EXACT SCIENCES CORP
Form 10-Q
November 06, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2007

OR

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

OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

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

(508) 683-1200

(Registrant s telephone number, including area code)

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

Indicate by 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 o Accelerated filer x Non-accelerated filer o

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

As of November 2, 2007, the registrant had 27,073,440 shares of Common Stock outstanding.

EXACT SCIENCES CORPORATION

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Part I - Financial Information

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EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,164	$ 4,831
Marketable securities	7,611	16,244
Prepaid expenses and other current assets	281	386
Total current assets	15,056	21,461
Property and Equipment, at cost:		
Laboratory equipment	3,730	3,832
Office and computer equipment	1,415	1,413
Leasehold improvements	1,259	1,259
Furniture and fixtures	299	299
	6,703	6,803
Less Accumulated depreciation and amortization	(6,033)	(5,959)
	670	844
Patent costs, net of accumulated amortization of $2,983 and $2,871 at September 30, 2007 and December 31, 2006, respectively	450	763
Restricted cash	700	800
	$ 16,876	$ 23,868
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 266	$ 158
Accrued expenses	2,226	1,844
Deferred license fees, current portion	1,350	4,363
Total current liabilities	3,842	6,365
Third party royalty obligation	250	
Deferred license fees, less current portion	3,038	2,545
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding 0 shares at September 30, 2007 and December 31, 2006		
Common stock, $0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 27,134,193 and 26,863,363 shares at September 30, 2007 and December 31, 2006, respectively	271	269
Additional paid-in capital	168,263	165,545
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	14	6
Accumulated deficit	(158,705)	(150,765)
Total stockholders equity	9,746	14,958

	$ 16,876	$	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 September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue:				
Product royalty fees	$ (239)	$ 40	$ (194)	$ 162
License fees	338	1,091	2,520	3,273
Product	14	24	72	135
	113	1,155	2,398	3,570
Cost of revenue:				
Product royalty fees	1	3	4	11
Product	45	99	45	772
	46	102	49	783
Gross profit	67	1,053	2,349	2,787
Operating expenses:				
Research and development (1)	1,009	1,705	3,618	5,583
Sales and marketing (1)	385	1,051	1,390	3,809
General and administrative (1)	2,290	1,700	5,169	4,838
Restructuring (1)	788		819	
	4,472	4,456	10,996	14,230
Loss from operations	(4,405)	(3,403)	(8,647)	(11,443)
Interest income	210	320	707	951
Net loss	$ (4,195)	$ (3,083)	$ (7,940)	$ (10,492)
Net loss per share basic and diluted	$ (0.16)	$ (0.12)	$ (0.30)	$ (0.40)
Weighted average common shares outstanding basic and diluted	27,017	26,562	26,897	26,448

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

Research and development	$ 49	$ 82	$ 482	$ 452
Sales and marketing	86	258	331	962
General and administrative	1,066	329	1,518	1,031
Restructuring	174		174	

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)

	Nine Months Ended September 30,	
	2007	**2006**
Cash flows from operating activities:		
Net loss	$ (7,940)	$ (10,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and write-offs of fixed assets	176	388
Amortization and write-offs of patents	349	765
Stock-based compensation	2,505	2,445
Amortization of deferred license fees	(2,520)	(3,273)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	105	641
Accounts payable	108	(138)
Accrued expenses	812	12
Net cash used in operating activities	(6,405)	(9,652)
Cash flows from investing activities:		
Purchases of marketable securities	(15,303)	(23,647)
Maturities of marketable securities	23,944	28,429
Purchases of property and equipment	(2)	(80)
Proceeds from sale of fixed assets	3	
Increase in patent costs and other assets	(36)	(185)
Net cash provided by investing activities	8,606	4,517
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	32	119
Decrease in restricted cash	100	220
Net cash provided by financing activities	132	339
Net increase (decrease) in cash and cash equivalents	2,333	(4,796)
Cash and cash equivalents, beginning of period	4,831	11,987
Cash and cash equivalents, end of period	$ 7,164	$ 7,191
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	$
Issuance of 85,800 shares of common stock to fund the Company s 401(k) matching contribution for 2005	$	$ 184

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.

The Company has generated limited operating revenues since its inception and, as of September 30, 2007, had an accumulated deficit of approximately $158.7 million. The Company s losses have historically resulted from costs incurred in conjunction with research, development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and, prior to August 31, 2007, costs related to its sales function to support the commercialization of its stool-based DNA screening technology.

The Company expects that its cash, cash equivalents and marketable securities balances at September 30, 2007 will be sufficient to fund its operations through 2008, based upon the Company s current cost structure and current assumptions regarding the studies and other requirements that it believes may be necessary to obtain U.S. Food and Drug Administration (FDA) regulatory clearance for the DNA-based colorectal cancer screening technology described in the October 11, 2007 warning letter from the FDA to the Company (the Warning Letter). See Note 7 for a description of the Warning Letter. The Company has no current sources of material ongoing revenue and, accordingly, it will likely need to raise additional capital in the next twelve months or further reduce the scale of the Company s operations, or both. There can be no assurance that the Company will be successful in any future capital raising efforts, or that it would be able to raise additional funds at an acceptable price level. An inability to fund the Company s operations would have a material adverse effect on its business, financial condition and results of operations.

(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 September 30, 2007 and December 31, 2006, $0.7 million and $0.8 million, respectively, of the Company s cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company s corporate headquarters.

Marketable Securities

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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 nine months ended September 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 September 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 nine months ended September 30, 2007 and 2006. Amounts included in the table are in thousands.

	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006
Patents, net of accumulated amortization, January 1, 2007	$ 763	$ 1,419
Patent costs capitalized	36	186
Amortization of patents	(112)	(461)
Write-offs of patents	(237)	(305)
Patents, net of accumulated amortization, September 30, 2007	$ 450	$ 839

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

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:

	September 30,	
(In thousands)	2007	2006
Shares issuable upon exercise of stock options	4,520	4,801
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,520	5,801

Revenue Recognition

License fees - License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, the Company entered into an amendment to its exclusive license agreement with LabCorp (the Second Amendment) (See Note 3) that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, the Company amortizes the remaining deferred revenue balance resulting from its license agreement with LabCorp at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees - Prior to the effective date of the Second Amendment, the Company s product royalty fees were based on a specified contractual percentage of LabCorp s cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp s cash receipts, as reported to the Company each month by

LabCorp. Subsequent to the effective date of the Second Amendment, the Company s product royalty fees are based on a specified contractual percentage of LabCorp s net revenues from sales of PreGen-Plus. Accordingly, subsequent to the effective date of the Second Amendment, the Company 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 annual net revenues from the sales of PreGen-Plus.

Additionally, pursuant to the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 3 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company s consolidated statements of operations.

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

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

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and nine months ended September 30, 2007 and 2006 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2007**	**2006**	**2007**	**2006**
Net loss	$ (4,195)	$ (3,083)	$ (7,940)	$ (10,492)
Unrealized (loss) gain on marketable securities	2	24	8	54
Comprehensive loss	$ (4,193)	$ (3,059)	$ (7,932)	$ (10,438)

(3) AMENDMENTS TO LABCORP LICENSE AGREEMENT

Second Amendment to LabCorp License Agreement - On June 27, 2007, the Company entered into the Second Amendment with LabCorp. The Second 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 Second Amendment until December 31, 2010.

Additionally, the Second Amendment clarifies the rights and obligations with respect to the Company s next-generation version of stool-based DNA screening technology for colorectal cancer screening (Version 2).

The Second 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 Second Amendment, the Company may be eligible for up to an aggregate of $40 million in milestone payments, all of which relate to the achievement of significant sales thresholds. Royalties due to the Company under the Second Amendment are equal to 15% of LabCorp s net revenues from tests performed using the Company s DNA technology licensed under the Second 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 Second 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 Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp s third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. The Company s liability to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp s sales volumes of PreGen-Plus during three separate measurement periods, as defined below. A significant increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical

PreGen-Plus sales volumes, could reduce the Company s potential obligation to zero during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until sales of PreGen-Plus increase to a level that would reduce this potential maximum obligation, if ever, the Company intends to record the maximum potential obligation under this provision of the Second Amendment ratably on a quarterly basis as a reduction in the product royalty fee line item in its consolidated statements of operations. Accordingly, based on the sales levels of PreGen-Plus during the three months ended September 30, 2007, the Company recorded a charge of $0.3 million under the caption Product royalty fees in its consolidated statements of operations. This obligation is recorded in the Company s consolidated balance sheets under the caption Third party royalty obligation .

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 as of the date of the Second Amendment ($4.7 million) related to up-front technology license fees received from LabCorp is amortized on a straight line basis over the extended exclusive license period beginning in the quarter ended September 30, 2007. Additionally, pursuant to the Second 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 recorded a liability of $45,000 pursuant to this provision of the Second Amendment during the quarter ended September 30, 2007 under the caption Cost of product revenue in its consolidated statements of operations.

The Second 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.

Third Amendment to LabCorp License Agreement **-** On August 31, 2007, the Company entered into a Third Amendment (the Third Amendment) to its exclusive license agreement with LabCorp that, among other things, added a potential $2.5 million milestone payment for which the Company may be eligible. The milestone obligation is based upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of PreGen-Plus over a defined measuring period. In addition, the Third Amendment provides that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp s stool-based DNA testing service. In accordance with the foregoing, LabCorp also agreed to offer at-will employment to certain former personnel of the Company.

(4) RESTRUCTURING

2006 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 2006 Restructuring). This workforce reduction was intended to reduce the Company s expenses and help preserve its existing cash and cash equivalents. Since the 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 (the ACS/MSTF-CRC), a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine;

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.

Pursuant to the 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 as outlined in the table below in connection with adjustments to estimates of one-time employee termination benefits, including severance and outplacement services, during the nine months ended September 30, 2007.

Amounts remaining in the 2006 Restructuring accrual at September 30, 2007 are expected to be paid through December 2007 and are recorded under the caption Accrued expenses in the condensed consolidated balance sheets at September 30, 2007. The following table summarizes the restructuring activities during the nine months ended September 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, September 30, 2007
Employee separation costs	$ 283	$ 29	$ (307)	$	$ 5
Total	$ 283	$ 29	$ (307)	$	$ 5

2007 Restructuring - In connection with the Third Amendment to the LabCorp agreement, during the third quarter of 2007, the Company notified five employees and one employee of their termination from the Company effective August 31, 2007 and October 31, 2007, respectively (the 2007 Restructuring). The 2007 Restructuring was principally designed to eliminate the Company s sales and marketing functions to reduce costs and help preserve the Company s cash resources. These restructuring activities were initiated under a plan of termination described in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, pursuant to which the Company recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007 under generally accepted accounting principles, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees. Since the 2007 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 ACS/MSTF-CRC;

Medicare coverage pursuit for stool-based DNA testing;

validation and optimization of the Company s Version 2 technology; and

the pursuit of FDA clearance for its stool-based DNA screening technologies.

The total restructuring charges of $0.8 million included $0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges. The Company extended by nine months, to August 31, 2008, the expiration date of stock options to purchase up to 726,052 shares, with a weighted average exercise price of $6.41 per share, held by employees that were terminated as a part of the 2007 Restructuring. Pursuant to the measurement provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), the Company recorded one time non-cash stock-based compensation charges in connection with these stock option modifications in its consolidated statements of operations during the quarter ended September 30, 2007.

Amounts remaining in the 2007 Restructuring accrual at September 30, 2007 are recorded under the caption Accrued expenses in the condensed consolidated balance sheet at September 30, 2007. The right of terminated employees to receive severance payments from the

Company will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, the Company s estimate of the total restructuring charges may be adjusted in future periods. 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. The following table summarizes the restructuring activities during the three months ended September 30, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, June 30, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, September 30, 2007
Employee separation costs	$	$ 617	$ (197)	$	$ 420
Total	$	$ 617	$ (197)	$	$ 420

The charges outlined in the table above exclude $0.2 million in non-cash stock-based compensation expense recorded in connection with the stock option modifications discussed above.

(5) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 1995 Stock Option Plan (1995 Option Plan), the 2000 Stock Option and Incentive Plan (2000 Option Plan) and the 2000 Employee Stock Purchase Plan (Employee Stock Purchase Plan). Note 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(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 $1.4 million and $2.5 million in stock-based compensation during the three and nine months ended September 30, 2007, respectively, in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants, as well as restricted common stock issued to a collaborator, certain stock option modifications discussed below 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 $2.4 million in stock-based compensation during the three and nine months ended September 30, 2006 in connection with the amortization of employee and non-employee director common stock and 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 nine months ended September 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.

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 September 30,		Nine Months Ended September 30,	
	2007	**2006**	**2007**	**2006**
Option Plan Shares				
Risk-free interest rates	4.16 - 4.60%	5.03%	4.16 - 4.60%	4.59 - 5.03%
Expected term (in years)	6	6	6	6
Expected volatility	70%	70%	70%	70%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	$1.92	$1.06	$1.87	$1.67
ESPP Shares				
Risk-free interest rates	(1)	5.06 - 5.22%	5.10 - 5.17%	4.57 - 5.22%
Expected term (in years)	(1)	0.5 - 2	0.5 - 2	0.5 - 2
Expected volatility	(1)	70%	70%	70%
Dividend yield	(1)	0%	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	$0.86	$1.08	$0.94

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

Stock Option Activity

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the nine months ended September 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	1,354,000	$2.65		
Exercised	(63,138)	$0.12		

Cancelled	(896,786)	$4.92		
Outstanding, September 30, 2007	4,520,016	$5.00	4.5	$1,814
Exercisable, September 30, 2007	3,515,523	$5.63	3.1	$1,222
Vested and expected to vest, September 30, 2007	4,520,016	$5.00	4.5	$1,814

(1) The aggregate intrinsic value of options outstanding at September 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 2,167,214 options that had exercise prices that were lower than the $3.39 market price of our common stock at September 30, 2007. The aggregate intrinsic value of options exercisable at September 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 1,206,400 options that had exercise prices that were lower than the $3.39 market price of our common stock at September 30, 2007.

As of September 30, 2007, there was $1.7 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.9 years.

Stock Option Modifications

In August 2007, in connection with the 2007 Restructuring and the resignation of Don M. Hardison as the Company s President and Chief Executive Officer, the Company s board of directors approved the following stock option modifications:

On August 31, 2007, the effective date of Mr. Hardison s resignation from the Company, the Company accelerated the vesting of 216,251 shares under Mr. Hardison s previously unvested stock options, with a weighted average exercise price of $2.94 per share, and extended the expiration date of all of Mr. Hardison s outstanding options, covering an aggregate of 1,025,560 shares, through August 31, 2009. Prior to August 31, 2009, Mr. Hardison is prohibited from selling any of the shares of common stock obtained upon the exercise of any accelerated stock options. As a result of these modifications, the Company recorded one-time stock-based compensation charges of approximately $0.7 million in the General and Administrative line item of the Company s consolidated statements of operations during the quarter ended September 30, 2007 in accordance with the provisions of SFAS No. 123(R).

On August 31, 2007, the Company extended by nine months the expiration date of stock options to purchase 726,052 shares, with a weighted average exercise price of $6.41 per share, held by employees that were terminated as a part of the 2007 Restructuring. Stock options subject to the extension now expire on August 31, 2008. In accordance with the measurement provisions of SFAS No. 123(R), the Company recorded one-time non-cash stock-based compensation charges of $0.2 million in the Restructuring line item of the Company s consolidated statements of operations during the quarter ended September 30, 2007 in connection with these modifications.

(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) RECEIPT OF FDA WARNING LETTER

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007 the FDA sent a warning letter to the Company (the Warning Letter) with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. The Company is currently in communication with the FDA to specifically address the matters raised in the Warning Letter and to determine the appropriate regulatory approval process to resolve the matters raised in the Warning Letter.

In an in-person meeting with the FDA on October 26, 2007, the Company presented a proposal to specifically address the matters raised in the Warning Letter by seeking FDA clearance pursuant to a 510(k) pre-market clearance notice (510(k)) for the technology that is the basis for the PreGen-Plus testing service (Version 1). Based on these discussions with the FDA, the Company intends to submit a 510(k) for its Version 1 technology with the FDA to address the matters raised in the Warning Letter. In this regard, on November 2, 2007, the Company submitted to the FDA a pre-IDE that describes the specifics of the Company s intended 510(k) filing approach and the reproducibility studies that the Company proposes to perform in connection therewith. The FDA has not yet indicated whether the submission would be a 510(k) or a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application (PMA) is the appropriate path forward for the Company with respect to its stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with the Company s submission, or that the Company s proposal is otherwise inadequate. There can be no assurance that the Company s filing of a 510(k) for its Version 1 technology will bring the Company into compliance with the matters raised by the FDA in the Warning Letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process.

Following submission of its filing for the Version 1 technology, the Company intends to engage in discussions with the FDA to determine the appropriate regulatory approval path for the Version 2 technology. The clearance or approval process for any version of the Company s DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k)) and may also necessitate the Company submitting pre-market clearance notices or

PMAs with the FDA for multiple versions of its technology simultaneously or in sequence, all of which could take substantial time and resources including investment by the Company of substantial additional funds.

There can be no assurance that any version of the Company s stool-based DNA technology will be cleared or approved by the FDA, that the Company s proposed 510(k) approach will satisfy the FDA s regulatory requirements for its Version 1 technology or any subsequent version of its technology, or that such FDA clearance or approval process can be completed without significant delays or expense. The Company may not have sufficient funds to complete any FDA regulatory clearance or approval process for its DNA-based technologies. Ongoing compliance with FDA regulations could also increase the cost of conducting the Company s business, subject the Company and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, the Company cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to the Company s business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase the Company s costs, limit the Company s revenue and cause material harm to its business and result in impairments of the Company s fixed assets or capitalized patent portfolio.

Following the 2006 Restructuring and 2007 Restructuring, as described in Note 4, the Company expects, based on its current operating plans, that its cash, cash equivalents and short-term investments on hand at September 30, 2007 will be sufficient to fund its current operations through 2008, based upon the Company s current cost structure and current assumptions regarding the studies and other requirements that it believes may be necessary to obtain FDA regulatory clearance of its Version 1 technology. While the Company is currently in discussions with the FDA regarding the approval process for its DNA-based technology, it has not reached final agreement regarding the studies that would be necessary for such approval. Accordingly, the costs of any such studies could require the Company to obtain additional funding before previously expected. The Company does not expect that product royalty payments or milestone payments under its license agreement with LabCorp will materially supplement its liquidity position in the next twelve months, if at all. Accordingly, the Company will likely need to raise additional capital in the next twelve months or further reduce the scale of its operations, or both. There can be no assurance that the Company will be successful in any future capital raising efforts, or that it would be able to raise additional funds at an acceptable price level. An inability to fund the Company s operations would have a material adverse effect on the its business, financial condition and results of operations.

(8) RECENT ACCOUNTING PRONOUNCEMENTS

In June 2006, the Financial Accounting Standards Board (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. The 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. The Company adopted the Interpretation effective January 1, 2007 and it did not have a material impact on its consolidated results of operations, financial position or cash flows.

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements* (SFAS No. 157). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements 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. The Company does not expect the adoption of this standard to have a material impact on its 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 the Company s financial statements.

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

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, or SEC.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as believes, expects, may, will, should, could, seek, plans, estimates, anticipates or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q include, among others, statements regarding the building of material market demand, the sufficiency of our capital resources, expected royalty fees and revenues, research and development and general and administrative expenses, the potential costs and impact of U.S. Food and Drug Administration, or FDA, regulatory action on the marketing and sale of our DNA-based technologies, the focus and level of research and development efforts and development of new technologies, expectations regarding third-party reimbursement of PreGen-Plus, expected restructuring charges, 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, or LabCorp®, for use in a commercial testing service developed and sold by LabCorp under the name PreGen-Plus . PreGen-Plus is LabCorp s non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. 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;

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; and

working with LabCorp on activities in support of the commercialization of PreGen-Plus.

We have generated limited operating revenues since our inception and, as of September 30, 2007, we had an accumulated deficit of approximately $158.7 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

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

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through September 30, 2007, LabCorp had accessioned approximately 14,000 PreGen-Plus samples, including 406 and 1,424 samples, respectively, during the three and nine months ended September 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 our DNA-based technologies, we believe that stool-based DNA testing must be broadly included in the colorectal cancer screening guidelines of the major guidelines organizations, including the guidelines of the American Cancer Society, or 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, or the MSTF-CRC, and together with ACS, the ACS/MSTF-CRC. As a result of a recent warning letter from the FDA classifying PreGen-Plus as a Class III medical device, we also believe that FDA clearance or approval will be necessary to continue the marketing and sale of our DNA-based colorectal cancer technologies, which could require additional studies to validate our technologies. 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 broadly included in colorectal cancer screening guidelines, FDA clearance or approval is obtained 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 next-generation version of stool-based DNA screening technology, or our Version 2 technology;

the specific regulatory requirements for, and any regulatory restrictions placed upon, PreGen-Plus or any other product based on our technologies, and the timing and potential costs of any required regulatory filings and approval processes;

whether LabCorp continues to offer PreGen-Plus commercially or commercially launches a testing service based on our Version 2 technology;

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 stool-based DNA screening 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 us and LabCorp with Medicare, including the approval by Medicare of our National Coverage Application, and other third-party payers for coverage and acceptable levels of reimbursement for stool-based DNA screening;

patient acceptance of stool-based DNA screening, 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 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 certain patent 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 potential third party royalty obligations in connection with our amended license agreement with LabCorp. In addition, as a result of the amendment to our license agreement with LabCorp, which also extended the exclusive license period under our agreement with LabCorp, we expect that license fee revenue for 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 would eliminate the use of Effipure in PreGen-Plus. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2007. The potential loss of this revenue during 2007 is not expected to have a material impact on our total revenues.

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.

In October 2006 and again in July 2007, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2006 Restructuring and the 2007 Restructuring, respectively, to help preserve our cash resources. The 2006 Restructuring eliminated 21 positions, or 48% of our staff at that time, across all departments. 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, optimization and validation of our Version 2 technology and, most recently, FDA clearance or approval of our stool-based DNA screening technologies. As part of the 2007 Restructuring, we eliminated our sales and marketing functions and terminated six employees. See Recent Developments below for a discussion of the 2007 Restructuring.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies and, effective as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R). As a result of restructuring our operations, we expect that our research and development costs in 2007 will be lower than 2006 levels. Any reduction in research and development costs will be offset, however, by the costs of any clinical or other studies that may be required to obtain FDA approval of our DNA-based technologies, as discussed in Recent Developments below. Our research and development efforts for the remainder of 2007 are expected to focus on the validation and optimization of our Version 2 technology, and any clinical or reproducibility studies or other activities that may be necessary to meet FDA clearance or approval requirements. While we have taken steps to lower research and development costs by focusing primarily on our Version 2 technology, we may need to invest substantial funds in additional research, design and development, or clinical or other studies that may be required to meet regulatory requirements to successfully commercialize the technology that is the basis for the PreGen-Plus testing service, or our Version 1 technology, or our Version 2 technology or other potential future products. In this regard, the costs of the reproducibility studies most recently proposed by us in a pre-IDE submission to the FDA in connection with our proposed 510(k) pre-market clearance notice, or 510(k), for our Version 1 technology are expected to be material.

Selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees and, as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123(R). As a result of the 2007 Restructuring, 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 third quarter of 2007 as a result of the elimination of our sales and marketing functions effective August 31, 2007. We expect general and administrative expenses in 2007 to be materially consistent with 2006 levels, although we expect our professional fees to increase during the remainder of 2007 as we focus our efforts on obtaining FDA regulatory clearance or approval of our DNA-based technologies.

During the fourth quarter of 2006 in connection with the 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 the 2007 Restructuring, six employees were terminated. Retention bonus payments in the aggregate amount of approximately $0.3 million were accelerated and paid to those employees during the third quarter of 2007 pursuant to their retention agreements. We intend to accrue the remaining cost of the retention bonuses for our remaining employees, currently estimated to be approximately $0.1 million, over the remaining retention period, which ends on December 31, 2007.

Recent Developments

Regulatory Status of PreGen-Plus. Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007 the FDA sent a warning letter to us, which we refer to as the Warning Letter, with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. We are currently in communication with the FDA to specifically address the matters raised in the Warning Letter and to determine the appropriate regulatory approval process to resolve the matters raised in the Warning Letter.

In an in-person meeting with the FDA on October 26, 2007, we presented a proposal to specifically address the matters raised in the Warning Letter by seeking FDA clearance

pursuant to a 510(k) for our Version 1 technology. Based on these discussions with the FDA, we intend to submit a 510(k) for our Version 1 technology with the FDA to address the matters raised in the Warning Letter. In this regard, on November 2, 2007, we submitted to the FDA a pre-IDE that describes the specifics of our intended 510(k) filing approach and the reproducibility studies that we propose to perform in connection therewith. The FDA has not yet indicated whether the submission would be a 510(k) or a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to our stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with our submission, or that our proposal is otherwise inadequate. There can be no assurance that our filing of a 510(k) for our Version 1 technology will bring us into compliance with the matters raised by the FDA in the Warning Letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process.

Following submission of our filing for our Version 1 technology, we intend to engage in discussions with the FDA to determine the appropriate regulatory approval path for our Version 2 technology. The clearance or approval process for any version of our DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k)) and may also necessitate us submitting pre-market clearance notices or PMAs with the FDA for multiple versions of our technology simultaneously or in sequence, all of which could take substantial time and resources including investment by us of substantial additional funds.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed 510(k) approach will satisfy the FDA s regulatory requirements for our Version 1 technology or any subsequent version of its technology, or that such FDA clearance or approval process can be completed without significant delays or expense. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. Ongoing compliance with FDA regulations could also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio.

Colorectal Cancer Screening Guidelines. On June 7, 2007 we were informed by officials of the ACS that the release of updated colorectal cancer screening guidelines, which are being drafted by the ACS/MSTF-CRC, 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 ($0.5 million at September 30, 2007) or our fixed assets. Moreover, we cannot assure you that the Warning Letter and matters relating to the regulatory status of stool-based DNA screening in general, or PreGen-Plus in particular, will not adversely affect the guidelines process, including by delaying a guidelines answer or by excluding stool-based DNA screening from the colorectal cancer screening guidelines altogether.

Amendments to LabCorp License Agreement.

Second Amendment to LabCorp License Agreement - On June 27, 2007, we entered into a second amendment, or Second Amendment, to our license agreement with LabCorp. 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, and to extend LabCorp s modified exclusive period under the Amendment until December 31, 2010. Additionally, the Second Amendment clarifies the rights and obligations with respect to our Version 2 technology for colorectal cancer screening.

The Second 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 Second Amendment are equal to 15% of LabCorp s net revenues from tests performed using our DNA technology licensed

under the Second 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 Second 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 Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalties payments if LabCorp s third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. Our liability to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp s sales volumes of PreGen-Plus during three separate measurement periods, as defined below. A significant increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical 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 the maximum potential obligation under this provision of the Second Amendment ratably on a quarterly basis as a reduction in the product royalty fee line item in our consolidated statements of operations. Accordingly, based on the sales levels of PreGen-Plus during the three months ended September 30, 2007, we recorded a charge of $0.3 million under the caption Product royalty fees in our consolidated statements of operations. This obligation is recorded in our consolidated balance sheets under the caption Third party royalty obligation .

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 as of the date of the Second Amendment ($4.7 million) related to up-front technology license fees received from LabCorp is amortized on a straight line basis over the extended exclusive license period beginning in the quarter ended September 30, 2007. Additionally, pursuant to the Second 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 recorded a liability of $45,000 pursuant to this provision of the Second Amendment during the quarter ended September 30, 2007 under the caption Cost of product revenue in our consolidated statements of operations.

The Second 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.

Third Amendment to LabCorp License Agreement - On August 31, 2007, we entered into the third amendment, or Third Amendment, to our exclusive license agreement with LabCorp. The Third Amendment, among other things, added a potential $2.5 million milestone payment for which we may be eligible. The milestone payment is based upon specified minimum policy-level reimbursement approval from Medicare, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of PreGen-Plus over a defined measuring period. In addition, the Third Amendment provides that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp s stool-based DNA testing service. In accordance with the foregoing, LabCorp also agreed to offer at-will employment to certain of our former personnel.

2007 Restructuring - In connection with the Third Amendment to our license agreement with LabCorp, we notified five employees and one employee of their termination from the Company effective August 31, 2007 and October 31, 2007, respectively, which we refer to as the 2007 Restructuring. The 2007 Restructuring was principally designed to eliminate our sales and marketing functions to reduce costs and help preserve our cash resources. These restructuring activities were initiated under a plan of termination described in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS No. 146, pursuant to which we recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007 under

generally accepted accounting principles. The restructuring charges generally include one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Total restructuring charges of $0.8 million included $0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges. We extended by nine months, to August 31, 2008, the expiration date of stock options to purchase up to 726,052 shares, with a weighted average exercise price of $6.41 per share, held by employees that were terminated as a part of the 2007 Restructuring. Pursuant to the measurement provisions of SFAS No. 123(R), we recorded one time non-cash stock-based compensation charges in connection with these stock option modifications.

Amounts remaining in the 2007 Restructuring accrual at September 30, 2007 are recorded under the caption Accrued expenses in the condensed consolidated balance sheets at September 30, 2007. The right of terminated employees to receive severance payments from us will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, our estimate of the total restructuring charges may be adjusted in future periods. We continue to assess our facility needs and other operational costs and, as a result, could incur additional restructuring charges in the event we undertake additional activities to reduce our facilities or other operating costs. The following table summarizes the restructuring activities during the three months ended September 30, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, June 30, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, September 30, 2007
Employee separation costs	$	$ 617	$ (197)	$	$ 420
Total	$	$ 617	$ (197)	$	$ 420

The charges outlined in the table above exclude $0.2 million in non-cash stock-based compensation expense recorded in connection with the stock option modifications discussed above.

Reimbursement. On August 1, 2007, we were informed by officials of the Centers for Medicare & Medicaid Services, or 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, we do not believe that CMS has 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. Additionally, the FDA pre-market clearance or approval process with respect to our DNA-based colorectal cancer screening technology may delay, or negatively affect a decision by CMS regarding our application for a National Coverage Determination, which could materially limit our potential revenue and cause material harm to our business.

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 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 exclusive 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 amortize the remaining deferred revenue balance at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees - Prior to the effective date of the Second Amendment, our product royalty fees were based on a specified contractual percentage of LabCorp s cash receipts from performing PreGen-Plus tests. Accordingly, we recorded product royalty fees based on this specified percentage of LabCorp s cash receipts, as reported to us each month by LabCorp.

Subsequent to the effective date of the Second Amendment, our product royalty fees are based on a specified contractual percentage of LabCorp s net revenues from sales of PreGen-Plus. Accordingly, subsequent to the effective date of the 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. The current royalty rate is 15%, subject to increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of PreGen-Plus.

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

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

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

Patent Costs. Patent costs are capitalized as incurred and are amortized beginning when patents are issued over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, upon a decision by us to no longer pursue the patent, or when the related intellectual property is deemed to be no longer of value to us.

The following table summarizes activity with respect to our capitalized patents for the nine months ended September 30, 2007 and 2006. Amounts included in the table are in thousands.

	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006
Patents, net of accumulated amortization, January 1, 2007	$ 763	$ 1,419
Patent costs capitalized	36	186
Amortization of patents	(112)	(461)
Write-offs of patents	(237)	(305)
Patents, net of accumulated amortization, September 30, 2007	$ 450	$ 839

Capitalized patent costs written off during the nine months ended September 30, 2007 were primarily the result of our determination that we would likely not pursue commercialization of certain technologies which were unrelated to intellectual property

licensed to LabCorp for PreGen-Plus. Patent write-offs during the nine months ended September 30, 2007 also included the write-off of certain costs with respect to a capitalized pending patent application not critical to LabCorp s PreGen-Plus testing service that was not approved by the U.S. Patent and Trademark Office.

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets*, 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(R) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, as originally issued and EITF 96-18 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Prior to January 1, 2006, we accounted for stock-based compensation under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

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

Critical Accounting Estimate

Third Party Royalty Obligation. 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. In connection with this obligation, we recorded a charge of $0.3 million under the caption Product royalty fees in our consolidated statements of operations during the three months ended September 30, 2007. This obligation is recorded in our consolidated balance sheets under the caption Third party royalty obligation .

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*, or 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. The 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*, or SFAS No. 157. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements 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*, or 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.

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

Results of Operations

Revenue. Total revenue decreased to $0.1 million for the three months ended September 30, 2007 from $1.2 million for the three months ended September 30, 2006 and decreased to $2.4 million for the nine months ended September 30, 2007 from $3.6 million for the nine months ended September 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 nine months ended September 30, 2007 as compared to the same periods for the prior year was primarily the result of lower non-cash license fee amortization revenue resulting from the Second Amendment to our license agreement with LabCorp. Total revenues also decreased as a result of a decrease in product royalty fees.

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 if LabCorp does not have a suitable alternative to Effipure in place. As of December 31, 2006 and September 30, 2007, the carrying value of our Effipure inventory was $0. Under the terms of the Second Amendment to our license agreement with LabCorp, we may be obligated to pay LabCorp up to a maximum of $250,000 in connection with certain costs related to Effipure, $45,000 of which was charged to cost of sales in our consolidated statements of operations for the three months ended September 30, 20007.

Total cost of revenue decreased to $46,000 for the three months ended September 30, 2007 from $102,000 for the three months ended September 30, 2006 and decreased to $49,000 for the nine months ended September 30, 2007 from $783,000 for the nine months ended September 30, 2006. The decrease in the cost of product revenue for the three months ended September 30, 2007 as compared to the same period of the prior year was primarily the result of lower Effipure write-offs during the quarter ended September 30, 2007 as compared to the three months ended September 30, 2006. The decrease in the cost of product revenue for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006 was primarily due to $0.7 million in write-offs of Effipure inventory during the nine months ended September 30, 2006 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 $1.0 million for the three months ended September 30, 2007 compared to $1.7 million for the three months ended September 30, 2006. The decrease in the three months ended September 30, 2007 as compared to the same period of 2006 was primarily the result of the cost reduction plan undertaken in connection with the 2006 Restructuring and described under the heading Restructuring below. Pursuant to the 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 September 30, 2007, as compared to the three months ended September 30, 2006, were decreases of $0.3 million in personnel-related expenses, $0.1 million in laboratory supplies, $0.1 million in clinical study expenses, and $0.1 million in laboratory operating costs resulting from the reduction in the size of our research and development force from 19 employees at September 30, 2006 to eight employees at September 30, 2007.

Research and development expenses decreased to $3.6 million for the nine months ended September 30, 2007 from $5.6 million for the nine months ended September 30, 2006. This decrease included reductions of $0.8 million in personnel-related expenses, $0.5 million in laboratory supplies, $0.4 million in laboratory operating costs, and $0.3 million in clinical study expenses, all of which resulted from the restructuring activities discussed above. These decreases in operating expenses were partially offset by an increase in non-cash stock-based compensation expense of $27,000, resulting primarily from the cost associated with issuing 100,000 shares of our common stock to Oncomethylome Sciences S.A., or OMS, on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

Sales and marketing expenses. Sales and marketing expenses decreased to $0.4 million for the three months ended September 30, 2007 from $1.1 million for the three months ended September 30, 2006. Sales and marketing expenses decreased to $1.4 million for the nine months ended September 30, 2007 from $3.8 million for the nine months ended September 30, 2006. These decreases were primarily due to reductions of $0.4 million and $1.2 million, respectively, in personnel-related expenses for the three and nine months ended September 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 September 30, 2006 to zero employees at September 30, 2007. As described under the heading Restructuring below, in July 2007, we eliminated our sales and marketing functions, effective August 31, 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 $0.6 million, respectively, for the three and nine months ended September 30, 2007 when compared to the same periods of 2006. We also reduced our external advertising, marketing and promotional spending by $0.1 million and $0.6 million, respectively, during the three and nine months ended September 30, 2007 as compared to the three and nine months ended September 30, 2006.

General and administrative expenses. General and administrative expenses increased to $2.3 million for the three months ended September 30, 2007, compared to $1.7 million for the three months ended September 30, 2006. The increase was primarily the result of higher non-cash stock-based compensation expense due to the acceleration of the vesting of 216,251 shares under previously unvested stock options, with a weighted average exercise price of $2.94 per share, held by Don M. Hardison, our former President and Chief Executive Officer, as well as the extension of the expiration date of all of Mr. Hardison s outstanding options, covering an aggregate of 1,025,560 shares, through August 31, 2009. Mr. Hardison resigned from the Company effective August 31, 2007, and, pursuant to a separation agreement between the Company and Mr. Hardison, Mr. Hardison is prohibited from selling, prior to August 31, 2009, any of the shares of common stock obtained upon the exercise of any accelerated stock options. In connection with these stock option modifications, we recorded one-time stock-based compensation charges of approximately $0.7 million in the quarter ended September 30, 2007 in accordance with the provisions of SFAS No. 123(R). General and administrative expenses increased to $5.2 million for the nine months ended September 30, 2007 from $4.8 million for the nine months ended September 30, 2006. This increase was primarily the result of an increase of $0.5 million in non-cash stock-based compensation expense as a result of the stock option modifications described above with respect to Mr. Hardison. This increase was partially offset by a decrease of $0.2 million in salary and benefit costs due to a reduction in general and administrative headcount during the quarter ended September 30, 2007 as compared to the same period of the prior year.

Restructuring.

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 help preserve our existing cash and cash equivalents. Since the 2006 Restructuring, our 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, or

ACS/MSTF-CRC, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine;

Medicare coverage pursuit for stool-based DNA testing;

the pursuit of licensing arrangements relating to our stool-DNA technologies; and

validation and optimization of our Version 2 technology.

Pursuant to the 2006 Restructuring, 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 $29,000 in connection with adjustments to estimates of one-time employee termination benefits, including severance and outplacement services, during the nine months ended September 30, 2007.

***2007 Restructuring*.** In connection with the Third Amendment to our exclusive license agreement with LabCorp, during the third quarter of 2007, we terminated five employees and one employee effective August 31, 2007 and October 31, 2007, respectively. The 2007 Restructuring was principally designed to eliminate our sales and marketing functions to reduce costs and help preserve our cash resources. These restructuring activities were initiated under a plan of termination described in SFAS No. 146 pursuant to which we recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007 under generally accepted accounting principles. The restructuring charges generally include one-time termination benefits arising under retention and severance agreements with each of the terminated employees. Since the 2007 Restructuring, our 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 ACS/MSTF-CRC;

Medicare coverage pursuit for stool-based DNA testing;

validation and optimization of our Version 2 technology; and

the pursuit of FDA clearance for our stool-based DNA screening technologies.

We account for restructuring charges in accordance with 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 September 30, 2007 from $0.3 million for the three months ended September 30, 2006. Interest income decreased to $0.7 million for the nine months ended September 30, 2007 from $1.0 million for the nine months ended September 30, 2006. These decreases were due primarily to lower average cash, cash equivalents and marketable securities balances held during the three and nine months ended September 30, 2007 as compared to the same periods 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 license agreement. As of September 30, 2007, we had approximately $14.8 million in unrestricted cash, cash equivalents and marketable securities and $0.7 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit in connection with the lease for our Marlborough, Massachusetts facility.

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

Net cash used in operating activities was $6.4 million for the nine months ended September 30, 2007 as compared to $9.7 million for the same period of 2006. The principal use of cash in operating activities for the nine months ended September 30, 2007 and 2006 was to fund our net loss. The decrease in net cash used in operating activities for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006 was primarily due to decreases in sales and marketing and applied research spending as a result of cost reduction actions taken during 2007 and 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 $8.6 million for the nine months ended September 30, 2007, as compared to net cash provided by investing activities of $4.5 million nine months ended September 30, 2006. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $38,000 and $265,000 for the nine months ended September 30, 2007 and 2006, respectively.

Purchases of property and equipment of $2,000 during the nine months ended September 30, 2007 were significantly lower than purchases of property and equipment of $80,000 during the nine months ended September 30, 2006 primarily as a result of the cost reduction actions taken during 2007 and late 2006. Excluding activities that may be required by the FDA, we expect that purchases of

property and equipment during 2007 will be lower than amounts invested during 2006, although studies required by the FDA in connection with our technologies may require that we purchase additional property and equipment in 2007. We also reduced the expenditures related to our patent portfolio for the nine months ended September 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 $132,000 and $339,000 for the nine months ended September 30, 2007 and 2006, respectively, and was primarily the result of decreases in restricted cash in connection with the lease for our corporate headquarters, and to a lesser extent, proceeds received from the issuance of common stock under our employee stock option and purchase plans.

As a result of the restructuring actions taken in 2007 and 2006, we expect that cash, cash equivalents and short-term investments on hand at September 30, 2007 will be sufficient to fund our current operations through 2008, based upon our current cost structure and current assumptions regarding the studies and other requirements that we believe may be necessary to obtain FDA regulatory clearance of the DNA-based colorectal cancer screening technology described in the Warning Letter. We are currently in discussion with the FDA regarding the approval process for our DNA-based technology, however, we have not reached final agreement regarding the studies that would be necessary for such approval. The costs of any such studies could require us to obtain additional funding before previously expected. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. Under the terms of our amended license agreement with LabCorp, we are eligible to receive up to an aggregate of $42.5 million in milestone payments; $2.5 million of which is based on specified policy-level reimbursement approval from Medicare, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of PreGen-Plus over a defined measuring period, and the remaining $40.0 million of which relates 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, we do not believe that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. Accordingly, we will likely need to raise additional capital in the next twelve months or further reduce the scale of our operations, or both. 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.

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

		Payments Due by Period			
Description	**Total**	**Less Than One Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
			(in Thousands)		
Obligations under license and collaborative agreements	$ 5,339	$ 934	$ 630	$ 630	$ 3,145
Operating lease obligations	2,850	981	1,869		
Retention bonus obligations in connection with employment agreements	445	445			
Purchase obligations	367	367			
Total	$ 9,001	$ 2,727	$ 2,499	$ 630	$ 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. 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 with subleasing a portion of our 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 FDA submissions, clinical and other studies required for such FDA submissions, 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 specific regulatory requirements for PreGen-Plus, Version 2 and any subsequent versions of our technology, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory clearance or approval process;

our ability to attract third parties to support the development of an FDA-cleared or approved product based on our technologies;

acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party 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;

the ability and commitment by LabCorp to market and promote 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 products or 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 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 specific version of our technology or 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. Additionally, if our Version 1 technology is not cleared or approved by the FDA in the near term, LabCorp could decide to stop offering the current version of Pre-Gen Plus. Furthermore, LabCorp could decide not to launch Version 2 of its testing service, or could decide to defer any potential future launch of Version 2 of its testing service until that version has been approved or cleared by the FDA, if ever. Either of these situations will limit our revenue and materially adversely affect our business and cash reserves. Moreover, if our pursuit of FDA clearance or approval delays approval under our Medicare application for a National Coverage Determination, or if the FDA status of our technology causes the Centers for Medicare and Medicaid Services to reject our application outright or to let the time for consideration of the application expire without a positive decision, this will materially adversely affect our business and we may never be successful.

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. Further, to the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in significant dilution to our stockholders.

Off-Balance Sheet Arrangements

As of September 30, 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. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, all of which are currently invested in the U.S. and are classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

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

Item 4. Controls And Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15b promulgated under the Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 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 set forth in our Quarterly Report on Form 10-Q for the period ended June 30, 2007 and changes to the risk factors listed below to update for recent developments with the U.S. Food and Drug Administration, or FDA. 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 we or LabCorp fail to comply with FDA requirements, we or LabCorp may be limited or prohibited in our ability to commercialize stool-based DNA testing for colorectal cancer and may be subject to stringent penalties.

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or homebrew testing service. On October 11, 2007 the FDA sent a warning letter to us, which we refer to as the Warning Letter, with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. We are currently in communication with the FDA to specifically address the matters raised in the Warning Letter and to determine the appropriate regulatory approval process to resolve the matters raised in the Warning Letter.

In an in-person meeting with the FDA on October 26, 2007, we presented a proposal to specifically address the matters raised in the Warning Letter by seeking FDA clearance pursuant to a 510(k) pre-market clearance notice, or 510(k), for the technology that is the basis for the PreGen-Plus testing service, or our Version 1 technology. Based on these discussions with FDA, we intend to submit a 510(k) for our Version 1 technology with the FDA to address the matters raised in the Warning Letter. In this regard, on November 2, 2007, we submitted to the FDA a pre-IDE that describes the specifics of our intended 510(k) filing approach and the reproducibility studies that we propose to perform in connection therewith. The FDA has not yet indicated whether the submission would be a 510(k) or a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to our stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with our submission, or that our proposal is otherwise inadequate. There can be no assurance that our filing of a 510(k) for our Version 1 technology will bring us into compliance with the matters raised by the FDA in the Warning Letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process.

Following submission of our filing for our Version 1 technology, we intend to engage in discussions with the FDA to determine the appropriate regulatory approval path for our next-generation version of stool-based DNA screening technology for colorectal cancer screening, or our Version 2 technology. The clearance or approval process for any version of our DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k)) and may also necessitate us submitting pre-market clearance notices or PMAs with the FDA for multiple versions of our technology simultaneously or in sequence, all of which could take substantial time and resources including investment by us of substantial additional funds.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed 510(k) approach will satisfy the FDA s regulatory requirements for our Version 1 technology or any subsequent version of our technology, or that such FDA clearance or approval process can be completed without significant delays or expense. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. Ongoing compliance with FDA regulations could also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio.

We will likely need to raise additional funding, which may not be available on favorable terms, if at all, or without dilution to our stockholders. If we do not raise any necessary funds, we will need to cut back or terminate some or all aspects of our operations which would materially adversely affect our business prospects.

We believe that our existing cash, cash equivalents and investment balances will be sufficient to meet our anticipated cash requirements through 2008, based on our current cost structure and current assumptions regarding the clinical and other studies and other requirements that we believe may be necessary to obtain FDA approval of Version 1 of our DNA-based colorectal cancer screening technology. Because we are currently in discussions with the FDA regarding the approval process for our DNA-based technology, it is very difficult to predict the actual costs of the studies and other requirements that will be necessary to obtain FDA approval. In light of our receipt of the Warning Letter, we believe that the requirements for regulatory clearance or approval of our Version 1 and Version 2 technologies are likely to be significant and that, our current cash, cash equivalents and marketable securities balances are likely to be reduced significantly. We have no current sources of material ongoing revenue and, accordingly, we will likely need to raise additional funds in the next twelve months to continue the development and commercialization of our technologies. The amount of additional capital we will likely need to raise depends on many factors, including:

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 specific regulatory requirements for PreGen-Plus, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;

our ability to attract third parties to support the development of an FDA-cleared or approved product based on our technologies;

acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;

our ability to achieve milestones under our strategic agreement with LabCorp;

a determination that additional studies surrounding our technologies are needed;

stool-based DNA screening becoming a standard of care among prescribing physicians;

the scope of and progress made in our research and development activities;

the successful commercialization and near term 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.

We cannot be certain that additional capital will be available or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in biotechnology or life sciences companies or in the marketplace in general is limited due to the then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire or any time thereafter. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, or grant licenses on terms that are not favorable to us. If we are unable to obtain financing on terms favorable to us, we may be unable to execute our business plan and we may be required to cease development or commercialization of our technology, sell some of all of our technology or assets or merge with another entity.

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

On July 20, 2007, we adjourned our annual meeting of stockholders to distribute a proxy supplement regarding the status of Don M. Hardison, our former President and Chief Executive Officer and a director on our Board of Directors. On August 10, 2007, at our reconvened annual meeting of stockholders, the stockholders elected as a Class I director, to serve for a three-year term, Connie Mack, III (23,475,985 shares for; 328,679 shares withheld). The term of office for each of Sally W. Crawford, Edwin M. Kania, Jr., Lance Willsey and Patrick J. Zenner as directors of the Company continued following the annual meeting. A proposal to ratify Ernst & Young LLP as the Company s independent auditors for fiscal year 2007 was also approved (23,651,035 shares for, 137,715 shares against and 15,913 abstained).

Item 6. Exhibits

Exhibit Number	Description
10.1	Non-Employee Director Compensation Policy (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on August 15, 2007, which is incorporated herein by reference).
10.2	Executive Incentive Plan (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on August 15, 2007, which is incorporated herein by reference).
10.3**	Third Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of August 31, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on September 7, 2007, which is incorporated herein by reference).
10.4	Separation Agreement and Release between the Registrant and Don M. Hardison, dated as of August 31, 2007 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on September 7, 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.

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

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

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: November 6, 2007

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

Date: November 6, 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)

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