agreement in December 2013, after deducting certain allowable legal and other costs, to the University of Michigan. For the six-month period ended September 30, 2008, this cost of royalty revenue was \$536,000.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Research and development expenses were approximately \$4,548,000 and \$3,291,000 for the six-month periods ended September 30, 2008 and September 30, 2007, respectively, an increase of \$1,257,000 or 38%. The increase is due to increased overall activity, in comparison to the prior period, in our two clinical trials as well as ongoing research and development costs incurred investigating potential clinical candidates to be used in the treatment of Friedreich's Ataxia. Specifically, as patient enrollment continues to progress in our phase 3 clinical trial for RG1068, evaluating the use of human secretin in aiding pancreatic imaging, we have increased spending versus the prior period by \$647,000. In addition, we have engaged a clinical research organization to assist in the deployment of our phase 2b clinical trial for RG2417, evaluating the use of uridine to treat bi-polar depression, and otherwise increased overall clinical trial efforts, adding an incremental \$284,000 of spending compared to the prior period. Finally, our Friedreich's Ataxia spending has also increased by \$35,000 as we continue our research efforts. 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.

Table of Contents

Selling, general and administrative expenses were approximately \$2,976,000 and \$4,328,000 for the six-month periods ended September 30, 2008 and September 30, 2007, respectively, a decrease of \$1,352,000 or 31%. This decrease is largely attributable to a \$1,841,000 decrease in litigation expenses related to our patent infringement settlements with both ImClone and Bristol, partially offset by increased headcount and recruiting costs as we expand our business development and other functions to support the business.

Interest income

Interest income was approximately \$1,048,000 and \$623,000 for the six-month periods ended September 30, 2008 and September 30, 2007, respectively. The increase is primarily due to a significantly higher average investment balance during the six-month period ended September 30, 2008.

Income Tax Provision

The Company had income before taxes of approximately \$8,680,000 and \$41,374,000 for the six-month periods ended September 30, 2008 and 2007, respectively. The Company had an income tax provision of \$260,000 and \$827,000 for the six-month periods ended September 30, 2008 and 2007, respectively. Prior to the \$40.2 million litigation gain in the second quarter of fiscal 2008, the company had net operating losses and other research credits that reduced our effective tax rate to zero. For fiscal year 2009, we anticipate an effective tax rate of approximately 2.99%. The effective tax rate differs from the statutory tax rate due to the continued utilization of prior year net operating losses and credits, offset by the effects of the alternative minimum tax (AMT) on income derived during the fiscal year.

The Company has net operating loss carryforwards of approximately \$63,050,000, business tax credits carryforwards of approximately \$2,205,000, and other tax credits of approximately \$733,000 available to reduce future federal income taxes, if any. Additionally, the Company also has business tax credits carryforwards of approximately \$2,665,000 available to reduce future state income taxes, if any. The Company has utilized all available state net operating loss carryforwards. The net operating loss and business tax credits carryforwards will continue to expire at various dates through March 2026. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

As of September 30, 2008, a full valuation allowance has been provided against the net operating losses, business tax credits and other deferred tax assets, as it is uncertain if the Company will realize the benefits of such deferred tax assets.

Liquidity and capital resources

We have financed our operations primarily through sales of equity securities, revenues derived from product sales and grant and research agreements and more recently from consideration received as a result of the successful settlement of litigation. Our revenue for the foreseeable future will be primarily limited to our product revenue related to Protein A, royalties from Bristol for their United States net sales of Orenicia[®], research grants, interest income and other revenue. Revenues derived from the sales of SecreFlo[®] vials, as anticipated and previously disclosed, have ceased as of the six-month period ended September 30, 2008. 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. Total cash, cash equivalents and marketable securities at September 30, 2008 totaled approximately \$65,606,000, an increase of \$5,017,000 from \$60,589,000 at March 31, 2008.

Operating activities

Our operating activities provided cash of approximately \$5,513,000 for the six-month period ended September 30, 2008. Cash provided by operations is primarily due to net income of \$8,463,000, plus certain non-cash expenses such as \$503,000 for depreciation and \$359,000 in stock-based compensation expense, offset by a \$2,464,000 increase in accounts receivable, a \$1,552,000 increase in accounts payable and accrued liabilities and a \$210,000 decrease in inventory. Accounts receivable increased as a result of the \$1,780,000 royalty revenue from Bristol for Orenicia[®] sales for the three-months ended September 30, 2008 which were recognized when earned but is not due until after quarter end, as well as other increases in trade accounts receivable related to sales made in the last month of quarter. The decrease in accounts payable and accrued expenses from year end was largely the result of the payment of outstanding legal invoices associated with the Bristol litigation that was completed in April 2008.

Investing activities

Our investing activities consumed approximately \$10,920,000 for the six-month period ended September 30, 2008 as we made \$10,456,000 net purchases of marketable securities, investing the funds provided by our operating activities above. In addition, the Company invested

approximately \$463,000 in equipment purchases and improvements to the Company's facility.

Table of Contents

Financing activities

Stock option exercises provided cash proceeds of approximately \$258,000 for the six-month period ended September 30, 2008. Share repurchases for the period consumed \$289,000.

We do not currently use derivative financial instruments. We generally place our marketable security investments in high quality credit instruments as specified in our investment policy guidelines.

Working capital increased to approximately \$53,805,000 at September 30, 2008 from \$49,831,000 at March 31, 2008 due to the increases in receivables as well as the decrease in accounts payable noted above.

Our future capital requirements will depend on many factors, including the following:

the success of our clinical studies;

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

our ability to acquire additional product candidates;

the success of any proposed financing efforts; and

the ability to sustain sales and profits of our commercial products.

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash and investment balances are adequate to meet our needs for at least the next twenty four months. Our future capital requirements include, but are not limited to, continued investment in our research and development programs, capital expenditures primarily associated with purchases of equipment and facilities and continued investment in our intellectual property portfolio.

We plan to continue to invest in key research and development activities. We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. We continue to seek to acquire such potential assets that may offer us the best opportunity to create value for our shareholders. In order to acquire such assets, we may need to seek additional financing to fund these investments. This may require the issuance or sale of additional equity or debt securities. The sale of additional equity may result in dilution to our stockholders. Should we need to secure additional financing to acquire a product, fund future investment in research and development, or meet our future liquidity requirements, we may not be able to secure such financing, or obtain such financing on favorable terms because of the volatile nature of the biotechnology marketplace.

Off-Balance Sheet Arrangements

As of September 30, 2008, we did not have any off-balance sheet arrangements.

Commitments

As of September 30, 2008, we had the following fixed obligations and commitments:

Payments Due by Period

Edgar Filing: REPLIGEN CORP - Form 10-Q

(In thousands)	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating lease obligations	\$ 1,974	\$ 666	\$ 1,167	\$ 141	\$
Capital lease obligations (1)	73	44	29		
Purchase obligations (2)	775	775			
Contractual obligations (3)	376	103	179	75	19
Total	\$ 3,198	\$ 1,588	\$ 1,375	\$ 216	\$ 19

- (1) Represents principal payments only; principal and interest are payable through a fixed annual payments of approximately \$48,000.
- (2) Represents purchase orders for the procurement of raw material for manufacturing as well as clinical materials to support our upcoming trials.
- (3) Includes payments for license, supply and consulting agreements.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this Quarterly Report on Form 10-Q, as well as oral statements that may be made by Repligen or by officers, directors or employees of Repligen acting on its behalf, that are not historical facts constitute forward-looking statements which are made

Table of Contents

pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements in this Quarterly Report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements in this Quarterly Report on Form 10-Q which are not strictly historical statements, including, without limitation, statements regarding current or future financial performance, management's strategy, litigation strategy, costs of legal proceedings, disputes with suppliers, plans and objectives for future operations, clinical trials and results, marketing plans, revenue potential of therapeutic product candidates, product research, intellectual property and development, manufacturing plans and performance, delays in manufacturing by us or our partners, timing of customer orders, the anticipated growth in our target markets, including, without limitation, the market for neuropsychiatric disorders treatment, the market for pancreatic disease treatment, the monoclonal antibody market and the process chromatography industry and projected growth in product sales, costs of operations, sufficiency of funds to meet management objectives and availability of financing and effects of accounting pronouncements constitute forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from the historical results or from any results expressed or implied by such forward-looking statements, including, without limitation, risks associated with: the success of current and future collaborative relationships, the success of our clinical trials and our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of litigation regarding our patent and other intellectual property rights, the risk of litigation with collaborative partners, our limited sales and marketing experience and capabilities, our limited manufacturing capabilities and our dependence on third-party manufacturers and value-added resellers, our ability to hire and retain skilled personnel, the market acceptance of our products, our ability to compete with larger, better financed pharmaceutical and biotechnology companies that may develop new approaches to the treatment of our targeted diseases, our history of losses and expectation of incurring continued losses, our ability to generate future revenues, our ability to raise additional capital to continue our drug development programs, our volatile stock price, and the effects of our anti-takeover provisions. Further information on potential risk factors that could affect our financial results are included in the filings made by us from time to time with the Securities and Exchange Commission including under the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended March 31, 2008.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**Interest Rate Risk**

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

We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines. A hypothetical 100 basis point increase in interest rates would result in an approximate \$397,000 decrease in the fair value of our investments as of September 30, 2008. We believe, however, that the conservative nature of our investments mitigates our interest rate exposure, and our investment policy limits the amount of our credit exposure to any one issue, issuer (with the exception of U.S. agency obligations) and type of instrument. We do not expect any material loss from our marketable security investments and therefore believe that our potential interest rate exposure is limited. We intend to hold the majority of our investments to maturity, in accordance with our business plans.

ITEM 4. CONTROLS AND PROCEDURES

The Company's management, with the participation of the chief 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 chief 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 chief executive officer and the Company's principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

Table of Contents**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

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

ITEM 1A. RISK FACTORS

None.

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

A summary of our stock repurchase activity for the three months ended September 30, 2008 is as follows:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Maximum Number of Shares that May Yet be Purchased Under the Program
July 1 through July 31		\$		1,250,000
August 1 through August 31		\$		1,250,000
September 1 through September 30	75,411	\$ 4.78	75,411	1,174,589
	75,411	\$ 4.78	75,411	

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million 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 publicly announced the stock repurchase program on June 18, 2008. The Company has repurchased 75,441 shares under this program through September 30, 2008.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's Annual Meeting of Stockholders (the Annual Meeting) was held on September 12, 2008. At the Annual Meeting, the stockholders of the Company considered and acted upon a proposal to elect a Board of Directors for the ensuing year.

Proposal 1. Election of Directors:

The stockholders elected all of the Company's nominees for directors.

Edgar Filing: REPLIGEN CORP - Form 10-Q

Directors	Shares Voting in	
	Favor	Withhold
Karen Dawes*	24,355,614	2,652,208
Alfred L. Goldberg, Ph.D.*	24,479,476	2,528,346
Walter C. Herlihy, Ph.D.*	26,696,976	310,846
Alexander Rich, M.D.*	19,301,731	7,706,091
Thomas F. Ryan, Jr.*	22,096,771	4,911,051
Earl Webb Henry, M.D.*	24,481,346	2,526,476

* Incumbent

Table of Contents

Proposal 2. Approve Second Amended and Restated 2001 Repligen Corporation Stock Plan:

The stockholders voted to approve the Second Amended and Restated 2001 Repligen Corporation Stock Plan as follows:

	For	Against	Abstain	Broker Non Vote
Total Shares Voted	12,130,288	1,852,037	2,196,897	10,828,600

ITEM 5. OTHER INFORMATION

None.

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	Certificate of Designation of Series A Junior Participating Preferred Stock dated March 4, 2003 (filed as Exhibit A of Exhibit 1 to Repligen Corporation's Registration Statement on Form 8-A filed March 4, 2003 and incorporated herein by reference). (File No. 000-14656)
3.3	Amended and Restated By-laws (filed as Exhibit 3.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference). (File No. 000-14656)
10.1	Second Amended and Restated 2001 Repligen Corporation Stock Plan (filed as exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed September 19, 2008 and incorporated herein by reference).
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer.
31.2+	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial and Accounting Officer.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Filed herewith.

Table of Contents

SIGNATURE

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 7, 2008

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

Date: November 7, 2008

By: /s/ William J. Kelly
William J. Kelly
Vice President Finance and Administration
(Principal Financial and Accounting Officer)
Repligen Corporation

Table of Contents

EXHIBIT INDEX

Exhibit Number	Document Description
3.1	Restated Certificate of Incorporation, dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (File No. 000-14656)
3.2	Certificate of Designation of Series A Junior Participating Preferred Stock dated March 4, 2003 (filed as Exhibit A of Exhibit 1 to Repligen Corporation's Registration Statement on Form 8-A filed March 4, 2003 and incorporated herein by reference). (File No. 000-14656)
3.3	Amended and Restated By-laws (filed as Exhibit 3.2 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference). (File No. 000-14656)
10.1	Second Amended and Restated 2001 Repligen Corporation Stock Plan (filed as exhibit 10.1 to Repligen Corporation's Current Report on Form 8-K filed September 19, 2008 and incorporated herein by reference).
31.1+	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer.
31.2+	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial and Accounting Officer.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Filed herewith.