

EXACT SCIENCES CORP
Form 10-Q
May 08, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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

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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

As of May 4, 2007, the registrant had 26,843,543 shares of Common Stock outstanding.

EXACT SCIENCES CORPORATION

INDEX

Part I - Financial Information

Item 1.	Financial Statements	
	<u>Condensed Consolidated Balance Sheets as of March 31, 2007 and December 31, 2006 (Unaudited)</u>	3
	<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2007 and 2006 (Unaudited)</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2007 and 2006 (Unaudited)</u>	5
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	21
<u>Item 4.</u>	<u>Controls and Procedures</u>	21

Part II - Other Information

<u>Item 1A.</u>	<u>Risk Factors</u>	22
<u>Item 6.</u>	<u>Exhibits</u>	22
	<u>Signatures</u>	23
	<u>Exhibit Index</u>	24

EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	March 31, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,851	\$ 4,831
Marketable securities	14,708	16,244
Prepaid expenses and other current assets	540	386
Total current assets	19,099	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	(6,007)	(5,959)
	790	844
Patent costs, net of accumulated amortization of \$2,911 and \$2,871 at March 31, 2007 and December 31, 2006, respectively	609	763
Restricted cash	800	800
	\$ 21,298	\$ 23,868
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 139	\$ 158
Accrued expenses	1,771	1,844
Deferred license fees, current portion	4,363	4,363
Total current liabilities	6,273	6,365
Deferred license fees, less current portion	1,454	2,545
Commitments and contingencies		
Stockholders' Equity:		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 26,929,093 and 26,863,363 shares at March 31, 2007 and December 31, 2006, respectively	269	269
Additional paid-in capital	166,079	165,545
Treasury stock, 85,550 shares	(97)	(97)
Other comprehensive income	5	6
Accumulated deficit	(152,685)	(150,765)
Total stockholders' equity	13,571	14,958
	\$ 21,298	\$ 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 March 31,	
	2007	2006
Revenue:		
Product royalty fees	\$ 26	\$ 61
License fees	1,091	1,091
Product	53	42
	1,170	1,194
Cost of revenue:		
Product royalty fees	2	4
Product		584
	2	588
Gross profit	1,168	606
Operating expenses:		
Research and development (1)	1,277	1,960
Sales and marketing (1)	495	1,486
General and administrative (1)	1,542	1,641
Restructuring	33	
	3,347	5,087
Loss from operations	(2,179)	(4,481)
Interest income	259	318
Net loss	\$ (1,920)	\$ (4,163)
Net loss per share basic and diluted	\$ (0.07)	\$ (0.16)
Weighted average common shares outstanding basic and diluted	26,790	26,376
(1) Non-cash stock-based compensation expense included in these amounts are as follows:		
Research and development	\$ 74	\$ 264
Sales and marketing	118	407
General and administrative	216	396

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

EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands - unaudited)

	Three Months Ended March 31,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (1,920)	\$ (4,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and write-offs of fixed assets	56	198
Amortization and write-offs of patents	171	142
Stock-based compensation	409	1,067
Amortization of deferred license fees	(1,091)	(1,091)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(154)	(55)
Accounts payable	(19)	(202)
Accrued expenses	38	(187)
Net cash used in operating activities	(2,510)	(4,291)
Cash flows from investing activities:		
Purchases of marketable securities	(7,315)	(5,632)
Maturities of marketable securities	8,850	7,361
Purchases of property and equipment	(2)	(62)
Increase in patent costs and other assets	(17)	(45)
Net cash provided by investing activities	1,516	1,622
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	15	53
Increase in restricted cash		(1)
Net cash provided by financing activities	15	52
Net decrease in cash and cash equivalents	(979)	(2,617)
Cash and cash equivalents, beginning of period	4,831	11,987
Cash and cash equivalents, end of period	\$ 3,852	\$ 9,370
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	\$

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 August 2008 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 March 31, 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 months ended March 31, 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 March 31, 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 three months ended March 31, 2007. Amounts included in the table are in thousands.

	Three Months Ended March 31, 2007
Patents, net of accumulated amortization, January 1, 2007	\$ 763
Patent costs capitalized	17
Amortization of patents	(50)
Write-offs of patents	(121)
Patents, net of accumulated amortization, March 31, 2007	\$ 609

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

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

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share* (SFAS No. 128), for all periods presented. In accordance with SFAS No. 128, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period, 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 for the three months ended March 31, 2007 and 2006 because they would have an anti-dilutive effect due to net losses for such periods:

(In thousands)	March 31,	
	2007	2006
Shares issuable upon exercise of stock options	4,762	5,020
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,762	6,020

Revenue Recognition

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.

Product royalty fees on PreGen-Plus tests performed by LabCorp are recorded as revenue when cash payments are received from LabCorp pursuant to the Company's license agreement with LabCorp. Product royalty fees ultimately due to the Company are based upon the customer's remittance to LabCorp, not the amount billed. Until such time as the Company has sufficient historical reimbursement data necessary to estimate and record product royalty fees on an accrual basis, it will continue to recognize revenue from product royalty fees on a cash basis.

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.

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

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three months ended March 31, 2007 and 2006 was as follows:

(In thousands)	Three Months Ended March 31,	
	2007	2006
Net loss	\$ (1,920)	\$ (4,163)
Unrealized (loss) gain on marketable securities	(1)	12
Comprehensive loss	\$ (1,921)	\$ (4,151)

(3) 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 \$0.4 million in stock-based compensation during the three months ended March 31, 2007 in connection with the amortization of employee and non-employee director stock option awards, stock options granted to non-employee consultants, 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 May 2008. The Company recorded \$1.1 million in stock-based compensation during the three months ended March 31, 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 months ended March 31, 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.

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

	Three Months Ended March 31, 2007		2006	
Option Plan Shares				
Risk-free interest rates	4.50	%	4.59	%
Expected term (in years)	6		6	
Expected volatility	70	%	70	%
Dividend yield	0	%	0	%
Weighted average fair value per share of options granted during the period	\$1.83		\$1.73	
ESPP Shares				
Risk-free interest rates	5.10% - 5.17	%	3.81% - 4.61	%
Expected term (in years)	0.5 - 2		0.5 - 2	
Expected volatility	70	%	70	%
Dividend yield	0	%	0	%
Weighted average fair value per share of stock purchase rights granted during the period	\$1.08		\$1.18	

Stock Option Activity

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the three months ended March 31, 2007 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2007	4,125,940	\$5.69		
Granted	729,000	\$2.77		
Exercised		\$		
Cancelled	(93,088)	\$4.74		
Outstanding, March 31, 2007	4,761,852	\$5.26	5.8	\$434
Exercisable, March 31, 2007	3,434,671	\$6.16	4.5	\$396
Vested and expected to vest, March 31, 2007	4,752,836	\$5.26	5.8	\$434

(1) The aggregate intrinsic value of options outstanding at March 31, 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 1,113,623 options that had exercise prices that were lower than the \$2.68 market price of our common stock at March 31, 2007. The aggregate intrinsic value of options exercisable at March 31, 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 748,383 options that had exercise prices that were lower than the \$2.68 market price of our common stock at March 31, 2007.

As of March 31, 2007, there was \$2.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.8 years.

(4) THIRD PARTY ROYALTY CONTINGENCY

Under the terms of the Company's amended license agreement with LabCorp, the Company is contingently liable to reimburse LabCorp for a portion of certain fixed, third-party royalty payments (the "Royalty Amount") made by LabCorp to other parties in connection with its sales of PreGen-Plus. The Company's liability to pay the Royalty Amount is based on sales volumes of PreGen-Plus over the exclusive period of the license agreement that terminates on August 13, 2008, and is contingent upon LabCorp requesting such payment. LabCorp has not requested any such payment to date. Based on the sales volumes of PreGen-Plus through March 31, 2007, the Royalty Amount was \$2.7 million (the "Current Royalty Amount"). A significant increase in PreGen-Plus test sales volumes through August 13, 2008, could reduce this obligation, potentially to zero, while test volumes consistent with historical PreGen-Plus sales levels could increase the potential Royalty Amount by an additional approximately \$1.5 million, bringing the total potential Royalty Amount to approximately \$4.2 million over the entire exclusive period under the license agreement. In addition, if stool-based DNA screening for colorectal cancer is not included in colorectal cancer screening guidelines of the major guidelines organizations, LabCorp may request payment of the Royalty Amount.

The Company is currently in discussions with LabCorp regarding the terms of the license agreement. Based upon these discussions, the Company believes that at this time, it is not probable that LabCorp will request payment of the Current Royalty Amount and, accordingly, has not accrued any portion of the Royalty Amount in the accompanying financial statements. There can be no assurance that the Company will be able to successfully negotiate an amendment to the license agreement that would eliminate the Company's contingent liability to pay the amounts described above.

(5) RESTRUCTURING

In October 2006, the Company initiated a plan to reduce its cost structure by eliminating 21 positions, or 48% of its staff, across all departments. This workforce reduction was intended to reduce the Company's expenses and preserve its existing cash and cash equivalents. Since the workforce reduction, 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; 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 restructuring plan, 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 additional charges of \$33,000 in connection with one-time employee termination benefits, including severance and outplacement services, during the three months ended March 31, 2007 as a result of the elimination of an additional position in connection with the Company's restructuring plan. The Company continues to assess its current facility needs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements or other fixed assets, in the event facilities are consolidated. Until its facility plans are finalized, the Company can not currently estimate the amount of those charges, if any.

Amounts remaining in the restructuring accrual at March 31, 2007 are expected to be paid through September 2007 and are recorded under the caption "Accrued expenses" in the condensed consolidated balance sheets at March 31, 2007. The following table summarizes the restructuring activities during the three months ended March 31, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2006	Charges	Cash Payments	Non-cash Write-offs	Balance, March 31, 2007
Employee separation costs	\$ 283	\$ 33	\$ (207)	\$	\$ 109
Total	\$ 283	\$ 33	\$ (207)	\$	\$ 109

x

12

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 August 2008 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, including PreGen-Plus and our next generation Version 2 technology;
- 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;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our proprietary technologies to LabCorp;
- 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 March 31, 2007, we had an accumulated deficit of approximately \$152.7 million. Our losses have historically resulted from costs incurred in conjunction with our research and development initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing 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 as a result of continuing research, development, sales and marketing expenses.

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through March 31, 2007, LabCorp had accessioned approximately 13,100 PreGen-Plus samples, including 542 samples during the quarter ended March 31, 2007 and approximately 4,300, 4,000 and 3,700 samples, during the years ended December 31, 2004, 2005 and 2006, 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, 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 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 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 amounts 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;
- 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 regarding PreGen-Plus and patient compliance;
- our 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 reimbursement of 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 and license fee revenue for 2007 will be substantially consistent with amounts recorded in 2006. 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.

We account for PreGen-Plus royalty fees on a cash basis. 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, 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.

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, outplacement and fringe benefits. During the quarter ended March 31, 2007, we recorded additional restructuring charges of approximately \$33,000 related to one-time employee termination benefits, including severance and outplacement services, in connection with the elimination of one additional position. We continue to assess

14

our facility needs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements or other fixed assets, in the event facilities are consolidated. Until its facility plans are finalized, we cannot currently estimate the amount of those charges, if any.

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. We expect sales and marketing expenses in 2007 to be lower than 2006 levels primarily as a result of lower headcount and external promotional spending. We expect general and administrative expenses in 2007 to be consistent with 2006 levels.

In connection with our October 2006 restructuring, we entered into employment retention agreements with our 21 remaining employees, which provide for severance and a one-time retention bonus in the aggregate amount of approximately \$0.9 million payable on December 31, 2007 (subject to acceleration in certain circumstances), provided that they 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 addition, in June 2006, we entered into an employment agreement with Don M. Hardison, our President and Chief Executive Officer, under which he received a retention bonus payment of \$0.2 million on January 1, 2007 and is eligible to earn a second retention bonus in the amount of \$0.2 million payable on January 1, 2008, provided that he continues to be employed by us on January 1, 2008. As of March 31, 2007, we had accrued approximately \$0.4 million in compensation costs in connection with the retention bonuses for the remaining employees and Mr. Hardison. We intend to accrue the remaining cost of the retention bonuses, currently estimated to be approximately \$0.7 million, on a straight line basis over the remaining retention period, which ends on December 31, 2007.

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 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.

Product royalty fees on PreGen-Plus tests performed by LabCorp are recorded as revenue when cash payments are received from LabCorp pursuant to our license agreement with LabCorp. Product royalty fees ultimately due to us are based upon the customer's remittance to LabCorp, not the amount billed. Until such time as we have sufficient historical reimbursement data necessary to estimate and record our product royalty fees on an accrual basis, we will continue to recognize revenue from product royalty fees on a cash basis.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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. We bear the risk of obsolescence related to the Effipure inventory.

Revenue from milestone and other performance-based payments, if any, is 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 three months ended March 31, 2007. Amounts included in the table are in thousands.

	Three Months Ended March 31, 2007
Patents, net of accumulated amortization, January 1, 2007	\$ 763
Patent costs capitalized	17
Amortization of patents	(50)
Write-offs of patents	(121)
Patents, net of accumulated amortization, March 31, 2007	\$ 609

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

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets* (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 our stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

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

Critical Accounting Estimate

Third Party Royalty Contingency. Under the terms of our amended license agreement with LabCorp, we are contingently liable to reimburse LabCorp for a portion of certain fixed third-party royalty payments (the Royalty Amount) made by LabCorp to other

16

parties in connection with its sales of PreGen-Plus. Our liability to pay the Royalty Amount is based on sales volumes of PreGen-Plus over the exclusive period of the license agreement that terminates on August 13, 2008, and is contingent upon LabCorp requesting such payment. LabCorp has not requested any such payment to date. Based on the sales volumes of Pre-Gen-Plus through March 31, 2007, the potential Royalty Amount was \$2.7 million (the Current Royalty Amount). A significant increase in PreGen-Plus test sales volumes through August 13, 2008, could reduce this obligation, potentially to zero, while test volumes consistent with historical PreGen-Plus sales levels could increase the potential Royalty Amount by an additional approximately \$1.5 million, bringing the total potential Royalty Amount to approximately \$4.2 million over the entire exclusive period under the license agreement. In addition, if stool-based DNA screening for colorectal cancer is not included in colorectal cancer screening guidelines of the major guidelines organizations, LabCorp may request payment of the Royalty Amount.

We are currently in discussions with LabCorp regarding the terms of the license agreement. Based upon these discussions, we believe that, at this time, it is not probable that LabCorp will request payment of the Current Royalty Amount and, accordingly, we have not accrued any portion of the Royalty Amount in our financial statements. There can be no assurance that we will be able to successfully negotiate an amendment to our license agreement that would eliminate our contingent liability to pay the amounts described 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 for the three months ended March 31, 2007 of \$1.2 million was equal to our total revenue for the three months ended March 31, 2006. Revenue is primarily composed of amortization of up-front technology license fees associated with agreements signed with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in August 2008 and, to a lesser extent, royalties on LabCorp's sales of PreGen-Plus, and sales of Effipure units 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.

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

17

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 March 31, 2007, the carrying value of our Effipure inventory was \$0 and we do not anticipate purchasing additional Effipure inventory. Accordingly, any Effipure sales made to LabCorp during 2007 will result in 100% gross margin to us.

Total cost of revenue decreased to \$2,000 for the three months ended March 31, 2007 from \$0.6 million for the three months ended March 31, 2006. The decrease in the cost of product revenue for the quarter ended March 31, 2007 as compared to the same period of the prior year was primarily the result of the fact that the quarter ended March 31, 2006 included \$0.5 million in write-offs of Effipure inventory resulting from LabCorp's decision to discontinue use of Effipure in the processing of PreGen-Plus tests, and, to a lesser extent, Effipure sales to LabCorp during the three months ended March 31, 2007 being recorded with a 100% gross margin because the cost of the Effipure sold had been written off by us during 2006.

Research and development expenses. Research and development expenses decreased to \$1.3 million for the three months ended March 31, 2007 from \$2.0 million for the three months ended March 31, 2006. The decrease in the three months ended March 31, 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 March 31, 2007, as compared to the three months ended March 31, 2006, were decreases of \$0.2 million in personnel-related expenses and \$0.2 million in stock-based compensation expense recorded under SFAS No. 123(R) resulting from the reduction in the size of our research and development force from 20 employees at March 31, 2006 to nine employees at March 31, 2007. Also included in the decrease in research and development expenses for the three months ended March 31, 2007, as compared to the three months ended March 31, 2006, were decreases of \$0.2 million in laboratory supplies, \$0.1 million in clinical study expenses and approximately \$41,000 related to laboratory space.

Sales and marketing expenses. Sales and marketing expenses decreased to \$0.5 million for the three months ended March 31, 2007 from \$1.5 million for the three months ended March 31, 2006. This decrease was primarily due to reductions of \$0.4 million in personnel-related expenses and \$0.3 million in stock-based compensation expense recorded under SFAS No. 123(R) for the three months ended March 31, 2007 as compared to the same period of 2006 as a result of a reduction in the size of our sales and marketing force from 17 employees at March 31, 2006 to five employees at March 31, 2007. We also reduced our external advertising, marketing and promotional spending by \$0.3 million during the three months ended March 31, 2007 as compared to the three months ended March 31, 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.

General and administrative expenses. General and administrative expenses decreased to \$1.5 million for the three months ended March 31, 2007 from \$1.6 million for the three months ended March 31, 2006. This decrease was primarily the result of a decrease of \$0.2 million in stock-based compensation expense recorded in the three months ended March 31, 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 three months ended March 31, 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, 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-CRC, 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 additional charges of \$33,000 in connection with one-time employee termination benefits, including severance and outplacement services, during the three months ended March 31, 2007 as a result of the elimination of an additional position in connection with our restructuring plan. We continue to assess current facility needs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements or

18

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

other fixed assets, in the event facilities are consolidated. Until our facility plans are finalized, we cannot currently estimate the amount of those charges, if any.

Amounts remaining in the restructuring accrual at March 31, 2007 are expected to be paid through September 2007 and are recorded under the caption *Accrued expenses* in the condensed consolidated balance sheets at March 31, 2007. The following table summarizes the restructuring activities during the three months ended March 31, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2006	Charges	Cash Payments	Non-cash Write-offs	Balance, March 31, 2007
Employee separation costs	\$ 283	\$ 33	\$ (207)	\$	\$ 109
Total	\$ 283	\$ 33	\$ (207)	\$	\$ 109

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 \$259,000 for the three months ended March 31, 2007 from \$318,000 for the three months ended March 31, 2006. This decrease was due to lower average cash, cash equivalents and marketable securities balances held during the three months ended March 31, 2007 as compared to the three months ended March 31, 2006, partially offset by more favorable interest rates on investments held during the three months ended March 31, 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 March 31, 2007, we had approximately \$18.6 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, 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 \$2.5 million for the three months ended March 31, 2007 as compared to \$4.3 million for the same period of 2006. The principal use of cash in operating activities for the three months ended March 31, 2007 and 2006 was to fund our net loss. The decrease in net cash used in operating activities for the three months ended March 31, 2007 as compared to the three months ended March 31, 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 under 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 \$1.5 million for the three months ended March 31, 2007, as compared to net provided by investing activities of \$1.6 million three months ended March 31, 2006. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$19,000 and \$0.1 million for the three months ended March 31, 2007 and 2006, respectively.

Purchases of property and equipment of \$2,000 during the three months ended March 31, 2007 were significantly lower than purchases of property and equipment of \$62,000 during the three months ended March 31, 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 three months ended March 31, 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.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Net cash provided by financing activities was \$15,000 and \$52,000 for the three months ended March 31, 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, we expect that cash, cash equivalents and short-term investments on hand at March 31, 2007 will be sufficient to fund our current operations for at least the next twelve months, based upon our current 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. Although certain performance-based payments from LabCorp for which we may be eligible under our strategic agreement may supplement our liquidity position at some point in the future, the timing and receipt of these performance-based payments is unpredictable at this time. Of the remaining \$45 million of payments for which we may be eligible under our amended agreement with LabCorp, \$15 million currently relates to milestone payments associated with the inclusion of stool-based DNA testing for colorectal cancer into certain clinical guidelines as well as policy-level reimbursement approvals from the Centers for Medicare Services, and others that, in large part, depend upon decisions to be made by third parties. The remaining \$30 million relates to the achievement of certain significant cumulative LabCorp revenue thresholds that depend upon LabCorp's widespread success with respect to its sales of PreGen-Plus. Because these milestone and performance-based 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. Moreover, we are currently in discussion with LabCorp regarding the terms of our license agreement. These discussions could lead to amendments to our license agreement, including amendments to the milestones thereunder. In addition, we continue to selectively explore potential acquisitions or licensing of technologies to broaden our technology portfolio. 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 March 31, 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	\$ 5,441	\$ 898	\$ 630	\$ 768	\$ 3,145
Operating lease obligations	3,329	967	2,018	344	
Retention bonus obligations in connection with employment agreements	1,061	1,061			
Purchase obligations	159	159			
Total	\$ 9,990	\$ 3,085	\$ 2,648	\$ 1,112	\$ 3,145

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, as well as obligations under our employment agreement with Don Hardison, our President and Chief Executive Officer. Purchase obligations primarily represent commitments associated with our research and development activities. We do not have any special purpose entities or any other off balance sheet financing arrangements.

Our future capital requirements include, but are not limited to, continued funding of our research and development efforts, product development and potential FDA submissions, potential clinical studies required for such FDA submissions, potential in-licensing of new technologies for commercial development, sales and marketing efforts associated with the commercialization of stool-based DNA screening technologies, purchases of laboratory equipment 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-CRC) 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;
- 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 stool-based DNA screening is not included in colorectal cancer screening guidelines of one or more 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 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 March 31, 2007, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. 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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of March 31, 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.

21

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. 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.

Item 6. Exhibits

Exhibit

Number	Description
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.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: May 8, 2007

By: /s/ Don M. Hardison
Don M. Hardison
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 8, 2007

By: /s/ Jeffrey R. Luber
Jeffrey R. Luber
Senior Vice President, Chief Financial Officer, Treasurer,
General Counsel and Secretary
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit

Number

Description

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.

24
