

REPLIGEN CORP  
Form 10-Q  
February 08, 2007  
[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 December 31, 2006

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)

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

41 Seyon Street, Bldg. 1, Suite 100

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 7, 2007.

<b>Common Stock, par value \$.01 per share</b>	<b>30,385,635</b>
<b>Class</b>	<b>Number of Shares</b>

---

**Table of Contents**

REPLIGEN CORPORATION

INDEX

	<b><u>PAGE</u></b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements (Unaudited) Balance Sheets as of December 31, 2006 and March 31, 2006</u>	3
<u>Statements of Operations for the Three and Nine Month Periods Ended December 31, 2006 and 2005</u>	4
<u>Statements of Cash Flows for the Nine Months Ended December 31, 2006 and 2005</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>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	19
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	19
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>	20
<u>Signatures</u>	21
<u>Exhibit Index</u>	22

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

	<b>December 31, 2006</b>	<b>March 31, 2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,288,248	\$ 5,428,477
Marketable securities	14,204,039	13,447,600
Accounts receivable, less reserve of \$ 10,000	1,977,608	593,725
Inventories	1,089,600	1,465,592
Prepaid expenses and other current assets	518,150	575,038
<b>Total current assets</b>	<b>23,077,645</b>	<b>21,510,432</b>
Property, plant and equipment, at cost:		
Leasehold improvements	3,204,195	2,475,169
Equipment	2,231,788	1,769,367
Furniture and fixtures	205,806	186,874
	5,641,789	4,431,410
Less-accumulated depreciation and amortization	(2,458,984)	(2,074,049)
	3,182,805	2,357,361
Long-term marketable securities	2,431,797	4,531,548
Restricted cash	200,000	200,000
<b>Total assets</b>	<b>\$ 28,892,247</b>	<b>\$ 28,599,341</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 486,485	\$ 1,066,445
Accrued liabilities	2,896,119	1,869,349
<b>Total current liabilities</b>	<b>3,382,604</b>	<b>2,935,794</b>
Long-term liabilities	199,454	230,518
<b>Total liabilities</b>	<b>3,582,058</b>	<b>3,166,312</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, no shares issued or outstanding		
Common stock, \$.01 par value, 40,000,000 shares authorized, 30,385,635 shares issued and outstanding at December 31, 2006 and 30,377,635 shares at March 31, 2006, respectively	303,856	303,776
Additional paid-in capital	182,582,698	181,985,274
Deferred compensation		(61,950)
Accumulated deficit	(157,576,365)	(156,794,071)
<b>Total stockholders' equity</b>	<b>25,310,189</b>	<b>25,433,029</b>

Edgar Filing: REPLIGEN CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 28,892,247	\$ 28,599,341
--	---------------	---------------

See accompanying notes.

**Table of Contents**

**REPLIGEN CORPORATION**  
**STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	Three months ended December 31,		Nine months ended December 31,	
	2006	2005	2006	2005
<b>Revenue:</b>				
Product revenue	\$ 3,633,683	\$ 2,957,828	\$ 9,677,157	\$ 9,686,199
Other revenue	248,756	29,925	698,270	339,925
<b>Total revenue</b>	<b>3,882,439</b>	<b>2,987,753</b>	<b>10,375,427</b>	<b>10,026,124</b>
<b>Operating expenses: (1)</b>				
Cost of product revenue	804,913	817,562	2,712,885	2,663,141
Research and development	1,674,584	1,235,740	4,472,224	3,749,863
Selling, general and administrative	1,659,931	1,340,691	4,664,347	3,818,842
<b>Total operating expenses</b>	<b>4,139,428</b>	<b>3,393,993</b>	<b>11,849,456</b>	<b>10,231,846</b>
Income (loss) from operations	(256,989)	(406,240)	(1,474,029)	(205,722)
Investment income	240,290	203,928	700,765	552,620
Interest expense	(3,010)		(9,030)	
Other income				1,169,608
<b>Net income (loss)</b>	<b>\$ (19,709)</b>	<b>\$ (202,312)</b>	<b>\$ (782,294)</b>	<b>\$ 1,516,506</b>
<b>Basic and diluted earnings (loss) per share:</b>	<b>\$</b>	<b>\$ (0.01)</b>	<b>\$ (0.03)</b>	<b>\$ 0.05</b>
<b>Weighted average shares outstanding:</b>				
Basic	30,375,635	30,105,380	30,365,840	30,099,402
Diluted	30,375,635	30,105,380	30,365,840	30,666,688

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

Cost of product revenue	\$ 6,497	\$	\$ 19,058	\$
Research and development	59,335		170,158	
Selling, general and administrative	70,811		451,438	

See accompanying notes.

**Table of Contents**

**REPLIGEN CORPORATION**  
**STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	<b>Nine months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net (loss) income:	\$ (782,294)	\$ 1,516,506
Adjustments to reconcile net income to net cash used in operating activities		
Depreciation and amortization	384,935	267,223
Stock-based compensation expense	640,654	
Bad debt reserve		(5,000)
Changes in assets and liabilities:		
Accounts receivable	(1,383,883)	(891,457)
Inventories	375,992	(733,985)
Prepaid expenses and other current assets	45,049	137,530
Accounts payable	(579,960)	(379,136)
Accrued liabilities	1,064,662	262,606
Long-term liabilities	(31,064)	1,194
<b>Net cash (used in) provided by operating activities</b>	<b>(265,909)</b>	<b>175,481</b>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(10,194,849)	(9,218,663)
Redemptions of marketable securities	11,550,000	10,783,000
Purchases of property, plant and equipment	(1,210,379)	(558,283)
<b>Net cash provided by investing activities</b>	<b>144,772</b>	<b>1,006,054</b>
<b>Cash flows from financing activities:</b>		
Exercise of stock options	18,800	53,821
Principal payments under capital lease obligation	(37,892)	(5,646)
<b>Net cash provided by financing activities</b>	<b>(19,092)</b>	<b>48,175</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(140,229)</b>	<b>1,229,710</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>5,428,477</b>	<b>3,216,681</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 5,288,248</b>	<b>\$ 4,446,391</b>
<b>Supplemental disclosure of noncash activities:</b>		
Non-cash purchase of equipment through capital lease obligation	\$	\$ 170,550

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, 2006.

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**

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 an arrangement, the sale price is fixed or determinable and collection of the related receivable is reasonably assured.

During the three month period ended December 31, 2006, we recognized approximately \$213,000 in revenue 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. Additionally, during the three month period ended December 31, 2006, the Company earned and recognized approximately \$36,000 in royalty revenue from ChiRhoClin, Inc. Please see footnote 11 for a summary of the royalty arrangement with ChiRhoClin, Inc.

**3. Earnings (Loss) Per Share**

We follow the provisions of Statement of Financial Accounting Standard (SFAS) No. 128, Presenting Earnings Per Share, (SFAS No. 128). Basic earnings per share for the three and six month periods ended December 31, 2006 and 2005 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 No. 128. Dilutive potential common shares include outstanding stock options.

Basic and diluted weighted average shares outstanding were as follows:



**Table of Contents**

	Three Months Ended		Nine Months Ended	
	December 31,		December 31,	
	2006	2005	2006	2005
Weighted average common shares	30,375,635	30,105,380	30,365,840	30,099,402
Dilutive common stock options				567,286
Weighted average common share, assuming dilution	30,375,635	30,105,380	30,365,840	30,666,688

For the three and nine month periods ended December 31, 2006 options to purchase 2,410,750 shares of our common stock at a weighted average exercise price of \$3.16 were excluded from the calculation of diluted earnings per share because the Company incurred a net loss and they would be anti-dilutive.

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.

#### 4. Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board ( 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. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123, Accounting for Stock-Based Compensation, ( 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 financial statements based on their fair value over the requisite service period. Pro forma disclosure is no longer an alternative. In March 2005, the SEC issued Staff Accounting Bulletin ( SAB ) No. 107 ( SAB No. 107 ), which expressed the views of the SEC regarding the interaction between SFAS No. 123R and certain rules and regulations of the SEC. SAB No. 107 provides guidance related to the valuation of share-based payment arrangements for public companies, including assumptions such as expected volatility and expected term.

Effective April 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123R, using the modified prospective transition method. Under this transition method, compensation cost recognized in the statement of operations for the nine months ended December 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123 and (b) compensation cost for all share-based payments granted, modified or settled subsequent to April 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated.

For the three and nine months ended December 31, 2006, the Company recorded stock-based compensation expense of approximately \$137,000 and \$641,000 for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan. Basic and diluted earnings per share amounts for the three and nine months ended December 31, 2006 were decreased by \$0.00 and \$0.03 respectively as a result of the adoption of SFAS No. 123R.

The Company currently has the following stock-based employee compensation plans which are subject to the provisions of SFAS No. 123R: the 1992 Repligen Corporation Stock Option Plan, as amended, and the Amended and Restated 2001 Repligen Corporation Stock Plan (collectively, the Plans ). The 1992 Repligen Corporation Stock Option Plan expired on September 14, 2001, though this had no impact on outstanding option grants. Options granted prior to the date of termination remain outstanding and may be exercised in accordance with their terms.

The Plans allow for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of Common Stock. Historically, incentive options granted to employees under the Plans generally vested 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 December 31, 2006, options to purchase 1,432,250 shares were outstanding under the Amended and Restated 2001 Repligen Corporation Plan and 978,500 were outstanding under the 1992 Repligen Corporation Stock Option Plan. At



**Table of Contents**

December 31, 2006, 394,109 shares were available for future grant under the Amended and Restated 2001 Repligen Corporation Stock Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value on the grant date of stock-based compensation for stock options granted under the Plans. The fair values of stock options granted during the three and nine months ended December 31, 2006 and 2005 were calculated using the following estimated weighted- average assumptions:

	Three months ended		Nine months ended	
	December 31, 2006	December 31, 2005	December 31, 2006	December 31, 2005
Expected term (years)	6.5	7	6.5	7
Volatility	78.65%	92.17%	78.65%-91.86	92.17%-94.41
Risk-free interest rate	4.44%	4.46%	4.44%-5.07%	3.83%-4.46%

Expected dividend yield

**Expected term** - The expected term of options granted represents the period of time for which the options are expected to be outstanding and is derived from the Company's historical stock option exercise experience and option expiration data. For option grants made subsequent to the adoption of SFAS No. 123R, the expected life of stock options granted is based on the simplified method allowable under SAB No. 107.

Accordingly, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. In addition, for purposes of estimating the expected term, the Company has aggregated all individual option awards into one group as the Company does not expect substantial differences in exercise behavior among its employees.

**Expected volatility** - The expected volatility is a measure of the amount by which the Company's stock price is expected to fluctuate during the expected term of options granted. The Company determines the expected volatility solely based upon the historical volatility of the Company's Common Stock over a period commensurate with the option's expected term. The Company does not believe that the future volatility of its Common Stock over an option's expected term is likely to differ significantly from the past.

**Risk-free interest rate** - The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date.

**Expected dividend yield** - The Company has never declared or paid any cash dividends on any of its capital stock and does not expect to do so in the foreseeable future. Accordingly, the Company uses an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

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. Prior to the adoption of SFAS No. 123R, the Company accounted for forfeitures upon occurrence as permitted under SFAS No. 123. 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.

Prior to April 1, 2006, the Company applied the pro forma disclosure requirements under SFAS No. 123 and accounted for its stock-based employee compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, ( APB No. 25 ) and related interpretations. Accordingly, no stock-based employee compensation cost was recognized in the statement of operations for the three and nine month periods ended December 31, 2005, as all stock options granted under the Plans had an exercise price equal to the market value of the underlying Common Stock on the date of grant.

The following table illustrates the effect on net income and net income per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Plans for the three and nine months ended December 31, 2005. Since stock-based compensation expense for the three and nine months ended December 31, 2006 was calculated under the provisions of SFAS No. 123R, there is no disclosure of pro forma net income and net income per share for that period. For purposes of the pro forma disclosure for the three and nine months ended December 31, 2005 set forth in



**Table of Contents**

the table below, the value of the options is estimated using a Black-Scholes option pricing model and amortized on a straight-line basis to expense over the options vesting periods.

	Three Months Ended December 31, 2005	Nine Months Ended December 31, 2005
Net (loss) income as reported	\$ (202,312)	\$ 1,516,506
Deduct: Stock-based employee compensation cost that would have been included in the determination of net loss as reported if the fair value method had been applied to all awards	\$ (189,005)	\$ (541,968)
Pro forma net (loss) income	\$ (391,317)	\$ 974,538
Basic and diluted net income (loss) per common share, as reported	\$ (0.01)	\$ 0.05
Basic and diluted net income (loss) per common share, as pro forma	\$ (0.01)	\$ 0.03

Information regarding option activity for the nine months ended December 31, 2006 under the Plans is summarized below:

Options Outstanding (in thousands)	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousand)
Options outstanding at April 1, 2006	2,403	\$ 3.17	
Granted	204	2.98	
Exercised	(18)	1.04	
Forfeited/Cancelled	(178)	3.27	
Options outstanding at December 31, 2006	2,411	\$ 3.16	5.39 \$ 1,230
Options exercisable at December 31, 2006	1,642	\$ 3.13	4.01 \$ 1,057
Vested and expected to vest at December 31, 2006 (1)	2,343	\$ 2.56	5.30 \$ 1,221

(1) This represents the number of vested options as of December 31, 2006 plus the number of unvested options expected to vest as of December 31, 2006 based on the unvested outstanding options at December 31, 2006 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 previously in Note 4. 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 December 29, 2006 of \$2.81 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 December 29, 2006.

The weighted average grant date fair value of options granted during the nine months ended December 31, 2006 was \$2.31. The total fair value of stock options that vested during the three months ended December 31, 2006 and 2005 was approximately \$9,000 and \$11,000, respectively.



**Table of Contents**

As of December 31, 2006, there was \$1,460,000 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 3.00 years. The Company expects approximately 701,000 in unvested options to vest over the next five years.

The range of exercise prices for options outstanding and exercisable as of December 31, 2006 are as follows:

Range of Exercise Prices	Outstanding as of December 31, 2006			Exercisable as of December 31, 2006		
	Number of Shares	Weighted Average Remaining Contractual Life in years	Weighted Average Exercise price	Number of Shares	Weighted Average Exercise price	
\$0.00 - \$1.24	37,000	1.63	\$ 0.74	37,000	\$ 0.74	
\$1.25 - \$2.49	951,000	3.62	1.63	780,400	1.58	
\$2.50 - \$3.73	865,250	6.84	3.04	478,100	3.03	
\$3.74 - \$4.98	142,500	8.94	4.19	7,300	4.47	
\$4.99 - \$6.22	196,000	6.23	5.53	119,999	5.54	
\$6.23 - \$7.47	5,000	3.72	7.19	5,000	7.19	
\$7.48 - \$8.56	214,000	4.94	7.93	214,000	7.93	
	2,410,750	5.39	\$ 3.16	1,641,799	\$ 3.13	

**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, 2006, 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. Long-term marketable securities are investment grade securities with maturities of greater than one year.

At December 31, 2006, 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.

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

	December 31, 2006	March 31, 2006
Cash and cash equivalents	\$ 5,288,248	\$ 5,428,477
Marketable securities:		
U.S. Government and agency securities	\$ 3,449,656	\$ 8,048,129
Auction rate securities	775,000	1,075,000
Corporate and other debt securities	9,979,383	4,324,471
(Average remaining maturity, 4 months at December 31, 2006, assumes auction rate maturity set at date of next auction)	\$ 14,204,039	\$ 13,447,600
Long-term marketable securities:		
U.S. Government and agency securities	\$ 959,388	\$ 1,900,000

Edgar Filing: REPLIGEN CORP - Form 10-Q

Corporate and other debt securities	1,472,409	2,631,548
(Average remaining maturity, 13 months at December 31, 2006)	\$ 2,431,797	\$ 4,531,548

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, 2006 and March 31, 2006 consist of the following:

	<b>December 31, 2006</b>	<b>March 31, 2006</b>
Raw materials	\$ 516,601	\$ 600,948
Work -in -process	519,359	596,386
Finished goods	53,640	268,258
 Total	 \$ 1,089,600	 \$ 1,465,592

**7. Accrued Liabilities**

Accrued liabilities consist of the following:

	<b>As of December 31, 2006</b>	<b>As of March 31, 2006</b>
Payroll & payroll related costs	\$ 497,386	\$ 474,923
Research & development costs	809,820	436,016
Professional and consulting costs	671,303	320,694
Other accrued expenses	174,981	62,767
Unearned revenue	400,530	38,599
Other current liabilities	342,100	536,350
 Total	 \$ 2,896,119	 \$ 1,869,349

**8. Comprehensive Income/Loss**

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

**9. Segment Reporting**

We follow the provisions of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, ( SFAS No. 131 ). 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:

Edgar Filing: REPLIGEN CORP - Form 10-Q

	Three months ended December 31,		Nine months ended December 31,	
	2006	2005	2006	2005
Europe	36%	53%	53%	54%
US	64%	46%	46%	45%
Other	0%	1%	1%	1%
Total	100%	100%	100%	100%

**Table of Contents**

During the three months ended December 31, 2006 there were two customers who accounted for approximately 42% and 33% of product revenues, respectively. During the three months ended December 31, 2005 there were two customers who accounted for approximately 51% and 22% of product revenues, respectively. At December 31, 2006, two customers accounted for 43% and 37% of our accounts receivable. At March 31, 2006, four customers accounted for 25%, 25%, 13% and 11% of accounts receivable, respectively.

**10. New Accounting Pronouncements**

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109 (the *Interpretation*). The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. The Company has not completed its evaluation of the Interpretation, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In September 2006, FASB issued Statement No. 157, *Accounting for Fair Value Measurements* (SFAS 157). SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years, with early adoption permitted. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

**11. Settlement Agreement**

In February 2004, Repligen terminated the September 1999 Licensing Agreement with ChiRhoClin, its supplier of SecreFlo<sup>®</sup>, based on ChiRhoClin's alleged failure to meet its obligations under the Licensing Agreement.

On April 9, 2004, Repligen filed an arbitration demand against ChiRhoClin with the American Arbitration Association in New York seeking to recover payments made to ChiRhoClin and additional damages. In this arbitration demand, Repligen alleged that ChiRhoClin breached several of its obligations under the September 1999 Licensing Agreement including failure to use best efforts to obtain various FDA approvals and to manufacture and supply SecreFlo<sup>®</sup>, in a timely manner. In June 2004, ChiRhoClin filed a counterclaim alleging that Repligen had wrongfully terminated the Licensing Agreement.

On May 9, 2005, Repligen entered into a Settlement Agreement (the *Agreement*) with ChiRhoClin, Inc., in full settlement of the arbitration proceedings described above. Under the terms of the Agreement, Repligen received a payment of \$750,000 and is entitled to continue to market SecreFlo<sup>®</sup>, for the next couple of years under a royalty structure more favorable to Repligen than under the Licensing Agreement. ChiRhoClin is obligated to deliver a certain amount of SecreFlo<sup>®</sup> to Repligen over the next few years. This payment was recorded as *Accrued Liabilities* and has a balance of approximately \$302,000 as of December 31, 2006. The adoption by the Company of Emerging Issues Task Force (EITF) Issue No. 20-16, *Accounting by a Customer (including a Reseller) for Certain Consideration Received from a Vendor* (EITF 02-16) has resulted in the reduction of cost of goods sold as future inventory purchased from ChiRhoClin is sold. After depletion of all supplies of SecreFlo<sup>®</sup> provided by ChiRhoClin, including those to be delivered under the Agreement, Repligen will cease marketing and selling a secretin product supplied by ChiRhoClin. ChiRhoClin will pay Repligen a per unit royalty on all sales by ChiRhoClin of its secretin products subject to certain time and/or volume limits. Repligen was not required to pay approximately \$1,169,000 of unremitted royalties to ChiRhoClin related to sales from February 2004 to March 2005. This amount which was accrued at March 31, 2005 was recorded as other income in the quarter ended June 30, 2005. Repligen has received security for ChiRhoClin's performance under the Agreement.

---

**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 the treatment of diseases of 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 bipolar disorder and neurodegeneration. In addition, we sell two commercial products, Protein A for monoclonal antibody purification and SecreFlo® for assessment of pancreatic disorders.

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.

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 "Risk Factors" in our Annual Report on Form 10-K for the year ended March 31, 2006.

**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.

During the three month period ended December 31, 2006, we recognized 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 and nine-month periods ended December 31, 2006, the Company earned approximately \$36,000 and \$117,000, respectively, in royalty revenue pursuant to a settlement agreement with ChiRhoClin, Inc., discussed further in "Cost of Product Revenue" below. This amount is included in Other Revenue in the accompanying Statement of Operations.

**Inventory**

We value inventory at cost or, if lower, fair market value. We determine cost using the first-in, first-out method. We regularly review our inventories and record a provision for excess and obsolete inventory based on certain factors that may impact the realizable value of our inventory. Factors we consider include expected sales volume, production capacity and

**Table of Contents**

expiration dates. We write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements to cost of product revenue.

**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 Product Revenue**

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 is entitled to continue to market SecreFlo® for the next few years. The balance of the settlement payment of approximately \$302,000 is recorded in Accrued Liabilities as of December 31, 2006. 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.

**Stock-Based Compensation**

Effective April 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, Share-Based Payment An Amendment of FASB Statements No. 123 and 95, or SFAS No. 123R, using the modified prospective transition method. Under this transition method, compensation cost recognized in the statement of operations for the nine months ended December 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123 and (b) compensation cost for all share-based payments granted, modified or settled subsequent to April 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated.

Effective with the adoption of SFAS No. 123R, we have elected to use the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date.

The expected term of options granted represents the period of time for which the options are expected to be outstanding and is derived from our historical stock option exercise experience and option expiration data. For option grants made subsequent to the adoption of SFAS No. 123R, the expected life of stock options granted is based on the simplified method allowable under SAB No. 107. Accordingly, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. In addition, for purposes of estimating the expected term, we have aggregated all individual option awards into one group as we do not expect substantial differences in exercise behavior among its employees. The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determined the expected volatility solely based upon the historical volatility of our Common Stock over a period commensurate with the option's expected term. We do not believe that the future volatility of our Common Stock over an option's expected term is likely to differ significantly from the past. The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date. We have never declared or paid any cash dividends on any of our capital stock and do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

We recognize 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



---

**Table of Contents**

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. Prior to the adoption of SFAS No. 123R, we accounted for forfeitures upon occurrence as permitted under SFAS No. 123. Based on an analysis of historical data, we have 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 we believe 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 our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

Prior to April 1, 2006, we applied the pro forma disclosure requirements under SFAS No. 123 and accounted for our stock-based employee compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, ( APB No. 25 ) and related interpretations. Accordingly, no stock-based employee compensation cost was recognized in the statement of operations for the three and nine month periods ended December 31, 2005, as all stock options granted under the Plans had an exercise price equal to the market value of the underlying Common Stock on the date of grant.

For the three and nine months ended December 31, 2006, we recorded stock-based compensation expense of approximately \$137,000 and \$641,000 for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan. Basic and diluted earnings per share amounts for the three and nine months ended December 31, 2006 were decreased by \$0.00 and \$0.03 respectively, as a result of the adoption of SFAS No. 123R.

As of December 31, 2006, there was \$1,460,000 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 3.00 years. The Company expects approximately 701,000 in unvested options to vest over the next five years.

**Results of Operations****Three months ended December 31, 2006 vs. December 31, 2005****Total revenue**

Total revenue for the three-month periods ended December 31, 2006 and December 31, 2005 were approximately \$3,882,000 and \$2,988,000 respectively, an increase of \$894,000 or 30%. During the three-month period ended December 31, 2006, an increase in the volume of product sales accounted for the majority of the increase over the same period in the prior fiscal year. Our product revenues are subject to significant quarterly fluctuations based on the timing of large-scale production orders of Protein A.

During the three-month periods ended December 31, 2006 and December 31, 2005 we recognized \$213,000 and \$0, respectively of revenue 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. Additionally, during the three-month periods ended December 31, 2006 and 2005, we earned and recognized approximately \$36,000 and \$30,000 respectively in royalty revenue from ChiRhoClin, Inc.

**Operating expenses**

Total operating expenses for the three-month periods ended December 31, 2006 and December 31, 2005 were approximately \$4,139,000 and \$3,394,000, respectively, an increase of \$745,000 or 22%.

Cost of product revenue for the three-month periods ended December 31, 2006 and December 31, 2005 were approximately \$805,000 and \$818,000, respectively, a decrease of \$13,000 or 2%. This decrease in cost of product revenue primarily reflects reduced material costs of \$98,000 related to product mix being partially offset by increased personnel and occupancy costs of \$77,000 in the period ended December 31, 2006.

Research and development expenses for the three-month periods ended December 31, 2006 and December 31, 2005 were approximately \$1,675,000 and \$1,236,000, respectively, an increase of \$439,000 or 36%. During the three-month period ended December 31, 2006, this increase is largely attributable to an increase in clinical trial expenses of \$447,000. 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, 2006 and December 31, 2005 were approximately \$1,660,000 and \$1,341,000 respectively, an increase of \$319,000 or 24%. This increase is attributable to an increase in professional and personnel expenses of \$247,000, and stock option expenses of \$71,000, during the three-month period ended December 31, 2006.

### **Interest income**

Interest income for the three-month periods ended December 31, 2006 and December 31, 2005 was approximately \$240,000 and \$204,000 respectively. The increase in the three months ended December 31, 2006 is a result of increased interest rates.

### **Nine months ended December 31, 2006 vs. December 31, 2005**

#### **Total revenue**

Total revenue for the nine-month periods ended December 31, 2006 and December 31, 2005 were approximately \$10,375,000 and \$10,026,000 respectively, an increase of \$349,000 or 3%.

During the nine-month periods ended December 31, 2006 and December 31, 2005 we recognized \$581,000 and \$310,000, respectively, of revenue 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. Additionally, during the nine-month period ended December 31, 2006 and December 31, 2005 we earned and recognized approximately \$117,000 and \$30,000 in royalty revenue from ChiRhoClin, Inc.

#### **Operating expenses**

Total operating expenses for the nine-month periods ended December 31, 2006 and December 31, 2005 were approximately \$11,849,000 and \$10,232,000, respectively, an increase of \$1,617,000 or 16%.

Cost of product revenue for the nine-month periods ended December 31, 2006 and December 31, 2005 were approximately \$2,713,000 and \$2,663,000, respectively, an increase of \$50,000 or 2%. This increase in cost of product revenue primarily reflects increased professional and personnel costs of \$280,000, offset due by a reduction in material costs due to product mix of \$233,000 in the period ended December 31, 2006.

Research and development expenses for the nine-month periods ended December 31, 2006 and December 31, 2005 were approximately \$4,472,000 and \$3,750,000, respectively, an increase of \$722,000 or 19%. During the nine-month period ended December 31, 2006, this increase is largely attributable to an increase in personnel expenses of \$106,000, stock option expense of \$170,000 and clinical trial expenses of \$851,000 off-set by a \$404,000 decrease in external research and material and 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.

Selling, general and administrative expenses for the nine-month periods ended December 31, 2006 and December 31, 2005 were approximately \$4,664,000 and \$3,819,000 respectively, an increase of \$845,000 or 22%. This increase is attributable to an increase in personnel and professional fees of \$579,000, and stock option expense of \$451,000 off set by a decrease in legal expenses of \$186,000 during the nine-month period ended December 31, 2006.

### **Interest income**

Interest income for the nine-month periods ended December 31, 2006 and December 31, 2005 was approximately \$701,000 and \$553,000 respectively. The increase in the nine months ended December 31, 2006 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

---

## Table of Contents

to pay approximately \$1,169,000 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.

### **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®. However, after the depletion of all supplies of Secreflo® provided by ChiRhoClin, including those to be delivered under the Agreement, the Company will cease marketing and selling a secretin product supplied by ChiRhoClin. 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, 2006 totaled \$21,924,000, a decrease of \$1,484,000 from \$23,408,000 at March 31, 2006.

### Operating activities

Our operating activities used cash of approximately \$266,000 for the nine-month period ended December 31, 2006 relating to the construction of our fermentation suite. Cash uses from operating activities consisted of a net loss of approximately \$782,000, which includes non-cash charges of approximately \$385,000 for depreciation and amortization and \$641,000 in stock based compensation expense. The primary reasons our operating loss is higher than cash receipts for the nine-month period ended December 31, 2006, are spending associated with the expansion of our manufacturing facility and spending associated with our clinical trials. In addition the timing of shipments in the quarter resulted in an increased accounts receivable balance at period end.

### Investing activities

Our cash was reduced by capital expenditures of \$1,210,000 for the nine-month period ended December 31, 2006 relating to the construction of our fermentation suite. Our investing activities provided cash of approximately \$145,000 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.

Working capital increased to \$19,695,000 at December 31, 2006 from \$18,575,000 at March 31, 2006 primarily as a result of the change in classification for marketable securities which are now classified as short-term investments as they mature within twelve months of the period end date and the timing of shipments in the quarter resulting in an increased accounts receivable balance.

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 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.

## Edgar Filing: REPLIGEN CORP - Form 10-Q

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

**Table of Contents**

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, 2006, we did not have any off-balance sheet arrangements.

**Commitments**

As of December 31, 2006 we had the following fixed obligations and commitments:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
		(In thousands)			
Operating lease obligations	\$ 2,087	\$ 399	\$ 832	\$ 856	\$
Capital lease obligations (1)	136	40	86	10	
Purchase obligations (2)	34	34			
Contractual obligations (3)	698	161	262	226	49
<b>Total</b>	<b>\$ 2,955</b>	<b>\$ 634</b>	<b>\$ 1,180</b>	<b>\$ 1,092</b>	<b>\$ 49</b>

- (1) The above amounts represent principal payments only, while principal and interest are payable through a fixed annual payment of approximately \$52,000.
- (2) This amount represents a minimum commitment due under a third-party manufacturing agreement.
- (3) These amounts include 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 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

---

**Table of Contents**

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, 2006.

**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 \$62,000 decrease in the fair value of our investments as of December 31, 2006. 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 our chief executive officer and chief 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, our chief executive officer and chief 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 chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

**Imclone**

In July 2006, Repligen reported that the United States District Court for the District of Massachusetts issued a Summary Judgment ruling in favor of Repligen and The Massachusetts Institute of Technology (MIT) and rejected ImClone Systems Incorporated's (Imclone) defense of patent exhaustion in the ongoing patent infringement lawsuit over the production of Erbitux®. In their complaint, Repligen and MIT allege that ImClone's production of Erbitux® infringes U.S. patent 4,663,281 which covers certain genetic elements that increase protein production in a mammalian cell. This patent is assigned to MIT and exclusively licensed to Repligen.

ImClone had previously reported that it produced approximately \$1 billion worth of Erbitux® prior to the expiration of the patent-in-suit in 2004 and that Bristol-Myers Squibb, ImClone's commercial partner, has paid ImClone \$900 million in up-front and milestone payments as well as a 39% royalty on the net sales of Erbitux® in the United States.

**Table of Contents**

Repligen and MIT allege that the cell line that ImClone uses to produce Erbitux® employs key technology that is claimed in the patent-in-suit. Repligen and MIT also allege that the cell line was created under contract for the National Cancer Institute ( NCI ) by a predecessor to Repligen and subsequently transferred from the NCI to ImClone for use in research and development only. In its ruling, the Court found that neither the transfer to the NCI by Repligen’s predecessor nor the subsequent transfer to ImClone by the NCI exhausted the proprietary rights of Repligen and MIT. The Court’s ruling has eliminated these arguments as a potential defense for ImClone at trial. Repligen and MIT intend to seek damages adequate to compensate Repligen and MIT for ImClone’s unlicensed use of the patented technology and a multiplier of any such damage award based on ImClone’s willful infringement.

**Bristol-Myers Squibb Company ( Bristol )**

In January 2006, Repligen Corporation 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. On November 16, 2006, the Court held a scheduling conference. Jury selection for the trial in this matter is scheduled to commence on April 7, 2008. The outcome of this case is undeterminable at this time.

From time to time, we may be subject to legal proceedings and claims, other than those described in the Company’s Annual Report on Form 10-K for the period ended March 31, 2006 and the Company’s Quarterly Report on Form 10-Q for the periods ended June 30, 2006 and September 30, 2006, 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

<b>Exhibit Number</b>	<b>Document Description</b>
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).
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).
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 Officer.
32.1+	Certification 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: February 8, 2007

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

Date: February 8, 2007

By: /s/ Daniel W. Muehl  
Chief Financial Officer  
(Principal Financial and Accounting Officer)  
Repligen Corporation

**Table of Contents**

**EXHIBIT INDEX**

<b>EXHIBIT</b>	<b>DESCRIPTION</b>
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).
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 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