

REPLIGEN CORP  
Form 10-Q  
August 08, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2007

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

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**REPLIGEN CORPORATION**

(exact name of registrant as specified in its charter)

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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

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**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.)

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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 August 7, 2007.

Class	Number of Shares
Common Stock, par value \$.01 per share	30,620,599

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REPLIGEN CORPORATION

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	<b>June 30, 2007</b>	<b>March 31, 2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,776,964	\$ 7,726,505
Marketable securities	13,361,084	14,900,840
Accounts receivable, less reserve of \$10,000	2,689,216	1,143,694
Inventories	1,631,194	1,514,571
Prepaid expenses and other current assets	423,401	445,415
Total current assets	24,881,859	25,731,025
Property, plant and equipment, at cost:		
Leasehold improvements	3,222,853	3,212,916
Equipment	2,537,169	2,353,667
Furniture and fixtures	192,933	191,356
	5,952,955	5,757,939
Less-accumulated depreciation and amortization	(2,802,239)	(2,613,081)
	3,150,716	3,144,858
Long-term marketable securities	1,678,115	
Restricted cash	200,000	200,000
Total assets	\$ 29,910,690	\$ 29,075,883
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,430,340	\$ 1,161,504
Accrued liabilities	1,899,713	2,175,739
Total current liabilities	3,330,053	3,337,243
Long-term liabilities	195,077	200,342
Total liabilities	3,525,130	3,537,585
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, no shares issued or outstanding		
Common stock, \$.01 par value, 40,000,000 shares authorized, 30,615,599 shares issued and outstanding at June 30, 2007 and 30,477,635 shares at March 31, 2007, respectively	306,156	304,776
Additional paid-in capital	183,522,760	182,916,856
Accumulated deficit	(157,443,356)	(157,683,334)
Total stockholders' equity	26,385,560	25,538,298

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Total liabilities and stockholders' equity	\$ 29,910,690	\$ 29,075,883
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See accompanying notes

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

	Three months ended June 30, 2007	2006
Revenue:		
Product revenue	\$ 5,731,476	\$ 3,363,898
Other revenue	247,342	264,270
Total revenue	5,978,818	3,628,168
Operating expenses: (1)		
Cost of product revenue	1,714,299	993,016
Research and development	2,137,326	1,214,583
Selling, general and administrative	2,142,131	1,541,561
Total operating expenses	5,993,756	3,749,160
Income (loss) from operations	(14,938)	(120,992)
Investment income	257,367	224,736
Interest expense	(2,451)	(3,010)
Net income	\$ 239,978	\$ 100,734
Basic and diluted earnings per share:	\$ 0.01	\$
Weighted average shares outstanding:		
Basic	30,564,494	30,357,635
Diluted	31,127,099	30,825,764

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

Cost of product revenue	\$ 7,030	\$ 5,972
Research and development	55,066	52,196
Selling, general and administrative	124,478	190,366

See accompanying notes.

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

	Three months ended June 30, 2007	2006
Cash flows from operating activities:		
Net income:	\$ 239,978	\$ 100,734
Adjustments to reconcile net income to net cash used in operating activities		
Issuance of common stock for license	300,000	
Depreciation and amortization	189,158	124,887
Stock-based compensation expense	186,574	248,534
Changes in assets and liabilities:		
Accounts receivable	(1,545,522)	(514,526)
Inventories	(116,623)	224,566
Prepaid expenses and other current assets	3,359	(108,792)
Accounts payable	268,836	(266,838)
Accrued liabilities	(274,578)	(4,951)
Long-term liabilities	(5,265)	(108,124)
Net cash used in by operating activities	(754,083)	(304,510)
Cash flows from investing activities:		
Purchases of marketable securities	(7,319,705)	(3,871,320)
Redemptions of marketable securities	7,200,000	4,675,000
Purchases of property, plant and equipment	(195,016)	(584,895)
Net cash (used in) provided by investing activities	(314,721)	218,785
Cash flows from financing activities:		
Exercise of stock options	120,710	
Principal payments under capital lease obligation	(1,447)	(2,005)
Net cash provided by (used in) financing activities	119,263	(2,005)
Net decrease in cash and cash equivalents	(949,541)	(87,730)
Cash and cash equivalents, beginning of period	7,726,505	5,428,477
Cash and cash equivalents, end of period	\$ 6,776,964	\$ 5,340,747
Supplemental disclosure of noncash activities:		
Non-cash purchase of equipment through capital lease obligation	\$	\$ 133,261

See accompanying notes.

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**REPLIGEN CORPORATION**

**NOTES TO FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Basis of Presentation**

The financial statements included herein have been prepared by Repligen Corporation or 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, or SEC, for quarterly reports on Form 10-Q and Article 10 of Regulation S-X and do not include all of the information and footnote disclosures required by accounting principles generally accepted in the United States. These financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in our Form 10-K for the year ended March 31, 2007.

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

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

**2. Revenue Recognition**

The Company applies Staff Accounting Bulletin No. 104, Revenue Recognition, or SAB No. 104 to its revenue arrangements.

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

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

During the three-month period ended June 30, 2007, the Company recognized approximately \$200,000 of revenue from a sponsored research and development project with the Stanley Medical Research Institute or SMRI. Research revenue is recognized on a cost plus fixed-fee basis when the expense has been incurred and services have been performed. Determination of which costs incurred qualify for reimbursement under the terms of the contractual agreement and the timing of when such costs were incurred involves the judgment of management. The Company believes its calculations are consistent with the agreed-upon terms as stated in the arrangement. However, should the estimated calculations change or be challenged by SMRI, research revenue may be adjusted in subsequent periods. The calculations have not historically changed or been challenged and the Company does not anticipate any subsequent change in its revenue related to this sponsored research and development project.





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Additionally, during the three-month period ended June 30, 2007, the Company earned and recognized approximately \$47,000 in royalty revenue from ChiRhoClin. Revenues earned from ChiRhoClin royalties are recorded in the periods when they are earned based on royalty reports sent by ChiRhoClin to the Company.

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

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

We follow the provisions of Statement of Financial Accounting Standard or SFAS No. 128, Presenting Earnings Per Share, or SFAS No. 128. Basic earnings per share for the three month periods ended June 30, 2007 and 2006 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:

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
Weighted average common shares	30,564,494	30,357,635
Dilutive common stock options	562,605	468,129
Weighted average common share, assuming dilution	31,127,099	30,825,764

For the three month periods ended June 30, 2007 and 2006 options to purchase 530,500 and 940,500 shares of our common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares.

At June 30, 2007, there were outstanding options to purchase 2,245,250 shares of our common stock at a weighted average exercise price of \$3.27 per share.

**4. Stock-Based Compensation**

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

For the three months ended June 30, 2007, the Company recorded stock-based compensation expense of approximately \$187,000 for stock options granted under the Amended and Restated 2001 Repligen Corporation Stock Plan. The amount of stock-based compensation expense for the three months ended June 30, 2007 had no impact on basic and diluted earnings per share amounts for the period.

The Plans allow for the granting of incentive and nonqualified options and restricted stock and other equity awards to purchase shares of Common Stock. Incentive options granted to employees under the Plans generally vest over a four to five-year period, with 20%-25% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's Common Stock on the date of grant. At June 30, 2007, options to purchase 1,386,750 shares were outstanding under the Amended and Restated 2001 Repligen Corporation Plan and options to purchase 858,500 shares were outstanding under the 1992 Repligen Corporation Stock Option Plan. At June 30, 2007, 417,109 shares were available for future grant under the Amended and Restated 2001 Repligen Corporation Stock Plan.



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

Information regarding option activity for the three months ended June 30, 2007 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, 2007	2,293	\$ 3.25		
Granted	74	3.51		
Exercised	(51)	2.39		
Forfeited/Cancelled	(71)	3.41		
Options outstanding at June 30, 2007	2,245	\$ 3.27	5.04	\$ 2,624
Options exercisable at June 30, 2007	1,667	\$ 3.31	4.01	\$ 2,122
Vested and expected to vest at June 30, 2007 (1)	2,210	\$ 2.67	5.21	\$ 2,615

- (1) This represents the number of vested options as of June 30, 2007 plus the number of unvested options expected to vest as of June 30, 2007 based on the unvested outstanding options at June 30, 2007 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 June 29, 2007 of \$3.90 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 June 29, 2007.

The weighted average grant date fair value of options granted during the three months ended June 30, 2007 and 2006 was \$2.61 and \$2.31, respectively. The total fair value of stock options that vested during the three months ended June 30, 2007 and 2006 was approximately \$316,420 and \$455,000, respectively.

As of June 30, 2007, there was \$1,250,000 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 2.41 years. The Company expects approximately 567,000 in unvested options to vest over the next five years.

## 5. Cash, Cash Equivalents and Marketable Securities

We follow the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At June 30, 2007, 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.

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At June 30, 2007, 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

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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:

	June 30, 2007	March 31, 2007
Cash and cash equivalents	\$ 6,776,964	\$ 7,726,505
Marketable securities:		
U.S. Government and agency securities	\$ 1,661,939	\$ 3,460,664
Auction rate securities	475,000	475,000
Corporate and other debt securities	11,224,145	10,965,175
(Average remaining maturity, 6 months at June 30, 2007, assumes auction rate maturity set at date of next auction)	\$ 13,361,084	\$ 14,900,839
Long-term marketable securities:		
Corporate and other debt securities	\$ 1,678,115	\$
(Average remaining maturity, 15 months at June 30, 2007)		
Restricted cash of \$200,000 is related to our facility lease obligation.		

## 6. Inventories

Inventories relate to the Company's Protein A business. The Company values inventory at cost or, if lower, fair market value. Repligen determines cost using the first-in, first-out method. The Company reviews its inventories at least quarterly and records a provision for excess and obsolete inventory based on its estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in process and finished goods. Expected sales volumes are determined based on supply forecasts provided by key customers for the next three to twelve months. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements to cost of goods sold. Manufacturing of Protein A finished goods is done to order and tested for quality specifications prior to shipment.

A change in the estimated timing or amount of demand for our products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of inventory and reported operating results. During all periods presented in the accompanying financial statements, there has been no material adjustments related to a revised estimate of inventory valuations.

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 June 30, 2007 and March 31, 2007 consist of the following:

	June 30, 2007	March 31, 2007
Raw materials	\$ 897,498	\$ 733,112
Work-in-process	689,466	616,519
Finished goods	44,230	164,940
Total	\$ 1,631,194	\$ 1,514,571

**7. Accrued Liabilities**

The Company prepares its financial statements in accordance with accounting principles generally accepted in the United States. These principles require that the Company estimate accrued liabilities. This process involves identifying services, which have been performed on the Company's behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of estimated accrued expenses include: 1)

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Fees paid to contract manufacturers in conjunction with the production of clinical materials. These expenses are normally determined through a contract or purchase order issued by the Company; 2) Service fees paid to organizations for their performance in conducting clinical trials. These expenses are determined by contracts in place for those services and communications with project managers on costs which have been incurred as of each reporting date; 3) Professional and consulting fees incurred with law firms, audit and accounting service providers and other third party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred, or tracking costs incurred by service providers under fixed fee arrangements. The Company has processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that the Company does not identify certain costs which have begun to be incurred or the Company under or over-estimates the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often judgmental. The Company makes these judgments based upon the facts and circumstances known at the date of the financial statements.

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

Accrued liabilities consist of the following:

	As of June 30, 2007	As of March 31, 2007
Research & development costs	\$ 530,682	\$ 602,615
Professional and consulting costs	518,391	400,474
Payroll & payroll related costs	364,251	557,100
Other current liabilities	281,478	309,015
Other accrued expenses	145,423	122,836
Royalty expenses	59,488	56,529
Unearned revenue		127,170
Total	\$ 1,899,713	\$ 2,175,739

**8. Comprehensive Income/Loss**

We follow the provisions of SFAS No. 130, Reporting Comprehensive Income, or 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, or 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:



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	Three months ended June 30,	
	2007	2006
Europe	72%	68%
US	27%	31%
Other	1%	1%
Total	100%	100%

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During the three months ended June 30, 2007, there were two customers who accounted for approximately 70% and 11% of product revenues, respectively. During the three months ended June 30, 2006 there were two customers who accounted for approximately 65% and 10% of product revenues, respectively. At June 30, 2007, two customers accounted for 56% and 24% of our accounts receivable. At March 31, 2007, two customers accounted for 47% and 15% of accounts receivable, respectively.

### **10. New Accounting Pronouncements**

#### **Fair Value Option for Financial Assets and Financial Liabilities**

In February 2007, the FASB issued FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS No. 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. FASB has indicated it believes that SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. For example, SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in FASB Statement No. 157, *Fair Value Measurements* (SFAS No. 157), and FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments* (SFAS No. 107). SFAS No. 159 is effective as of the beginning of a company's first fiscal year beginning after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided that the company makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of SFAS No. 157. The Company has not yet completed its evaluation of SFAS No. 159, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

#### **Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities**

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. The Company is currently analyzing the effect, if any, EITF 07-3 will have on its financial position and results of operations.

### **11. Scripps Agreement**

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

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Pursuant to the Agreement, the Company agreed to pay Scripps an initial license fee of \$300,000, certain royalty and sublicense fees and, in the event the Company achieves specified developmental and commercial milestones, certain additional milestone payments. In addition, the Company issued Scripps 87,464 shares of the Company's common stock (the "Shares") representing \$300,000 as of the Effective Date. If the value of the Shares does not equal at least \$300,000 on the one-year anniversary of the Effective Date, the Company shall make a cash payment to Scripps equal to the difference between the actual total value of the Shares on the one-year anniversary of the Effective Date and the Effective Date. The Company issued the Shares in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. The Shares were issued exclusively to Scripps as an accredited investor (as such term is defined in Rule 501(a) of Regulation D) without general solicitation or advertising and did not involve a public offering.

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

## **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 while reducing our financial risk.

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, 2007.

### **Critical Accounting Policies and Estimates**

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Consolidated Financial Statements included in our Annual Report on Form 10-K dated March 31, 2007.

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### **Results of Operations**

#### **Three months ended June 30, 2007 vs. June 30, 2006**

##### **Total revenue**

Total revenue for the three-month periods ended June 30, 2007 and June 30, 2006 were approximately \$5,978,000 and \$3,628,000 respectively, an increase of \$2,350,000 or 65%. Substantially all of our products based on recombinant Protein A are sold to customers who incorporate our manufactured products into their proprietary antibody purification systems to be sold directly to the pharmaceutical industry. Monoclonal antibodies are a well-established class of drug with applications in rheumatoid arthritis, asthma, Crohn's disease and a variety of cancers. Sales of Protein A are therefore impacted by the timing of large-scale production orders and on the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

During the three months ended June 30, 2007, Protein A sales increased by \$2,289,000 or 78% over the same period in fiscal 2007. We shipped 75% more volume of Protein A in the first quarter of fiscal 2008 compared to the same period in fiscal 2007. The mix of products sold had more favorable pricing resulting in an additional 3% positive impact on total revenue. The Company sells different Protein A products at different price points. The mix of products sold varies and impacts the fluctuations in total sales revenue from year to year.

Sales of SecreFlo® increased \$78,000 or 18% in the first quarter of fiscal 2008. Increased volume impacted revenue by 2% and increased sales prices positively impacted revenues by 16%.

The settlement in fiscal 2005 with our sole supplier of SecreFlo® provides for a certain amount of vials of product that we can ultimately ship. The last shipment of SecreFlo® to the Company from ChiRhoClin was received in July 2007 and is expected to allow us to fill sales orders into fiscal year 2009. We expect SecreFlo® revenues will decline by one third in fiscal 2008 as we continue to reduce sales and marketing efforts and focus our sales efforts on key customers.

During the three-month periods ended June 30, 2007 and June 30, 2006, we recognized approximately \$200,000 and \$220,000, respectively, of revenue from a sponsored research and development project under an agreement with SMRI. Research revenue is recognized for costs plus fixed-fee contracts as costs are incurred. Additionally, during the three-month periods ended June 30, 2007 and June 30, 2006, we earned and recognized approximately \$47,000 and \$44,000, respectively in royalty revenue from ChiRhoClin. We expect that total research and license revenues will decline moderately in fiscal 2008.

##### **Operating expenses**

Total operating expenses for the three-month periods ended June 30, 2007 and June 30, 2006 were approximately \$5,993,000 and \$3,750,000, respectively, an increase of \$2,243,000 or 60%.

Cost of product revenue for the three-month periods ended June 30, 2007 and June 30, 2006 were approximately \$1,714,000 and \$993,000, respectively, an increase of \$721,000 or 73%. This increase in cost of product revenue is consistent with our increase in volume of Protein A shipped and primarily reflects increased material costs of \$436,000, increased personnel and occupancy costs of \$113,000 and increased consulting and manufacturing services of \$142,000 in the period ended June 30, 2007.

Research and development expenses for the three-month periods ended June 30, 2007 and June 30, 2006 were approximately \$2,137,000 and \$1,215,000, respectively, an increase of \$922,000 or 76%. This increase is largely attributable to increased licensing expense of \$600,000 attributable to the payment of milestones associated with the signing of the License Agreement with The Scripps Research Institute (or the Scripps License Agreement) which were paid in cash and through the issuance of common stock, as well as increased external research expenses of \$262,000 due to clinical trial expenses and expenses associated with our Friedreich's ataxia project. 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 three-month periods ended June 30, 2007 and June 30, 2006 were approximately \$2,142,000 and \$1,542,000, respectively, an increase of \$600,000 or 39%. This increase is largely attributable to an increase in litigation expenses of \$595,000 associated with the prosecution of our patent infringement lawsuits against Bristol-Myers Squibb and Imclone.



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### **Interest income**

Interest income for the three-month periods ended June 30, 2007 and June 30, 2006 was approximately \$257,000 and \$225,000 respectively. The increase in the three months ended June 30, 2007 is a result of more favorable interest rates.

### **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®. Revenues derived from the sales of SecreFlo® vials are expected only through calendar year 2009. 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 June 30, 2007 totaled approximately \$21,816,000, a decrease of \$811,000 from \$22,627,000 at March 31, 2007.

### **Operating activities**

Our operating activities used cash of approximately \$754,000 for the three-month period ended June 30, 2007. Cash use is primarily driven by changes in operating assets and liabilities being partially offset by net income of approximately \$240,000, which includes non-cash charges of approximately \$189,000 for depreciation and amortization, \$187,000 in stock based compensation expense and \$300,000 for issuance of common stock for the Scripps License Agreement.

### **Investing activities**

Cash spending of approximately \$195,000 for the three-month period ended June 30, 2007 relates to equipment purchases and facility improvements for our manufacturing suites. Additional cash was used to purchase new marketable securities in the period for amounts in excess of proceeds received from the redemption of marketable securities which matured in the period.

### **Financing activities**

Stock option exercises provided cash proceeds of approximately \$121,000.

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

Working capital decreased to approximately \$21,552,000 at June 30, 2007 from \$22,394,000 at March 31, 2007 primarily as a result of cash use in the first quarter of fiscal 2008.

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

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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.

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

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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 June 30, 2007, we did not have any off-balance sheet arrangements.

**Commitments**

As of June 30, 2007 we had the following fixed obligations and commitments:

	Total	Payments Due by Period			
		Less than 1	1-3	3-5	More than 5
		Year	Years	Years	Years
(In thousands)					
Operating lease obligations	\$ 2,099	\$ 450	\$ 933	\$ 716	\$
Capital lease obligations (1)	116	41	75		
Purchase obligations (2)	298	298			
Contractual obligations (3)	435	112	152	146	25
Total	\$ 2,948	\$ 901	\$ 1,160	\$ 862	\$ 25

- (1) The above amounts represent principal payments only, while principal and interest are payable through a fixed annual payment of approximately \$48,000.
- (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



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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, 2007.

### **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 \$89,000 decrease in the fair value of our investments as of June 30, 2007. 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 Systems**

In June 2007, Repligen reported that the United States District Court for the District of Massachusetts set a trial date of September 10, 2007 in the ongoing patent infringement lawsuit brought by Repligen and The Massachusetts Institute of Technology or MIT against ImClone Systems, Incorporated or ImClone. In their complaint, Repligen and MIT allege that ImClone's production of Erbitu<sup>®</sup> infringes U.S. patent 4,663,281 or the '281 patent which covers certain genetic elements that increase protein production in a mammalian cell. This patent is assigned to MIT and exclusively licensed to Repligen.

Repligen also announced in June 2007 that the Court issued a favorable ruling on the sanctions motion filed by Repligen and MIT against ImClone based on conduct that, in Repligen's view, constituted intimidation of a central witness in the case, one of the inventors of the '281 patent. The Court found that the actions of ImClone's in-house and outside counsel were intended to block the cooperation of the inventor and that these actions prejudiced Repligen and MIT from fully prosecuting their case. As one of the remedies, the Court granted Repligen and MIT permission to introduce evidence of the improper conduct of ImClone's attorneys at trial to lay the foundation for the jury to infer that ImClone itself believed that the witness's testimony supported Repligen and MIT's claims in the litigation.



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ImClone 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.

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 or NCI by a predecessor to Repligen and subsequently transferred from the NCI to ImClone for use in research and development only. In its summary judgment ruling issued in July 2006 and previously reported by Repligen, 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 summary judgment ruling 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. The outcome of this case is undeterminable at this time.

### **Bristol-Myers Squibb**

In January 2006, Repligen Corporation and The University of Michigan jointly filed a complaint against Bristol-Myers Squibb in the United States District Court for the Eastern District of Texas for infringement of U.S. Patent No. 6,685,941 or 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-Myers Squibb answered the complaint and counterclaimed seeking a declaratory judgment that the '941 patent is invalid and unenforceable and that Bristol-Myers Squibb does not infringe the patent. 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.

### **Other**

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

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

### **Recent Sale of Unregistered Securities**

On April 6, 2007, in connection with the Scripps License Agreement entered into between the Company and The Scripps Research Institute, the Company issued Dr. Joel Gottesfeld a warrant to purchase up to an aggregate of 150,000 shares of the Company's Common Stock at an exercise price per share of \$0.01. The warrant may be exercised only upon the achievement of certain milestones related to the development of a pharmaceutical treatment for Friedreich's Ataxia. The warrant expires on April 6, 2014. Based on the fact that the Company issued the warrant to only one individual, the Company issued the warrant without registration and effected the private placement on reliance on Rule 4(2) of the Securities Act.

## **ITEM 6. EXHIBITS**

### **(a) Exhibits**

#### **Exhibit**

#### **Number Document Description**

- |     |   |
|-----|---|
| 3.1 | Restated Certificate of Incorporation dated June 30, 1992 and amended September 17, 1999 (filed as Exhibit 3.1 to Repligen Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference). (File No. 000-14656) |
|-----|---|

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- 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).

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### **Exhibit**

#### **Number Document Description**

- 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).
- 4.1+ Common Stock Purchase Warrant dated April 6, 2007
- 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.

### **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: August 8, 2007

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

(Principal Executive Officer)

Repligen Corporation

Date: August 8, 2007

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

(Principal Financial and Accounting Officer)

Repligen Corporation

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**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). (File No. 000-14656)
3.2	Certificate of Designation of Series A Junior Participating Preferred Stock dated March 4, 2003 (filed as Exhibit A of Exhibit 1 to Repligen Corporation's Registration Statement on Form 8-A filed March 4, 2003 and incorporated herein by reference).
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).
4.1+	Common Stock Purchase Warrant dated April 6, 2007
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.

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+ Filed herewith