

EXACT SCIENCES CORP  
Form 10-Q  
May 09, 2008

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

**For the quarterly period ended March 31, 2008**

**OR**

- 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)

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**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**02-0478229**

(I.R.S. Employer  
Identification Number)

**100 Campus Drive, Marlborough, Massachusetts**

(Address of principal executive offices)

**01752**

(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  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of May 8, 2008, the registrant had 27,160,906 shares of Common Stock outstanding.

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EXACT SCIENCES CORPORATION

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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	March 31, 2008	December 31, 2007
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,999	\$ 4,486
Marketable securities	5,488	8,101
Prepaid expenses and other current assets	453	275
Total current assets	9,940	12,862
Property and Equipment, at cost:		
Laboratory equipment	3,730	3,730
Office and computer equipment	1,420	1,420
Leasehold improvements	1,161	1,161
Furniture and fixtures	299	299
	6,610	6,610
Less Accumulated depreciation and amortization	(6,068)	(6,009)
	542	601
Patent costs, net of accumulated amortization of \$3,053 and \$3,019 at March 31, 2008 and December 31, 2007, respectively	452	432
Restricted cash	700	700
	\$ 11,634	\$ 14,595
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 275	\$ 245
Accrued expenses	2,105	2,811
Third party royalty obligation	1,500	1,200
Deferred license fees, current portion	1,350	1,350
Total current liabilities	5,230	5,606
Deferred license fees, less current portion	2,363	2,701
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding 0 shares at March 31, 2008 and and December 31, 2007		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 27,233,957 and 27,225,541 shares at March 31, 2008 and December 31, 2007, respectively	273	273
Additional paid-in capital	169,083	168,813
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	24	23
Accumulated deficit	(165,242)	(162,724)
Total stockholders' equity	\$ 4,041	\$ 6,288
	\$ 11,634	\$ 14,595

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



## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data - unaudited)

	Three Months Ended March 31,	
	2008	2007
Revenue:		
Product royalty fees	\$ (292)	\$ 26
License fees	338	1,091
Product	5	53
	51	1,170
Cost of revenue:		
Product royalty fees	1	2
Gross profit	50	1,168
Operating expenses:		
Research and development (1)	859	1,277
General and administrative (1)	1,835	1,648
Sales and marketing (1)		389
Restructuring	(2)	33
	2,692	3,347
Loss from operations	(2,642)	(2,179)
Interest income	124	259
Net loss	\$ (2,518)	\$ (1,920)
Net loss per share basic and diluted	\$ (0.09)	\$ (0.07)
Weighted average common shares outstanding basic and diluted	27,145	26,790

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

Research and development	\$ 44	\$ 74
General and administrative	257	249
Sales and marketing		85

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

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Cash Flows

(Amounts in thousands - unaudited)

	Three Months Ended March 31,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (2,518)	\$ (1,920)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	59	56
Amortization and write-offs of patents	34	171
Stock-based compensation	301	409
Amortization of deferred license fees	(338)	(1,091)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(178)	(154)
Accounts payable	30	(19)
Accrued expenses	(743)	38
Third party royalty obligation	300	
Net cash used in operating activities	(3,053)	(2,510)
Cash flows from investing activities:		
Purchases of marketable securities	(2,466)	(7,315)
Maturities of marketable securities	5,080	8,850
Purchases of property and equipment		(2)
Increase in patent costs and other assets	(54)	(17)
Net cash provided by investing activities	2,560	1,516
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	6	15
Net cash provided by financing activities	6	15
Net decrease in cash and cash equivalents	(487)	(979)
Cash and cash equivalents, beginning of period	4,486	4,831
Cash and cash equivalents, end of period	\$ 3,999	\$ 3,852
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of 56,675 shares of restricted common stock to collaborators in lieu of cash payments	\$	\$ 158

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

**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 develops 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 developed by LabCorp and marketed under the name PreGen-Plus. PreGen-Plus is a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. The Company has devoted the majority of its efforts to date on research and development and commercialization support of PreGen-Plus.

**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 March 31, 2008, had an accumulated deficit of approximately \$165.2 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 there is substantial doubt about the Company's



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ability to continue as a going concern. The Company expects that its cash, cash equivalents and short-term investments on hand at March 31, 2008 will be sufficient to fund its current operations through 2008. This projection is based on the Company's current cost structure and its current assumptions regarding the cost and timing of the studies it expects to initiate in 2008 in connection with its efforts to obtain U.S. Food and Drug Administration (FDA) regulatory clearance for its next-generation version of stool-based DNA screening technology for colorectal cancer screening (Version 2). The Company has no current sources of material ongoing revenue and, accordingly, it will need to raise additional capital in the next eight months through a debt or equity financing, third-party collaboration or other strategic opportunity, if any, or further reduce the scale of the Company's operations, or some combination of the foregoing to continue operations beyond the end of 2008. If the Company is unable to obtain additional capital prior to the end of 2008, it will not be able to sustain 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 financial statements 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. To date, the Company has not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith.

## **(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 March 31, 2008 and December 31, 2007, \$0.7 million 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

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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.

All of the Company's investments 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. 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 months ended March 31, 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 March 31, 2008, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with PreGen-Plus.

The following table summarizes activity with respect to the Company's capitalized patents for the three months ended March 31, 2008 and 2007. Amounts included in the table are in thousands.

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	Three Months Ended March 31, 2008	Three Months Ended March 31, 2007
Patents, net of accumulated amortization, Beginning of period	\$ 432	\$ 763
Patent costs capitalized	54	17
Amortization of patents	(34)	(50)
Write-offs of patents		(121)
Patents, net of accumulated amortization, End of period	\$ 452	\$ 609

During the three month period ended March 31, 2007, the Company determined that it would likely not pursue commercialization of certain technologies and, accordingly, wrote off approximately \$121,000 in capitalized patents related to these technologies. Capitalized patents written off during the three month period ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus.

The Company applies SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, 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)	March 31,	
	2008	2007
Shares issuable upon exercise of stock options	4,433	4,762
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,433	5,762

#### Accounting for Stock-Based Compensation

The Company adopted SFAS No. 123(R), *Share-Based Payment* ( 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

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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* ( EITF 96-18 ). Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB No. 25 ).

### 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** 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. 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 sales of PreGen-Plus, 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 PreGen-Plus.

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 consolidated statements of operations.

**Product revenue** Product revenue from the sale of certain components of the Company's Effipure technology to LabCorp is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

**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 months ended March 31, 2008 and 2007 was as follows:

(In thousands)	Three Months Ended March 31,	
	2008	2007
Net loss	\$ (2,518)	\$ (1,920)
Unrealized gain (loss) on marketable securities	1	(1)
Comprehensive loss	\$ (2,517)	\$ (1,921)

### (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 Version 2 and restricted certain of the Company's termination rights in the event the 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 the Company's Version 2 technology.

**(4) 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 PreGen-Plus during three separate measurement periods, as defined below. A significant

increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation to zero 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 sales of PreGen-Plus 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 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 anticipated 2008 PreGen-Plus sales volumes, as of March 31, 2008, the Company has accrued the entire \$1.5 million obligation related to the first measurement period ending in December 2008. The Company recorded charges of \$0.3 million and \$1.2 million during the quarter ended March 31, 2008 and the year ended December 31, 2007, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in the Company's consolidated statements of operations for the quarter and year ended March 31, 2008 and December 31, 2007, respectively. This obligation is recorded in the Company's consolidated balance sheets under the caption "Third-party royalty obligation." Amounts included in the table are in thousands.

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

##### (5) 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, 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 expected to be 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



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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 March 31, 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 right of terminated employees to receive severance payments from the Company will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, the Company's estimate of the total restructuring charges may be adjusted in future periods.

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The following table summarizes changes made to the restructuring accrual during the quarter ended March 31, 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 / (Reversals)	Cash Payments	Non-cash Write-offs	Balance, March 31, 2008
Employee separation costs	\$ 224	\$ (2)	\$ (138)		\$ 84
Facility consolidation costs	268		(42)		226
<b>Total</b>	<b>\$ 492</b>	<b>\$ (2)</b>	<b>\$ (180)</b>		<b>\$ 310</b>

### (6) 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 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. Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the provisions of APB No. 25.

The Company recorded \$0.3 million in stock-based compensation during the three months ended March 31, 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 stock-based compensation expense related to the Company's 2008 401(k) match. The Company recorded \$0.4 million in stock-based compensation during the three months ended March 31, 2007 in connection with the amortization of employee and non-employee director stock option awards, stock options granted to non-employee consultants, common stock issued to a collaborator, and stock-based compensation expense related to the Company's 2007 401(k) match, which was approved by the Company's board of directors and will be made in Company common stock in May 2008.

#### Determining Fair Value

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**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.

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**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.

	Three Months Ended March 31,	
	2008	2007
<b>Option Plan Shares</b>		
Risk-free interest rates	2.80%	4.50%
Expected term (in years)	6	6
Expected volatility	70%	70%
Dividend yield	0%	0%
Weighted average fair value per share of options granted during the period	\$1.17	\$1.83
<b>ESPP Shares</b>		
Risk-free interest rates	(1)	5.10% - 5.17%
Expected term (in years)	(1)	0.5 - 2
Expected volatility	(1)	70%
Dividend yield	(1)	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	\$1.08

(1) The Company did not issue stock purchase rights under its Employee Stock Purchase Plan during the period indicated.

**Stock Option Activity**

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the three months ended March 31, 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	498,600	\$ 1.83		
Exercised	(8,416)	\$ 0.67		
Cancelled	(53,471)	\$ 6.77		
Outstanding, March 31, 2008	4,433,401	\$ 4.52	5.2	\$ 1,280
Exercisable, March 31, 2008	3,199,848	\$ 5.32	3.6	\$ 668

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Vested and expected to vest, March 31, 2008	4,433,401	\$	4.52	5.2	\$	1,280
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(1) The aggregate intrinsic value of options outstanding at March 31, 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 2,424,979 options that had exercise prices that were lower than the \$2.91 market price of our common stock at March 31, 2008. The aggregate intrinsic value of options exercisable at March 31, 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 1,271,411 options that had exercise prices that were lower than the \$2.91 market price of our common stock at March 31, 2008.

As of March 31, 2008, there was \$1.7 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 1.8 years.

#### **(7) 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 and fecal occult blood testing, or FOBT, as well as combinations of some of these methods. On March 5, 2008, the ACS and the MSTF-CRC, 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, 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. 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 PreGen-Plus, 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.

#### **(8) REGULATORY STATUS**

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service 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 is the basis for LabCorp's PreGen-Plus testing service. In addition to the Company's Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, the Company has also developed a Version 2 colorectal cancer screening technology that it believes has greater sensitivity and is more cost effective than Version 1. In April 2008, the Company began focusing its regulatory efforts on pursuing FDA clearance for Version 2 of its technology. In this regard, in April 2008, the Company 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 is to seek confirmation from the FDA that the filing of a *de novo* 510(k) 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 support such a *de novo* 510(k) regulatory path. The FDA has not yet indicated whether the Company's proposed submission with respect to Version 2 of its technology would be a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for the Company with respect to Version 2 of its stool-based DNA technology. The Company believes that additional clinical studies, which will likely be material in cost and time-intensive, will be required in connection with any approval or clearance of its Version 2 technology regardless of whether it is a *de novo* 510(k) or a PMA. The Company does not believe that its cash, cash equivalents and marketable securities as of March 31, 2008 will be sufficient to fund any such studies through completion. Accordingly, the Company may be required to seek additional funds prior to initiation of any such studies.

There can be no assurance that any version of the Company's stool-based DNA technology will be cleared or approved by the FDA, that the Company's proposed *de novo* 510(k) approach or proposed studies will satisfy the FDA's regulatory requirements for its Version 2 technology or any version of its technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense. Because the Company does not currently have sufficient funds to complete any FDA regulatory clearance or approval process for its DNA-based technologies, the Company may delay any such activities and process to preserve funds for on-going operations or otherwise.

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Moreover, the Company will require the support of third parties to assist it in the achievement of objectives relating to FDA clearance of its technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting its business, subject the Company and LabCorp to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with these requirements. Moreover, the Company cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to the Company's business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase the Company's costs, limit the Company's

revenue and cause material harm to the Company's business and result in impairments of the Company's fixed assets or capitalized patent portfolio (\$0.5 million at March 31, 2008).

**(9) 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 consolidated results of operations, financial position or cash flows.

SFAS 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 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.

In accordance with the disclosure provisions of SFAS No. 157, the following table presents the Company's fair value measurements as of March 31, 2008 along with the level within the fair value hierarchy prescribed by SFAS No. 157 in which the fair value measurements in their entirety fall, segregating fair value measurements using quoted prices in active markets for identical assets or liabilities (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). Cash and cash equivalents are recorded at cost, which approximates fair value. Amounts in the table are in thousands.

Description	Fair Value at March 31, 2008	Fair Value Measurement at March 31, 2008 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)



Available-for-Sale					
Marketable Securities	\$	5,488	\$	5,488	\$
Total	\$	5,488	\$	5,488	\$

**(10) SUBSEQUENT EVENT****Employee Retention Agreements**

On April 18, 2008, the Company entered into amended and restated employee retention agreements (the "Agreements") with certain employees, including Jeffrey R. Lubert, 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. Lubert and Carelli on October 23, 2006.

Including existing employee retention agreements as described in Note 6 to the Company's consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2007, the total potential severance and other obligations upon the occurrence of certain triggering events, such as a change of control or termination without cause was approximately \$2.3 million. As of March 31, 2008, the Company has not recorded any amount related to the potential severance payments because no triggering events had occurred as of that date.

#### **(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 adoption of SFAS No. 159 in the first quarter of fiscal 2008 did not have any impact on the Company's financial statements.

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 consolidated results of operations, financial position or cash flows.

## 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, research and development and general and administrative expenses, 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, the focus and level of research and development efforts and development of new technologies, expectations regarding third-party reimbursement of PreGen-Plus, expected restructuring charges, our expectations concerning our commercial strategy, and the effectiveness and market acceptance of our technologies and PreGen-Plus. 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 through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®, for use in a commercial testing service developed and sold by LabCorp under the name PreGen-Plus. PreGen-Plus is LabCorp's non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. Our Version 1 technology is the basis for LabCorp's PreGen-Plus test. 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;

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- 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; and
- working with LabCorp on activities in support of the commercialization of PreGen-Plus and our Version 2 technology.

We have generated limited operating revenues since our inception and, as of March 31, 2008, we had an accumulated deficit of approximately \$165.2 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.

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through March 31, 2008, LabCorp had accessioned approximately 14,700 PreGen-Plus samples, including approximately 300 in the quarter ended March 31, 2008 and approximately 1,800, 3,700, and 4,000 samples during the years ended December 31, 2007, 2006 and 2005, respectively. In addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. 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.

To increase market adoption of our stool-based DNA screening technologies, we are currently focusing our efforts on achieving the following corporate goals:

- Obtaining FDA clearance for our stool-based DNA screening technologies; and
- Obtaining formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors.

### **Colorectal Cancer Screening Guidelines**

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society, or 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 and fecal occult blood testing, or FOBT, as well as combinations of some of these methods. On March 5, 2008, the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer, or MSTF-CRC, 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, 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. PreGen-Plus is therefore now the first DNA-based, non-invasive colorectal cancer screening test to be included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population. While we view inclusion of our stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for PreGen-Plus, we believe that FDA clearance for our technology, and reimbursement from CMS and other third-party payors will be necessary to achieve any significant increase in demand for our technology.

### **Government Regulation**

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007 the FDA sent a warning letter to us, which we refer to as 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

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appropriate pre-market approval or clearance from the FDA. Our Version 1 technology is the basis for LabCorp's PreGen-Plus testing service. In addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. In April 2008, we began focusing our regulatory efforts on pursuing FDA clearance for Version 2 of our technology. In this regard, in April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA for our Version 2 technology.

The objective of the pre-IDE process is to seek confirmation with the FDA that the filing of a *de novo* 510(k) is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission support such a *de novo* 510(k) regulatory path. The FDA has not yet indicated whether our proposed submission with respect to Version 2 of our technology would be a *de novo* 510(k). Moreover, the FDA may 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. We believe that additional clinical studies, which will likely be material in cost and time-intensive, will be required in connection with any approval or clearance of our Version 2 technology regardless of whether it is a *de novo* 510(k) or a PMA. We do not believe that our cash, cash equivalents and marketable securities as of March 31, 2008 will be sufficient to fund any such studies through completion. Accordingly, we may be required to seek additional funds prior to initiation of any such studies.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach or proposed studies will satisfy the FDA's regulatory requirements for our Version 2 technology or any version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense. Because we do not currently have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies, we may delay any such activities and process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio (\$0.5 million at March 31, 2008).

### **Reimbursement**

An important component of our reimbursement strategy is to obtain a National Coverage Determination, or NCD, from CMS for inclusion of our stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our stool-based DNA technology, which was accepted by CMS on August 1, 2007. Following acceptance of our application by CMS, we received the Warning Letter from the FDA. CMS subsequently issued a proposed and then, on April 28, 2008, a final decision memorandum regarding our application. In these memoranda, CMS decided to not provide national coverage for our Version 1 technology, in part because of the FDA's determination as set forth in the Warning Letter. However, the decision memoranda also indicated that CMS would reconsider our application for coverage of stool-based DNA screening for colorectal cancer following any such FDA clearance or approval of our DNA screening technology. Accordingly, we intend to submit our NCD application for reconsideration following any such FDA clearance or approval and our accumulation of other information and evidence that may be necessary for such submission. There can be no assurance that Version 2, or any subsequent versions of our technology, will be cleared or approved by the FDA. Even if cleared or approved by the FDA, there can be no assurance that CMS will reach a positive coverage decision regarding our request for an NCD on any version of our technologies. Moreover, even if CMS issues a positive coverage decision for any version of our stool-based DNA screening technology, such coverage does not guarantee adequate levels of reimbursement. We could incur significant costs, over an extended period of time, to obtain the necessary data for a positive coverage and reimbursement decisions from CMS. Additionally, despite the fact that our technology is included in the ACS and MSTF-CRC guidelines, the Warning Letter may have a similar impact on private third-party payors in that those payors may defer reimbursement policy decisions with respect to our technology until such time as we obtain FDA clearance for our technologies.

In addition, at its February 2008 meeting, the CPT Editorial Panel of the American Medical Association considered a request from gastroenterology specialty physician organizations to create a category III code for a stool-based DNA test. While the CPT Editorial Panel decided to postpone discussion on the issue, the application can be reconsidered at any future meeting, unless it is withdrawn. The CPT Editorial Panel meets three times each year; the next two 2008 meetings are scheduled for June and October. Category III codes are temporary codes which are used to designate emerging technologies, services and procedures and are issued semi-annually unlike Category I codes which are issued annually. Payors typically do not cover services with Category III codes because they consider emerging technologies to be an investigational service and are therefore not covered services. The creation of Category III code for our stool-based DNA technology could limit the number of payors that could potentially reimburse stool-based DNA colorectal cancer screening, which would materially limit our revenues and adversely affect our operating results and financial position.

### **Other Factors Affecting Potential Revenue Growth**

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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. 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 PreGen-Plus. Despite the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, we do not expect material revenue growth until such time as FDA clearance or approval is obtained, reimbursement is provided by Medicare and other third-party payors at an acceptable level and sufficient funds and managerial time are invested in sales and marketing efforts. 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:



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- 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 PreGen-Plus or any other product based on our technologies;
- whether LabCorp continues to offer PreGen-Plus commercially or commercially launches a testing service based on our Version 2 technology;
- 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 Medicare 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. To date, we have not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith.

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, product royalty fees on PreGen-Plus tests sold by LabCorp, and product revenue from the sale to LabCorp of Effipure components, which are used by LabCorp in processing PreGen-Plus tests. We expect that product royalty fees for the full year 2008 will be materially consistent with 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.

LabCorp informed the FDA during 2006 that they were working on changes to PreGen-Plus that would eliminate the use of Effipure in PreGen-Plus. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2008. The potential loss of this revenue is not expected to have a material impact on our total revenues. In this regard, LabCorp's supply of Effipure includes components that have a finite useful life the duration of which, we believe, may be nearly exhausted. We also believe that inventory levels at LabCorp relating to other components necessary for the ongoing commercialization of Version 1 of PreGen-Plus may also be nearly exhausted. If LabCorp is unable or unwilling to extend the useful life of these components or acquire new components, LabCorp may be unable to continue to process PreGen-Plus tests in the near term. Any such interruption in the commercial availability of PreGen-Plus could have a material adverse affect on our business.

#### **Amendment to LabCorp License Agreement**

***Fourth Amendment to LabCorp License Agreement.*** On March 17, 2008, we entered into the fourth amendment, or Fourth Amendment, to our 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 our Version 2 technology and restricted certain of our termination rights in the event the FDA limits LabCorp's ability to market products that incorporate technology licensed to LabCorp under our amended license agreement. In addition, the Fourth Amendment eliminated certain of our 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 our Version 2 technology.

#### **Our Cost Structure**

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. 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.

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 took steps in 2006 and 2007 to lower research and development costs by focusing primarily on our Version 2 technology, we may 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, and to successfully commercialize our Version 2 technology, or any future versions of our technologies or products. In this regard, the costs of clinical, reproducibility, or other studies, that may be required by the FDA in connection with our proposed *de novo* 510(k) pre-market clearance notice for our Version 2 and any subsequent filings for other versions of our technologies are expected to be material. We therefore expect that our research and development costs in 2008 could be materially higher than 2007 levels, depending on the scope of studies required by the FDA. See discussion of the FDA status of our technology in *Government Regulation* above.

Selling, general and administrative expenses consist 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 higher than 2007 levels, primarily as a result of increased professional fees during 2008 in connection with our ongoing efforts to obtain FDA regulatory clearance or approval of our DNA-based technologies.

### **Significant Accounting Policies**

This management's discussion and analysis of our financial condition and results of operations is based on our 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 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 preparation of our consolidated financial statements. As described below, we believe 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

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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** - 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. 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 sales of PreGen-Plus, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to increase to

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17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of PreGen-Plus.

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 of 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 is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

**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.

The following table summarizes activity with respect to capitalized patents for the three months ended March 31, 2008 and 2007. Amounts included in the table are in thousands.

	Three Months Ended March 31, 2008	Three Months Ended March 31, 2007
Patents, net of accumulated amortization, Beginning of period	\$ 432	\$ 763
Patent costs capitalized	54	17
Amortization of patents	(34)	(50)
Write-offs of patents		(121)
Patents, net of accumulated amortization, End of period	\$ 452	\$ 609

During the three month period ended March 31, 2007, we determined that we would likely not pursue commercialization of certain technologies and, accordingly, wrote off approximately \$121,000 in capitalized patents related to these technologies. Capitalized patents written off during the three month period ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus.

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets*, or SFAS No. 144, which requires us to continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of

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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 whether stool-based DNA screening is included in colorectal cancer screening guidelines or a change in the regulatory requirements for PreGen-Plus. We did not record any impairment charges during the quarter ended March 31, 2008.

**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 are potentially 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 PreGen-Plus during three separate measurement periods, as defined below. A significant increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation to zero 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 sales of PreGen-Plus 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 our consolidated statements of operations, in accordance with EITF No. 01-09. Based on anticipated 2008 PreGen-Plus sales volumes, as of March 31, 2008, we have accrued the entire \$1.5 million obligation related to the first measurement period ending in December 2008. We recorded charges of \$0.3 million and \$1.2 million during the quarter ended March 31, 2008 and the year ended December 31, 2007, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in our consolidated statements of operations for the quarter and year ended March 31, 2008 and December 31, 2007, respectively. This obligation is recorded in our consolidated balance sheets under the caption "Third-party royalty obligation." The table below outlines our potential obligations in connection with the Second Amendment. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	\$	\$ 1,500
January 1, 2009	December 31, 2009		1,000
January 1, 2010	December 31, 2010		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.



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**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.

In accordance with the disclosure provisions of SFAS No. 157, the following table presents our fair value measurements as of March 31, 2008, along with the level within the fair value hierarchy prescribed by SFAS No. 157 in which the fair value measurements in their entirety fall, segregating fair value measurements using quoted prices in active markets for identical assets or liabilities (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). Cash and cash equivalents are recorded at cost, which approximates fair value. Amounts in the table are in thousands.

Description	Fair Value at March 31, 2008	Fair Value Measurement at March 31, 2008 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-Sale				
Marketable Securities	\$ 5,488	\$	\$ 5,488	\$
Total	\$ 5,488	\$	\$ 5,488	\$

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. The adoption of SFAS No. 159 in the first quarter of fiscal 2008 did not have any impact on our financial statements.

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 \$0.1 million for the quarter ended March 31, 2008, from \$1.2 million for the quarter ended March 31, 2007. Total revenue is primarily 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 and, to a lesser extent, royalties on LabCorp's sales of PreGen-Plus, and sales of Effipure units to LabCorp.

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The decrease in total revenue for the quarter ended March 31, 2008 when compared to the same quarter of 2007 was primarily the result of a decrease of approximately \$0.8 million in non-cash license fee amortization revenue resulting from 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 addition, product royalty revenues were \$0.3 million lower for the quarter ended March 31, 2008, when compared to the quarter ended March 31, 2007, due to charges of \$0.3 million recorded in the product royalty revenue line item of our consolidated statements of operations in the quarter ended March 31, 2008 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 quarter ended March 31, 2008. Our obligation to pay LabCorp under this provision of our amended

license agreement is based on LabCorp's sales volumes of PreGen-Plus during three measurement periods over the exclusive license period, which ends in December 2010. A significant increase in PreGen-Plus test sales volumes during any of the measurement periods described under the heading *Critical Accounting Estimate Third-Party Royalty Obligation* above could reduce our obligation related to that period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp of up to \$3.5 million over the remaining exclusive license period. Based on sales volumes that we anticipate in light of the current regulatory and reimbursement status of our technology, as of March 31, 2008, we have accrued the entire \$1.5 million obligation related to the first measurement period ending in December 2008. We recorded charges of \$0.3 million and \$1.2 million during the quarter ended March 31, 2008 and the year ended December 31, 2007, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption *Product royalty fees* in our consolidated statements of operations for the quarter and year ended March 31, 2008 and December 31, 2007, respectively. 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.

During 2006, LabCorp informed the FDA that it was working on changes to PreGen-Plus that could eliminate the use of Effipure. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2008 or beyond. The loss of this revenue during 2008 is not expected to have a material impact on our total revenues. There can be no assurance that LabCorp will be able to identify an alternative process for Effipure in connection with LabCorp's processing of the PreGen-Plus test, which could result in interruption in the PreGen-Plus testing service and could materially harm our business.

**Research and development expenses.** Research and development expenses decreased to \$0.9 million for the quarter ended March 31, 2008 from \$1.3 million for the quarter ended March 31, 2007. This decrease was primarily the result of the continuing effect of the cost reduction plans undertaken in 2006 and 2007 as described under the heading *Our Cost Structure* above. Included in the decrease in research and development expenses for the quarter ended March 31, 2008, as compared to the quarter ended March 31, 2007, were decreases of \$0.2 million in licensing costs, \$0.1 million in personnel-related expenses and \$0.1 million in other operating expenses.

**General and administrative expenses.** General and administrative expenses increased to \$1.8 million for the quarter ended March 31, 2008, compared to \$1.6 million for the quarter ended March 31, 2007. The increase was primarily the result of higher professional fees of \$0.4 million in connection with our ongoing reimbursement efforts with CMS and regulatory efforts with the FDA. This increase was partially offset by a decrease of \$0.2 million in salary, benefit and other costs due to a reduction in general and administrative headcount during the quarter ended March 31, 2008, as compared to the same quarter of 2007.

**Sales and marketing expenses.** Sales and marketing expenses decreased to \$0 for the quarter ended March 31, 2008 from \$0.4 million for the quarter ended March 31, 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.

**2007 Restructuring.** On August 31, 2007, we entered into a third amendment, or 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, 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 terminated five employees and one employee effective August 31, 2007 and October 31, 2007, respectively, 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 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.

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Restructuring charges recorded during the third quarter of 2007 of \$0.8 million included \$0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and \$0.2 million in non-cash stock-based compensation charges recorded in connection with certain stock option modifications.

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 March 31, 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 right of terminated employees to continue to receive severance payments from us will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, our estimate of the total restructuring charges may be adjusted in future periods.

The following table summarizes the costs accrued during the quarter ended March 31, 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 / (Reversals)	Cash Payments	Non-cash Write-offs	Balance, March 31, 2008
Employee separation costs	\$ 224	\$ (2)	\$ (138)	\$	\$ 84
Facility consolidation costs	268		(42)		226
Total	\$ 492	\$ (2)	\$ (180)	\$	\$ 310

We account for restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS No. 146. SFAS No. 146 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 \$0.1 million for the quarter ended March 31, 2008 from \$0.3 million for the quarter ended March 31, 2007. The decrease in interest income was due primarily to lower average cash, cash equivalents and marketable securities balances held during the quarter ended March 31, 2008 as compared to the quarter ended March 31, 2007, and, to a lesser extent, lower interest rates on securities held during the quarter ended March 31, 2008 as compared to the same quarter 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 March 31, 2008, we had approximately \$9.5 million in unrestricted cash, cash equivalents and marketable securities and \$0.7 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.

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Net cash used in operating activities was \$3.1 million for the quarter ended March 31, 2008 as compared to \$2.5 million for the quarter ended March 31, 2007. The principal use of cash in operating activities for the three months ended March 31, 2008 and 2007 was to fund our net loss. The increase in net cash used in operating activities for quarter ended March 31, 2008 as compared to the quarter ended March 31, 2007, was primarily due to increased spending in connection with our ongoing regulatory efforts. Cash flows from 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 \$2.6 million for the quarter ended March 31, 2008 compared to \$1.5 million for the three months ended March 31, 2007. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$55,000 for the quarter ended March 31, 2008 compared to \$19,000 for the quarter ended March 31, 2007.

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Purchases of property and equipment were not material during the quarters ended March 31, 2008 and 2007. Excluding activities that may be required by the FDA, we expect that purchases of property and equipment during 2008 will be consistent with amounts invested during 2007, although studies required by the FDA in connection with our technologies may require that we purchase additional property and equipment in 2008. We continued to invest in our capitalized patent portfolio during the quarter ended March 31, 2008. We expect that investments made in our patent portfolio during 2008 will be higher than amounts capitalized in 2008 as a result of the timing of certain payments in connection with our patent portfolio.

Net cash provided by financing activities of \$6,000 and \$15,000 for the three months ended March 31, 2008 and 2007, respectively, represents proceeds received from the issuance of common stock under our employee stock option and purchase 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. We expect that cash, cash equivalents and short-term investments on hand at March 31, 2008 will be sufficient to fund our current operations through 2008. This projection is based on our current cost structure and our current assumptions regarding the cost and timing of the studies we expect to initiate in 2008 in connection with our efforts to obtain FDA regulatory clearance for our Version 2 technology. We do not believe, however, that our cash, cash equivalents and marketable securities at March 31, 2008 will be sufficient to fund any such studies through their expected completion and, as a result, we may delay commencement of any such study. In addition, because we have not yet reached agreement with the FDA regarding any studies that would be necessary for the clearance or approval of Version 2 of our stool-based DNA technology, the costs of any such studies will likely require us to obtain additional funding or engage in a strategic collaboration with a third party before previously expected. 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 funds during 2008 through the sale of debt or equity securities, collaborations with third parties or other strategic opportunities, if any, to continue our operations beyond the end of our 2008 fiscal year. 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 seek bankruptcy protection. Even if we successfully raise sufficient funds to continue our operations beyond fiscal 2008, 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 March 31, 2008:

Description	Total	Less Than One Year	Payments Due by Period		More Than 5 Years
			1 - 3 Years (in Thousands)	3 - 5 Years	
Obligations under license and collaborative agreements	\$ 8,939	\$ 2,711	\$ 2,768	\$ 630	\$ 2,830
Operating lease obligations	2,362	995	1,367		
Purchase obligations	407	407			
Total	\$ 11,708	\$ 4,113	\$ 4,135	\$ 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 to reimburse LabCorp for a certain third-party royalty, 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 PreGen-Plus during the measurement periods, the total potential \$3.5 million obligation has been included in the table above based on historical sales levels of PreGen-Plus. 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. Purchase obligations primarily represent a potential \$0.3 million obligation to

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reimburse LabCorp for certain costs related to Effipure as well as commitments associated with our research and development activities.

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



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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 PreGen-Plus, 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;
- threats posed by competing technologies;
- new out-licensing arrangements relating to our technologies; and
- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies.

Additionally, LabCorp could decide to stop offering the current version of Pre-Gen Plus. Furthermore, LabCorp could decide not to launch Version 2 of its testing service, or could decide to defer any potential future launch of Version 2 of its testing service until that version has been approved or cleared by the FDA, if ever. Alternatively, based on a number of factors, including a finite supply of materials required to process Version 1, LabCorp may decide to discontinue the use of Version 1 of our technologies and convert to the use of Version 2. Such conversion could result in an interruption in service and a delay during which no version of the test utilizing our technologies remains on the market. 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. To date, we have not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith.

#### **Off-Balance Sheet Arrangements**

As of March 31, 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.

**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 March 31, 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.

## 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 changes 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.

*Our independent auditors have expressed substantial doubt about our ability to continue as a going concern, and we may be unable to raise additional capital on acceptable terms in the future.*

We have incurred substantial losses to date and we expect to incur substantial losses for the foreseeable future. As of March 31, 2008, we had an accumulated deficit of approximately \$165.2 million. 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. We expect that cash, cash equivalents and short-term investments on hand at March 31, 2008 will be sufficient to fund our current operations through 2008. This projection is based on our current cost structure and our current assumptions regarding the cost and timing of the studies we expect to initiate in 2008 in connection with our efforts to obtain FDA regulatory clearance for our Version 2 technology. We do not believe, however, that our cash, cash equivalents and marketable securities at March 31, 2008 will be sufficient to fund any such studies through their expected completion and, as a result, we may delay commencement of any such study. In addition, because we have not yet reached agreement with the FDA regarding any studies that would be necessary for the clearance or approval of Version 2 of our stool-based DNA technology, the costs of any such studies will likely require us to obtain additional funding or engage in a strategic collaboration with a third party before previously expected. Our future liquidity and capital requirements will depend upon numerous factors, including the following:

- the regulatory requirements for PreGen-Plus, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- 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 Laboratory Corporation of America Holdings, or 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; and
- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies.

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 funds during 2008 through the sale of debt or equity securities, strategic collaborations with third parties and other strategic opportunities, if any, to continue our business operations beyond the end of our 2008 fiscal year. In March 2008, we announced that we have engaged an investment bank to advise our Board of Directors in its evaluation of strategic alternatives for the business, including, but not limited to, the sale of the company or merger with another entity. We cannot assure you that our evaluation of strategic alternatives will result in such a transaction being successfully consummated or, if successful, that any such transaction would achieve our goal of maximizing the value of our business for our stockholders. We also cannot assure you that our actual cash requirements will not be greater than anticipated. In addition, the going concern explanatory paragraph included in our auditor's report on our consolidated financial statements could inhibit our ability to enter into license agreements or other collaborations or our ability

to raise additional financing. If we are unable to obtain the required 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 required to further reduce the scale of our operations and our business, our results of operation and financial condition would be materially adversely affected and we may be required to seek bankruptcy protection.

Additionally, even if we do raise sufficient capital and generate revenues to support our operating expenses beyond fiscal 2008, there can be no assurances that the revenue will be sufficient to enable us to develop our business to a level where it will generate profits and cash flows from operations. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, or grant licenses on terms that are not favorable to us. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations.

***If we or LabCorp fail to comply with FDA requirements, we or LabCorp may be limited or prohibited in our ability to commercialize stool-based DNA testing for colorectal cancer and may be subject to stringent penalties.***

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007 the FDA sent a warning letter to us, which we refer to as 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 is the basis for LabCorp's PreGen-Plus testing service. In addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. In April 2008, we began focusing our regulatory efforts on pursuing FDA clearance for Version 2 of our technology. In this regard, in April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA for our Version 2 technology.

The objective of the pre-IDE process is to seek confirmation with the FDA that the filing of a *de novo* 510(k) is an appropriate regulatory path for our Version 2 technology and that the studies and other objectives proposed in our Version 2 pre-IDE submission support such a *de novo* 510(k) regulatory path. The FDA has not yet indicated whether our proposed submission with respect to Version 2 of our technology would be a *de novo* 510(k). Moreover, the FDA may 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. We believe that additional clinical studies, which will likely be material in cost and time-intensive, will be required in connection with any approval or clearance of our Version 2 technology regardless of whether it is a *de novo* 510(k) or a PMA. We do not believe that our cash, cash equivalents and marketable securities as of March 31, 2008 will be sufficient to fund any such studies through completion. Accordingly, we may be required to delay the start of any such studies and seek additional funds prior to initiation of any such studies.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach or proposed studies will satisfy the FDA's regulatory requirements for our Version 2 technology or any version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense. Because we do not currently have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies, we may delay any such activities and process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action against LabCorp or us, which could involve criminal or civil penalties and cause material harm to our business.

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Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, could launch the Version 2 technology and subsequently be required by the FDA to stop offering the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would

materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio (\$0.5 million at March 31, 2008).

***The lack of a recommended screening interval for stool-based DNA screening in the guidelines of the American Cancer Society and the U.S. Multisociety Task Force on Colorectal Cancer, as well as annual updates to such guidelines, may limit the acceptance of our technologies among physicians and third-party payors, including Medicare.***

The inclusion of stool-based DNA screening in the colorectal cancer screening guidelines of the ACS and the MSTF-CRC, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and American College of Physicians/Society of Internal Medicine, issued on March 5, 2008 did not specify any recommended screening interval. By contrast, the ACS and MSTF-CRC guidelines made specific interval recommendations for each of the other six other colorectal cancer screening modalities included in such guidelines. In addition, it is possible that the ACS, in connection with its future annual updates to the colorectal cancer screening guidelines, may recommend a screening interval that would prevent our technologies from being cost-effective or may limit broad inclusion of our technologies or particular versions of our technologies in the guidelines. Lack of a definitive screening interval recommendation, a future recommendation for a screening interval that is not cost-effective or any limitation on the inclusion of our technologies, including particular versions of our technology, in future guidelines may lead to reluctance on the part of doctors to order and reorder colorectal cancer screening tests using our technologies, which would limit our revenues and materially harm our business and financial results. Such events may also lead to a reluctance by third-party payors, including Medicare, to provide adequate reimbursement for our technologies, if at all, which would also have a material adverse effect on our results of operations and financial position.



**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
10.1**	Fourth Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of March 17, 2008.
10.2	Amended and Restated Employee Retention Agreement between the Registrant and Jeffrey R. Luber, dated as of April 18, 2008 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference).
10.3	Amended and Restated Employee Retention Agreement between the Registrant and Charles R. Carelli, Jr., dated as of April 18, 2008 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference).
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.

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

*Indicates a management contract or any compensatory plan, contract or arrangement.*

**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: May 9, 2008

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

Date: May 9, 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)

**EXHIBIT INDEX**

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