

REPLIGEN CORP
Form 10-Q
February 09, 2006
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 December 31, 2005

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)

Delaware
(State or other jurisdiction of incorporation or

organization)

41 Seyon Street, Bldg. 1, Suite 100

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

02453

Edgar Filing: REPLIGEN CORP - Form 10-Q

Waltham, MA
(Address of principal executive offices)

(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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 February 8, 2006.

Common Stock, par value \$.01 per share
Class

30,120,135
Number of Shares

Table of Contents

REPLIGEN CORPORATION

INDEX

	PAGE
PART I. FINANCIAL INFORMATION	
Item 1. <u>Financial Statements (Unaudited) Balance Sheets as of December 31, 2005 and March 31, 2005</u>	3
<u>Statements of Operations for the Three and Nine Month Periods Ended December 31, 2005 and 2004</u>	4
<u>Statements of Cash Flows for the Nine Months Ended December 31, 2005 and 2004</u>	5
<u>Notes to Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	17
Item 1A. Risk Factors None	
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds None	
Item 3. Defaults Upon Senior Securities None	
Item 4. Submission of Matters to a Vote of Security Holders None	
Item 5. Other Information None	
Item 6. <u>Exhibits</u>	17
<u>Signatures</u>	18
<u>Exhibit Index</u>	19

Table of Contents**REPLIGEN CORPORATION****BALANCE SHEET****Unaudited**

	<u>December 31, 2005</u>	<u>March 31, 2005</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,446,391	\$ 3,216,681
Marketable securities	13,149,745	13,675,956
Accounts receivable, less bad debt reserve of \$10,000 and \$15,000 at December 31, 2005 and March 31, 2005, respectively	1,660,689	764,232
Inventories	1,367,299	633,314
Prepaid expenses and other current assets	556,437	580,862
	<u>21,180,561</u>	<u>18,871,045</u>
Total current assets	21,180,561	18,871,045
Property, plant and equipment, at cost:		
Leasehold improvements	2,462,152	2,311,841
Equipment	1,729,154	1,194,249
Furniture and fixtures	209,520	165,903
	<u>4,400,826</u>	<u>3,671,993</u>
Less-accumulated depreciation and amortization	(2,033,808)	(1,766,585)
	<u>2,367,018</u>	<u>1,905,408</u>
Long-term marketable securities	5,479,448	6,630,679
Restricted cash	200,000	200,000
	<u>5,679,448</u>	<u>6,830,679</u>
Total assets	<u>\$ 29,227,027</u>	<u>\$ 27,607,132</u>
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 637,822	\$ 1,016,958
Accrued liabilities	2,467,266	2,180,625
	<u>3,105,088</u>	<u>3,197,583</u>
Total current liabilities	3,105,088	3,197,583
Long-term liabilities	261,954	119,891
	<u>261,954</u>	<u>119,891</u>
Total liabilities	3,367,042	3,317,474
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$.01 par value		
Authorized 5,000,000 shares Issued and outstanding none		
Common Stock, \$.01 par value		
Authorized 40,000,000 shares Issued and outstanding 30,113,635 shares at December 31, 2005 and 30,094,435 shares at March 31, 2005		
	301,136	300,944
Additional paid-in capital	181,533,274	181,479,645

Edgar Filing: REPLIGEN CORP - Form 10-Q

Accumulated deficit	(155,974,425)	(157,490,931)
Total stockholders' equity	25,859,985	24,289,658
Total liabilities and stockholders' equity	\$ 29,227,027	\$ 27,607,132

See accompanying notes

Table of Contents

REPLIGEN CORPORATION

STATEMENTS OF OPERATIONS

	Three months ended December 31,		Nine months ended December 31,	
	2005	2004	2005	2004
Revenue:				
Product revenue	\$ 2,957,828	\$ 2,259,763	\$ 9,686,199	\$ 6,365,649
Other revenue	29,925		339,925	
Total revenue	2,987,753	2,259,763	10,026,124	6,365,649
Operating expenses:				
Cost of product revenue	817,562	1,028,615	2,663,141	2,864,537
Research and development	1,235,740	1,039,812	3,749,863	3,703,122
Selling, general and administrative	1,340,691	1,241,890	3,818,842	3,410,224
Total operating expenses	3,393,993	3,310,317	10,231,846	9,977,883
Loss from operations	(406,240)	(1,050,554)	(205,722)	(3,612,234)
Investment income	203,928	107,325	552,620	305,291
Other income		750,000	1,169,608	750,000
Net income (loss)	\$ (202,312)	\$ (193,229)	\$ 1,516,506	\$ (2,556,943)
Earnings (loss) per share:				
Basic and diluted	\$ (.01)	\$ (.01)	\$.05	\$ (.09)
Weighted average shares outstanding:				
Basic	30,105,380	30,064,836	30,099,402	30,055,838
Diluted	30,105,380	30,064,836	30,666,688	30,055,838

See accompanying notes

Table of Contents

REPLIGEN CORPORATION

STATEMENT OF CASH FLOWS

UNAUDITED

	Nine months ended December 31,	
	2005	2004
Cash flows from operating activities:		
Net income (loss)	\$ 1,516,506	\$ (2,556,943)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	267,223	661,438
Stock based compensation expense		77,146
Reduction in bad debt reserve	(5,000)	
Changes in assets and liabilities:		
Accounts receivable	(891,457)	360,678
Inventories	(733,985)	190,241
Prepaid expenses and other current assets	137,530	(17,325)
Accounts payable	(379,136)	(205,233)
Accrued liabilities	262,606	384,859
Long-term liabilities	1,194	92,979
Net cash provided by (used in) operating activities	175,481	(1,012,160)
Cash flows from investing activities:		
Purchases of marketable securities	(9,218,663)	(12,308,387)
Redemptions of marketable securities	10,783,000	12,704,624
Purchases of property, plant and equipment	(558,283)	(24,401)
Net cash provided by investing activities	1,006,054	371,836
Cash flows from financing activities:		
Exercise of stock options	53,821	5,501
Principal payments under capital lease obligation	(5,646)	
Net cash provided by financing activities	48,175	5,501
Net increase (decrease) in cash	1,229,710	(634,823)
Cash and cash equivalents, beginning of period	3,216,681	3,958,677
Cash and cash equivalents, end of period	\$ 4,446,391	\$ 3,323,854
Non cash purchases of property, plant and equipment through capital lease obligation	\$ 170,550	\$
Disposal of fixed assets	\$	\$ 128,629

See accompanying notes

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 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 Form 10-K for the year ended March 31, 2005.

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.

Certain reclassifications of prior period data have been made to conform to the current reporting period.

2. Revenue Recognition

We apply the provisions of Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition to our revenue arrangements. We generate product revenues from the sale of our 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 No. 104, we recognize revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of any related receivable is reasonably assured.

During the nine-month period ended December 31, 2005, the Company received \$310,000 of cash from a sponsored research and development project under an agreement with the Stanley Medical Research Institute. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Research expenses in the accompanying statements of operations include funded and unfunded expenses. Additionally, during the three-month period ended December 31, 2005, the Company earned and recognized approximately \$30,000 in royalty revenue from ChiRhoClin, Inc.

3. Earnings (Loss) Per Share

We follow the provisions of Statement of Financial Accounting Standard (SFAS) No. 128, Presenting Earnings Per Share. Basic earnings per share for the periods ended December 31, 2005 and 2004 was 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 No. 128. Dilutive potential common shares include outstanding stock options.

Table of Contents

Basic and diluted weighted average shares outstanding were as follows:

	Three Months Ended		Nine Months Ended	
	December 31,		December 31,	
	2005	2004	2005	2004
Weighted average common shares outstanding	30,105,380	30,064,386	30,099,402	30,055,838
Dilutive common stock options			567,286	
Weighted average common shares outstanding, assuming dilution	30,105,380	30,064,386	30,666,688	30,055,838

For the three month period ended December 31, 2005, options to purchase 2,412,150 shares of our common stock at a weighted average exercise price of \$2.92 per share, were not included in the calculation of earnings per share because to do so would have been antidilutive. For the nine-month period ended December 31, 2005, options to purchase 962,950 shares at a weighted average exercise price of \$4.80 per share, 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.

As of December 31, 2004, there were outstanding options to purchase 2,199,400 shares of our common stock at a weighted average exercise price of \$3.00 per share and outstanding warrants to purchase 154,946 shares of our common stock at a weighted average exercise price of \$8.82 per share were not included in the calculation of earnings per share because to do so would have been antidilutive.

4. Stock-Based Compensation

We account for stock-based compensation under the provisions of SFAS No. 123 Accounting for Stock-Based Compensation. We continue to apply the intrinsic value method proscribed by APB No. 25 for employee stock options awards and elect the disclosure-only alternative for the same under SFAS No. 123. We follow the disclosure provisions of Statement of Financial Accounting Standards No. 148 (SFAS 148),

Accounting for Stock-Based Compensation Transition and Disclosure, and amendment of FASB Statement No. 123. SFAS 148 requires prominent disclosures in both annual and interim financial statements regarding the method of accounting for stock-based employee compensation and the effect of the method used to report results.

We have computed the pro forma disclosures required under SFAS Nos. 123 and 148 for all stock options granted to employees using the Black-Scholes option-pricing model prescribed by SFAS No. 123.

Table of Contents

If compensation expense for our stock plan had been determined in a manner consistent with SFAS No. 123, the pro forma net income (loss) and net income (loss) per share would have been as follows:

	Three months ended December 31, 2005	Three months ended December 31, 2004	Nine months ended December 31, 2005	Nine months ended December 31, 2004
Net income (loss) as reported	\$ (202,312)	\$ (193,229)	\$ 1,516,506	\$ (2,556,943)
Add:				
Stock-based employee compensation expense included in reported net income (loss)				63,167
Deduct:				
Stock-based employee compensation expense determined under fair value based method for all employee awards	(189,005)	(189,981)	(541,968)	(800,227)
Pro forma net income (loss)	(391,317)	(383,210)	974,538	(3,294,003)
Basic and diluted earnings per share:				
As reported	\$ (.01)	\$ (.01)	\$.05	\$ (.09)
Pro forma	\$ (.01)	\$ (.01)	\$.03	\$ (.11)

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 December 31, 2005, our investments included short-term marketable securities, the majority of which are classified as held-to-maturity investments as we have the positive intent and ability to hold to maturity. As a result, these investments are recorded at amortized cost. Marketable securities are investments with original maturities of greater than 90 days.

At December 31, 2005, marketable securities also include investment grade auction rate securities, which provide higher yields than money market and other cash equivalent investments. 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, which creates a highly liquid market for these securities. We do not intend to hold these securities to maturity, but rather to use the securities to provide liquidity as necessary. Auction rate securities are classified as available-for-sale and reported at fair value. Due to the reset feature and their carrying value equaling their fair value, there are no gross unrealized gains or losses from these short-term investments.

Long-term marketable securities are investment grade securities with maturities of greater than one year.

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

December 31, 2005

March 31, 2005

Edgar Filing: REPLIGEN CORP - Form 10-Q

Cash and cash equivalents	\$ 4,446,391	\$ 3,216,681
Marketable securities		
U.S. Government and agency securities	\$ 7,600,000	\$ 4,013,245
Auction rate securities	1,075,000	
Corporate and other debt securities	4,474,745	9,662,711
(Average remaining maturity, 6 months at December 31, 2005, assumes auction rate maturity set at date of next auction)		
	\$ 13,149,745	\$ 13,675,956
Long-term marketable securities		
U.S. Government and agency securities	\$ 2,847,620	\$ 5,200,000
Corporate and other debt securities	2,631,828	1,430,679
(Average remaining maturity, 17 months at December 31, 2005)		
	\$ 5,479,448	\$ 6,630,679

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

Table of Contents**6. Inventories**

Inventories are stated at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, outside processing costs and manufacturing overhead. Inventories at December 31, 2005 and March 31, 2005 consist of the following:

	<u>December 31, 2005</u>	<u>March 31, 2005</u>
Raw materials	\$ 739,223	\$ 172,336
Work-in-process	518,917	260,080
Finished goods	109,159	200,898
	<u> </u>	<u> </u>
Total	<u>\$ 1,367,299</u>	<u>\$ 633,314</u>

7. Accrued Liabilities

Accrued liabilities consist of the following:

	<u>December 31, 2005</u>	<u>March 31, 2005</u>
Other current liabilities	\$ 612,219	\$ 27,033
Research & development costs	518,041	248,490
Payroll & payroll related costs	405,744	290,139
Manufacturing related costs	514,631	
Professional and consulting costs	196,176	176,282
Other accrued expenses	130,700	172,031
Unearned revenue	4,635	71,494
Royalty expenses	85,120	1,195,156
	<u> </u>	<u> </u>
	<u>\$ 2,467,266</u>	<u>\$ 2,180,625</u>

8. Comprehensive Income/Loss

We follow the provisions of SFAS No. 130, Reporting Comprehensive Income. SFAS No. 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 nonowner sources. Our comprehensive income (loss) is equal to our reported net income (loss) for all periods presented.

9. 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 No. 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 No. 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 how to allocate resources and assess performance, identifies operating segments as 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 percentage of total revenue classified by geographic area:

	Three months ended		Nine months ended	
	December 31,		December 31,	
	2005	2004	2005	2004
Europe	53%	68%	54%	57%
US	46%	31%	45%	42%
Other	1%	1%	1%	1%
Total	100%	100%	100%	100%

Table of Contents

During the three months ended December 31, 2005 there were two customers who accounted for approximately 51% and 22% of revenues, respectively. During the three months ended December 31, 2004, there were two customers who accounted for approximately 66% and 16% of revenues, respectively. During the nine months ended December 31, 2005 there were two customers who accounted for 52% and 24% of revenues, respectively. During the nine months ended December 31, 2004 there were two customers who accounted for approximately 54% and 17% of revenues, respectively. At December 31, 2005, two customers accounted for 41% and 40% of our accounts receivable, respectively. At March 31, 2005, three customers accounted for 54%, 13% and 11% of accounts receivable, respectively.

10. New Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95 (SFAS No. 123R), which requires all companies to measure compensation cost for all share-based payments, including employee stock options, at fair value, effective for public companies for annual periods beginning after November 15, 2005. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123. However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The adoption of SFAS No. 123R may have a significant impact on our results of operations, although it will have no impact on our overall financial position. The Company is evaluating SFAS No. 123R and has not yet determined the estimated financial impact on future operations of expensing the fair value of stock options.

In April 2005, the SEC issued Staff Accounting Bulletin 107, Shares-Based Payment, which expresses the SEC Staff's views regarding the application of SFAS No. 123(R). At present, we have not evaluated the effect of this standard.

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151 (SFAS No. 151), Inventory Costs, an Amendment of APB No. 43, Chapter 4. The amendments made by SFAS No. 151 will require that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) be recognized as current-period charges and requires the allocation of fixed production overheads to inventory, based on the normal capacity of production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after November 15, 2005. The Company expects that the adoption of SFAS No. 151 will not have a significant impact on its financial position and results of operations.

11. Settlement Agreement

During the three-month period ended June 30, 2005, Repligen entered into a Settlement Agreement (the Agreement) with ChiRhoClin, Inc., in full settlement of their arbitration proceedings. Under terms of the Agreement, Repligen was not required to pay approximately \$1,170,000 of unremitted royalties to ChiRhoClin related to sales from February 2004 through March 2005. This amount, which was accrued at March 31, 2005, was reversed at the time the Agreement was signed and was recorded as other income in the quarter ended June 30, 2005.

In addition, Repligen received a payment of \$750,000 and is entitled to continue to market SecreFlo® for the next several years under a royalty structure more favorable to Repligen than under the original Licensing Agreement. ChiRhoClin is obligated to deliver a certain amount of SecreFlo® to Repligen over the next few years. This payment was recorded as Accrued Liabilities and has a balance of \$567,000 as of December 31, 2005. Application of the provisions of Emerging Issues Task Force (EITF) Issue No. 02-16, Accounting by a Customer (including a Reseller) for Certain Consideration Received from a Vendor (EITF 02-16) will result in the reduction of cost of goods sold as inventory purchased from ChiRhoClin is sold. During the nine months ended December 31, 2005, cost of goods sold was reduced approximately 9% as a result of the application of the provisions of EITF 02-16 to the settlement proceeds. We anticipate that this will continue to result in an improved gross margin for the remainder of fiscal 2006 compared to fiscal 2005.

Table of Contents

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

Overview

We are a biopharmaceutical company focused 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 naturally occurring drug candidates in diseases such as schizophrenia, obsessive-compulsive disorder, bipolar disorder and neurodegeneration. In addition, we sell Protein A for monoclonal antibody purification and SecreFlo[®] for assessment of pancreatic disorders. In fiscal 2005 and for the first nine months of fiscal 2006, we have experienced significant growth in sales and profits from our commercial products business. Our business strategy is to deploy the profits from our current commercial products and any revenue that we may receive from our patents to enable us to invest in the development of our product candidates in the treatment area of neuropsychiatric diseases while at the same time minimize our operating losses.

We are subject to a number of risks typically associated with similar companies in the biotechnology industry. Principally those risks are associated with our dependence on collaborative arrangements, development by us or our competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, results of clinical trials, compliance with the U.S. Food and Drug Administration and other governmental regulations and approval requirements, as well as the ability to grow our business and to obtain adequate capital to fund this growth, as well as other potential risk factors included in the filings made by us from time to time with the SEC, including under the section entitled "Certain Factors That May Affect Future Results" in our Annual Report on Form 10-K for the year ended March 31, 2005.

Critical Accounting Policies and Estimates

The SEC requires that reporting companies discuss their most critical accounting policies in Management's Discussion and Analysis of Financial Condition and Results of Operations. The SEC indicated that a critical accounting policy is one that is important to the portrayal of a company's financial condition and operating 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.

We have identified the policies and estimates below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management's Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see the Notes to Financial Statements of this report.

Revenue Recognition

We apply Staff Accounting Bulletin No. 104, Revenue Recognition (SAB No. 104) to our revenue arrangements. We generate product revenues from the sale of our 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 No. 104, we recognize revenue related to product sales upon delivery of the product to the customer as long as there is persuasive evidence of a sale, the price is fixed or determinable and collection of the related receivable is reasonably assured.

Edgar Filing: REPLIGEN CORP - Form 10-Q

During the nine month period ended December 31, 2005 we received non-product revenues from sponsored research and development projects under an agreement with the Stanley Medical Research Institute. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Research expenses in the accompanying statements of operations include funded and unfunded expenses. Additionally, during the three-month period ended December 31, 2005, the Company earned approximately \$30,000 in royalty revenue pursuant to a settlement agreement with ChiRhoClin, Inc., discussed further in Cost of Goods Sold, below. This amount is included in Other Revenue in the accompanying Statement of Operations.

Table of Contents

Accrued Liabilities

We prepare our financial statements in accordance with accounting principles generally accepted in the United States. These principles require that we estimate accrued liabilities. This process involves identifying services, which have been performed on our 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 expenses for which we accrue expenses include fees paid to our contract manufacturers in conjunction with the production of clinical materials and service fees paid to organizations for their performance in conducting our clinical trials. In the event that we do not identify certain costs which have begun to be incurred or we under or over-estimate the level of services performed or the costs of such services, our 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. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Cost of Goods Sold

During the three-month period ended June 30, 2005, Repligen entered into a Settlement Agreement (the Agreement) with ChiRhoClin, Inc., (CRC) in full settlement of their arbitration proceedings. Under the terms of the Agreement, Repligen received a payment of \$750,000 and will be entitled to continue to market SecreFlo® for the next several years. The balance of this payment is recorded in Accrued Liabilities as of December 31, 2005. CRC also agreed to continue to supply additional product to the Company. The Emerging Issues Task Force (EITF) Issue No. 02-16, Accounting by a Customer (including a Reseller) for Certain Consideration Received from a Vendor (EITF 02-16) addresses the accounting and income statement classification for consideration given by a vendor to a customer in connection with the sale of the vendor's products. The EITF concluded that such consideration received from vendors should be reflected as a decrease in prices paid for inventory and recognized in cost of sales as the related inventory is sold, unless specific criteria are met qualifying the consideration for treatment as reimbursement of specific, identifiable incremental costs. Application of the provisions of EITF 02-16 will result in the reduction of cost of goods sold as inventory purchased from CRC is sold. During the three months ended December 31, 2005, cost of goods sold was lower by approximately 9% as a result of the application of the provisions of EITF 02-16 to the settlement proceeds. We anticipate this will continue to contribute to an improved gross margin for the remainder of fiscal 2006 compared to fiscal 2005.

Results of Operations

Three months ended December 31, 2005 vs. December 31, 2004

Total revenue

Total revenue for the three-month periods ended December 31, 2005 and December 31, 2004, were approximately \$2,988,000 and \$2,260,000 respectively, an increase of \$728,000 or 32%. During the three-month period ended December 31, 2005 an increase in the volume of Protein A sales accounted for the majority of the increase as they increased to \$2,412,000 from \$1,725,000 during the same period in the prior fiscal year. Our revenues are subject to significant quarterly fluctuations based on the timing of large-scale production orders of Protein A.

Operating expenses

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total operating expenses for the three-month periods ended December 31, 2005 and December 31, 2004 were approximately \$3,394,000 and \$3,310,000, respectively, an increase of \$84,000 or 3%.

Research and development expenses for the three-month periods ended December 31, 2005 and December 31, 2004 were approximately \$1,236,000 and \$1,039,000, respectively, an increase of \$196,000 or 19%. During the three-month period ended December 31, 2005, this increase is largely attributable to an increase in clinical trial expenses of \$198,000, clinical material expenses of \$59,000 and personnel expenses of \$56,000 off-set by a \$103,000 decrease in external research expenses and \$27,000 decrease in consulting costs. 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 for the three-month periods ended December 31, 2005 and December 31, 2004 were approximately \$1,341,000 and \$1,242,000 respectively, an increase of \$99,000 or 8%. This increase is attributable to an increase in professional fees of \$47,000 and increased personnel expenses of \$66,000 during the three-month period ended December 31, 2005.

Cost of product revenue for the three-month periods ended December 31, 2005 and December 31, 2004 were approximately \$817,000 and \$1,029,000, respectively, a decrease of \$211,000 or 21%. This decrease in cost of product revenue primarily reflects the decrease in royalty and amortization expense of license fees on the SecreFlo® product of \$178,000 and a one time inventory write off of \$113,000 incurred during the period ended December 31, 2004 being partially offset by costs associated with increased revenue and increased personnel costs of \$60,000 in the period ended December 31, 2005. Gross profit for the three-month periods ended December 31, 2005 and 2004 was \$2,141,000 or 72% of product revenue and \$1,231,000 or 54% of product revenue, respectively. Gross profit is positively impacted in periods when product sales are higher because there is more absorption of fixed costs. We anticipate that higher product sales and the aforementioned settlement with ChiRhoClin will result in an improved margin for the remainder of fiscal 2006 compared to fiscal 2005.

Interest income

Interest income for the three-month periods ended December 31, 2005 and December 31, 2004 was approximately \$204,000 and \$107,000 respectively. The increase in the three months ended December 31, 2005 is a result of increased interest rates.

Nine months ended December 31, 2005 vs. December 31, 2004

Total revenue

Total revenue for the nine-month periods ended December 31, 2005 and December 31, 2004 was approximately \$10,026,000 and \$6,366,000 respectively, an increase of \$3,660,000 or 57%. During the nine-month period ended December 31, 2005 Protein A sales increased to \$8,169,000 from \$4,804,000 during the same period in the prior fiscal year. This increase in total revenue is attributable to increased demand for our Protein A products during the nine-month period ended December 31, 2005. Our revenues are subject to quarterly fluctuations, based on the timing of large-scale production orders of Protein A.

Operating expenses

Total operating expenses for the nine-month periods ended December 31, 2005 and December 31, 2004 were approximately \$10,232,000 and \$9,978,000, respectively, an increase of \$254,000 or 3%.

Research and development expenses for the nine-month periods ended December 31, 2005 and December 31, 2004 were approximately \$3,750,000 and \$3,703,000, respectively, an increase of \$47,000 or 1%. Significant fluctuations in research and development expenses may occur from period to period depending on the nature and extent of development activities over any given time frame. This increase is largely attributable to increases in clinical trial expenses of \$170,000, off-set by a decrease of \$137,000 in external research expenses during the

Edgar Filing: REPLIGEN CORP - Form 10-Q

nine-month period ended December 31, 2005.

Selling, general and administrative expenses for the nine-month periods ended December 31, 2005 and December 31, 2004 were approximately \$3,819,000 and \$3,410,000, respectively, an increase of \$409,000 or 12%. This increase is largely attributable to increased litigation expenses of \$148,000, professional expenses of \$139,000 as well as increased personnel expenses of \$130,000 in fiscal year 2006.

Cost of product revenue for the nine-month periods ended December 31, 2005 and December 31, 2004 were approximately \$2,663,000 and \$2,865,000, respectively, a decrease of \$202,000 or 7%. Gross profit for the nine-month periods ended December 31, 2005 and 2004 was \$7,023,000 or 73% of product revenue and \$3,501,000 or 55% of total revenue, respectively. This decrease in cost of product revenue in the nine-month period ended December 31, 2005 is attributable to the decrease of royalties and amortization expense of license fees on the SecreFlo® product of \$895,000 due to the ChiRhoClin settlement, offset by an increase in direct material expenses due to higher sales of \$631,000. Gross profit is positively impacted in periods when product sales are higher because there is more

Table of Contents

absorption of fixed costs. We anticipate that higher product sales and the aforementioned settlement with ChiRhoClin will result in an improved margin in fiscal 2006 compared to fiscal 2005.

Interest income

Interest income for the nine-month periods ended December 31, 2005 and December 31, 2004 was approximately \$553,000 and \$305,000, respectively. The increase in the nine months ended December 31, 2005 is a result of increased interest rates.

Other income

During the nine-month period ended December 31, 2005, Repligen entered into a Settlement Agreement with ChiRhoClin, Inc., in full settlement of their arbitration proceedings. Under terms of the Agreement, Repligen was not required to pay approximately \$1,170,000 of previously accrued but unremitted royalties to ChiRhoClin related to SecreFlo® sales from February 2004 to March 2005. This amount, which was accrued at March 31, 2005, was reversed at the time of settlement and is recorded as other income in the nine months ended December 31, 2005.

Other income for the nine-month period ended December 31, 2004 consists of \$750,000 in proceeds from a legal settlement from Pro-Neuron, received in November 2004 (for further information, see Legal Proceedings in the Form 10-K for the year ended March 31, 2005).

Liquidity and capital resources

We have financed our operations primarily through sales of equity securities and revenues derived from product sales and grant and research agreements. Our revenue for the foreseeable future will be primarily limited to our product revenue related to Protein A and SecreFlo®. 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 and marketable securities at December 31, 2005 totaled \$23,076,000, a decrease of \$447,000 from \$23,523,000 at March 31, 2005.

Our operating activities provided cash of approximately \$175,000 for the nine-month period ended December 31, 2005 consisting of net income of approximately \$1,517,000 and non-cash charges of approximately \$267,000 for depreciation and amortization. These sources of cash were offset by a decrease in accounts payable of approximately \$379,000, as well as an increase in accrued liabilities of \$263,000. An increase of approximately \$734,000 in inventories was a result of purchases related to a manufacturing process conversion that will produce salable product in upcoming quarters. Additionally, an increase in accounts receivable of approximately \$891,000 was a result of timing of shipments during the quarter. We do not expect further significant increases for the remainder of the fiscal year.

In May 2005, we announced a settlement with our sole supplier of SecreFlo®. As a result of this settlement we received a payment of \$750,000 in the period ended September 30, 2005 and will continue to market SecreFlo® for the next several years under a more favorable royalty structure. In addition, as a result of this settlement we were relieved of our previously accrued but unremitted obligation to pay approximately

Edgar Filing: REPLIGEN CORP - Form 10-Q

\$1,170,000 in royalties related to prior sales. This was recorded as other income in the period ended June 30, 2005.

Our cash was reduced by capital expenditures of \$558,000 for the nine-month period ended December 31, 2005. Our investing activities provided cash of approximately \$1,006,000 primarily from redemptions of marketable securities. 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. Our investment policy also limits the amount of credit exposure to any one issue, issuer (with the exception of U.S. agency obligations) and type of investment. We do not expect any material loss from our investment in marketable securities.

Working capital increased to \$18,075,000 at December 31, 2005 from \$15,673,000 at March 31, 2005 primarily as a result of an increase in inventories, cash and accounts receivable.

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.

Table of Contents

Absent an acquisition of a product candidate, 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 continued investment in our intellectual property portfolio. We expect to incur approximately \$1,000,000 of capital investment primarily to expand our Protein A manufacturing facility in the next twelve months.

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 December 31, 2005, we did not have any debt arrangements that were not reflected in our balance sheet.

Commitments

As of December 31, 2005 we had the following fixed obligations and commitments:

	Payments Due By Period				
		Less than 1	1 3	3 5	More than 5
	Total	Year	Years	Years	Years
	(In thousands)				
Operating lease obligations	\$ 2,471	\$ 384	\$ 910	\$ 856	\$ 321
Capital lease obligations (1)	197	62	93	42	
Purchase obligations (2)	74	74			
Contractual obligations (3)	720	161	297	232	30
Total	\$ 3,462	\$ 681	\$ 1,300	\$ 1,130	\$ 351

(1) The above amounts represent principal payments only, while principal and interest are payable through a fixed annual payment of approximately \$52,000.

(2) These amounts represent minimum commitments due under third-party manufacturing agreements and non-cancelable purchase orders.

(3) These amounts include payments for license, supply and consulting agreements.

Table of Contents**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 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 current and future 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 "Certain Factors That May Affect Future Results" in our Annual Report on Form 10-K for the year ended March 31, 2005.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 increase in interest rates would result in an approximate \$123,000 decrease in the fair value of our investments as of December 31, 2005. 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

Edgar Filing: REPLIGEN CORP - Form 10-Q

As of December 31, 2005, Repligen, under the supervision and with the participation of Repligen's management, including Walter C. Herlihy, Repligen's Chief Executive Officer and President (Principal executive officer), and Dan W. Muehl, Repligen's Chief Financial Officer, (Principal accounting and financial officer) evaluated the effectiveness of Repligen's disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, Repligen's Chief Executive Officer and President (Principal executive officer) and Chief Financial Officer (Principal accounting and financial officer), concluded that, as of December 31, 2005, Repligen's disclosure controls and procedures are effective

Table of Contents

in ensuring that material information relating to Repligen required to be disclosed by Repligen in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such material information is accumulated and communicated to Repligen's management, including Repligen's Chief Executive Officer and President (Principal executive officer) and Chief Financial Officer (Principal accounting, and financial officer), as appropriate to allow timely decisions regarding required disclosure. During the period covered by this report, there have been no changes in Repligen's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, Repligen's internal control over financial reporting.

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

On January 5, 2006, Repligen and The University of Michigan jointly filed a complaint against Bristol-Myers Squibb Corporation in the United States District Court for the Eastern District of Texas for infringement of U.S. Patent No. 6,685,941 for the manufacture for commercial sale of Orencia®. The 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 United States Navy. Repligen has retained Fish & Richardson P.C. to represent it in this matter.

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 the business, financial condition or results of operations.

ITEM 6. EXHIBITS

(a) Exhibits

EXHIBIT	DESCRIPTION
3.1	Restated Certificate of Incorporation, dated November 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).
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).
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).
10.1	Repligen Executive Incentive Compensation Plan (filed as Exhibit 10.1 to Repligen Corporation's Current Report on form 8-K filed on December 14, 2005 and incorporated herein by reference).
31.1	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer (furnished herewith).
31.2	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer (furnished herewith).
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 (furnished 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: February 9, 2006

By: /s/ Walter C. Herlihy
Chief Executive Officer and President

(Principal Executive Officer)

Repligen Corporation

Date: February 9, 2006

By: /s/ Daniel W. Muehl
Chief Financial Officer

(Principal Financial and Accounting Officer)

Repligen Corporation

Table of Contents

EXHIBIT INDEX

EXHIBIT	DESCRIPTION
3.1	Restated Certificate of Incorporation, dated November 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).
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).
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).
10.1	Repligen Executive Incentive Compensation Plan (filed as Exhibit 10.1 to Repligen Corporation's Current Report on form 8-K filed on December 14, 2005 and incorporated herein by reference).
31.1	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer (furnished herewith).
31.2	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer (furnished herewith).
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 (furnished herewith).