

EXACT SCIENCES CORP  
Form 10-Q  
August 08, 2007

**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 June 30, 2007

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)

**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

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Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of August 2, 2007, the registrant had 26,977,573 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)

	June 30, 2007	December 31, 2006
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,835	\$ 4,831
Marketable securities	13,108	16,244
Prepaid expenses and other current assets	356	386
Total current assets	17,299	21,461
Property and Equipment, at cost:		
Laboratory equipment	3,824	3,832
Office and computer equipment	1,415	1,413
Leasehold improvements	1,259	1,259
Furniture and fixtures	299	299
	6,797	6,803
Less Accumulated depreciation and amortization	(6,061)	(5,959)
	736	844
Patent costs, net of accumulated amortization of \$2,947 and \$2,871 at June 30, 2007 and December 31, 2006, respectively	557	763
Restricted cash	800	800
	\$ 19,392	\$ 23,868
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 163	\$ 158
Accrued expenses	1,951	1,844
Deferred license fees, current portion	1,350	4,363
Total current liabilities	3,464	6,365
Deferred license fees, less current portion	3,376	2,545
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, \$0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding 0 shares at June 30, 2007 and December 31, 2006		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 27,063,123 and 26,863,363 shares at June 30, 2007 and December 31, 2006, respectively	270	269
Additional paid-in capital	166,877	165,545
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	12	6
Accumulated deficit	(154,510)	(150,765)
Total stockholders equity	12,552	14,958
	\$ 19,392	\$ 23,868

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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
<b>Revenue:</b>				
Product royalty fees	\$ 19	\$ 61	\$ 45	\$ 122
License fees	1,091	1,091	2,182	2,182
Product	5	69	58	111
	1,115	1,221	2,285	2,415
<b>Cost of revenue:</b>				
Product royalty fees	1	4	3	8
Product		89		673
	1	93	3	681
<b>Gross profit</b>	<b>1,114</b>	<b>1,128</b>	<b>2,282</b>	<b>1,734</b>
<b>Operating expenses:</b>				
Research and development (1)	1,332	1,918	2,609	3,878
Sales and marketing (1)	510	1,272	1,005	2,758
General and administrative (1)	1,337	1,497	2,879	3,138
Restructuring	(2)	)	31	
	3,177	4,687	6,524	9,774
<b>Loss from operations</b>	<b>(2,063)</b>	<b>(3,559)</b>	<b>(4,242)</b>	<b>(8,040)</b>
<b>Interest income</b>	<b>238</b>	<b>313</b>	<b>497</b>	<b>631</b>
<b>Net loss</b>	<b>\$ (1,825)</b>	<b>\$ (3,246)</b>	<b>\$ (3,745)</b>	<b>\$ (7,409)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.07)</b>	<b>\$ (0.12)</b>	<b>\$ (0.14)</b>	<b>\$ (0.28)</b>
<b>Weighted average common shares outstanding basic and diluted</b>	<b>26,880</b>	<b>26,402</b>	<b>26,835</b>	<b>26,389</b>

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

Research and development	\$ 357	\$ 103	\$ 431	\$ 368
Sales and marketing	127	300	244	707
General and administrative	237	306	454	702

*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)

	Six Months Ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (3,745 )	\$ (7,409 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and write-offs of fixed assets	110	299
Amortization and write-offs of patents	239	439
Stock-based compensation	1,129	1,777
Amortization of deferred license fees	(2,182 )	(2,182 )
Changes in assets and liabilities:		
Prepaid expenses and other current assets	30	263
Accounts payable	5	(235 )
Accrued expenses	296	76
Net cash used in operating activities	(4,118 )	(6,972 )
Cash flows from investing activities:		
Purchases of marketable securities	(12,934 )	(10,824 )
Maturities of marketable securities	16,076	18,758
Purchases of property and equipment	(2 )	(73 )
Increase in patent costs and other assets	(33 )	(135 )
Net cash provided by investing activities	3,107	7,726
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	15	71
Decrease in restricted cash		20
Net cash provided by financing activities	15	91
Net (decrease) increase in cash and cash equivalents	(996 )	845
Cash and cash equivalents, beginning of period	4,831	11,987
Cash and cash equivalents, end of period	\$ 3,835	\$ 12,832
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of 56,675 shares of restricted common stock to collaborator in lieu of cash to settle semi-annual license obligation	\$ 158	\$
Issuance of 34,030 shares of common stock to fund the Company's 401(k) matching contribution for 2006	\$ 103	\$

*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**

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.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**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, 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.

These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006, filed with the SEC.

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.

**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 June 30, 2007 and December 31, 2006, \$0.8 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 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 and six months ended June 30, 2007 and 2006.

### 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 June 30, 2007, 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 six months ended June 30, 2007 and 2006. Amounts included in the table are in thousands.

	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006
Patents, net of accumulated amortization, beginning of period	\$ 763	\$ 1,419
Patent costs capitalized	33	135
Amortization of patents	(86	) (298
Write-offs of patents	(153	) (141
Patents, net of accumulated amortization, end of period	\$ 557	\$ 1,115

During the three months 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 months ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus. During the three months ended June 30, 2007, a capitalized pending patent application, which is not critical to LabCorp's PreGen-Plus testing service, was not approved by the U.S. Patent and Trademark Office, and, accordingly, the Company wrote off approximately \$32,000 in connection with this patent application.

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, less shares subject to repurchase. 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)	June 30,	
	2007	2006
Shares issuable upon exercise of stock options	4,328	4,865
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,328	5,865

**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 a Second Amendment to the license agreement between the Company and LabCorp dated June 26, 2002, as amended (the Amendment ) (See Note 3), which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 to December 2010. Accordingly, the Company will amortize the remaining deferred revenue balance of \$4.7 million as of June 30, 2007 on a straight-line basis over the remaining extended exclusive license period.

**Product royalty fees** - Prior to the effective date of the 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 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 Amendment, the Company will record 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 increase to 17% in the event that LabCorp achieves a specified significant threshold of net revenues from the sales of PreGen-Plus.

**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 and six months ended June 30, 2007 and 2006 was as follows:



(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Net loss	\$ (1,825 )	\$ (3,246 )	\$ (3,745 )	\$ (7,409 )
Unrealized (loss) gain on marketable securities	7	18	6	30
Comprehensive loss	\$ (1,818 )	\$ (3,228 )	\$ (3,739 )	\$ (7,379 )

### (3) AMENDMENT TO LABCORP LICENSE AGREEMENT; LETTER OF INTENT

On June 27, 2007, the Company entered into the Amendment with LabCorp. The Amendment modified LabCorp's exclusive rights to the Company's DNA technology for colorectal cancer screening to permit the Company to license its technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Amendment until December 31, 2010. Additionally, the Amendment clarifies the rights and obligations with respect to the Company's Version 2 technology for colorectal cancer screening.

The Amendment also revised the milestone and royalty obligations of LabCorp. The milestones were revised to eliminate milestone payments aggregating \$15 million based upon stool-based colorectal cancer screening being included as standard of care and certain policy-level reimbursement approvals. As revised under the Amendment, the Company may be eligible for up to an aggregate of \$40 million in milestone payments, all of which now relate to the achievement of significant sales thresholds. Royalties due to the Company under the Amendment are equal to 15% of LabCorp's net revenues from tests performed using the Company's DNA technology licensed under the Amendment, and could increase to 17% if LabCorp achieves a significant annual PreGen-Plus net revenue threshold. LabCorp also retains preferential pricing terms over third-party organizations and commercial service laboratories to whom the Company may license its DNA technology for colorectal cancer screening.

The Amendment also eliminated an approximate \$3.0 million contingent liability of the Company to LabCorp resulting from a historical third-party royalty obligation of LabCorp. Under the terms of the Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as outlined in the table below. The Company's liability to pay LabCorp pursuant to this provision of the 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 the maximum potential obligation under this provision of the Amendment ratably on a quarterly basis as a reduction in the product royalty fee line item in the Company's consolidated statements of operations beginning in the quarter ended September 30, 2007.

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	\$	\$ 1,500,000
January 1, 2009	December 31, 2009		1,000,000
January 1, 2010	December 31, 2010		1,000,000
		\$	\$ 3,500,000

In addition, as a result of extending the exclusive license period from August 2008 to December 2010, the amortization of the remaining deferred revenue of \$4.7 million related to up-front technology license fees received from LabCorp will be amortized on a straight line basis over the extended exclusive license period beginning in the quarter ended September 30, 2007. Additionally, pursuant to the Amendment, the Company could be obligated to reimburse LabCorp for certain costs related to Effipure, up to a maximum of \$0.3 million during the term of the exclusive period. The Company will record any liabilities incurred pursuant to this provision in the cost of product sold line item in its consolidated statements of operations.



The Amendment also provides LabCorp with termination rights if stool-based colorectal cancer screening is not accepted as standard of care in the near term (i.e. included in screening guidelines of the American Cancer Society or the American Gastroenterological Association), if the Company's Version 2 technology is not commercially launched in the near term, or if the Company's Version 2 technology does not attain certain sensitivity and specificity thresholds during technology validation.

In July 2007, the Company entered into a non-binding letter of intent with LabCorp to further modify the terms of the Company's license agreement with LabCorp as discussed in Note (7) below.

#### (4) **STOCK-BASED COMPENSATION**

##### **Stock-Based Compensation Plans**

Note 8 to the Company's consolidated financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2006, 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 (revised 2004), *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 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, 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*.

The Company recorded \$0.7 million and \$1.1 million in stock-based compensation during the three and six months ended June 30, 2007 in connection with the amortization of employee and non-employee director stock option awards, stock options granted to non-employee consultants, restricted common stock issued to a collaborator, and stock-based compensation expense related to the Company's 2007 401(k) match, which, if approved by the Company's board of directors, will be made in Company common stock in 2008. The Company recorded \$0.7 million and \$1.8 million in stock-based compensation during the three and six months ended June 30, 2006 in connection with the amortization of employee and non-employee director stock option awards, stock options and restricted stock awards granted to non-employee consultants, and stock-based compensation expense related to the Company's 2006 401(k) match, which was approved by the Company's board of directors. The Company's annual employee grant of stock options generally occurs in February of each year, subject to board approval. The fair value of stock-based awards for the three and six months ended June 30, 2007 and 2006 was determined as outlined below.

**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 following table. 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 Bulletin 107, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. This method allows the Company to estimate the expected life using the average of the vesting period and the contractual life of the stock options granted.

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

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

**Forfeitures** - As required by SFAS No. 123(R), the Company records share-based compensation expense only for those awards that are expected to vest. The Company does not estimate forfeitures because all share based awards vest monthly and expense is trued up at each period end.





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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 June 30, 2007		Six Months Ended June 30, 2007		2006	
<b>Option Plan Shares</b>						
Risk-free interest rates	(1)	4.91% - 4.95 %	4.50	%	4.59% - 4.95	%
Expected term (in years)	(1)	6	6		6	
Expected volatility	(1)	70	% 70	%	70	%
Dividend yield	(1)	0	% 0	%	0	%
Weighted average fair value per share of options granted during the period	(1)	\$2.04	\$1.83		\$1.73	
<b>ESPP Shares</b>						
Risk-free interest rates	(1)	(1 )	5.10% - 5.17 %		3.81% - 4.61	%
Expected term (in years)	(1)	(1 )	0.5 - 2		0.5 - 2	
Expected volatility	(1)	(1 )	70	%	70	%
Dividend yield	(1)	(1 )	0	%	0	%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1 )	\$1.08		\$1.17	

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

**Stock Option Activity**

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the six months ended June 30, 2007 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, 2007	4,125,940	\$5.69	5.3	
Granted	729,000	\$2.77		
Exercised		\$0.00		
Cancelled	(526,792 )	\$6.23		
Outstanding, June 30, 2007	4,328,148	\$5.12	6.1	\$750
Exercisable, June 30, 2007	3,188,388	\$5.91	5.0	\$587
Vested and expected to vest, June 30, 2007	3,790,903	\$5.43	6.6	\$673

(1) The aggregate intrinsic value of options outstanding at June 30, 2007 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 1,841,359 options that had exercise prices that were lower than the \$2.89 market price of our common stock at June 30, 2007. The aggregate intrinsic value of options exercisable at June 30, 2007 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 890,276 options that had exercise prices that were lower than the \$2.89 market price of our common stock at June 30, 2007. The aggregate intrinsic value of options vested and expected to vest at June 30, 2007 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 1,369,979 options that had exercise prices that were lower than the \$2.89 market price of our common stock at June 30, 2007.

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As of June 30, 2007, there was \$2.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.5 years.

**(5) RESTRUCTURING**

In October 2006, the Company initiated a plan to reduce its cost structure by eliminating 21 positions, or 48% of its staff at that time, across all departments (the October 2006 Restructuring). This workforce reduction was intended to reduce the Company's expenses and preserve its existing cash and cash equivalents. Since the October 2006 Restructuring, the Company's efforts have been focused on:

- the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines that will result from the joint efforts of the American Cancer Society and the U.S. Multisociety Task Force on Colorectal Cancer, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine (the ACS/MSTF-CRC);
- Medicare coverage pursuit for stool-based DNA testing;
- the pursuit of licensing arrangements relating to its stool-DNA technologies; and
- validation and optimization of the Company's Version 2 technology.

The Company accounts for its restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (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.

Pursuant to the October 2006 Restructuring, the Company accrued charges of \$0.7 million in the quarter ended December 31, 2006 in connection with one-time employee termination benefits, including severance and outplacement services. The company recorded changes in estimates to the restructuring accrual of \$(2,000) and \$31,000, respectively, in connection with adjustments to estimates of one-time employee termination benefits, including severance and outplacement services, during the three and six months ended June 30, 2007.

Amounts remaining in the October 2006 Restructuring accrual at June 30, 2007 are expected to be paid through September 2007 and are recorded under the caption *Accrued expenses* in the condensed consolidated balance sheets at June 30, 2007. The following table summarizes the restructuring activities during the three months ended June 30, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2006	Charges	Cash Payments	Non-cash Write-offs	Balance, June 30, 2007
Employee separation costs	\$ 283	\$ 31	\$ (271 )	\$	\$ 43
Total	\$ 283	\$ 31	\$ (271 )	\$	\$ 43

**(6) ISSUANCE OF COMMON STOCK**

On June 14, 2007, pursuant to the terms of a Manufacturing and Supply Agreement by and between Oncomethylome Sciences S.A. (OMS) and the Company dated June 8, 2007, the Company issued to OMS 100,000 shares of the Company's common stock, \$.01 par value per share (the Common Stock). The Company recorded a non-recurring non-cash stock-based compensation charge of approximately \$0.3 million in its consolidated statements of operations during the quarter ended June 30, 2007 in connection with the Common Stock issuance.



(7) **SUBSEQUENT EVENTS**

In July 2007, the Company entered into a non-binding letter of intent with LabCorp to transition responsibility for all sales and marketing activities related to LabCorp's testing service, PreGen-Plus. The letter of intent also provides for an additional \$2.5 million milestone payment related to the inclusion of stool-based DNA testing in the updated colorectal cancer screening guidelines, Medicare reimbursement and specified increases in sales of PreGen-Plus. The letter of intent is non-binding on the parties and there can be no assurance that the Company will enter into a definitive amendment to its license agreement with LabCorp on favorable terms, if at all. If the Company is unable to successfully enter into a definitive amendment to its license agreement to formalize the provisions of the letter of intent, the continued commercialization of PreGen-Plus by LabCorp could be delayed and the Company's ability to generate revenues could be materially harmed.

In connection with the letter of intent with LabCorp, on July 18, 2007 and August 2, 2007, the Company notified five employees and one employee, respectively, of their termination from the Company, effective August 31, 2007. These restructuring activities were initiated under a plan of termination described in SFAS No. 146 pursuant to which charges will be incurred under generally accepted accounting principles (the 2007 Restructuring). The 2007 Restructuring is designed to eliminate the Company's sales and marketing functions to reduce costs and better preserve the Company's cash resources.

The Company estimates that the total charges related to the five employees notified of their termination on July 18, 2007 will range from between \$100,000 and \$800,000 and include one-time termination benefits arising under retention and severance agreements with each of the terminated employees. The Company estimates that total charges related to the August 2, 2007 termination will range from \$100,000 to \$200,000 and include one-time termination benefits arising under a retention and severance agreement with the terminated employee. The costs related to the 2007 Restructuring, which, when aggregated could range from \$200,000 to \$1.0 million, are expected to be recorded in the third fiscal quarter of 2007. Because the right 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, the charges that will actually be recorded cannot be determined at this time. All of the charges will result in future cash expenditures. The Company continues to assess its facility needs and other operational costs and, as a result, could incur additional restructuring charges in the event the Company undertakes additional activities to reduce its facilities or other operating costs.

In July 2007, Don M. Hardison, the Company's former President and Chief Executive Officer, announced his resignation from the Company effective August 31, 2007. Pursuant to terms of Mr. Hardison's employment agreement with the Company, Mr. Hardison received a retention bonus payment of \$0.2 million in January 2007 and the Company had accrued a proportional amount of the remaining \$0.2 million retention bonus which would have been payable on January 1, 2008, if he had continued employment with the Company. As a result of Mr. Hardison's resignation from the Company in July 2007, the remaining potential retention bonus of \$0.2 million will not be paid out and the expense previously accrued in connection with Mr. Hardison's remaining retention bonus (approximately \$0.1 million as of June 30, 2007) has been reversed in the statement of operations for the three and six month periods ended June 30, 2007.

## 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, 2006, which has been filed with the Securities and Exchange Commission (the "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, intends, 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 capital resources, expected royalty fees and revenues, expected sales and marketing, research and development and general and administrative expenses, the impact of regulatory agency action on the marketing and sale of PreGen-Plus, 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, inclusion of stool-based DNA screening in colorectal cancer screening guidelines, 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, 2006. 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 ( "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. Since our inception in February 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;
- conducting clinical studies to validate our colorectal cancer screening technologies;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- pursuing reimbursement for stool-based DNA screening with third-party payors, including the Centers for Medicare and Medicaid Services;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our proprietary technologies to LabCorp and others;

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- working to further the adoption of stool-based DNA testing for colon cancer, including seeking inclusion of such technology in the guidelines of the major guidelines organizations;
- working with LabCorp on activities in support of the commercialization of PreGen-Plus; and
- sales and marketing efforts in support of PreGen-Plus.

We have generated limited operating revenues since our inception and, as of June 30, 2007, we had an accumulated deficit of approximately \$154.5 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 the build-out of our sales infrastructure to support the commercialization and marketing of PreGen-Plus. We expect that our losses will continue for the next several years.

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through June 30, 2007, LabCorp had accessioned approximately 13,500 PreGen-Plus samples, including 476 and 1,018 samples, respectively, during the three and six months ended June 30, 2007 and approximately 3,700, 4,000, and 4,300 samples, during the years ended December 31, 2006, 2005 and 2004, respectively. To achieve sufficient demand for PreGen-Plus, we believe that stool-based DNA testing must be included in the colorectal cancer screening guidelines of the major guidelines organizations (including the guidelines of the American Cancer Society, (the ACS), and the U.S. Multisociety Task Force on Colorectal Cancer, which is 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 (the MSTF-CRC), together the ACS/MSTF-CRC). In addition, we believe that substantial funds and managerial attention will likely need to be invested in sales and marketing efforts over the next several years. 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. Even if stool-based DNA screening is included in colorectal cancer screening guidelines and sufficient funds and managerial time are invested in sales and marketing efforts, our success will also depend upon a number of factors that are largely out of our control, including the following:

- the positioning of stool-based DNA screening within guidelines such that it is not limited among the screening options offered and that any inclusion in screening guidelines includes our Version 2 technologies;
- the regulatory requirements for, and any regulatory restrictions placed upon, PreGen-Plus or any other product based on our technologies, and the timing of any required regulatory filings and approval processes;
- whether LabCorp continues to offer PreGen-Plus commercially;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payers;
- effective LabCorp sales and sales management personnel and processes to educate physicians and their staffs and consumers regarding PreGen-Plus and patient compliance;
- success in educating third-party payers, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- effective negotiation and contracting by LabCorp with Medicare and other third-party payers for coverage and acceptable levels of reimbursement for PreGen-Plus;
- patient acceptance of PreGen-Plus, including its novel sample collection process;
- stool-based DNA screening becoming a standard of care among prescribing physicians; and
- the quality and service of the LabCorp testing process.

Until such time as some or all of the factors outlined above are in place, we do not expect material revenue growth. Our revenue is comprised of product royalty fees on PreGen-Plus tests sold by LabCorp, product revenue from the sale to LabCorp of Effipure components, which are used by LabCorp in processing PreGen-Plus tests, and the amortization of license fees for the licensing of product rights to LabCorp under our strategic license agreement. We expect that product royalty fees for 2007 will be significantly lower than amounts recorded in 2006 as a result of certain potential third party royalty obligations in connection with our recently amended license agreement with LabCorp. In addition, as a result of the recent amendment to our license agreement with LabCorp, which also extended the exclusive license period under the Agreement, we expect that license fee revenue for 2007 will be lower than amounts recorded in 2006 as a result of the extended amortization period over which our remaining deferred revenue will be amortized. See Recent Developments below for a discussion of recent modifications to our license agreement with LabCorp. LabCorp informed the FDA during 2006 that they were working on changes to PreGen-Plus that could 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 2007. The potential loss of this revenue during 2007 is not expected to have a material impact on our total revenues.



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While LabCorp has received payment on approximately 50% of the PreGen-Plus tests accessioned by LabCorp to date, laboratory operating factors such as turnaround times for the testing process, possible pre- and post-analytical sample and sample processing deficiencies and third-party reimbursement all influence the timing and whether an accession by LabCorp will eventually be recognized as revenue by us.

On October 17, 2006, we initiated a plan to reduce our cost structure by eliminating 21 positions, or 48% of our staff at that time, across all departments to reduce expenses. Since this workforce reduction, our efforts have focused on the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines of the ACS/MSTF-CRC, Medicare coverage pursuit for stool-based DNA testing, and optimization and validation of our Version 2 technology. On July 18, 2007 we eliminated our sales and marketing functions and terminated five employees in connection with a proposed transition to

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LabCorp of all sales and marketing activities related to PreGen-Plus. On August 2, 2007 we eliminated one additional position. See *Recent Developments* below for a discussion of the July and August 2007 restructuring activities.

Pursuant to the October 2006 restructuring plan, we accrued charges of \$0.7 million in the quarter ended December 31, 2006 in connection with one-time employee termination benefits, including severance, outplacement and fringe benefits. During the three and six months June 30, 2007, we recorded changes in estimates to the restructuring accrual of approximately \$(2,000) and \$31,000, respectively, related to adjustments to estimates of one-time employee termination benefits, including severance and outplacement services. Under the July 2007 restructuring we expect to record restructuring charges ranging from \$100,000 to \$800,000 during the quarter ended September 30, 2007 related to one-time employee termination benefits. In connection with the elimination of one additional position in August 2007, we expect to record additional restructuring charges ranging from \$100,000 to \$200,000 during the quarter ended September 30, 2007. We expect to record total one-time charges related to our July and August 2007 restructuring activities of between \$200,000 and \$1.0 million. We continue to assess our facility needs and operational costs and, as a result, could incur additional restructuring charges in the event that we undertake additional activities to reduce facility and other 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 related to the amortization of the fair value of stock option awards granted to employees. As a result of restructuring our operations, we expect that our research and development costs in 2007 will be lower than 2006 levels. Our research and development efforts in 2007 will focus on the validation and optimization of the next generation of our colorectal cancer screening technology, or Version 2 of our technology. While we have taken steps to lower research and development costs by focusing on Version 2 of our technology, we may need to invest substantial funds in additional research, design and development to successfully commercialize our Version 2 technology or other potential future products.

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 related to the amortization of the fair value of stock option awards granted to employees. As a result of the July and August 2007 restructuring activities, described below under *Recent Developments*, in which we eliminated our sales and marketing functions, we expect sales and marketing expenses in 2007 to be significantly lower than 2006 levels. Specifically, we do not expect to incur material sales and marketing operating expenses subsequent to the July 2007 restructuring as a result of the elimination of our five sales and marketing positions effective August 31, 2007. We expect general and administrative expenses in 2007 to be materially consistent with 2006 levels.

During the fourth quarter of 2006 in connection with our October 2006 restructuring, we entered into employment retention agreements with our remaining employees, which provide for severance and a one-time retention bonus in the aggregate amount of approximately \$0.9 million in total across all employees, payable on December 31, 2007 (subject to acceleration in certain circumstances), provided that such employees continue to be employed on the date of payment. The retention agreements also provide that upon the occurrence of certain triggering events, such as a change of control or termination without cause, remaining employees will be entitled to receive any unpaid retention bonus and severance payments, at a rate equal to their base salary at the time of termination of employment, for periods ranging from three to twelve months. In connection with our July and August 2007 restructuring activities, six employees were terminated. Retention bonus payments in the aggregate amount of approximately \$0.4 million will be accelerated and paid to those employees during the third quarter of 2007 pursuant to their retention agreements. We intend to accrue the cost of the retention bonuses for our remaining employees, currently estimated to be approximately \$0.3 million, over the remaining retention period, which ends on December 31, 2007.

In addition, in June 2006, we entered into an employment agreement with Don M. Hardison, our former President and Chief Executive Officer, under which he received a retention bonus payment of \$0.2 million on January 1, 2007 and would have been eligible to earn a second retention bonus in the amount of \$0.2 million payable on January 1, 2008, provided that he continued to be employed by us on January 1, 2008. As a result of Mr. Hardison's resignation from the Company in July 2007, the remaining \$0.2 million potential retention bonus will not be paid to Mr. Hardison and expense recorded to date for this payment (approximately \$0.1 million) has been reversed in the three and six month periods ended June 30, 2007.

### **Recent Developments**

***Colorectal Cancer Screening Guidelines.*** On June 7, 2007 we were informed by officials of the American Cancer Society, or ACS, that the release of updated colorectal cancer screening guidelines, which are being drafted by the ACS and the U.S Multi-Society Task Force, or MSTF, would not be issued in June 2007. No additional information was available regarding when the process would be completed. The timing and determination as to whether stool-based DNA screening is included in colorectal cancer screening guidelines is outside of our control. We cannot assure you that a decision regarding stool-based DNA will be made or that



stool-based DNA screening will ever be included in colorectal cancer screening guidelines. If our stool-based DNA screening technologies are not included in colorectal cancer screening guidelines for sufficiently broad and or sufficiently frequent use within the population, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected. In such event, we could be required to further significantly curtail our operations. In addition, an adverse guidelines determination could result in the impairment of the recorded value of our patent portfolio (\$0.6 million at June 30, 2007) or our fixed assets.

**Amendment to LabCorp License Agreement.** On June 27, 2007, we entered into a second amendment to our license agreement with LabCorp dated June 26, 2002. This amendment modified LabCorp's exclusive rights to our DNA technology for colorectal cancer screening to permit us to license our technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Amendment until December 31, 2010. Additionally, the Amendment clarifies the rights and obligations with respect to our Version 2 technology for colorectal cancer screening.

The amendment also revised certain milestone and royalty obligations of LabCorp. The milestones were revised to eliminate milestone payments aggregating \$15 million based upon policy-level reimbursement approval from key payors including Medicare and the inclusion of stool-based DNA screening in clinical practice guidelines. As revised, we may be eligible for up to an aggregate of \$40 million in milestone payments, all of which now relate to the achievement of significant sales thresholds. Royalties due to us under the Amendment are equal to 15% of LabCorp's net revenues from tests performed using our DNA technology licensed under the Amendment, and could increase to 17% if LabCorp achieves a significant annual PreGen-Plus net revenue threshold. LabCorp also retains preferential pricing terms over third-party organizations and commercial service laboratories to which we may license our DNA technology for colorectal cancer screening.

The amendment also eliminated our approximately \$3.0 million contingent liability to LabCorp resulting from a certain third-party royalty obligation of LabCorp. Under the terms of the amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalties, as outlined in the table below. Our liability to pay LabCorp pursuant to this provision of the 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 sales PreGen-Plus sales levels 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 over 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 maximum potential obligation under this provision of the amendment ratably on a quarterly basis as a reduction in the product royalty fee line item in our consolidated statements of operations beginning in the quarter ended September 30, 2007.

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	\$	\$ 1,500,000
January 1, 2009	December 31, 2009		1,000,000
January 1, 2010	December 31, 2010		1,000,000
		\$	\$ 3,500,000

In addition, as a result of extending the exclusive license period from August 2008 to December 2010, the amortization of the remaining deferred revenue of \$4.7 million as of June 30, 2007 related to up-front technology license fees received from LabCorp will be amortized on a straight line basis over the extended exclusive license period, resulting in lower non-cash license fee revenue each quarter beginning in the quarter ended September 30, 2007. Additionally, pursuant to the amendment, we could be obligated to reimburse LabCorp for certain costs related to Effipure, up to a maximum of \$0.3 million during the term of the exclusive period. We will record any liabilities incurred pursuant to this provision in the cost of product sold line item in our consolidated statements of operations.

The amendment also provides LabCorp with termination rights if stool-based colorectal cancer screening is not accepted as standard of care in the near term, if our Version 2 technology is not commercially launched in the near term, or if our Version 2 technology does not attain certain sensitivity and specificity thresholds during technology validation.



**July 2007 Restructuring.** In July 2007, we entered into a non-binding letter of intent with LabCorp to transition responsibility for all sales and marketing activities related to LabCorp's testing service, PreGen-Plus. In connection with the letter of intent with LabCorp, on July 18, 2007 and August 2, 2007 we notified five employees and one employee, respectively, of their termination from EXACT, effective August 31, 2007. These restructuring activities were designed to eliminate our sales and marketing functions to reduce costs and better preserve our cash resources.

We expect that the total charges related to the five employees notified of their termination on July 18, 2007 will range from between \$100,000 and \$800,000 and include one-time termination benefits arising under retention and severance agreements with each of the terminated employees. We expect that total charges related to the August 2, 2007 termination will range from \$100,000 to \$200,000 and include one-time termination benefits arising under a retention and severance agreement with the terminated employee. The restructuring costs related to the July 2007 and August 2007 staff reductions, which, when aggregated could range from \$200,000 to \$1.0 million, are expected to be recorded in the third fiscal quarter of 2007 in accordance with the provisions of SFAS No. 146. Because the right 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, the charges that will actually be recorded cannot be determined at this time. All of the charges will result in future cash expenditures. We continue to assess our facility needs and other costs and could incur additional restructuring charges in the event facilities or other operating costs are reduced.

**Reimbursement.** On August 1, 2007, we were informed by officials of the Centers for Medicare & Medicaid Services (CMS) that our application for a National Coverage Determination for our stool-based DNA cancer screening technology had been accepted. The timing of any coverage decision by CMS is not within our control. We would not expect CMS to make a coverage decision sooner than nine months from the date of the acceptance of our National Coverage Determination application. There can be no assurance that CMS will reach a positive coverage decision regarding our request for a National Coverage Determination. Moreover, even if CMS issues a positive coverage decision for stool-based DNA screening, such coverage may not provide adequate levels of reimbursement or may not include reimbursement for all current and future versions of our technologies. Further, CMS has not yet determined whether any potential coverage decision would provide for stool-based DNA screening for colorectal cancer broadly, or whether any potential CMS coverage would relate solely to a particular version of our technology.

#### **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, 2006, 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 amended our license agreement with LabCorp 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 will amortize the remaining deferred revenue balance as of June 30, 2007 (\$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 our Amendment to the license agreement with LabCorp, 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

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effective date of the 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 amendment, we will 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.

**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 our capitalized patents for the six months ended June 30, 2007 and 2006. Amounts included in the table are in thousands.

	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006
Patents, net of accumulated amortization, beginning of period	\$ 763	\$ 1,419
Patent costs capitalized	33	135
Amortization of patents	(86)	(298)
Write-offs of patents	(153)	(141)
Patents, net of accumulated amortization, end of period	\$ 557	\$ 1,115

During the three months 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 months ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus. During the three months ended June 30, 2007, a capitalized patent application, which is not critical to LabCorp's PreGen-Plus testing service, was not approved by the U.S. Patent and Trademark Office, and, accordingly, we wrote off approximately \$32,000 in connection with this patent application.

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets* (SFAS No. 144), which requires us to continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles may warrant revision or that the carrying value of these assets may be impaired. Such events may include 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 year ended December 31, 2006.

**Stock-Based Compensation.** We adopted SFAS No. 123 (revised 2004), *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 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**

**Potential Third Party Royalty Obligation.** Under the terms of our amended license agreement with LabCorp, we are potentially liable to reimburse LabCorp for a certain third-party royalty payment made by LabCorp in connection with its sales of PreGen-Plus. Our potential liability is described under the section **Recent Developments** above.

#### **Recent Accounting Pronouncements**

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109* (the *Interpretation*). The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. We adopted the Interpretation effective January 1, 2007 and it did not have a material impact on our consolidated results of operations, financial position or cash flows.

In September 2006, 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 would be 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, with early adoption permitted. We do not expect the adoption of this standard to have a material impact on our consolidated results of operations, financial position or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB No. 108). SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB No. 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the company's balance sheet and statement of operations and the related financial statement disclosures. SAB No. 108 permits existing public companies to record the cumulative effect of initially applying this approach in the first year ending after November 15, 2006 by recording the necessary correcting adjustments to the carrying values of assets and liabilities as of the beginning of that year with the offsetting adjustment recorded to the opening balance of retained earnings. Additionally, the use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB No. 108 in the first quarter of fiscal 2007 did not have any impact on our financial statements.

#### **Results of Operations**

**Revenue.** Total revenue decreased to \$1.1 million for the three months ended June 30, 2007 from \$1.2 million for the three months ended June 30, 2006 and decreased to \$2.3 million for the six months ended June 30, 2007 from \$2.4 million for the six months ended June 30, 2006. Revenue is primarily composed of 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.

The decrease in total revenue for the three and six months ended June 30, 2007 as compared to the same periods for the prior year was the result of lower product royalty revenues resulting from a decline in LabCorp's sales of PreGen-Plus, as well as a decrease in sales of Effipure to LabCorp. During 2006, LabCorp informed the FDA that they were 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 2007 or beyond. The loss of this revenue during 2007 is not expected to have a material impact on our total revenues.

The prospective impact of our amended license agreement with LabCorp on our license fee revenue and our product royalty fee revenue is described under the section **Recent Developments** above.



**Cost of revenue.** Total cost of revenue includes both the cost of Effipure components sold to LabCorp as well as the cost of product royalty revenue owed to third-parties for technology currently incorporated into PreGen-Plus. During 2006, we wrote-off the cost of our remaining Effipure inventory as a result of LabCorp's decision to discontinue use of Effipure in the processing of PreGen-Plus tests. 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. There can also be no assurance that LabCorp will cease using Effipure in the processing of PreGen-Plus tests in 2007 if LabCorp does not have a suitable alternative to Effipure in place. As of December 31, 2006 and June 30, 2007, the carrying value of our Effipure inventory was \$0. Under the terms of our amended license agreement with LabCorp, we may be obligated to pay LabCorp up to a maximum of \$250,000 in connection with the purchase of additional Effipure, which will be charged to cost of sales in our consolidated statements of operations as such liabilities are incurred.

Total cost of revenue decreased to \$1,000 for the three months ended June 30, 2007 from \$93,000 for the three months ended June 30, 2006 and decreased to \$3,000 for the six months ended June 30, 2007 from \$681,000 for the six months ended June 30, 2006. The decrease in the cost of product revenue for the three months ended June 30, 2007 as compared to the same period of the prior year was primarily the result of Effipure sales to LabCorp during the three months ended June 2007 being recorded at zero cost of sales because the cost of the Effipure sold had been written off by us during 2006. The decrease in the cost of product revenue for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily due to \$0.6 million in write-offs during the six months ended June 30, 2006 of Effipure inventory resulting from LabCorp's decision to discontinue use of Effipure in the processing of PreGen-Plus tests.

**Research and development expenses.** Research and development expenses were \$1.3 million for the three months ended June 30, 2007 compared to \$1.9 million for the three months ended June 30, 2006. The decrease in the three months ended June 30, 2007 as compared to the same period of 2006 was primarily the result of the cost reduction plan undertaken in October 2006 and described under the heading "Restructuring" below. Pursuant to the October 2006 restructuring, we took actions to reduce our headcount across all departments in order to lower our overall cost structure and focused our research and development organization on the optimization and validation of our Version 2 technology. Included in the decrease in research and development expenses for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, were decreases of \$0.3 million in personnel-related expenses, \$0.2 million in laboratory supplies, \$0.2 million in clinical study expenses and \$0.2 million in laboratory operating costs resulting from the reduction in the size of our research and development force from 21 employees at June 30, 2006 to eight employees at June 30, 2007. These decreases in operating expenses were offset by an increase in non-cash stock-based compensation expense of \$0.3 million, resulting primarily from the cost associated with issuing 100,000 shares of our common stock to Oncomethylome Sciences S.A. ( "OMS" ) on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

Research and development expenses decreased to \$2.6 million for the six months ended June 30, 2007 from \$3.9 million for the six months ended June 30, 2006. This decrease included reductions of \$0.5 million in personnel-related expenses, \$0.4 million in laboratory supplies, \$0.2 million in clinical study expenses and \$0.2 million in laboratory operating costs, all of which resulted from the restructuring activities discussed above. These decreases in operating expenses were offset by an increase in non-cash stock-based compensation expense of \$0.1 million, resulting primarily from the cost associated with issuing 100,000 shares of our common stock to OMS on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

**Sales and marketing expenses.** Sales and marketing expenses decreased to \$0.5 million for the three months ended June 30, 2007 from \$1.3 million for the three months ended June 30, 2006. Sales and marketing expenses decreased to \$1.0 million for the six months ended June 30, 2007 from \$2.8 million for the six months ended June 30, 2006. These decreases were primarily due to reductions of \$0.4 and \$0.8 million, respectively, in personnel-related expenses for the three and six months ended June 30, 2007 when compared to the same periods of 2006 as a result of a reduction in the size of our sales and marketing force from 16 employees at June 30, 2006 to five employees at June 30, 2007. This workforce reduction also drove reductions in our stock-based compensation expense recorded under SFAS No. 123(R), which decreased by \$0.2 million and \$0.5 million, respectively, for the three and six months ended June 30, 2007 when compared to the same periods of 2006. We also reduced our external advertising, marketing and

promotional spending by \$0.2 million and \$0.5 million, respectively, during the three and six months ended June 30, 2007 as compared to the three and six months ended June 30, 2006. These reductions reflect a focus on spending primarily on those initiatives that directly or indirectly support guidelines inclusion, as well as a shift away from direct marketing to physicians to third-party payer groups, self-insured employers and technology assessment groups. In July 2007, we eliminated our sales and marketing functions, effective August 31, 2007, and we therefore do not expect to incur material operating expenses related sales and marketing subsequent to August 31, 2007.

*General and administrative expenses.* General and administrative expenses decreased to \$1.3 million for the three months ended June 30, 2007, compared to \$1.5 million for the three months ended June 30, 2006. The decrease was primarily the result of lower

salary, benefit and employee stock-based compensation costs due to a reduction in general and administrative headcount during the quarter ended June 30, 2007 as compared to the same period of the prior year. General and administrative expenses decreased to \$2.9 million for the six months ended June 30, 2007 from \$3.1 million for the six months ended June 30, 2006. This decrease was primarily the result of decreases of \$0.3 million in stock-based compensation expense and \$0.1 million in facility related expenses recorded in the six months ended June 30, 2007 as compared to the same period of 2006, which was partially offset by an increase in professional fees of \$0.1 million in the six months ended June 30, 2007 as compared to the same period of 2006.

**Restructuring.** In October 2006, we initiated a plan to reduce our cost structure by eliminating 21 positions, or 48% of our staff at that time, across all departments. This workforce reduction was intended to reduce our expenses and preserve existing cash, cash equivalents and marketable securities. Since the workforce reduction, our efforts have been focused on pursuing inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines which will result from the joint efforts of the ACS/MSTF, Medicare coverage pursuit for stool-based DNA testing, and validation and optimization of our Version 2 technology.

Pursuant to the restructuring plan, we accrued charges of \$0.7 million in the quarter ended December 31, 2006 in connection with one-time employee termination benefits, including severance and outplacement services. We recorded changes in estimates to the restructuring accrual of \$(2,000) and \$31,000, respectively, in connection with adjustments to estimates of one-time employee termination benefits, including severance and outplacement services, during the three and six months ended June 30, 2007. We continue to assess current facility needs and other costs and, as a result, could incur additional restructuring charges in the event that we undertake additional activities to reduce facility and other costs. Until our facility plans are finalized, we cannot currently estimate the amount of those charges, if any.

Amounts remaining in the restructuring accrual at June 30, 2007 are expected to be paid through September 2007 and are recorded under the caption *Accrued expenses* in the condensed consolidated balance sheets at June 30, 2007. The following table summarizes the restructuring activities during the three months ended June 30, 2007. Amounts included in the table are in thousands. Amounts included in the table do not reflect additional charges expected as a result of our July and August 2007 restructuring activities discussed in *Recent Developments* above.

Type of Liability	Balance, December 31, 2006	Charges	Cash Payments	Non-cash Write-offs	Balance, June 30, 2007
Employee separation costs	\$ 283	\$ 31	\$ (271)	) \$	\$ 43
Total	\$ 283	\$ 31	\$ (271)	) \$	\$ 43

We account for restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( 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 \$0.2 million for the three months ended June 30, 2007 from \$0.3 million for the three months ended June 30, 2006. Interest income decreased to \$0.5 million for the six months ended June 30, 2007 from \$0.6 million for the six months ended June 30, 2006. These decreases were due to lower average cash, cash equivalents and marketable securities balances held during the three and six months ended June 30, 2007 as compared to the same periods of 2006, partially offset by more favorable interest rates on investments held during the three and six months ended June 30, 2007 as compared to the same period of 2006.

### 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 strategic alliance. As of June 30, 2007, we had approximately \$16.9 million in unrestricted cash, cash equivalents and marketable securities and \$0.8 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,



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consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was \$4.1 million for the six months ended June 30, 2007 as compared to \$7.0 million for the same period of 2006. The principal use of cash in operating activities for the six months ended June 30, 2007 and 2006 was to fund our net loss. The decrease in net cash used in operating activities for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily due to decreases in sales and marketing and applied research spending as a result of cost reduction actions taken during 2006 which are discussed elsewhere in this report. 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 \$3.1 million for the six months ended June 30, 2007, as compared to net cash provided by investing activities of \$7.7 million six months ended June 30, 2006. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$35,000 and \$208,000 for the six months ended June 30, 2007 and 2006, respectively.

Purchases of property and equipment of \$2,000 during the six months ended June 30, 2007 were significantly lower than purchases of property and equipment of \$73,000 during the six months ended June 30, 2006 as a result of the cost reduction actions taken during 2006. We expect that purchases of property and equipment during 2007 will be lower than amounts invested during 2006. We also reduced the expenditures related to our patent portfolio for the six months ended June 30, 2007 compared to the same period of the prior year and we expect that investments made in our patent portfolio during 2007 will be lower than amounts invested during 2006.

Net cash provided by financing activities was \$15,000 and \$71,000 for the six months ended June 30, 2007 and 2006, respectively, and were the result of proceeds received from the issuance of common stock under our employee stock option and purchase plans.

As a result of the restructuring actions taken in October 2006 and in July and August 2007, we expect that cash, cash equivalents and short-term investments on hand at June 30, 2007 will be sufficient to fund our current operations at least into the second quarter of 2009, based upon our currently anticipated spending levels. 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. Under the terms of our amended license agreement with LabCorp, we are eligible to receive up to an aggregate of \$40 million in milestone payments that relate to the achievement of certain significant cumulative LabCorp sales thresholds that depend upon LabCorp's widespread success with respect to its sales of PreGen-Plus. Because these milestone payments are not expected in the foreseeable future, if at all, no assurance can be given that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. If revenue and other payments from LabCorp are insufficient to meet our liquidity needs, if we change our strategic direction or pursue an acquisition of new technologies, or if we determine that our sales, marketing or research and development expenses must increase to achieve our goals, we will be required to raise additional capital or further reduce the scale of our operations, or both.

The table below reflects our estimated fixed obligations and commitments as of June 30, 2007:

Description	Total (in Thousands)	Payments Due by Period			More Than 5 Years
		Less Than One Year	1 - 3 Years	3 - 5 Years	
Obligations under license and collaborative agreements	\$ 5,487	\$ 944	\$ 630	\$ 768	\$ 3,145
Operating lease obligations	3,092	974	2,032	86	
Retention bonus obligations in connection with employment agreements	842	842			
Purchase obligations	439	439			
<b>Total</b>	<b>\$ 9,860</b>	<b>\$ 3,199</b>	<b>\$ 2,662</b>	<b>\$ 854</b>	<b>\$ 3,145</b>

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. 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. Retention bonus obligations represent commitments to our remaining employees following our October 2006 restructuring. Purchase obligations primarily represent a potential \$0.3 million obligation to reimburse LabCorp for certain costs related to Effipure as well as commitments associated with our research and development activities. As described under Recent





Developments above, under the terms of our amended license agreement with LabCorp, we may be obligated to reimburse LabCorp for a certain third-party royalty, up to an aggregate maximum of \$3.5 million during the period from June 28, 2007 through December 31, 2010. Payment of this potential liability is dependent upon LabCorp's sales levels of PreGen-Plus and is therefore not included in the table above. Additionally, as we seek to reduce our lease and facility related operating costs, we could incur short-term, one-time costs in connection moving to a smaller facility. We do not have any special purpose entities or any other off balance sheet financing arrangements.

Our anticipated future capital requirements include, but are not limited to, continued funding of our development efforts, including product development and potential FDA submissions, potential clinical studies required for such FDA submissions, potential in-licensing or out-licensing of technologies for commercial use and development, and continued investment in our intellectual property estate. Our future capital requirements may depend on many factors, including the following:

- the inclusion of stool-based DNA screening in colorectal cancer screening guidelines of major guidelines organizations (including the ACS/MSTF) and the timing thereof;
- 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 payers;
- our ability to receive milestone payments under our strategic agreement with LabCorp and the timing and receipt, if any, of such payments from LabCorp;
- a determination that additional studies surrounding our technologies are needed;
- a sustained level of interest and commitment by LabCorp in the commercialization of PreGen-Plus;
- 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;
- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies; and
- a shift in our strategic direction or entry into new markets.

Until such time as some or all of the factors outlined above are in place, we do not expect material revenue growth. Moreover, if our Version 2 stool-based DNA screening technology is not included in the colorectal cancer screening guidelines of one or more of the major organizations issuing guidelines recommendations, or if inclusion or notification of inclusion in such screening guidelines is limited in any respect (for example, in terms of the frequency of use or population for whom stool-based DNA screening may be recommended), or is significantly delayed, our business, financial condition and results of operations would be materially adversely affected and our business direction may change. In such event, we would likely be required to further significantly curtail our operations.

We cannot assure you that our business will ever generate sufficient cash flow from operations, or that we will be able to liquidate our investments or obtain financing when needed or desirable. While we may, from time to time, seek to access the capital markets, there can be no assurance that we will be successful in any future capital raising efforts, or that we would be able to raise additional funds at an acceptable price level. An inability to fund our operations would have a material adverse effect on our business, financial condition and results of operations.

**Off-Balance Sheet Arrangements**

As of June 30, 2007, we had no off-balance sheet arrangements.

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**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. governments 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 June 30, 2007, 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, 2006. 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, 2006 other than changes to the risk factors listed below to update for recent activities and the elimination of the risk factor in our Annual Report on Form 10-K entitled *If we cannot successfully amend our license agreement with LabCorp, we may be required to reimburse LabCorp for past (\$2.4 million as of December 31, 2006), and future amounts (up to an additional \$1.8 million) in connection with royalty payments made by LabCorp to a third party in order to secure intellectual property required to run PreGen-Plus.* 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.

*If stool-based DNA screening is not included in colorectal cancer screening guidelines of the major organizations issuing guidelines recommendations, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected.*

Our future revenues will depend, in large part, upon whether stool-based DNA screening is included in colorectal cancer screening guidelines of major guidelines organizations (including the U.S. Multisociety Task Force on Colorectal Cancer, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and American College of Physicians/Society of Internal Medicine (the MSTF-CRC)), and the American Cancer Society (ACS). Although the ACS Colorectal Cancer Advisory Committee and the MSTF-CRC, together, the ACS/MSTF-CRC, commenced a review of stool-based DNA and other colorectal cancer screening technologies in June 2006, which continued in September 2006, it did not make any decision regarding the inclusion of stool-based DNA technology in colorectal cancer screening guidelines. The timing and determination as to whether stool-based DNA screening is included in colorectal cancer screening guidelines is outside of our control. We cannot assure you that a decision regarding stool-based DNA will be made or that stool-based DNA screening will ever be included in colorectal cancer screening guidelines. Even if a recommendation is made to include stool-based DNA screening in guidelines, such inclusion could involve a process spanning many months from the meeting of key guidelines decision-makers to notification of inclusion or exclusion from guidelines.

In addition, following its June 2006 meeting, the ACS/MSTF-CRC requested certain information from us relating primarily to our Version 2 next generation colorectal cancer technology. It is possible that ACS/MSTF-CRC may reject stool-based DNA screening or defer a recommendation regarding such screening for a number of reasons, including until such time as our Version 2 colorectal cancer screening technology is fully developed and adequately supported by clinical data, which could take several years, if it happens at all. Moreover, even if a recommendation is made to include stool-based DNA screening in guidelines, such inclusion may not involve a recommendation for our Version 2 technology, which may substantially limit adoption of stool-based DNA screening, or such recommendation could relate only to a narrow screening purpose or subset of the population, or for some other limited purpose or application of stool-DNA screening that does not provide for broad use of stool-DNA screening. If stool-based DNA screening is not included in colorectal cancer screening guidelines for broad and sufficiently frequent use within the population at the next anticipated meeting of the ACS/MSTF-CRC, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected and our business direction may change. In such event, we could be required to further significantly curtail our operations. An adverse guidelines determination could also result in the impairment of the recorded value of our patent portfolio, which was \$0.6 million at June 30, 2007, or our fixed assets.

#### *Our business is substantially dependent on the success of our strategic agreement with LabCorp*

We have a strategic alliance with LabCorp, under which we licensed to LabCorp certain of our technologies, including improvements to such technologies, that are required for the commercialization of PreGen-Plus. If LabCorp were to terminate the agreement, fail to meet its obligations under the agreement, decide to stop processing PreGen-Plus commercially, or otherwise decrease its commitment to PreGen-Plus, our revenues would be materially adversely affected, the commercialization of PreGen-Plus would be interrupted and we could become insolvent. We cannot guarantee that we would be able to enter into a similar agreement with another company to commercialize this technology. Moreover, if we do not achieve certain milestones, or LabCorp does not



achieve certain revenue and performance thresholds within the time periods prescribed in the agreement, we may not fully realize the expected benefits of the agreement.

On June 27, 2007, we entered into a second amendment to the license agreement with LabCorp. The second amendment extended LabCorp's exclusive period under the agreement until December 31, 2010. Additionally, the second amendment modified LabCorp's exclusive rights to our DNA technology for colorectal cancer screening to permit us to license our technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms. There can be no assurance that we will be able to license our technologies to any party other than LabCorp in light of LabCorp's preferential pricing terms, as well as the restrictive and evolving regulatory environment pertaining to in-house developed tests, or "home brew" tests that are primarily regulated under CLIA, but over which the FDA also maintains regulatory authority. Additionally, the second amendment provides LabCorp with termination rights if stool-based colorectal cancer screening is not included in clinical practice guideline in the near term, if the our Version 2 technology is not commercially launched in the near term, or if our Version 2 technology does not attain certain sensitivity and specificity thresholds in connection with technical validation.

To accomplish our long-term business objectives, we may be required to enter into additional amendments to our license agreement with LabCorp. For instance, we are currently in discussions that could result in an amendment to the license agreement. We recently entered into a non-binding letter of intent with LabCorp to, among other things, transition responsibility for all sales and marketing activities related to LabCorp's testing service, PreGen-Plus. We cannot assure you that our prior amendments, these recent discussions or other strategic initiatives with LabCorp will accomplish the long-term goals of either party. If one or more additional amendments to our agreement with LabCorp become necessary as a result of the continuing evolution of PreGen-Plus, developments in our relationship with LabCorp or otherwise, we cannot assure you that any such amendment could be entered into on favorable terms, if at all.

Disagreements with LabCorp could delay or terminate the continued commercialization of PreGen-Plus by LabCorp or result in litigation or arbitration, any of which would have a material adverse affect on our business, financial condition and results of operations. Moreover, if we are unsuccessful in managing our strategic relationship with LabCorp, we would be required to enter into other strategic relationships for the commercialization of PreGen-Plus or attempt to commercialize the testing service ourselves. We cannot assure you that we would be able to license our technology to another commercial laboratory or otherwise successfully commercialize the testing service, and our failure to do either of the foregoing would materially and adversely affect our ability to generate revenues.

***The loss of key members of our senior management team could adversely affect our business.***

Our success depends upon the continued services of key members of our senior management team. Although we have entered into retention agreements with member of our management team, which provide for certain retention bonuses for their continued employment with the Company through December 31, 2007, each of our executive officers could terminate his relationship with us at any time. For instance, in July 2007, Don M. Hardison resigned his position as our President and Chief Executive Officer and is expected to continue as an employee of the Company through the end of August 2007. Mr. Hardison has been critical to the pursuit of our business goals and we may experience difficulties developing our technologies and testing processes, and implementing our business strategies. The loss of any member of our senior management team could significantly delay or prevent the achievement of our business or development objectives and could materially harm our business. In addition, in October 2006, July 2007 and August 2007, as part of our restructurings we notified 21, five and one employees, representing 48%, 25% and 7%, respectively, of our staff at those times, of their termination from the Company. These restructurings could materially harm our ability to attract and retain skilled personnel, including our management.

**Item 5. Other Information**

On May 15, 2007, we elected to make a matching contribution in the form of common stock pursuant to our qualified 401(k) retirement savings plan (the 401(k) Plan ) and issued an aggregate of 34,030 shares of our common stock to the 401(k) Plan for the benefit of our employees for the plan year ended December 31, 2006. The 401(k) Plan paid no consideration for the shares. The shares were valued at \$3.08 per share, the closing price of our common stock on May 15, 2007. The shares will be allocated pursuant to the terms of the 401(k) Plan. The issuance of shares was exempt from registration under the Securities Act of 1933, as amended (the Act ), as the contribution of the shares to the 401(k) Plan for the benefit of our employees, without payment of consideration by the 401(k) Plan or employees, does not constitute a sale of the common stock for the purposes of the Act.

On August 2, 2007, our Chief Operating Officer, David W. Nikka, was terminated as Chief Operating Officer (principal operating officer) effective August 31, 2007. The termination of Mr. Nikka was made pursuant to a plan of termination initiated by us on July 18, 2007 described in paragraph 8 of FASB Statement of Financial Accounting Standards No. 146 Accounting For Costs Associated With Exit or Disposal Activities, under which charges will be incurred under generally accepted accounting principles. The plan of termination was initiated to reduce the Company s overall cost structure and to preserve its cash resources.

We estimate that the total charges for the termination of Mr. Nikka will range from between \$100,000 and \$200,000, relating to one-time termination benefits arising under a severance agreement with Mr. Nikka. When combined with the estimated costs related to the termination of five employees on July 18, 2007 that we previously disclosed, we expect that total charges under the plan of termination will range from \$200,000 to \$1.0 million. These costs are expected to be recorded in the third fiscal quarter of 2007. Because the right 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, the charges that will actually be recorded cannot be determined at this time. All of the charges will result in future cash expenditures. We continue to assess our facility needs and other costs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements, other fixed assets or other facility charges in the event facilities are reduced.

**Item 6. Exhibits**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.1**	Second Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of June 27, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on July 3, 2007, 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.



**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: August 8, 2007

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

Date: August 8, 2007

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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