EXACT SCIENCES CORP
Form 10-Q
November 07, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**02-0478229**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
100 Campus Drive, Marlborough, Massachusetts	**01752**
(Address of principal executive offices)	(Zip Code)

(508) 683-1200

(Registrant s telephone number, including area code)

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

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 3, 2008, the registrant had 27,247,381 shares of Common Stock outstanding.

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EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,069	$ 4,486
Marketable securities		8,101
Prepaid expenses and other current assets	255	275
Total current assets	6,324	12,862
Property and Equipment, at cost:		
Laboratory equipment	3,730	3,730
Office and computer equipment	1,420	1,420
Leasehold improvements	55	1,161
Furniture and fixtures	299	299
	5,504	6,610
Less Accumulated depreciation and amortization	(5,354)	(6,009)
	150	601
Patent costs, net of accumulated amortization of $2,843 and $3,019 at September 30, 2008 and December 31, 2007, respectively	213	432
Restricted cash	600	700
	$ 7,287	$ 14,595
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 236	$ 245
Accrued expenses	1,520	2,811
Third party royalty obligation	3,000	1,200
Deferred license fees, current portion	1,350	1,350
Total current liabilities	6,106	5,606
Deferred license fees, less current portion	1,688	2,701
Commitments and contingencies		
Stockholders Equity (Deficit):		
Preferred stock, $0.01 par value Authorized 5,000,000 shares Issued and outstanding 0 shares at September 30, 2008 and and December 31, 2007		
Common stock, $0.01 par value Authorized 100,000,000 shares Issued and outstanding 27,331,318 and 27,225,541 shares at September 30, 2008 and December 31, 2007, respectively	273	273
Additional paid-in capital	169,673	168,813
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income		23
Accumulated deficit	(170,356)	(162,724)
Total stockholders equity (deficit)	(507)	6,288
	$ 7,287	$ 14,595

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

(Amounts in Thousands, except per share data unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenue:				
Product royalty fees	$ (1,000)	$ (239)	$ (1,787)	$ (194)
License fees	337	338	1,013	2,520
Product		14	16	72
	(663)	113	(758)	2,398
Cost of revenue:				
Product royalty fees		1	1	4
Product		45		45
		46	1	49
Gross profit	(663)	67	(759)	2,349
Operating expenses:				
Research and development (1)	577	1,009	1,964	3,618
General and administrative (1)	1,271	2,456	4,601	5,551
Sales and marketing (1)		219		1,008
Restructuring (1)	539	788	532	819
	2,387	4,472	7,097	10,996
Loss from operations	(3,050)	(4,405)	(7,856)	(8,647)
Interest income	36	210	224	707
Net loss	$ (3,014)	$ (4,195)	$ (7,632)	$ (7,940)
Net loss per share basic and diluted	$ (0.11)	$ (0.16)	$ (0.28)	$ (0.30)
Weighted average common shares outstanding basic and diluted	27,233	27,017	27,184	26,897

(1) Non-cash stock-based compensation expense included in these amounts are as follows:

Research and development	$ 16	$ 49	$ 85	$ 482
General and administrative	246	1,107	707	1,630
Sales and marketing		45		219
Restructuring	3	174	3	174

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands - unaudited)

	Nine Months Ended September 30, 2008	2007
Cash flows from operating activities:		
Net loss	$ (7,632)	$ (7,940)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and write-offs of fixed assets	174	176
Restructuring	281	
Amortization and write-offs of patents	320	349
Stock-based compensation	795	2,505
Amortization of deferred license fees	(1,013)	(2,520)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	20	105
Accounts payable	(9)	108
Accrued expenses	(1,232)	812
Third party royalty obligation	1,800	
Net cash used in operating activities	(6,496)	(6,405)
Cash flows from investing activities:		
Purchases of marketable securities	(3,458)	(15,303)
Maturities of marketable securities	11,536	23,944
Purchases of property and equipment	(4)	(2)
Proceeds from sale of fixed assets		3
Increase in patent costs and other assets	(101)	(36)
Net cash provided by investing activities	7,973	8,606
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	6	32
Decrease in restricted cash	100	100
Net cash provided by financing activities	106	132
Net increase in cash and cash equivalents	1,583	2,333
Cash and cash equivalents, beginning of period	4,486	4,831
Cash and cash equivalents, end of period	$ 6,069	$ 7,164
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of 27,660 shares of common stock to fund the Company s 401(k) matching contribution for 2007	$ 59	$
Issuance of 34,030 shares of common stock to fund the Company s 401(k) matching contribution for 2006	$	$ 103
Issuance of 56,675 shares of restricted common stock to collaborator in lieu of cash to settle semi-annual license obligation	$	$ 158

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

EXACT Sciences Corporation (the Company) was incorporated in February 1995. The Company has developed proprietary DNA-based technologies for use in the detection of cancer. The Company has selected colorectal cancer as the first application of its technologies. The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to Laboratory Corporation of America® Holdings (LabCorp®) for use in a commercial testing service for the detection of colorectal cancer developed by LabCorp. LabCorp s first generation testing service, PreGen-Plus , was a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population and was marketed by LabCorp from August 2003 through June 1, 2008. In July 2008, LabCorp began offering ColoSure , its new non-invasive laboratory developed stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. The Company has devoted the majority of its efforts to date on research and development and commercialization support of its colorectal cancer detection technologies.

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company are unaudited and have been prepared on a basis substantially consistent with the Company s audited financial statements. These condensed consolidated financial statements assume that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business, and, in the opinion of management, include all normal and recurring adjustments which are necessary to present fairly the results of operations for the reported periods. These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) for interim reporting.

The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full fiscal year.

The Company has generated limited operating revenues since its inception and, as of September 30, 2008, had an accumulated deficit of approximately $170.4 million. The Company s losses have historically resulted from costs incurred in conjunction with research, development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and, prior to August 31, 2007, costs related to its sales and marketing functions to support the commercialization of its stool-based DNA screening technology.

The audit opinion with respect to the Company s consolidated financial statements for the year ended December 31, 2007 issued by its independent registered public accounting firm included an explanatory paragraph to emphasize that there is substantial doubt about the Company s ability to continue as a going concern. The Company expects that its cash and cash equivalents on hand at September 30, 2008 will be sufficient to fund its current operations through the end of the second quarter of 2009. This projection is based on the Company s current cost structure and its current operating assumptions. Based on the Company s decision to suspend its Version 2 clinical study in July 2008, this projection does not provide for any funding related to clinical validation and other studies for the Company s Version 2 technology.The Company has no current sources of material ongoing revenue and, accordingly, it will need to raise additional capital in the next seven months through a strategic transaction, debt or equity financing, or third-party collaboration, if any, or some combination of the foregoing, to continue operations beyond the end of the second quarter of 2009. If the Company is unable to obtain additional capital prior to the end of the second quarter of 2009, it will not be able to sustain its operations and would likely be required to cease its operations. In addition, if the Company s expenses exceed its current estimates, the Company will be required to obtain additional funds even sooner. These conditions raise substantial doubt about the Company s ability to continue as a going concern. The condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

As a result of the foregoing, the Company engaged an investment bank in the first quarter of 2008 to assist its board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, the Company announced that it revised its corporate strategy to take immediate actions to preserve existing cash while focusing on the pursuit of a strategic transaction, including a sale of the Company s business. The Company s revised corporate strategy may not result in a strategic alternative in the near future, if at all.

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(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company s wholly-owned subsidiary, EXACT Sciences Securities Corporation, a Massachusetts securities corporation. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly-liquid investments with maturities of 90 days or less at the time of acquisition to be cash equivalents. Cash equivalents primarily consist of money market funds.

Restricted Cash

At September 30, 2008 and December 31, 2007, $0.6 million and $0.7 million, respectively, of the Company s cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company s corporate headquarters.

Marketable Securities

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is

adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

At September 30, 2008, the Company held no marketable securities. At December 31, 2007, the Company s investments were comprised of fixed income investments and all were deemed available-for-sale. The objectives of the Company s investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company s investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sale of available-for-sale securities during the three and nine months ended September 30, 2008 and 2007.

Patent Costs

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred and are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is deemed to be no longer of value to the Company. As of September 30, 2008, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with its stool-based DNA colorectal cancer screening service.

The following table summarizes activity with respect to the Company s capitalized patents for the nine months ended September 30, 2008 and 2007. Amounts included in the table are in thousands.

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	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Patents, net of accumulated amortization, Beginning of period	$ 432	$ 763
Patent costs capitalized	101	36
Amortization of patents	(67)	(112)
Write-offs of patents	(253)	(237)
Patents, net of accumulated amortization, End of period	$ 213	$ 450

In July 2008, the Company announced that it was taking certain actions to reduce its cost structure to preserve existing cash, including suspending the clinical validation study of its Version 2 technology and eliminating approximately eight positions. These cost reduction actions were deemed to be impairment indicators pursuant to SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). After performing the requisite impairment analysis, the Company wrote off approximately $253,000 in capitalized patents during the quarter ended June 30, 2008 related specifically to one of the components of its Version 2 technology that is not used in LabCorp s current ColoSure testing service.

Capitalized patent costs written off during the nine months ended September 30, 2007 were primarily the result of the Company s determination that it would likely not pursue commercialization of certain technologies unrelated to intellectual property licensed to LabCorp for PreGen-Plus. Patent write-offs during the nine months ended September 30, 2007 also included the write-off of certain costs with respect to a capitalized pending patent application not critical to LabCorp s stool-based DNA colorectal cancer screening service, which was not approved by the U.S. Patent and Trademark Office.

The Company applies SFAS No. 144, which requires the Company to evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles and goodwill may warrant revision or that the carrying value of these assets may be impaired.

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share* (SFAS No. 128), for all periods presented. In accordance with SFAS No. 128, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	September 30, 2008	2007

Shares issuable upon exercise of stock options	3,685	4,520
Shares issuable upon exercise of outstanding warrants		1,000
	3,685	5,520

In conjunction with its strategic alliance with LabCorp, in June 2002, the Company issued to LabCorp a warrant (the LabCorp Warrant) to purchase 1,000,000 shares of its common stock, exercisable over a three-year period at an exercise price of $16.09 per share. At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, the Company extended the expiration date of the LabCorp Warrant to August 13, 2008, which was the expiration date of the exclusive period at the time of the extension. On August 13, 2008, the LabCorp Warrant expired unexercised.

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Accounting for Stock-Based Compensation

The Company accounts for share-based payments to employees in accordance with SFAS No. 123(R), *Share-Based Payment* (SFAS No. 123(R)), which requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. Share-based payment transactions with parties other than employees are accounted for in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

Revenue Recognition

License fees License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, the Company entered into an amendment to its exclusive license agreement with LabCorp (the Second Amendment) that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, the Company amortizes the remaining deferred revenue balance resulting from its license agreement with LabCorp at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company s Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of the Company s intellectual property. The Company will be entitled to the same royalty and milestone structure on any sales of ColoSure as it was entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, the Company s product royalty fees were based on a specified contractual percentage of LabCorp s cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp s cash receipts, as reported to the Company each month by LabCorp. Subsequent to the effective date of the Second Amendment, the Company s product royalty fees are based on a specified contractual percentage of LabCorp s net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, the Company records product royalty fees based on the specified contractual percentage of LabCorp s net revenues from its sales of such colorectal cancer screening tests, as reported to the Company each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company s condensed consolidated statements of operations.

Product revenue Product revenue from the sale of certain components of the Company s Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and collection of the receivable was probable. LabCorp has indicated that Effipure is not used as a component in LabCorp s ColoSure offering and the Company therefore does not expect to record product revenue in connection with Effipure sales in future periods.

Other revenue Revenue from milestone and other performance-based payments will be recognized as revenue when the milestone or performance is achieved and collection of the receivable is estimable and probable.

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and nine months ended September 30, 2008 and 2007 was as follows:

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(In thousands)	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Net loss	$ (3,014)	$ (4,195)	$ (7,632)	$ (7,940)
Unrealized (loss) gain on marketable securities	(1)	2	(23)	8
Comprehensive loss	$ (3,015)	$ (4,193)	$ (7,655)	$ (7,932)

Reclassifications

Certain prior year expenses previously included in the sales and marketing line item in the Company s consolidated statements of operations have been reclassified as general and administrative expenses to conform to the current year presentation. This change had no impact on the Company s net loss or net loss per share as previously reported.

(3) FOURTH AMENDMENT TO LABCORP LICENSE AGREEMENT

On March 17, 2008, the Company entered into the fourth amendment (the Fourth Amendment) to its exclusive license agreement with LabCorp. Among other things, the Fourth Amendment further clarified certain license rights of the parties, amended LabCorp s termination rights relating to the failure to launch the Company s Version 2 technology and restricted certain of the Company s termination rights in the event the U.S. Food and Drug Administration (FDA) limits LabCorp s ability to market products that incorporate technology licensed to LabCorp under the amended license agreement. In addition, the Fourth Amendment eliminated certain of the Company s termination rights for a specified period of time during which LabCorp is not marketing any stool-based DNA test for colorectal cancer as a result of preparing for a commercial launch of a stool-based DNA test for colorectal cancer based on certain of the Company s intellectual property.

(4) CONTINGENCIES

Third Party Royalty Obligation

Pursuant to the terms of the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp s third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. The Company s obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp s sales volumes of colorectal cancer screening tests using the Company s technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company s potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp s sales of colorectal cancer screening tests using the Company s technology increase to a level that would reduce this potential maximum obligation, if ever, the Company intends to record its estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its condensed consolidated statements of operations, in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of September 30, 2008, the Company had accrued a total of $3.0 million related to the total potential $3.5 million obligation to LabCorp. The Company recorded charges of $1.0 million and $1.8 million, respectively, during the three and nine months ended September 30, 2008 in connection with this third-party royalty obligation. These charges were recorded under the caption Product royalty fees in the Company s condensed consolidated statements of operations. This obligation is recorded in the

Company s condensed consolidated balance sheets under the caption Third-party royalty obligation. Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of the Company s condensed consolidated statements of operations. Amounts included in the table are in thousands.

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Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	January 30, 2009	$	$ 1,500
January 1, 2009	December 31, 2009	January 30, 2010		1,000
January 1, 2010	December 31, 2010	January 30, 2011		1,000
			$	$ 3,500

Employee Severance and Retention Agreements

On April 18, 2008, the Company entered into amended and restated employee retention agreements (the Agreements) with certain employees, including Jeffrey R. Luber, the Company s President and Chief Executive Officer, and Charles R. Carelli, Jr., the Company s Senior Vice President, Chief Financial Officer, Treasurer and Secretary. The Agreements supersede and replace the prior employee retention agreements entered into between the Company and Messrs. Luber and Carelli on October 23, 2006.

The total potential severance and other obligations of the Company upon the occurrence of certain triggering events under the Agreements, including a termination without cause following a change of control of the Company, was approximately $1.9 million at September 30, 2008. As of September 30, 2008, the Company has not recorded any amount related to the potential severance payments because no triggering events had occurred as of that date.

(5) RESTRUCTURING

2008 Restructuring

On July 16, 2008, the Company implemented certain cost reduction initiatives, including the suspension of the clinical validation study for its Version 2 technology and the elimination of eight positions, or 67% of the Company s workforce (the 2008 Restructuring), in connection with the Company s revised corporate strategy of reducing costs to better preserve existing cash.

The 2008 Restructuring was initiated under a plan of termination described in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), pursuant to which the Company recorded restructuring charges of approximately $0.5 million during the three months ended September 30, 2008 under generally accepted accounting principles, including $0.2 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and $0.3 million resulting from the write-off of leasehold improvements abandoned by the Company in connection with the reduction in force. The Company s decision to eliminate 67% of its workforce was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, non-cash asset impairment charges of $0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), the Company recorded one-time non-cash stock-based compensation charges of approximately $3,000 in the Restructuring line item of the Company s condensed consolidated statements of operations during the quarter ended September 30, 2008.

Amounts remaining in the 2008 Restructuring accrual at September 30, 2008, which are expected to be paid out in cash through February 2009, are recorded under the caption Accrued expenses in the Company s condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the three months ended September 30, 2008 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

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Type of Liability	Balance, June 30, 2008	Charges	Cash Payments	Non-cash Write-offs	Balance, September 30, 2008
Employee separation costs	$	$ 255	$ (102)	$	$ 153
Facility consolidation costs		281		(281)	
Total	$	$ 536	$ (102)	$ (281)	$ 153

2007 Restructuring

On August 31, 2007, the Company entered into a third amendment (the Third Amendment) to its exclusive license agreement with LabCorp that, among other things, added a potential $2.5 million milestone payment for which the Company may be eligible upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of ColoSure over a defined measuring period. The Third Amendment also provided that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp s stool-based DNA testing service, and provided that LabCorp would offer at-will employment to certain former personnel of the Company. In connection with the Third Amendment, the Company notified six employees of their termination from the Company (the 2007 Restructuring). The 2007 Restructuring was principally designed to eliminate the Company s sales and marketing functions to reduce costs and help preserve the Company s cash resources. In connection with the 2007 Restructuring, the Company recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs which were paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges associated with extending the period of exercise for vested stock option awards for terminated employees.

During the fourth quarter of 2007, the Company entered into a sublease agreement (the Sublease Agreement) with INTRINSIX Corporation (the Subtenant) to sublease to the Subtenant approximately 11,834 square feet of rentable area in the Company s corporate headquarters. In connection with the Sublease Agreement, the Company recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption Facility consolidation costs in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between the Company s committed lease payments and the estimated sublease rental income under the Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the Sublease Agreement. The Company s decision to enter into the Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one time real estate transaction fees in connection with the Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at September 30, 2008, which are expected to be paid out through July 2010, are recorded under the caption Accrued expenses in the Company s condensed consolidated balance sheets.

The following table summarizes changes made to the restructuring accrual during the nine months ended September 30, 2008 relating to the 2007 Restructuring and Sublease Agreement. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, September 30, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$	$
Facility consolidation costs	268		(84)		184
Total	$ 492	$ (7)	$ (301)	$	$ 184

The Company is pursuing efforts to further reduce its costs and may record additional restructuring charges related to such reductions in future periods.

(6) DELISTING NOTICE FROM NASDAQ

On July 10, 2008, the Company received notice from The NASDAQ Stock Market LLC that the Company was not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A) (the Rule), which requires an issuer to maintain a minimum $50 million market

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value of its listed securities for continued listing on The NASDAQ Global Market. The Company was provided a period of 30 calendar days, or until August 11, 2008, to regain compliance with the Rule by evidencing a market value of listed securities of at least $50 million for a minimum of 10 consecutive business days. On August 12, 2008, the Company received a letter from NASDAQ advising that it had not regained compliance with the Rule by August 11, 2008 and, as a result, the Company s common stock would be subject to delisting from The NASDAQ Global Market on August 21, 2008 unless the Company requested a hearing before the NASDAQ Listing Qualifications Panel (the Panel). The Company requested a hearing before the Panel, which was held on October 2, 2008. The delisting of the Company s common stock has been stayed pending the issuance of a formal decision by the Panel. The Panel has not yet issued its decision in this matter.

The delisting of the Company s common stock could significantly affect the ability of investors to trade the Company s securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of the Company s common stock could adversely affect the Company s ability to enter into a strategic transaction or to raise capital on terms acceptable to the Company, or at all. Delisting from The NASDAQ Stock Market could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

(7) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 1995 Stock Option Plan (1995 Option Plan), the 2000 Stock Option and Incentive Plan (2000 Option Plan) and the 2000 Employee Stock Purchase Plan (Employee Stock Purchase Plan). Note 9 to the Company s consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the SEC, includes a description of the Company s stock-based compensation plans.

Stock-Based Compensation Expense

The Company recorded $0.3 million and $0.8 million, respectively, in stock-based compensation during the three and nine months ended September 30, 2008 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants as well as certain stock option modifications discussed below. The Company recorded $1.4 million and $2.5 million in stock-based compensation during the three and nine months ended September 30, 2007, respectively, in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants, as well as restricted common stock issued to a collaborator, certain stock option modifications recorded and previously disclosed in connection with the 2007 Restructuring and stock-based compensation expense related to the Company s 2007 401(k) match, which was made in Company common stock in May 2008.

Determining Fair Value

Valuation and Amortization Method - The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the table below. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period.

Expected Term - The Company uses the simplified calculation of expected life, described in the SEC s Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected life is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility - Expected volatility is based on the Company s historical volatility from the time of its initial public offering in January 2001 through the measurement date of the awards.

Risk-Free Interest Rate - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Forfeitures - As required by SFAS No. 123(R), the Company records share-based compensation expense only for those awards that are expected to vest. The Company does not need to estimate forfeitures because all share based awards vest monthly.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the following table.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Option Plan Shares				
Risk-free interest rates	3.02%	4.16% - 4.60%	2.80% - 3.02%	4.16% - 4.60%
Expected term (in years)	6	6	6	6
Expected volatility	75%	70%	70% - 75%	70%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	$0.48	$1.92	$1.10	$1.87
ESPP Shares				
Risk-free interest rates	(1)	(1)	(1)	5.10% - 5.17%
Expected term (in years)	(1)	(1)	(1)	0.5 - 2
Expected volatility	(1)	(1)	(1)	70%
Dividend yield	(1)	(1)	(1)	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1)	(1)	$1.08

(1) The Company did not issue stock options or stock purchase rights under its stock-based compensation plans during the periods indicated.

Stock Option Activity

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the nine months ended September 30, 2008 is as follows:

Options *(Aggregate intrinsic value in thousands)*	**Shares**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (Years)**	**Aggregate Intrinsic Value (1)**
Outstanding, January 1, 2008	3,996,688	$ 4.88	4.8	
Granted	628,600	$ 1.54		
Exercised	(78,117)	$ 0.08		
Cancelled	(861,713)	$ 6.13		
Outstanding, September 30, 2008	3,685,458	$ 4.12	5.4	$ 34
Exercisable, September 30, 2008	2,770,784	$ 4.71	4.2	$ 24
Vested and expected to vest, September 30, 2008	3,685,458	$ 4.12	5.4	$ 34

(1) The aggregate intrinsic value of options outstanding, as well as options vested and expected to vest, at September 30, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company s common stock for the 118,462 options that had exercise prices that were lower than the $0.87 market price of our common stock at September 30, 2008. The aggregate intrinsic value of options exercisable at September 30, 2008 is calculated as the difference between the exercise price of the

underlying options and the market price of the Company s common stock for the 55,957 options that had exercise prices that were lower than the $0.87 market price of our common stock at September 30, 2008.

As of September 30, 2008, there was $1.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.6 years.

Stock option modifications

In connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a

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weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), the Company recorded one-time stock-based compensation charges of approximately $3,000 in the Restructuring line item of the Company s condensed consolidated statements of operations during the quarter ended September 30, 2008.

(8) COLORECTAL CANCER SCREENING GUIDELINES

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society (ACS), the American College of Gastroenterology and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, such recommendations consisted of colonoscopy, flexible sigmoidoscopy, double contrast barium enema and fecal occult blood testing (FOBT), as well as combinations of some of these methods. On March 5, 2008, the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine (the MSTF-CRC), and the American College of Radiology announced that non-invasive, stool-based DNA screening technology has been included in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and above, a population of approximately 90 million Americans. These new guidelines now divide colorectal cancer screening into two groups, one including non-invasive methods for the early detection of colorectal cancer and the other including invasive techniques for the prevention and early detection of colorectal cancer. Non-invasive technologies include fecal occult blood testing and stool-based DNA screening for individuals unwilling or unable to use invasive screening procedures. Invasive procedures include colonoscopy, flexible sigmoidoscopy, CT colonography, and double contrast barium enema and, according to the new guidelines, are designed to detect both early cancer and adenomatous polyps and should be encouraged if resources are available and patients are willing to undergo an invasive test. While the Company views inclusion of its stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for any stool-based DNA screening test for colorectal cancer, the Company believes that FDA clearance for its technologies, and reimbursement from the Centers for Medicare and Medicaid Services and other third-party payors will be necessary to achieve any significant increase in demand for its technologies. In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need only detect a majority of colorectal cancers in a screening population to meet guidelines criteria. The Company has not performed a stand-alone colorectal cancer screening study of LabCorp s ColoSure test and there can be no assurance that the guidelines groups will agree that existing studies using our Version 2 technologies, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of such technologies in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on the Company s business.

(9) REGULATORY STATUS

From August 2003 through June 2008, LabCorp offered its PreGen-Plus testing service, which included the Effipure component from the Company, as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007, the FDA sent the Company a warning letter (the Warning Letter) with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. The Company s Version 1 technology was the basis for LabCorp s PreGen-Plus testing service. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In addition to the Company s Version 1 technology underlying the PreGen-Plus testing service that was offered by LabCorp, the Company has also developed a Version 2 colorectal cancer screening technology. In April 2008, the Company began to focus its regulatory efforts on pursuing FDA clearance for Version 2 of its technology, a two-marker version that the Company believes offers greater sensitivity and can be more cost-effective than its earlier, 23 marker Version 1 technology. In this regard, in April 2008, the Company submitted a pre-Investigational

Device Exemption (pre-IDE) request to the FDA for its Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for the Company s Version 2 technology and that the clinical and other studies proposed in its Version 2 pre-IDE submission would likely support such a *de novo* regulatory path.

On July 14, 2008, LabCorp announced that it would begin offering a new single marker in-house laboratory-developed test called ColoSure, which is based on certain of the Company s Version 2 intellectual property and that does not use the Effipure component. There can be no assurance that LabCorp s offering of ColoSure falls within the category of in-house developed laboratory tests, or home-brew tests, over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp may be required to discontinue offering ColoSure and, under such circumstances, our business would likely be materially adversely affected.

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Also in July 2008, the Company confirmed with the FDA the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of its two-marker Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on its discussions with the FDA, the Company believes that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. The Company estimates that total costs to complete its Version 2 validation studies and the related regulatory submission process would range from $6.5 million to $8.5 million. The FDA may ultimately determine that a pre-market approval application (PMA) is the appropriate path forward for the Company with respect to Version 2 of its stool-based DNA technology instead of a *de novo* pathway, or that additional samples, and a more expensive and time-consuming study or studies may be required for clearance or approval. Moreover, the Company may determine that accruing additional patients and cancer samples to further bolster the statistical strength of any such study, which may require redrafting and resubmission of a pre-IDE application with FDA. Such a study, with additional samples, would be more expensive and time-consuming than the current protocol upon which the Company s current estimates are based. The Company believes that the studies required in connection with any approval or clearance of its Version 2 technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve a *de novo* classification request or approve a PMA submitted by the Company.

As described in Note 5, in July 2008, the Company further reduced its cost structure by suspending the clinical validation study and other studies for its Version 2 technology and eliminating eight positions within the Company. Because the Company does not currently have sufficient funds to complete any clinical validation or other FDA-related study of its Version 2 technology, it will need to gain access to additional capital through a strategic transaction, a merger or sale of the Company, a debt or equity financing, or third-party collaboration, if any, and/or some combination of any of the foregoing in order to fund any FDA regulatory clearance or approval process of its Version 2 technology. There can be no assurance that the Company will be successful in securing or gaining access to any additional capital to pursue the clinical validation study for its Version 2 technology under any potential strategic transaction or capital structure. If the Company is unable to finance the requisite clinical and other studies of its Version 2 technology, it will not be able to complete and submit its application to seek FDA approval or clearance of its Version 2 technology.

(10) FAIR VALUE MEASUREMENTS

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements* (SFAS No. 157). SFAS No. 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 are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on its condensed consolidated results of operations, financial position or cash flows.

SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established by SFAS No. 157 in order of priority are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect the Company s assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

As of September 30, 2008, the Company s balance sheet contained no assets or liabilities requiring fair value measurement disclosures pursuant to the provisions of SFAS No. 157. Cash and cash equivalents are recorded at cost, which approximates fair value. Cash equivalents at September 30, 2008 consist of money market funds and short term commercial paper.

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(11) NEW ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for the company in 2008. The Company did not elect the fair value option for any of its eligible financial instruments and other items, therefore, the adoption of SFAS No. 159, effective January 1, 2008, did not materially impact its financial position, results of operations or cash flows.

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* (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 adopted EITF 07-3 on January 1, 2008 and it did not have any impact on its condensed consolidated results of operations, financial position or cash flows.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of the financial condition and results of operations of EXACT Sciences Corporation should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the Securities and Exchange Commission, or SEC.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as believes, expects, may, will, should, could, seek, plans, estimates, anticipates or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q include, among others, statements regarding the building of material market demand, the sufficiency of our capital resources, expected royalty fees and revenues, the potential costs and impact of U.S. Food and Drug Administration, or FDA, regulatory action on the marketing and sale of our DNA-based technologies, expectations regarding third-party reimbursement of tests using our technology, expected restructuring charges, our expectations concerning our commercial strategy, and the effectiveness and market acceptance of our technologies and ColoSure. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, including those risks and uncertainties described in Item 1A of this report and our Annual Report on Form 10-K for the year ended December 31, 2007. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

EXACT Sciences Corporation develops proprietary DNA-based technologies for use in the detection of cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis in the United States and Canada through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®. LabCorp developed and commercially offered PreGen-Plus, its first generation non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure , its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our technologies. We are entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus. Since our inception in February 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;

- conducting clinical studies to validate our colorectal cancer screening technologies;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- pursuing reimbursement for stool-based DNA screening with third-party payors, including the Centers for Medicare and Medicaid Services, or CMS;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our proprietary technologies to LabCorp and others;
- working to further the adoption of stool-based DNA testing for colorectal cancer, including seeking inclusion of such technology in the guidelines of the major guidelines organizations;
- pursuing U.S. Food and Drug Administration, or FDA, clearance or approval, or exemptions therefrom for our stool-based DNA screening technology for colorectal cancer;
- working with LabCorp on activities in support of the commercialization of tests using our technology; and
- pursuing strategic alternatives for our business.

We have generated limited operating revenues since our inception and, as of September 30, 2008, we had an accumulated deficit of approximately $170.4 million. Our losses have historically resulted from costs incurred in conjunction with our research, development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing

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programs and, prior to August 31, 2007, the build-out of our sales infrastructure to support the commercialization of stool-based DNA screening. We expect that our losses will continue for the next several years and we may never achieve profitability.

From the date of commercial launch through June 2008, when LabCorp stopped commercially offering PreGen-Plus, LabCorp had accessioned approximately 14,900 PreGen-Plus samples, including approximately 500 in the six months ended June 30, 2008 and approximately 1,800, 3,700 and 4,000 samples during the years ended December 31, 2007, 2006 and 2005, respectively. On July 14, 2008, LabCorp began to commercially offer ColoSure , its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our technologies. From such date until October 31, 2008, LabCorp has accessioned approximately 250 ColoSure samples.

In addition to our Version 1 technology underlying the PreGen-Plus testing service formerly offered by LabCorp, we have also developed or licensed technologies related to a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than the Version 1 technology. Our Version 2 technology includes two DNA markers that, in published studies, have been shown to be associated with colorectal cancer. These markers include the aberrant methylation of the Vimentin gene promoter region, which we refer to as Vimentin, and DIA®, or long DNA. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University, or Case Western, under which we pay a royalty and certain other fees to Case Western in return for the right to use and sublicense the Vimentin technology. We own the rights to DIA and do not pay any royalties on the use of DIA. In a recent research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. LabCorp s ColoSure testing service relies solely on the Vimentin gene and does not use the DIA marker that is also included in our Version 2 technology.

Recent Developments

Regulatory Update

From August 2003 through June 2008, LabCorp offered its PreGen-Plus testing service, which included the Effipure component from us, as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007, the FDA sent us a warning letter (the Warning Letter) with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. Our Version 1 technology was the basis for LabCorp s PreGen-Plus testing service. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In addition to our Version 1 technology underlying the PreGen-Plus testing service that was offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology. In April 2008, we began to focus our regulatory efforts on pursuing FDA clearance for Version 2 of its technology, a two-marker version that we believe offers greater sensitivity and can be more cost-effective than our earlier, 23 marker Version 1 technology. In this regard, in April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA for its Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in its Version 2 pre-IDE submission would likely support such a *de novo* regulatory path.

On July 14, 2008, LabCorp announced that it would begin offering a new single marker in-house laboratory-developed test called ColoSure, which is based on certain of our Version 2 intellectual property and that does not use the Effipure component. There can be no assurance that LabCorp s offering of ColoSure falls within the category of in-house developed laboratory tests, or home-brew tests, over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp may be required to discontinue offering ColoSure and, under such circumstances, our business would likely be materially adversely affected.

Also in July 2008, we confirmed with the FDA the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of our two-marker Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. We estimate that total costs to complete our Version 2 validation studies and the related regulatory submission process would range from $6.5 million to $8.5 million. The FDA may ultimately determine that a pre-market approval application, or PMA is the appropriate path forward for us with respect to Version 2 of our stool-based DNA technology instead of a *de novo* pathway, or that additional samples, and a more expensive and time-consuming study or studies may be required for clearance or approval. Moreover, we may determine that accruing additional patients and cancer samples to further bolster the statistical strength of any such study, which may require redrafting and resubmission of a pre-IDE application with FDA. Such a study, with additional samples, would be more expensive and time-consuming than the current protocol upon which our current estimates are based. The Company believes that the studies required in connection with

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any approval or clearance of our Version 2 technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve a *de novo* classification request or approve a PMA submitted by us.

As described under the heading 2008 Restructuring below, in July 2008, we further reduced our cost structure by suspending the clinical validation study and other studies for our Version 2 technology and eliminating eight positions within the Company. Because we do not currently have sufficient funds to complete any clinical validation or other FDA-related study of our Version 2 technology, we will need to gain access to additional capital through a strategic transaction, a merger or sale of the Company, a debt or equity financing, or third-party collaboration, if any, and/or some combination of any of the foregoing in order to fund any FDA regulatory clearance or approval process of our Version 2 technology. There can be no assurance that we will be successful in securing or gaining access to any additional capital to pursue the clinical validation study for our Version 2 technology under any potential strategic transaction or capital structure. If we are unable to finance the requisite clinical and other studies of its Version 2 technology, we will not be able to complete and submit our application to seek FDA approval or clearance of its Version 2 technology.

Delisting Notice from NASDAQ

On July 10, 2008, we received notice from The NASDAQ Stock Market LLC that we were not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), or the Rule, which requires an issuer to maintain a minimum $50 million market value of its listed securities for continued listing on The NASDAQ Global Market. We were provided a period of 30 calendar days, or until August 11, 2008, to regain compliance with the Rule by evidencing a market value of listed securities of at least $50 million for a minimum of 10 consecutive business days. On August 12, 2008, we received a letter from NASDAQ advising that we had not regained compliance with the Rule by August 11, 2008 and, as a result, our common stock would be subject to delisting from The NASDAQ Global Market on August 21, 2008 unless we requested a hearing before the NASDAQ Listing Qualifications Panel, or the Panel. We requested a hearing before the Panel, which was held on October 2, 2008. The delisting of our common stock has been stayed pending the issuance of a formal decision by the Panel following the hearing. The Panel has not yet issued its decision in this matter.

The delisting of our common stock could significantly affect the ability of investors to trade our securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could adversely affect our ability to enter into a strategic transaction or to raise capital on terms acceptable to us, or at all. Delisting from The NASDAQ Stock Market could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

Our Cost Structure

In July 2008, we took actions to further reduce our cost structure to help preserve our cash resources, which we refer to as the 2008 Restructuring. These actions included including suspending the clinical validation study of our Version 2 technology, eliminating eight positions, or 67% of our staff, and seeking the re-negotiation of certain fixed commitments. We continue to assess our facility needs and other operating costs and, as a result, could incur additional restructuring charges in the event we undertake additional activities to reduce facility or other operating costs.

In addition to the 2008 Restructuring, in October 2006 and again in July 2007, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2006 Restructuring and the 2007 Restructuring, respectively, to help preserve our cash resources. The 2006 Restructuring eliminated 21 positions, or 48% of our staff at that time, across all departments. As part of the 2007 Restructuring, we eliminated our sales and marketing functions, terminated six employees, and subleased a portion of our leased space at our corporate headquarters.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies and, effective as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R). Although we have suspended the Version 2 clinical validation study, and took steps in 2006, 2007 and 2008 to lower research and development costs, we will still likely need to invest substantial funds in additional research, design and development, or clinical or other studies that may be required for FDA approval or clearance of our stool-based DNA screening technologies, to successfully commercialize our Version 2 technology, or any future versions of our technologies or products. In this regard, the costs of the clinical and related technical validation studies that we believe are required by the FDA in connection with any future *de novo* 510(k) pre-market clearance notice for our Version 2 technology, as well as any subsequent studies or filings for other versions of our technologies, are expected to be material. We do not have, and can make no assurance that we can raise or otherwise secure, the capital necessary to initiate the

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Version 2 clinical validation study or the related regulatory submission. As a result of the cost reduction actions taken in 2008, we expect research and development costs in 2008 to be lower than 2007 levels.

Selling, general and administrative expenses have consisted primarily of non-research personnel salaries, office expenses, professional fees and, as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123(R). As a result of the 2007 Restructuring, in which we eliminated our sales and marketing functions effective August 31, 2007, we do not expect to incur material sales and marketing operating expenses in 2008. We expect general and administrative expenses in 2008 to be lower than 2007 levels, primarily as a result of decreased non-cash stock-based compensation charges due to lower headcount in 2008 as compared to 2007.

Other Factors Affecting Potential Revenue Growth

We believe that substantial funds and managerial attention will likely need to be invested in sales and marketing efforts over the next several years for our stool-based DNA screening technologies to be commercially successful. We do not have, and we cannot assure you that LabCorp will devote, the funds or management resources that we believe are likely necessary to build sufficient demand for ColoSure. Despite the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, we do not expect material revenue growth from sales of ColoSure until such time as FDA clearance or approval is obtained, if ever, and reimbursement is provided by CMS and other third-party payors at an acceptable level. In addition, we believe our success will also depend upon a number of additional factors that are largely out of our control, including the following:

- the impact that the inclusion of stool-based DNA screening in guidelines will have on prescribing physicians, third-party payors, including CMS, and health care consumers;
- any regulatory restrictions placed upon ColoSure or any other product or testing service based on our technologies;
- success in educating third-party payors, including CMS, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- effective negotiation and contracting by us and LabCorp with CMS and other third-party payors for coverage at acceptable levels of reimbursement for stool-based DNA screening;
- patient acceptance of stool-based DNA screening, including its novel sample collection process;
- the absence of competing technologies that offer equal or better attributes than stool-based DNA screening;
- stool-based DNA screening becoming a standard of care among prescribing physicians; and
- the quality and service of the LabCorp testing process.

As a result of the foregoing, we engaged an investment bank in the first quarter of 2008 to assist our board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, we announced a revised corporate strategy to take immediate actions to preserve existing cash while continuing to focus on the pursuit of a strategic transaction, including a sale of the business. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all.

Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp under our strategic license agreement and product royalty fees on tests sold by LabCorp utilizing our technology, which has historically been based on PreGen-Plus sales but will now be based on ColoSure sales. We expect that product royalty fees for the full year 2008 will be lower than amounts recorded in 2007 as a result of potential third-party royalty obligations in connection with our amended license agreement with LabCorp. In addition, as a result of the second amendment to our license agreement with LabCorp, which also extended the exclusive license period under our agreement with LabCorp, we expect that license fee revenue for 2008 will be lower than amounts recorded in 2007 as a result of the extended amortization period over which our remaining deferred revenue will be amortized.

Significant Accounting Policies

This management s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, certain third party royalty obligations,and intangible assets. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2007, which has been filed with the SEC, include a summary of the significant accounting policies and methods used in the

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preparation of our consolidated financial statements. As described below, we believe that that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition.

License fees - License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, we entered into an amendment to our exclusive license agreement with LabCorp, or the Second Amendment, which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we amortize the remaining deferred revenue balance at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our Version 2 technology. We will be entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, our product royalty fees were based on a specified contractual percentage of LabCorp s cash receipts from performing PreGen-Plus tests. Accordingly, we recorded product royalty fees based on this specified percentage of LabCorp s cash receipts, as reported to us each month by LabCorp. Subsequent to the effective date of the Second Amendment, our product royalty fees are based on a specified contractual percentage of LabCorp s net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, we record product royalty fees based on the specified contractual percentage of LabCorp s net revenues from its sales of such colorectal cancer screening tests, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 to the condensed consolidated financial statements located elsewhere in this quarterly report on Form 10-Q. To the extent we incur liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in our consolidated statements of operations.

Product revenue - Product revenue from the sale of certain components of our Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and

collection of the receivable was probable. Effipure is not used as a component in LabCorp s ColoSure offering and we therefore do not expect to record product revenue in connection with Effipure sales in future periods.

Other revenue - Revenue from milestone and other performance-based payments will be recognized as revenue when the milestone or performance is achieved and collection of the receivable is estimable and probable.

Patent Costs. Patent costs are capitalized as incurred and are amortized beginning when patents are issued over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, upon a decision by us to no longer pursue the patent, or when the related intellectual property is deemed to be no longer of value to us. As of September 30, 2008, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with its stool-based DNA colorectal cancer screening service.

The following table summarizes activity with respect to our capitalized patents for the nine months ended September 30, 2008 and 2007. Amounts included in the table are in thousands.

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	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Patents, net of accumulated amortization, Beginning of period	$ 432	$ 763
Patent costs capitalized	101	36
Amortization of patents	(67)	(112)
Write-offs of patents	(253)	(237)
Patents, net of accumulated amortization, End of period	$ 213	$ 450

In July 2008, we announced that we were taking certain actions to reduce our cost structure to preserve existing cash, including suspending the clinical validation study of our Version 2 technology and eliminating eight positions. These cost reduction actions were deemed to be impairment indicators pursuant to SFAS No. 144. After performing the requisite impairment analysis, we wrote off approximately $253,000 in capitalized patents during the quarter ended June 30, 2008 related specifically to one of the components of its Version 2 technology that is not used in LabCorp s current ColoSure testing service.

Capitalized patent costs written off during the nine months ended September 30, 2007 were primarily the result of our determination to not pursue commercialization of certain technologies unrelated to intellectual property licensed to LabCorp for PreGen-Plus. Patent write-offs during the nine months ended September 30, 2007 also included the write-off of certain costs with respect to a capitalized pending patent application not critical to LabCorp s PreGen-Plus testing service, which was not approved by the U.S. Patent and Trademark Office.

We apply SFAS No. 144, which requires us to continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles may warrant revision or that the carrying value of these assets may be impaired. Such events may include a change in the regulatory requirements for ColoSure.

Stock-Based Compensation. We adopted SFAS No. 123(R) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, as originally issued and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Prior to January 1, 2006, we accounted for stock-based compensation under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Critical Accounting Estimate Third-Party Royalty Obligation

Pursuant to the terms of the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp s third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. Our obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp s sales volumes of colorectal cancer screening tests using our technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp s sales of colorectal cancer screening tests using our technology increase to a level that would reduce this potential maximum obligation, if ever, we intend to record our estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).* Based on sales volumes of PreGen-Plus through June 1, 2008 and anticipated sales volumes of ColoSure, as of September 30, 2008, we had accrued a total of $3.0

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million related to the total potential $3.5 million obligation to LabCorp. We recorded charges of $1.0 million and $1.8 million, respectively, during the three and nine months ended September 30, 2008 in connection with this third-party royalty obligation. These charges were recorded under the caption Product royalty fees in our consolidated statements of operations. This obligation is recorded in our consolidated balance sheets under the caption Third-party royalty obligation. Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of our consolidated statements of operations. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	January 30, 2009	$	$ 1,500
January 1, 2009	December 31, 2009	January 30, 2010		1,000
January 1, 2010	December 31, 2010	January 30, 2011		1,000
			$	$ 3,500

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements*, or SFAS No. 157. SFAS No. 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 are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on our consolidated results of operations, financial position or cash flows.

SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established by SFAS No. 157 in order of priority are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect our assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

As of September 30, 2008, our balance sheet contained no assets or liabilities requiring fair value measurement disclosures pursuant to the provisions of SFAS No. 157. Cash and cash equivalents are recorded at cost, which approximates fair value. Cash equivalents at September 30, 2008 consist of money market funds and short term commercial paper.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115*, or SFAS No. 159. SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for us in 2008. We did not elect the fair value

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option for any of our eligible financial instruments and other items, therefore, the adoption of SFAS 159, effective January 1, 2008, did not materially impact our financial position, results of operations or cash flows.

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. We adopted EITF 07-3 on January 1, 2008 and it did not have any impact on our consolidated results of operations, financial position or cash flows.

Results of Operations

Revenue. Total revenue decreased to $(0.7) million for the three months ended September 30, 2008 from $0.1 million for the three months ended September 30, 2007, and decreased to $(0.8) million for the nine months ended September 30, 2008 from $2.4 million for the nine months ended September 30, 2007. Total revenue during these periods is composed of the amortization of up-front technology license fees associated with our amended license agreement with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in December 2010, royalties on LabCorp s sales of PreGen-Plus and sales of Effipure units to LabCorp.

The decrease in total revenue for the three and nine months ended September 30, 2008 when compared to the same periods of 2007 was primarily the result of decreases of approximately $0.8 million and $1.6 million for the three and nine months ended September 30, 2008, respectively, due to charges of $1.0 million and $1.8 million recorded in the product royalty revenue line item of our consolidated statements of operations in the three and nine months ended September 30, 2008, respectively, in connection with our third-party royalty reimbursement obligation to LabCorp. These charges to product royalty revenue were recorded pursuant to the Second Amendment and resulted in negative product royalty revenue for the three and nine months ended September 30, 2008.

In addition, non-cash license fee amortization revenue was $1.5 million lower in the nine months ended September 30, 2008 when compared to the same period of 2007 as a result of the Second Amendment, which extended the exclusive period under our license agreement with LabCorp from August 2008 to December 2010. As a result of this extension, the remaining unamortized up-front license fees that LabCorp previously paid to us ($4.7 million at the time of the Second Amendment) are now being recognized over a longer period of time, resulting in lower non-cash license fee amortization as compared to prior periods.

In June 2008, LabCorp stopped offering PreGen-Plus, the version of the stool-based DNA technology that has been the subject of FDA inquiry over the past several years. In July 2008, LabCorp began offering a new stool-based DNA test, which is different from our Version 2 technology and is based solely on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. Pursuant to our license agreement with LabCorp, we are entitled to the same royalty and milestone structure on sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Research and development expenses. Research and development expenses decreased to $0.6 million for the three months ended September 30, 2008 from $1.0 million for the three months ended September 30, 2007, and decreased to $2.0 million for the nine months ended September 30, 2008 from $3.6 million for the nine months ended September 30, 2007. The decrease in the three and nine months ended September 30, 2008 as compared to the same periods of 2007 was primarily the result of the continuing effect of the cost reduction plans undertaken in 2006, 2007 and 2008 as described under the heading Our Cost Structure above. The decrease in research and development expenses for the quarter ended September 30, 2008, as compared to the quarter ended September 30, 2007, included decreases of $0.3 million in lab-related operating expenses and $0.1 million in personnel-related expenses. Included in the decrease in research and development expenses for the nine months ended September 30, 2008, as compared to the nine months ended September 30, 2007, were decreases of $0.7 million in lab-related operating expenses, $0.3 million in personnel-related expenses, $0.3 million in licensing costs, and $0.4 million in non-cash stock-based compensation charges resulting from the June 2007 issuance of 100,000 shares of our common stock to Oncomethylome Sciences S.A., or OMS, on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

General and administrative expenses. General and administrative expenses decreased to $1.3 million for the quarter ended September 30, 2008, compared to $2.5 million for the quarter ended September 30, 2007. This decrease was primarily due to a decrease in non-cash stock-based compensation expense of $0.9 million when comparing the quarter ended September 30, 2008 to the same period of 2007. During the three months ended September 30, 2007, we recorded non-cash stock-based compensation charges of $0.7 million related to the acceleration and the extension of the expiration date of certain stock options held by Don M. Hardison, our former President and Chief Executive Officer, pursuant to a separation agreement between the Company and Mr. Hardison in connection with his resignation from the Company in August 2007. The decrease in general and administrative expenses for the quarter ended September 30, 2008 as compared to the same period of 2007 also included decreases of $0.2 million in professional fess and $0.1 million in personnel-related expenses.

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General and administrative expenses decreased to $4.6 million for the nine months ended September 30, 2008 from $5.6 million for the nine months ended September 30, 2007. The decrease was primarily the result of lower non-cash stock-based compensation charges of $0.9 million resulting primarily from the option modification charges described above in connection with Mr. Hardison s resignation from the Company in August 2007, as well as a decrease of $0.5 million in salary, benefit and other costs due to lower general and administrative headcount during the nine months ended September 30, 2008, as compared to the same period of 2007. These decreases were partially offset by an increase of $0.4 million in professional fees in connection with our reimbursement efforts with CMS and our regulatory efforts with the FDA.

Sales and marketing expenses. Sales and marketing expenses decreased to $0 for the three and nine months ended September 30, 2008 from $0.2 million and $1.0 million for the three and nine months ended September 30, 2007 as a result of the elimination of our sales and marketing functions effective August 31, 2007, as described under the heading Our Cost Structure above.

Restructuring.

2008 Restructuring

On July 16, 2008, we implemented the 2008 Restructuring. The 2008 Restructuring was initiated under a plan of termination described in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, pursuant to which we recorded restructuring charges of approximately $0.5 million during the three months ended September 30, 2008 under generally accepted accounting principles, including $0.2 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and $0.3 million resulting from the write-off of leasehold improvements abandoned by us in connection with the reduction in force. Our decision to eliminate 67% of our workforce was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, non-cash asset impairment charges of $0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, we accelerated the vesting of 15,523 shares under terminated employees previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees outstanding options as of their date of termination, covering an aggregate of 166,575 shares with a weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), we recorded one-time non-cash stock-based compensation charges of approximately $3,000 in the Restructuring line item of our consolidated statements of operations during the quarter ended September 30, 2008.

Amounts remaining in the 2008 Restructuring accrual at September 30, 2008, which are expected to be paid out through February 2009, are recorded under the caption Accrued expenses in our condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the three months ended September 30, 2008 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

	Balance,		**Balance,**

Type of Liability	June 30, 2008	Charges	Cash Payments	Non-cash Write-offs	September 30, 2008
Employee separation costs	$	$ 255	$ (102)	$	$ 153
Facility consolidation costs		281		(281)	
Total	$	$ 536	$ (102)	$ (281)	$ 153

2007 Restructuring

On August 31, 2007, we entered into a third amendment, which we refer to as the Third Amendment, to our exclusive license agreement with LabCorp that, among other things, added a potential $2.5 million milestone payment for which we may be eligible upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of ColoSure over a defined measuring period. The Third Amendment also provided that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp s stool-based DNA testing service, and provided that LabCorp would offer at-will employment to certain of our former personnel. In connection with the Third Amendment, we notified six employees of their termination from the Company, which we refer to as the 2007 Restructuring. The 2007 Restructuring was principally designed to eliminate our sales and marketing functions to reduce costs and help preserve our cash resources. In connection with the 2007 Restructuring, we recorded restructuring

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charges of approximately $0.8 million during the three months ended September 30, 2007, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs which were paid out in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges associated with extending the period of exercise for vested stock option awards for terminated employees.

During the fourth quarter of 2007, we entered into a sublease agreement, or the Sublease Agreement, to sublease approximately 11,834 square feet of rentable area in our corporate headquarters. In connection with the Sublease Agreement, we recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption Facility consolidation costs in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between our committed lease payments and the estimated sublease rental income under the Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned in connection with the Sublease Agreement. Our decision to enter into the Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one-time real estate transaction fees in connection with the Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at September 30, 2008, which are expected to be paid out through July 2010, are recorded under the caption Accrued expenses in our condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the nine months ended September 30, 2008 relating to the 2007 Restructuring and Sublease Agreement. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, September 30, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$	$
Facility consolidation costs	268		(84)		184
Total	$ 492	$ (7)	$ (301)	$	$ 184

We are pursuing efforts to further reduce our costs and may record additional restructuring charges related to such reductions in future periods. We account for restructuring charges in accordance with SFAS No. 146, which requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at its fair value in the period in which the liability is incurred, except for one-time termination benefits that meet specified requirements.

Interest income. Interest income decreased to $36,000 for the three months ended September 30, 2008 from $0.2 million for the three months ended September 30, 2007. Interest income decreased to $0.2 million for the nine months ended September 30, 2008 from $0.7 million for the nine months ended September 30, 2007. These decreases were due to lower average cash, cash equivalents and marketable securities balances held during the three and nine months ended September 30, 2008 as compared to the same periods of 2007, as well as less favorable interest rates on investments held during the three and nine months ended September 30, 2008 as compared to the same period of 2007.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, public offerings of common stock in February 2001 and February 2004 and cash received from LabCorp in connection with our license agreement. As of September 30, 2008, we had approximately $6.1 million in unrestricted cash and cash equivalents and $0.6 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit in connection with the lease for our Marlborough, Massachusetts facility.

All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return, consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was $6.5 million for the nine months ended September 30, 2008 as compared to $6.4 million for the nine months ended September 30, 2007. The principal use of cash in operating activities for the nine months ended September 30, 2008 and 2007 was to fund our net loss. Net cash used in operating activities for the nine months ended September 30, 2008 was materially consistent with net cash used in operating activities for the nine months ended September 30, 2007. Cash flows from

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operations can vary significantly due to various factors, including changes in our operations, prepaid expenses, accounts payable and accrued expenses.

Net cash provided by investing activities was $8.0 million for the nine months ended September 30, 2008 compared to $8.6 million for the nine months ended September 30, 2007. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was approximately $105,000 for the nine months ended September 30, 2008 compared to $35,000 for the nine months ended September 30, 2007.

Purchases of property and equipment were not material during the nine months ended September 30, 2008 and 2007. We expect that purchases of property and equipment during 2008 will be consistent with amounts invested during 2007. We continued to invest in our capitalized patent portfolio during the nine months ended September 30, 2008, primarily in the form of recurring maintenance fees on patents. We expect that investments made in our patent portfolio during 2008 will higher than amounts capitalized in 2008 as a result of the timing certain payments in connection with our patent portfolio.

Net cash provided by financing activities of $106,000 and $132,000 for the nine months ended September 30, 2008 and 2007, respectively, and for each period was primarily the result of decreases in restricted cash in connection with the lease for our corporate headquarters and, to a lesser extent, proceeds received from the issuance of common stock under our employee stock option plans.

The audit opinion with respect to our consolidated financial statements for the year ended December 31, 2007 issued by our independent registered public accounting firm included an explanatory paragraph to emphasize there is substantial doubt about our ability to continue as a going concern. As a result of the 2008 Restructuring, we expect that cash, cash equivalents and short-term investments on hand at September 30, 2008 will be sufficient to fund our current operations through the end of the second quarter of 2009. This projection is based on our current cost structure and our current operating assumptions. Based on our decision to suspend our Version 2 clinical study in July 2008, this projection does not provide for any funding of our Version 2 clinical validation studies. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. Since we have no current sources of material ongoing revenue, we will have to raise additional capital during the next seven months through a strategic transaction, debt or equity financing, or third-party collaboration, if any, or some combination of the foregoing to continue operations beyond the end of the second quarter of 2009. In addition, if our expenses exceed our current estimates, we will be required to obtain additional capital even sooner. We cannot assure you that any of these alternatives will be successful, or even available, or that our actual cash requirements will not be greater than anticipated. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of any financing or other strategic opportunities that may become available to us, we will be unable to sustain our operations, our results of operations and financial condition would be materially adversely affected and we may be required to cease our operations. Even if we successfully raise sufficient funds to continue our operations beyond the end of the second quarter of 2009, we cannot assure you that our business will ever generate sufficient cash flow from operations.

The table below reflects our estimated fixed obligations and commitments as of September 30, 2008:

		Payments Due by Period		
		Less Than		More Than

Description	Total	One Year	1 - 3 Years	3 - 5 Years	5 Years
			(in Thousands)		
Obligations under license and collaborative agreements	$ 7,565	$ 1,975	$ 2,130	$ 630	$ 2,830
Operating lease obligations	1,869	1,009	860		
Severance obligations	153	153			
Purchase obligations	192	192			
Total	$ 9,779	$ 3,329	$ 2,990	$ 630	$ 2,830

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. This category includes a potential obligation of $3.0 million to reimburse LabCorp for a certain third-party royalty, which is recorded in our consolidated balance sheets at September 30, 2008 under the caption third party royalty obligation . This obligation could increase by an additional $500,000 up to an aggregate maximum of $3.5 million during three defined measurement periods between June 28, 2007 and December 31, 2010. Although payment of this potential obligation is dependent upon LabCorp s sales levels of colorectal cancer screening tests using our technology during the measurement periods, our current estimate of the potential obligation of $3.0 million has been accrued in our financial statements and included in the table above based on historical sales levels of PreGen-Plus and anticipated sales volumes of ColoSure. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with leased facilities in Marlborough, Massachusetts. Severance obligations represent remaining

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severance payments due to former employees terminated in connection with the 2008 Restructuring. Purchase obligations represent outstanding purchase commitments associated with our research and development activities.

For personnel remaining employed by the Company after the 2008 Restructuring, the total potential severance and other obligations upon the occurrence of certain triggering events, including a termination without cause following a change of control of the Company, was approximately $1.9 million at September 30, 2008. As of September 30, 2008, such amounts have not been included in the table above because no triggering events had occurred as of that date.

We do not have any special purpose entities or any other off-balance sheet financing arrangements.

Our anticipated future capital requirements include, but are not limited to, continued funding of our development efforts, including product development and FDA submissions, clinical and other studies required for such FDA submissions and resubmission of our CMS application for approval of our technologies, and continued investment in our intellectual property estate. Our future capital requirements may depend on many factors, including the following:

- the regulatory requirements for ColoSure, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- our ability to attract third parties to support the development of an FDA-cleared or approved product based on our technologies;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with LabCorp;
- a determination that additional studies surrounding our technologies are needed;
- a sustained level of interest and commitment by LabCorp in the commercialization of our technologies;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the scope of and progress made in our research and development activities;
- opportunities to license additional third-party intellectual property;
- threats posed by competing technologies;
- new out-licensing arrangements relating to our technologies; and

- the successful commercialization and sales growth of ColoSure, or other stool-based DNA testing services utilizing our technologies.

Additionally, LabCorp could decide, or be required, to stop offering ColoSure, or could decide to stop offering ColoSure until it has been approved or cleared by the FDA, if ever. Either of these situations will limit our revenue and materially adversely affect our business and cash reserves.

As a result of the foregoing, we engaged an investment bank in the first quarter of 2008 to assist our board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, we announced a revised corporate strategy to take immediate actions to preserve existing cash while continuing to focus on the pursuit of a strategic transaction, including a sale of our business. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all.

Off-Balance Sheet Arrangements

As of September 30, 2008, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, all of which are currently invested in the U.S. and are classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

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Item 4. Controls And Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15b promulgated under the Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2008, our disclosure controls and procedures were effective in enabling us to record, process, summarize and report information required to be included in our periodic SEC filings within the required time period. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Part II - Other Information

Item 1A. Risk Factors

Factors That May Affect Future Results

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. There are no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 other than the following: changes set forth in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2008 and June 30, 2008; and changes as set forth below to update for recent developments. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. If any of the foregoing risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

We have recently revised our corporate strategy to pursue a strategic transaction for our business, and our new strategy may not be successful.

On July 16, 2008, we announced that we revised our corporate strategy to take immediate actions to preserve existing cash while pursuing strategic alternatives for the business. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all. For instance, the terms of our existing collaboration with Laboratory Corporation of America Holdings, or LabCorp, and other agreements to which we are a party may hinder any potential strategic transaction. Any potential strategic transaction could also require the cooperation of LabCorp, as well as the approval of our stockholders. We cannot assure you that we would be able to obtain such cooperation or approval. In addition, the threat of litigation may discourage third-parties from pursuing a transaction with us, or otherwise delay or prevent a strategic transaction. Although we are not currently aware of any legal claims filed by any of our stockholders against us, our management or our Board of Directors, and we believe that any such claims would be without merit, we have received correspondence from certain of our stockholders threatening litigation if we were to consummate a dilutive financing. Further, one of our largest stockholders, Intrinsic Value Asset Management, Inc., has indicated on an amended Schedule 13D filed with the SEC on August 18, 2008 that it no longer supports a sale of our company and that it intends to pursue all available legal remedies to prevent the sale of our company to any purchaser in which any members of our Board of Directors or management have an interest. If we do not raise additional capital before the end of the second quarter of 2009 through a strategic transaction, the sale of debt or equity securities, or strategic collaborations with third parties, we will likely be unable to continue our business operations beyond the end of the second quarter of 2009 and we would likely be required to cease our operations. A lawsuit against us could distract our management from our business and could cause us to incur substantial costs defending against the claim, even if the claim is without merit, which would further deplete our limited available cash.

Our common stock may be delisted from The NASDAQ Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on The NASDAQ Global Market. On July 10, 2008, we received notice from The NASDAQ Stock Market LLC that we were not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), or the Rule, which requires an issuer to maintain a minimum $50 million market value of its listed securities for continued listing on The NASDAQ Global Market. We were provided a period of 30 calendar days, or until August 11, 2008, to regain compliance with the Rule by evidencing a market value of listed securities of at least $50 million for a minimum of 10 consecutive business days. On August 12, 2008, we received a letter from NASDAQ advising that we had not regained compliance with the Rule by August 11, 2008 and, as a result, our common stock would be subject to delisting from The NASDAQ Global Market on August 21, 2008 unless we requested a hearing before the NASDAQ Listing Qualifications Panel, or the Panel. We requested a hearing before the Panel, which was held on October 2, 2008. The delisting of our common stock has been stayed pending the issuance of a formal decision by the Panel following the hearing. The Panel has not yet issued its decision in this matter.

The delisting of our common stock could significantly affect the ability of investors to trade our securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could adversely affect our ability to enter into a strategic transaction or to raise capital on terms acceptable to us, or at all. Delisting from The NASDAQ Stock Market could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

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Our stock price may be volatile.

The market price of our common stock has fluctuated widely. Consequently, the current market price of our common stock may not be indicative of future market prices and we may be unable to sustain or increase the value of an investment in our common stock.

Our common stock is listed on the NASDAQ Global Market under the symbol EXAS. Factors affecting our stock price may include:

- FDA regulation of our or LabCorp s products and services;
- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to the PreGen-Plus test, stool-based DNA testing in general, or technologies of our competitors;
- stool DNA screening becoming a standard of care among prescribing physicians;
- reimbursement decisions by Medicare and other third party payors;
- the establishment of collaborative partnerships;
- health care legislation;
- intellectual property disputes and other litigation;
- additions or departures of key personnel;

- the performance characteristics of our technologies;

- general market conditions;

- the rate of market acceptance of ColoSure; and

- sales of our common stock or debt securities

Because we are a company with no significant operating revenue, you may consider any one of these factors to be material.

In addition, the stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have recently experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. There have been dramatic fluctuations in the market prices of securities of biotechnology companies such as us. These price fluctuations may be rapid and severe and may leave investors little time to react. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Sharp drops in the market price of our common stock expose us to securities class-action litigation. Such litigation could result in substantial expenses and a diversion of management s attention and resources, which would seriously harm our business, financial condition, and results of operations.

Item 4. Submission of Matters to a Vote of Security Holders

On July 18, 2008, at our annual meeting of stockholders, the stockholders elected as Class II directors, each to serve for a three-year term, the following individuals: Lance Willsey, MD (16,536,295 shares for; 5,831,062 shares withheld) and Patrick J. Zenner (15,235,095 shares for; 7,132,262 shares withheld). The term of office for each of Jeffrey R. Luber, Connie Mack, III, Sally W. Crawford and Edwin M. Kania as directors of the Company continued following the annual meeting.

A proposal to ratify Ernst & Young LLP as the Company s independent auditors for fiscal year 2008 was approved (20,686,893 shares for, 141,530 shares against and 1,538,934 abstained).

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Item 5. Other Information

On November 4, 2008, we entered into Amendment Nos. 5 and 6 to our Amended and Restated License Agreement with The Johns Hopkins University, or JHU, originally dated March 25, 2003. Under the Amended and Restated License Agreement, as amended to date, or the License Agreement, JHU has granted us an exclusive license to use certain technologies, including the BEAMing technology for the detection of colon cancer. The License Agreement provides for us to pay annual royalties to JHU based on the greater of a set annual fee or royalties derived from the sale of products or services containing the licensed technology. We also have the right under the License Agreement to sublicense the licensed technology to third parties. The License Agreement terminates upon the later of 20 years from the effective date and the expiration of the last to expire of the patents for the licensed technology, or upon certain uncured defaults of either party.

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Item 6. Exhibits

Exhibit Number	Description
10.1**	Amended and Restated License Agreement between The Johns Hopkins University and the Registrant, dated as of March 25, 2003, as amended.
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

** *Confidential treatment has been requested for portions of this exhibit.*

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SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: November 7, 2008

By: /s/ Jeffrey R. Luber
Jeffrey R. Luber
President and Chief Executive Officer
(Authorized Officer)

Date: November 7, 2008

By: /s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(Authorized Officer and Principal Financial Officer)

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