EXACT SCIENCES CORP
Form 10-Q
November 09, 2006

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, 2006

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 or 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 3, 2006, the registrant had 26,655,213 shares of Common Stock outstanding.

EXACT SCIENCES CORPORATION

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EXACT SCIENCES CORPORATION
Condensed Consolidated Balance Sheets
(Amounts in thousands, except share data - unaudited)

	December 31, 2005	September 30, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,007	$ 7,991
Marketable securities	21,112	16,384
Prepaid expenses and other current assets	1,158	517
Total current assets	35,277	24,892
Property and Equipment, at cost:		
Laboratory equipment	4,123	3,801
Office and computer equipment	1,407	1,407
Leasehold improvements	1,259	1,259
Furniture and fixtures	299	299
	7,088	6,766
Less Accumulated depreciation and amortization	(5,939)	(5,925)
	1,149	841
Patent costs and other assets, net of accumulated amortization of $2,279 and $2,740 at December 31, 2005 and September 30, 2006, respectively	1,419	839
	$ 37,845	$ 26,572
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 468	$ 330
Accrued expenses	1,485	1,393
Deferred license fees, current portion	4,363	4,363
Total current liabilities	6,316	6,086
Deferred License Fees, less current portion	6,908	3,636
Commitments and contingencies		
Stockholders Equity:		
Common stock, $0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 26,436,498 and 26,690,863 shares at December 31, 2005 and September 30, 2006, respectively	264	267
Additional paid-in capital	162,349	165,013
Treasury stock, 85,550 shares	(97)	(97)
Other comprehensive (loss) income	(45)	9
Accumulated deficit	(137,850)	(148,342)
Total stockholders equity	24,621	16,850
	$ 37,845	$ 26,572

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,	
	2005	2006	2005	2006
Revenue:				
Product royalty fees	$ 51	$ 40	$ 165	$ 162
License fees	1,111	1,091	2,737	3,273
Product	33	24	163	135
	1,195	1,155	3,065	3,570
Cost of revenue:				
Product royalty fees	2	3	9	11
Product	330	99	503	772
	332	102	512	783
Gross profit	863	1,053	2,553	2,787
Operating Expenses:				
Research and development (1)	1,907	1,705	6,143	5,583
Sales and marketing (1)	1,181	1,051	4,457	3,809
General and administrative (1)	1,354	1,700	3,949	4,838
Restructuring			626	
	4,442	4,456	15,175	14,230
Loss from operations	(3,579)	(3,403)	(12,622)	(11,443)
Interest income	290	320	797	951
Net loss	$ (3,289)	$ (3,083)	$ (11,825)	$ (10,492)
Net loss per share basic and diluted	$ (0.13)	$ (0.12)	$ (0.45)	$ (0.40)
Weighted average common shares outstanding basic and diluted	26,291	26,562	26,248	26,448

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

Research and development	$ (30)	$ 82	$ 50	$ 452
Sales and marketing	(10)	258	48	962
General and administrative	(41)	329	176	1,031
Total	$ (81)	$ 669	$ 274	$ 2,445

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,	
	2005	**2006**
Cash flows from operating activities:		
Net loss	$ (11,825)	$ (10,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	598	388
Amortization and write-offs of patents	541	765
Restructuring	282	
Stock-based compensation	274	2,445
Amortization of deferred license fees	(3,368)	(3,273)
Non-cash revenue reduction recorded in connection with warrant extension	630	
Changes in assets and liabilities:		
Prepaid expenses and other current assets	619	641
Accounts payable	(92)	(138)
Accrued expenses	(587)	12
Net cash used in operating activities	(12,928)	(9,652)
Cash flows from investing activities:		
Purchases of marketable securities	(15,006)	(23,647)
Maturities of marketable securities	32,157	28,429
Purchases of property and equipment	(216)	(80)
Increase in patent costs and other assets	(113)	(185)
Net cash provided by investing activities	16,822	4,517
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	138	119
Net cash provided by financing activities	138	119
Net increase (decrease) in cash and cash equivalents	4,032	(5,016)
Cash and cash equivalents, beginning of period	13,092	13,007
Cash and cash equivalents, end of period	$ 17,124	$ 7,991
Supplemental disclosure of non-cash financing activities:		
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 August 2008 to Laboratory Corporation of America® Holdings (LabCorp®) for use in a commercial testing service developed by LabCorp and marketed under the name PreGen-Plus . PreGen-Plus is a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. The Company has devoted the majority of its efforts to date on research and development and commercialization support of PreGen-Plus.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

These condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto which are contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2005, 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. At December 31, 2005 and September 30, 2006, $1.0 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. Cash equivalents primarily consist of money market funds and certificates of deposit at December 31, 2005 and September 30, 2006.

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, 2005 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 issued 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. Other assets principally consist of license fees and deposits.

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

The following potentially issuable common shares were not included in the computation of diluted net loss per share for the three and nine months ended September 30, 2005 and 2006 because they would have an anti-dilutive effect due to net losses for such periods:

	September 30,	
(in thousands)	**2005**	**2006**
Shares issuable upon exercise of stock options	4,898	4,801
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,898	5,801

Revenue Recognition

License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period.

Royalties earned on PreGen-Plus tests performed by LabCorp are based upon the customer s remittance to LabCorp, not the amount billed. Until such time as the Company has sufficient history and experience to estimate the percentage of PreGen-Plus accessions to LabCorp that will ultimately result in revenue for the Company, it will continue to recognize royalties as LabCorp customers make payments. The timing of such payments to LabCorp is uncertain because of the variable time lag between invoicing and payment and the number of parties involved in the reimbursement process.

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

Revenue from milestone and other performance-based payments, if any, is 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, 2005 and 2006 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2005**	**2006**	**2005**	**2006**
Net loss	$ (3,289)	$ (3,083)	$ (11,825)	$ (10,492)
Unrealized gain on marketable securities	18	24	64	54
Comprehensive loss	$ (3,271)	$ (3,059)	$ (11,761)	$ (10,438)

(3) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

1995 Stock Option Plan **-** Under the 1995 stock option plan (the 1995 Option Plan), the Company s board of directors could grant incentive and non-qualified stock options to purchase an aggregate of up to 3,987,500 shares of common stock to employees, directors and consultants of the Company. The exercise price of each option is determined by the board of directors. Incentive stock options may not be less than the fair market value of the stock on the date of grant, as defined by the board of directors. Options granted under the 1995 Option Plan vest over a three-to-five-year period and expire 10 years from the grant date.

The 1995 Option Plan was terminated on January 31, 2001, the effective date of the Company s registration statement in connection with its initial public offering. Options granted prior to the date of termination remain outstanding and may be exercised in accordance with their terms. At September 30, 2006, options to purchase 551,674 shares were outstanding under the 1995 Option Plan.

2000 Stock Option Plan **-** The Company adopted the 2000 Stock Option and Incentive Plan (the 2000 Option Plan) on October 17, 2000. At September 30, 2006, a total of 5,696,690 shares of common stock have been authorized and reserved for issuance under the 2000 Option Plan. The 2000 Option Plan provides that the number of shares authorized for issuance will automatically increase on each January 1 by (i) the greater of 5% of the outstanding number of shares of common stock on the preceding December 31, or that number of shares underlying option awards issued during the one-year period prior to such January 1, or (ii) such lesser number as may be approved by the board of directors. Under the terms of the 2000 Option Plan, the Company is authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2000 Option Plan expire ten years

from the date of grant. Grants made from the 2000 Option Plan prior to January 1, 2006 generally vest over a period of three to five years. Grants made from the 2000 Option Plan subsequent to January 1, 2006 generally vest monthly over a three-year period.

The 2000 Option Plan is administered by the compensation committee of the Company s board of directors, which selects the individuals to whom equity-based awards will be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, all options to purchase common stock will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all options then outstanding under the 2000 Option Plan held by that employee will immediately become exercisable. At September 30, 2006, options to purchase 4,249,588 shares were outstanding under the 2000 Option Plan and 1,255,331 shares were available for future grant under the 2000 Option Plan.

2000 Employee Stock Purchase Plan **-** The 2000 Employee Stock Purchase Plan (the 2000 Purchase Plan) was initially adopted by the Company in October 2000, and subsequently amended and restated. The 2000 Purchase Plan provides participating employees the right to purchase common stock at a discount through a series of offering periods. The 2000 Purchase Plan provides that the number of shares authorized for issuance will automatically increase on each February 1 by (i) the greater of 0.75% of the outstanding number of shares of common stock on the immediately preceding December 31, or that number of shares issued during the one-year period prior to such February 1, or (ii) such lesser number as may be approved by the Company s board of directors. At September 30, 2006, the 2000 Purchase Plan had available an aggregate of 737,767 shares of common stock for purchase by participating employees.

The compensation committee of the Company s board of directors administers the 2000 Purchase Plan. Generally, all employees whose customary employment is more than 20 hours per week and for more than five months in any calendar year are eligible to participate in the 2000 Purchase Plan. Participating employees authorize an amount, between 1% and 15% of the employee s compensation, to be deducted from the employee s pay during the offering period. On the last day of the offering period, the employee is deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2000 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2000 Purchase Plan and no employee can purchase more than $25,000 of the Company common stock under the 2000 Purchase Plan in any calendar year. Rights granted under the 2000 Purchase Plan terminate upon an employee s voluntary withdrawal from the 2000 Purchase Plan at any time or upon termination of employment.

Adoption of SFAS No. 123(R)

Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). The Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, *Accounting for Stock Based Compensation* (SFAS No.123), as originally issued and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Under the modified prospective transition method, the Company recognized stock-based compensation expense during the three and nine months ended September 30, 2006 in connection with: (a) stock options and restricted stock awards granted and employee stock purchase plan awards with offering periods commencing prior to, but not yet vested, as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) stock options and restricted stock awards granted and employee stock purchase plan awards with offering periods commencing subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Under the modified prospective transition method, results for prior periods are not restated. As a result of the adoption of SFAS No. 123(R), the Company recorded incremental stock-based compensation expense in connection with the foregoing in its consolidated statements of operations for the three and nine months ended September 30, 2006 of $0.6 million and $2.2 million, respectively.

Total stock-based compensation recorded in the three and nine months ended September 30, 2006 of $0.7 million and $2.4 million, respectively, included $42,000 and $0.2 million, respectively, recorded in connection with stock options and restricted stock awards granted to non-employee consultants and directors as well as stock-based compensation expense related to the Company s 2006 401(k) match which, if approved by the Company s board of directors, is made annually in Company common stock. Prior to the adoption of SFAS No. 123(R) on January 1, 2006, the Company, in accordance with APB No. 25, recognized expenses related to non-employee consultant stock option grants and restricted stock awards and the Company s 401(k) match in its consolidated statements of operations.

The amounts in the table below represent solely the impact of expenses recorded in the Company s consolidated statements of operations in connection with employee and director stock option grants and the 2000 Purchase Plan in accordance with SFAS No. 123(R). Non-employee consultant stock option grants, restricted stock awards and the Company s 2006 401(k) match are accounted for similarly under both APB No. 25 and SFAS No. 123(R) and are therefore excluded from the table below.

(in thousands)	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 74	$ 388
Sales and marketing	271	884
General and administrative	282	954
	$ 627	$ 2,226

As a result of adopting SFAS No. 123(R) on January 1, 2006, the Company s loss from operations, as well as its net loss, for the three and nine months ended September 30, 2006, were $0.6 million and $2.2 million higher, respectively, than if it had continued to account for stock-based compensation under APB No. 25. Basic and diluted loss per share for the three and nine months ended September 30, 2006 were $0.02 and $0.08 higher, respectively, than if the Company had continued to account for stock-based compensation under APB No. 25.

Determining Fair Value

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

Expected Term - The Company uses the simplified calculation of expected life, described in the SEC s Staff Accounting 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 of 2001 through September 30, 2006. Expected volatility was lower in the first half of 2006 when compared to the same period of 2005 as the Company refined its expectation because, as of January 2006, it had at least five years of historical volatility data on which to base its expectation. Prior to January 1, 2006, sufficient historical volatility data did not exist to reasonably justify a lower expected volatility.

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 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,	
	2005	2006	2005	2006
Option Plan Shares				
Risk-free interest rates	4.06%	5.03%	3.94% - 4.06%	4.59% - 5.03%
Expected term (in years)	7	6	7	6
Expected volatility	100%	70%	100%	70%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	$1.97	$1.06	$3.21	$1.67
ESPP Shares				
Risk-free interest rates	N/A	5.06% - 5.22%	N/A	4.57% - 5.22%
Expected term (in years)	N/A	0.5 - 2	N/A	0.5 - 2
Expected volatility	N/A	70%	N/A	70%
Dividend yield	N/A	0%	N/A	0%
Weighted average fair value per share of stock purchase rights granted during the period	N/A	$0.86	N/A	$0.94

Pro Forma Information Under SFAS No. 123 for Periods Prior to January 1, 2006

The following table illustrates the effect on net income and earnings per common share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation. Note that the pro forma disclosures below are provided for the three and nine months ended September 30, 2005 only because employee stock options were not accounted for using the fair value method during that period. When the Company presents its financial statements for the three and nine months ended September 30, 2007, it will not present any comparative pro-forma disclosures because share-based payments will have been accounted for under the SFAS No. 123(R) fair value method for the three and nine months ended September 30, 2006 and 2007.

(In thousands, except per share data)	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss as reported	$ (3,289)	$ (11,825)
Add: Stock-based compensation included in reported net loss	(81)	274
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(1,652)	(5,980)
Pro forma net loss - SFAS No. 123	$ (5,022)	$ (17,531)
Basic and diluted net loss per share:		
As reported	$ (0.13)	$ (0.45)
Pro forma net loss - SFAS 123	$ (0.19)	$ (0.67)

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, 2006 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, December 31, 2005	4,499,927	$ 6.10	7.17	
Granted	930,921	2.53		
Exercised	(122,045)	0.24		
Cancelled	(507,541)	7.56		
Outstanding, September 30, 2006	4,801,262	$ 5.40	6.22	$ 321
Exercisable, September 30, 2006	3,466,179	$ 6.17	5.31	$ 321
Vested and expected to vest, September 30, 2006 (2)	4,462,714	$ 5.54	6.96	$ 321

(1) The aggregate intrinsic value of options outstanding at September 30, 2006 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 192,597 options that had exercise prices that were lower than the $2.03 market price of our common stock at September 30, 2006. The total intrinsic value of options exercised during the three and nine months ended September 30, 2006 was $43,000 and $0.2 million, respectively, determined as of the date of exercise.

(2) Represents the number of vested options as of September 30, 2006 plus the number of unvested options expected to vest as of September 30, 2006. Unvested options expected to vest are based on the total unvested outstanding options at September 30, 2006, less 338,548 unvested outstanding options of the 21 employees terminated in the Company s October 2006 restructuring, as described in note 6 of these notes to our financial statements.

As of September 30, 2006, there was $3.2 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 estimated forfeitures. We expect to recognize that cost over a weighted average period of 1.4 years.

The Company received $10,000 and $29,000 from stock option exercises during the three and nine months ended September 30, 2006. During the three and nine months ended September 30, 2006, 22,989 and 46,520 shares, respectively, of common stock were issued under the Company s 2000 Purchase Plan resulting in proceeds to the Company of $0.1 million.

(4) THIRD PARTY ROYALTY CONTINGENCY

Under the terms of the Company s amended license agreement with LabCorp, the Company is contingently liable to reimburse LabCorp for a portion of certain fixed, third-party royalty payments (the Royalty Amount) made by LabCorp to other parties in connection with its sales of PreGen-Plus. The Company s liability to pay the Royalty Amount is based on sales volumes of PreGen-Plus over the exclusive period of the license agreement that terminates on August 13, 2008, and is contingent upon LabCorp requesting such payment. LabCorp has not requested any such payment to date. Based on the sales volumes of PreGen-Plus through September 30, 2006, the potential Royalty Amount was $2.2 million. A significant increase in PreGen-Plus test sales volumes through August 13, 2008, would reduce this obligation, potentially to zero, while test volumes consistent with historical PreGen-Plus sales levels could increase the potential Royalty Amount.

The Company is currently in discussions with LabCorp regarding the terms of the license agreement. Based upon these discussions, the Company believes that at this time, it is not probable that LabCorp will request payment of the Royalty Amount and, accordingly, has not

accrued any portion of the Royalty Amount in the accompanying financial statements. There can be no assurance

that the Company will be able to successfully negotiate an amendment to the license agreement that would eliminate the Company s contingent liability to pay the amounts described above.

(5) EMPLOYMENT ARRANGEMENTS

On June 27, 2006, the Company entered into an Employment Agreement with Don M. Hardison, the Company s President and Chief Executive Officer. Under the Employment Agreement, Mr. Hardison will be paid an annual salary of $355,000 and will be eligible to earn an annual performance bonus on the basis of the achievement of certain Company and personal objectives. Additionally, Mr. Hardison will be eligible to earn an annual retention bonus in the amount of $0.2 million, payable on each of January 1, 2007 and January 1, 2008, provided Mr. Hardison continues to be employed by the Company. The Employment Agreement provides that upon the occurrence of certain triggering events, such as a change of control or termination without cause, Mr. Hardison will be entitled to receive any unpaid retention bonus, and severance payments for a period of twelve months at a rate equal to his base salary at the time of termination of employment. The agreement provides a term of 24 months, subject to automatic twelve month renewals unless either Mr. Hardison or the Company provide sixty days prior written notice to the other of such party s election not to extend the term of the Employment Agreement.

In connection with the October 2006 restructuring described in note 6 below, the Company is in the process of entering into employment retention agreements (Retention Agreements) with its 23 remaining employees (Remaining Employees), including Jeffrey R. Luber, the Company s Senior Vice President, Chief Financial Officer, Treasurer, General Counsel and Secretary, and Charles R. Carelli, Jr., the Company s Vice President Finance. Under the terms of the Retention Agreements, in addition to their existing salary and benefits, Remaining Employees will be eligible to earn a one-time retention bonus in the aggregate amount of approximately $0.9 million payable on December 31, 2007 (subject to acceleration in certain instances), provided that the Remaining Employees continue to be employed by the Company on the payment date. 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 for periods ranging from three to twelve months at a rate equal to their base salary at the time of termination of employment.

As of September 30, 2006, the Company has accrued approximately $0.1 million in compensation costs in connection with the retention bonuses for the Remaining Employees and Mr. Hardison. The Company intends to accrue the remaining cost of the retention bonuses, currently estimated to be approximately $1.3 million, on a straight line basis over the remaining retention period, which ends on December 31, 2007.

(6) SUBSEQUENT EVENT

On October 17, 2006, the Company initiated a plan to reduce its cost structure by eliminating 21 positions, or 48% of its staff, across all departments. This workforce reduction reflects the Company s intention to reduce its expenses and preserve its existing cash and cash equivalents. Following the workforce reduction, the Company s efforts are expected to focus on the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations (including the guidelines of the American Cancer Society, American College of Gastroenterology, and the American Gastroenterological Association), Medicare coverage pursuit for stool-based DNA testing, and validation of the Company s Version 2 technology.

Estimated charges of approximately $0.7 million are expected to be recorded in the fourth quarter of 2006 in connection with one-time employee termination benefits, including severance, outplacement and fringe benefits. All of the charges will result in future cash expenditures. The Company is in the process of assessing its current facility needs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements or other fixed assets, in the event facilities are consolidated. Until its facility plans are finalized, the Company can not currently estimate the amount of those charges, if any.

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 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, 2005, which has been filed with the Securities and Exchange Commission (the SEC).

Forward-Looking Statements

This Quarterly Report on Form 10-Q, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as believes, expects, may, will, should, could, seek, plans, estimates, anticipates or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q include, among others, statements regarding the building of material market demand, the sufficiency of capital resources, expected royalty fees and revenues, expected revenues and sales and marketing expenses, the impact of regulatory agency action on the marketing and sale of PreGen-Plus, the focus and level of research and development efforts and development of new technologies, expectations regarding third-party reimbursement of PreGen-Plus, expected restructuring charges, inclusion of stool-based DNA screening in colorectal cancer screening guidelines, our expectations concerning our commercial strategy, and the effectiveness and market acceptance of our technologies and PreGen-Plus. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, including those risks and uncertainties described in Item 1A of this report and our Annual Report on Form 10-K for the year ended December 31, 2005. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

EXACT Sciences Corporation develops proprietary DNA-based technologies for use in the detection of cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis through August 2008 to Laboratory Corporation of America® Holdings (LabCorp®) for use in a commercial testing service developed by LabCorp and marketed under the name PreGen-Plus . PreGen-Plus is a non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. Since our inception in February 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;
- conducting clinical studies to validate our colorectal cancer screening technologies;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our proprietary technologies to LabCorp;
- working to further the adoption of stool-based DNA testing for colon cancer, including seeking inclusion of such technology in the guidelines of the major guidelines organizations;
- working with LabCorp on activities in support of the commercialization of PreGen-Plus; and

- sales and marketing efforts in support of PreGen-Plus.

We have generated limited operating revenues since our inception and, as of September 30, 2006, we had an accumulated deficit of approximately $148.3 million. Our losses have historically resulted from costs incurred in conjunction with our research and development initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and the build-out of our sales infrastructure to support the commercialization and marketing of PreGen-Plus. We expect that our losses will continue for the next several years as a result of continuing research, development, sales and marketing expenses.

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through September 30, 2006, LabCorp had accessioned approximately 11,900 PreGen-Plus samples, including approximately 4,000 samples during the year ended December 31, 2005 and approximately 800 and 3,000 samples during the three and nine months ended September 30, 2006, respectively. To achieve sufficient demand for PreGen-Plus, we believe that stool-based DNA testing must be included in colorectal cancer screening guidelines of the major guidelines organizations (including the guidelines of the American Cancer Society, American College of Gastroenterology, and the American Gastroenterological Association) and that substantial funds will likely need to be invested in sales and marketing efforts over the next several years. We do not have, and we cannot assure you that LabCorp will devote, the funds that we believe are likely necessary to build sufficient demand for PreGen-Plus. Even if stool-based DNA screening is included in colorectal cancer screening guidelines and sufficient amounts are invested in sales and marketing efforts, our success will also depend upon a number of factors that are largely out of our control, including the following:

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

- whether LabCorp continues to offer PreGen-Plus commercially;

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

- effective LabCorp sales and sales management personnel and processes to educate physician staffs regarding PreGen-Plus and patient compliance;

- our success in educating third-party payors, managed care organizations, and technology assessment groups regarding stool-based DNA screening;

- patient acceptance of PreGen-Plus, including its novel sample collection process;

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

- the quality and service of the LabCorp testing process.

Until such time as some or all of the factors outlined above are in place, we do not expect material revenue growth. Our revenue is comprised of product royalty fees on PreGen-Plus tests sold by LabCorp, product revenue from the sale to LabCorp of Effipure components, which are used by LabCorp in processing PreGen-Plus tests, and the amortization of license fees for the licensing of product rights to LabCorp under our strategic license agreements. We expect that product royalty fees and product revenue for 2006 will be substantially consistent with amounts recorded in 2005. LabCorp informed the FDA that they are working on changes to PreGen-Plus that could eliminate the use of Effipure by the end of 2006. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp after December 2006. The potential loss of this revenue beginning in 2007 is not expected to have a material impact on our gross margins because, under our agreement with LabCorp, our Effipure sales to LabCorp resulted in no gross margin as LabCorp reimbursed us only for our costs to provide Effipure to them.

We account for PreGen-Plus royalty fees on a cash basis and expect to continue to do so until such time as we have sufficient history and experience to estimate the percentage of PreGen-Plus accessions that will ultimately result in revenue for us. 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. We recognize our license fee revenue on a straight-line basis over the applicable exclusive license period. License fee revenue for 2006 is expected to be higher than license fee revenue recorded in 2005 due to the one time, non-cash reduction in license fee revenue of $0.6 million recorded in the quarter ended June 30, 2005 in connection with the extension of the expiration date of a warrant issued to LabCorp.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies and, effective as of January 1, 2006, non-cash stock-based compensation related to the amortization of the fair value of stock option awards granted to employees. In 2006, our research and development efforts have focused on improving the sensitivity and other performance aspects of our stool-based DNA screening technology for colorectal cancer and, accordingly, we expect that research and development expenses in 2006 will be lower than 2005 levels. We continue to optimize and validate the next generation of our colorectal cancer screening technology, or Version 2.0 of our technology, and we may need to invest substantial funds in

additional research, design and development associated with such efforts.

Selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees and, as of January 1, 2006, non-cash stock-based compensation related to the amortization of the fair value of stock option awards granted to employees. We expect sales and marketing expenses in 2006 to be lower than 2005 levels primarily as a result of lower headcount and external promotional spending. We expect general and administrative expenses to be higher in 2006 than 2005 levels

as a result of increases in non-cash stock-based compensation recorded in 2006 as a result of the adoption of Statement of Financial Accounting Standards (SFAS) No. 123(R) on January 1, 2006.

Recent Developments

October 2006 Restructuring. On October 17, 2006, we initiated a plan to reduce our cost structure by eliminating 21 positions, or 48% of our staff, across all departments to reduce expenses. Following the workforce reduction, our efforts are expected to focus on the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations (including the guidelines of the American Cancer Society, American College of Gastroenterology, and the American Gastroenterological Association), Medicare coverage pursuit for stool-based DNA testing, and optimization and validation of our Version 2 technology.

Estimated charges of approximately $0.7 million are expected to be recorded in the fourth quarter of 2006 in connection with one-time employee termination benefits, including severance, outplacement and fringe benefits. All of the charges will result in future cash expenditures. We are in the process of assessing our current facility needs and could incur additional restructuring charges, in the form of write-offs of leasehold improvements or other fixed assets, in the event facilities are consolidated. Until our facility plans are finalized, we can not currently estimate the amount of those charges, if any.

In connection with our October 2006 restructuring, we are in the process of entering into employment retention agreements (Retention Agreements) with our 23 remaining employees (Remaining Employees), including Jeffrey R. Luber, our Senior Vice President, Chief Financial Officer, Treasurer, General Counsel, and Secretary, and Charles R. Carelli, Jr., our Vice President Finance. Under the terms of the Retention Agreements, in addition to being paid their base annual salaries, Remaining Employees will be eligible to earn a one-time retention bonus in the in the aggregate amount of approximately $0.9 million payable on December 31, 2007 (subject to acceleration in certain circumstances), provided that the Remaining 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 for periods ranging from three to twelve months at a rate equal to their base salary at the time of termination of employment. In addition to the Retention Agreements described above, in June 2006 we entered into an employment agreement with Don M. Hardison, our President and Chief Executive Officer, under which he is eligible to earn an annual retention bonus in the amount of $0.2 million payable on each of January 1, 2007 and January 1, 2008, provided that he continues to be employed by on the date of payment. As of September 30, 2006, we had accrued approximately $0.1 million in compensation costs in connection with the retention bonuses for the Remaining Employees and Mr. Hardison. We intend to accrue the remaining cost of the retention bonuses, currently estimated to be approximately $1.3 million, on a straight line basis over the remaining retention period, which ends on December 31, 2007. See note 5 of the notes to our condensed consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q for a description of the employment agreement between the Company and Don M. Hardison.

Colorectal Cancer Screening Guidelines. In June 2006, the American Cancer Society Colorectal Cancer Advisory Committee and the U.S. Multi-Society Task Force on Colorectal Cancer (the ACS-MSTF) commenced a review of stool-based DNA and other colorectal cancer screening technologies as part of their review of colorectal cancer screening guidelines. In September 2006, the ACS-MSTF convened for a second time to discuss revised colorectal cancer screening guidelines pertaining to new and existing technologies, including stool-based DNA testing, computed tomographic colonography (i.e., virtual colonoscopy), traditional colonoscopy, flexible sigmoidoscopy, double contrast barium enema, and new and existing approaches to detect blood in stool (i.e., guaiac- and immunochemical-FOBT). Subsequent to the September ACS-MSTF meeting, we were informed that no guidelines decisions on any technology were made and that deliberations regarding such technologies are continuing.

It is possible that the ACS-MSTF may reject stool-based DNA screening or defer a recommendation regarding such screening for a number of reasons, including, potentially, until such time as our Version 2.0 colorectal cancer screening technology is fully developed and adequately supported by clinical data, which could take several years, if it happens at all. Moreover, even if a recommendation is made to include stool-based DNA screening in guidelines, such inclusion could involve a recommendation for only a narrow screening purpose or subset of the population, or for some other limited purpose or application of stool-DNA screening that does not provide for broad use of stool-DNA screening or otherwise enable us to maintain a viable business model.

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. Additionally, even if a recommendation is made to include stool-based DNA screening in guidelines,

such inclusion could involve a process spanning many months from the meeting of key guidelines decision-makers to notification of inclusion or exclusion from guidelines. If stool-based DNA screening is 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 ($0.8 million at September 30, 2006) or our fixed assets.

Regulatory Developments. On January 13, 2006, the U.S. Food and Drug Administration (the FDA) sent correspondence to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure component used in processing PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device and that the device cannot be commercially distributed without an appropriate pre-market determination from the FDA. Pursuant to our and LabCorp s subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, we and LabCorp agreed, among other things, to revise our promotional activities with respect to LabCorp s PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests by the end of 2006. Based on the actions outlined above and our communications with the FDA, we believe that LabCorp intends to continue to market, sell and process the PreGen-Plus test as a homebrew testing service. Since the commercial launch of PreGen-Plus, LabCorp has offered the testing service as an in-house developed laboratory test, or homebrew testing service. The FDA has historically exercised enforcement discretion with regard to such homebrew tests, by not requiring FDA pre-market clearance or approval for such testing services. On September 7, 2006, however, the FDA issued a Draft Guidance Document in which the FDA said that homebrew tests were subject to FDA regulation as devices, and that the FDA would not exercise enforcement discretion with respect to laboratories that offer certain types of homebrew tests involving the use of algorithms and/or scoring of results. Although we do not believe that the PreGen-Plus test represents the type of algorithm-based or scoring test to which this Draft Guidance Document refers, we cannot assure you that the FDA will view LabCorp s PreGen-Plus testing service, in whole or in part, as exempt from pre-market approval requirements. If the FDA does not view LabCorp s PreGen-Plus testing service as exempt from pre-market approval, LabCorp s use of PreGen-Plus could be delayed, halted or prevented and enforcement action could be initiated which could involve criminal or civil penalties, any of which would impair the commercialization of PreGen-Plus and materially harm our business.

In addition, as part of our long-term development plan for our Version 2.0 technology, we are in the early stages of planning for the potential development of a stool-based DNA *in vitro* diagnostic test kit that we believe would be required to be submitted to the FDA for approval prior to marketing. This is distinct from LabCorp s PreGen-Plus testing service, which remains on the market today as a homebrew testing service. LabCorp s license to our technologies includes rights to current versions of our technologies for a homebrew developed testing service, as well as any improvements we make to such technology, including Version 2.0. LabCorp does not have rights to a FDA-approved *in vitro* diagnostic test kit of Version 2.0 that we may develop.

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, 2005, 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 accounting policies most critical to aid in fully understanding and evaluating our reported financial results are revenue recognition and the assessment of the recoverability of long-lived assets, primarily intellectual property.

Revenue Recognition. License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period.

Royalties earned on PreGen-Plus tests performed by LabCorp are based upon the customer s remittance to LabCorp, not the amount billed. Until such time as we have sufficient history and experience to estimate the percentage of PreGen-Plus accessions to LabCorp that will ultimately result in revenue for us, we will continue to recognize royalties as LabCorp customers make payments.

The timing of payments to LabCorp is uncertain because of the variable time lag between invoicing and payment and the number of parties involved in the reimbursement process.

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

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

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

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 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.

Stock-Based Compensation

Prior to January 1, 2006, we accounted for our stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). We adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (ESPP) to be recognized in the financial statements based on their fair values. SFAS 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No.123, *Accounting for Stock Based Compensation* (SFAS No. 123), as originally issued and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Under the modified prospective transition method, we recognized stock-based compensation expense during the three and nine months ended September 30, 2006 in connection with: (a) stock options and restricted stock awards granted and employee stock purchase plan awards with offering periods commencing prior to, but not yet vested, as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) stock options and restricted stock awards granted, and employee stock purchase plan awards with offering periods commencing subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Under the modified prospective transition method, results for prior periods are not restated. As a result of the adoption of SFAS No. 123(R), we recorded incremental stock-based compensation expense in connection with the foregoing in our consolidated statements of operations for the three and nine months ended September 30, 2006 of $0.6 million and $2.2 million, respectively.

Total stock-based compensation recorded in the three and nine months ended September 30, 2006 of $0.7 million and $2.4 million, respectively, included $42,000 and $0.2 million, respectively, recorded in connection with stock options and restricted stock awards granted to non-employee consultants and directors as well as stock-based compensation expense related to our 2006 401(k) match which, if approved by our board of directors, is made annually in our common stock. Prior to the adoption of SFAS No. 123(R) on January 1, 2006, we, in accordance with APB 25, recognized expenses related to non-employee consultant stock option grants and restricted stock awards and our 401(k) match in our consolidated statements of operations.

The amounts in the table below represent solely the impact of expenses recorded in our consolidated statements of operations in connection with employee and director stock option grants and the 2000 Purchase Plan in accordance with SFAS No. 123(R). Non-employee consultant stock option grants, restricted stock awards and our 2006 401(k) match are accounted for similarly under both APB No. 25 and SFAS No. 123(R) and are therefore excluded from the table below.

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(in thousands)	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 74	$ 388
Sales and marketing	271	884
General and administrative	282	954
	$ 627	$ 2,226

As a result of adopting SFAS No. 123(R) on January 1, 2006, our loss from operations, as well as our net loss, for the three and nine months ended September 30, 2006, were $0.6 million and $2.2 million higher, respectively, than if we had continued to account for stock-based compensation under APB No. 25. Basic and diluted loss per share for the three and nine months ended September 30, 2006 were $0.02 and $0.08 higher, respectively, than if we had continued to account for stock-based compensation under APB No. 25.

Determining Fair Value

Valuation and Amortization Method - The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the 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 - We use the simplified calculation of expected life, described in the SEC s Staff Accounting Bulletin 107, as we do not currently have sufficient historical exercise data on which to base an estimate of expected term. This method allows us 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 our historical volatility from the time of our initial public offering in January of 2001 through September 30, 2006. Expected volatility was lower in the first three quarters of 2006 when compared to the same period of 2005 as we refined our expectation because, as of January 2006, we had at least five years of historical volatility data on which to base our expectation. Prior to January 1, 2006, sufficient historical volatility data did not exist to reasonably justify a lower expected volatility.

Risk-Free Interest Rate - We base 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), we record share-based compensation expense only for those awards that are expected to vest.

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, 2005		Three Months Ended September 30, 2006		Nine Months Ended September 30, 2005		Nine Months Ended September 30, 2006	
Option Plan Shares								
Risk-free interest rates	4.06	%	5.03	%	3.94% - 4.06	%	4.59% - 5.03	%
Expected term (in years)	7		6		7		6	
Expected volatility	100	%	70	%	100	%	70	%
Dividend yield	0	%	0	%	0	%	0	%
Weighted average fair value per share of options granted during the period	$1.97		$1.06		$3.21		$1.67	
ESPP Shares								
Risk-free interest rates	N/A		5.06% - 5.22	%	N/A		4.57% - 5.22	%

Expected term (in years)	N/A	0.5 - 2	N/A	0.5 - 2	
Expected volatility	N/A	70	% N/A	70	%
Dividend yield	N/A	0	% N/A	0	%
Weighted average fair value per share of stock purchase rights granted during the period	N/A	$0.86	N/A	$0.94	

Pro Forma Information Under SFAS No. 123 for Periods Prior to January 1, 2006

The following table illustrates the effect on net income and earnings per common share if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation. Note that the pro forma disclosures below are provided for the three and nine months ended September 30, 2005 only because employee stock options were not accounted for using the fair value

method during that period. When we present our financial statements for the three and nine months ended September 30, 2007, we will not present any comparative pro-forma disclosures because share-based payments will have been accounted for under the SFAS No. 123(R) fair value method for the three and nine months ended September 30, 2006 and 2007.

(In thousands, except per share data)	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss as reported	$ (3,289)	$ (11,825)
Add: Stock-based compensation included in reported net loss	(81)	274
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(1,652)	(5,980)
Pro forma net loss - SFAS No. 123	$ (5,022)	$ (17,531)
Basic and diluted net loss per share:		
As reported	$ (0.13)	$ (0.45)
Pro forma net loss - SFAS 123	$ (0.19)	$ (0.67)

Results of Operations

Revenue. Total revenue was $1.2 million for the three months ended September 30, 2006 and 2005. Total revenue increased to $3.6 million for the nine months ended September 30, 2006 from $3.1 million for the nine months ended September 30, 2005. Revenue is primarily composed of the amortization of up-front technology license fees associated with agreements signed with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in August 2008, and, to a lesser extent, royalties on LabCorp s sales of PreGen-Plus, and sales of Effipure units to LabCorp.

The increase in total revenue for the nine months ended September 30, 2006 as compared to the same period for the prior year was primarily the result of a one-time, non-cash reduction in revenue of $0.6 million recorded in June 2005 in connection with the amendment of a warrant issued to LabCorp in June 2002 to purchase 1,000,000 shares of our common stock, at an exercise price of $16.09 per share (the LabCorp Warrant). At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, we entered into an amendment to the LabCorp Warrant to extend the expiration date of the LabCorp Warrant to August 13, 2008, which is the expiration date of the exclusive period under our license agreement with LabCorp. All other terms of the LabCorp Warrant were unaffected. We assigned a value to the LabCorp Warrant extension of $0.6 million using the Black-Scholes option pricing model. In accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer*, we recorded the cost of the LabCorp Warrant extension as a one-time, non-cash reduction in license fee revenue of $0.6 million in the quarter ended June 30, 2005.

During 2006, LabCorp informed the FDA that they are working on changes to PreGen-Plus that could eliminate the use of Effipure by the end of 2006. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp after December 2006. The loss of this revenue beginning in 2007 is not expected to have a material impact on our gross margins because, under our agreement with LabCorp, our Effipure sales to LabCorp resulted in no gross margin as LabCorp reimbursed us only for our costs to provide Effipure to them.

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. Total cost of revenue decreased to $0.1 million for the three months ended September 30, 2006 from $0.3 million for the three months ended September 30, 2005 and increased to $0.8 million for the nine months ended September 30, 2006 as compared to $0.5 million for the nine months ended September 30, 2005. The decrease in total cost of revenue for the three months ended September 30, 2006 as compared to the same period of 2005 was the result of lower write-offs of excess Effipure inventory. We wrote off $0.1 million and $0.3 million in excess Effipure inventory during the three months ended September 30, 2006 and 2005, respectively. The increase in the cost of product revenue for the nine months ended September 30, 2006 as compared to the same period of the prior year was primarily the result of higher write-offs of Effipure inventory. We wrote off $0.7 million and $0.4 million in excess Effipure inventory during the nine months ended September 30, 2006 and 2005, respectively. Specifically, we wrote-off approximately $0.5 million in excess Effipure inventory units during the quarter ended March 31, 2006 as a result of LabCorp s decision to

discontinue use of Effipure in the processing of PreGen-Plus tests beyond 2006.

During the development of the manufacturing and supply chain processes for Effipure components, we entered into agreements with certain suppliers and contract manufactures to produce components utilized in Effipure. Certain of these supply agreements

included minimum purchase commitments to be fulfilled by us over the life of the agreements, the last of which expired in April 2006. As of September 30, 2006, the carrying value of our Effipure inventory was approximately $25,000 and was recorded under the caption Prepaid expenses and other current assets in our consolidated balance sheets. We do not anticipate purchasing additional Effipure inventory.

We expect to continue to sell Effipure to LabCorp until LabCorp discontinues use of Effipure in the processing of PreGen-Plus tests, which we expect may occur by the end of 2006 based on LabCorp s communications to the FDA. There can be no assurance that LabCorp will be able to identify an alternative process for Effipure in connection with LabCorp s processing 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 by the end of 2006 if LabCorp does not have a suitable alternative to Effipure in place at that time.

Research and development expenses. Research and development expenses decreased to $1.7 million for the quarter ended September 30, 2006 from $1.9 million for the quarter ended September 30, 2005. The decrease in the three months ended September 2006 as compared to the same period of 2005 was primarily the result of the completion of the primary clinical study supporting Version 2 of our stool-based DNA technology in late 2005, resulting in lower research and development expenses in the three months ended September 30, 2006 as compared to the same period of 2005. Included in the total decrease for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005 were decreases of $0.1 million in clinical study expenses, $0.1 million in laboratory supplies and $0.1 million in personnel related expenses. These decreases were partially offset by an increase of $0.1 million in stock-based compensation expense for the three months ended September 30, 2006 as compared to the same period of 2005 as a result of the adoption of SFAS No 123(R) on January 1, 2006. See discussion of the adoption of SFAS No. 123(R) under the section Stock-Based Compensation above.

Research and development expenses decreased to $5.6 million for the nine months ended September 30, 2006 from $6.1 million for the nine months ended September 30, 2005. The decrease in the nine months ended September 30, 2006 as compared to the same period of 2005 was primarily the result of the completion of the primary clinical study supporting Version 2 of our stool-based DNA technology in late 2005, resulting in lower research and development expenses in the nine months ended September 30, 2006 as compared to the same period of 2005. In addition, we took actions in February 2005 to focus research and development efforts on improving the sensitivity and other performance aspects of our technologies and reduced our cost structure accordingly. As described under the heading Restructuring below, we discontinued certain research efforts and reduced our workforce by ten employees, principally in the research and development functions. Included in the decrease in research and development expenses for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005 were decreases of $0.4 million in personnel-related expenses, $0.3 million in clinical study expenses, $0.2 million related to laboratory space and $0.1 million in laboratory supplies. These decreases were partially offset by an increase of $0.4 million in stock-based compensation expense for the nine months ended September 30, 2006 as compared to the same period of 2005 as a result of the adoption of SFAS No 123(R) on January 1, 2006. See discussion of the adoption of SFAS No. 123(R) under the section Stock-Based Compensation above.

Sales and marketing expenses. Sales and marketing expenses decreased to $1.1 million for the three months ended September 30, 2006 from $1.2 million for the three months ended September 30, 2005 and decreased to $3.8 million for the nine months ended September 30, 2006 from $4.5 million for the nine months ended September 30, 2005. These decreases were primarily due to decreases of $0.4 million and $1.1 million, respectively, in personnel related expenses for the three and nine months ended September 30, 2006 as compared to the same periods of 2005 as a result of a reduction in the size of our sales and marketing force from twenty-five employees at September 30, 2005 to sixteen employees at September 30, 2006. We also reduced our external advertising, marketing and promotional spending by $0.5 million during the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. These reductions reflect a focus on spending primarily on those initiatives that directly or indirectly support guidelines inclusion, as well as a shift away from direct marketing to physicians to third-party payor groups, self-insured employers and technology assessment groups. These decreases were partially offset by increases of $0.3 million and $0.9 million, respectively, in stock-based compensation expense for the three and nine months ended September, 2006 as compared to the same periods of 2005 as a result of the adoption of SFAS No 123(R) on January 1, 2006. See discussion of the adoption of SFAS No. 123(R) under the section Stock-Based Compensation above.

General and administrative expenses. General and administrative expenses increased to $1.7 million for the three months

ended September 30, 2006 from $1.4 million for the three months ended September 30, 2005. General and administrative expenses increased to $4.8 million for the nine months ended September 30, 2006 from $3.9 million for the nine months ended September 30, 2005. These increases were primarily due to increases of $0.4 million and $0.9 million, respectively, in stock-based compensation expense recorded in the three and nine months ended September 30, 2006 as compared to the same periods of 2005 as a result of the adoption of SFAS No. 123(R) on January 1, 2006. See discussion of the adoption of SFAS No. 123(R) under the section Stock-Based Compensation above.

Restructuring. In February 2005, we took steps to focus our research and development efforts primarily on improving the sensitivity and other performance aspects of our technology and reduced our cost structure accordingly. We discontinued certain research efforts, reduced our workforce by ten employees, principally in the research and development functions, and amended the lease for our corporate headquarters in Marlborough, MA to reduce the total space leased at the facility from approximately 56,000 square feet to approximately 37,000 square feet.

Pursuant to the restructuring plan, we accrued charges of $0.6 million in the quarter ended March 31, 2005. As of June 30, 2005 all liabilities related to the restructuring had been paid. The table below summarizes the restructuring activities during the year ended December 31, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, December 31, 2005
Employee separation costs	$	$ 246	$ (246)	$	$
Facility consolidation costs		380	(98)	(282)	
Total	$	$ 626	$ (344)	$ (282)	$

Employee separation costs in the table above relate to severance packages and out-placement services for employees affected by the restructuring. Our decision to reduce the total space leased and abandon the related leasehold improvements was deemed to be an impairment indicator under SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. As a result of performing the impairment evaluations, asset impairment charges of $0.3 million (included opposite the caption Facility consolidation costs in the table above) were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one time real estate transaction fees in connection with the lease amendment to reduce the space occupied at our corporate headquarters.

Interest income. Interest income was $0.3 million for the three months ended September 30, 2006 and 2005. Interest income increased to $1.0 million for the nine months ended September 30, 2006 from $0.8 million for the nine months ended September 30, 2005. This increase was due to an increase in interest rates on investments held during the nine months ended September 30, 2005 as compared to the same period from the prior year partially offset by lower average cash, cash equivalents and marketable securities balances held during the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005.

Third Party Royalty Contingency

Under the terms of our amended license agreement with LabCorp, we are contingently liable to reimburse LabCorp for a portion of certain fixed third-party royalty payments (the Royalty Amount) made by LabCorp to other parties in connection with its sales of PreGen-Plus. Our liability to pay the Royalty Amount is based on sales volumes of PreGen-Plus over the exclusive period of the license agreement that terminates on August 13, 2008, and is contingent upon LabCorp requesting such payment. LabCorp has not requested any such payment to date. Based on the sales volumes of Pre-Gen-Plus through September 30, 2006, the potential Royalty Amount was $2.2 million. A significant increase in PreGen-Plus test sales volumes through August 13, 2008, would reduce this obligation, potentially to zero, while test volumes consistent with historical PreGen-Plus sales levels could increase the potential Royalty Amount due.

We are currently in discussions with LabCorp regarding the terms of the license agreement. Based upon these discussions, we believe that, at this time, it is not probable that LabCorp will request payment of the Royalty Amount and, accordingly, we have not accrued any portion of the Royalty Amount in our financial statements. There can be no assurance that we will be able to successfully negotiate an amendment to our license agreement that would eliminate our contingent liability to pay the amounts described above.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, public offerings of common stock in February 2001 and February 2004 and cash received from LabCorp in connection with our strategic alliance. As of September 30, 2006, we had approximately $24.4 million in cash, cash equivalents and marketable securities, of which approximately $0.8 million has been pledged as collateral for an outstanding letter of credit.

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 $9.7 million for the nine months ended September 30, 2006 as compared to $12.9 million for the nine months ended September 30, 2005. The principal use of cash in operating activities for the nine months ended September 30, 2006 and 2005 was to fund our net loss. The decrease in net cash used in operating activities for the nine months ended September 30, 2006 as compared the nine months ended September 30, 2005 was primarily due to decreases in sales and marketing and applied research spending as 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 $4.5 million for the nine months ended September 30, 2006, as compared to net cash provided by investing activities of $16.8 million for the nine months ended September 30, 2005. Excluding the impact of purchases and maturities of marketable securities (which fund the majority of our ongoing operations), net cash used in investing activities was $0.3 million for the nine months ended September 30, 2006 and 2005.

Purchases of property and equipment of $0.1 million during the nine months ended September 30, 2006 were materially consistent with purchases of property and equipment of $0.2 million during the nine months ended September 30, 2005. We expect that purchases of property and equipment during the remainder of 2006 will be substantially consistent with the $0.2 million invested in the full year 2005. We continued to invest in our patent portfolio for the nine months ended September 30, 2006 and we expect that investments made in our patent portfolio for the remainder of 2006 will be substantially consistent with the $0.2 million invested during 2005.

Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2006 and 2005 and represented proceeds from the issuance of common stock under our employee stock option and purchase plans.

Assuming no material cash outlays relating to a shift in our strategic direction or entry into new markets, we expect that cash, cash equivalents and short-term investments on hand at September 30, 2006 will be sufficient to fund our current operations for at least the next twelve months based upon our current operational plan following the restructuring actions taken in October 2006. We do not expect that product royalty payments from LabCorp will materially supplement our liquidity position in the next twelve months given that, among other things, a determination has not yet been made regarding the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, the Centers for Medicare and Medicaid Services (CMS) have not approved stool-based DNA colorectal cancer screening for payment and no payors have issued formal broad policy approving payment for stool-based DNA screening. Although milestone and other performance-based payments from LabCorp for which we may be eligible under our strategic agreement may supplement our liquidity position, the timing and receipt of milestone and performance-based payments is unpredictable at this time. Of the remaining $45 million of payments for which we may be eligible under our amended agreement with LabCorp, $15 million relates to milestone payments associated with the inclusion of stool-based DNA testing for colorectal cancer into certain clinical guidelines and policy-level reimbursement approvals that, in large part, depend upon decisions to be made by third parties. The remaining $30 million relates to the achievement of certain significant cumulative LabCorp revenue thresholds that depend upon LabCorp s widespread success with respect to its sales of PreGen-Plus. Because these milestones are not expected in the foreseeable future, if at all, no assurance can be given that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. In addition, we continue to selectively explore potential acquisitions or licensing of technologies to broaden our technology portfolio. If revenue and other payments from LabCorp are insufficient to meet our liquidity needs, if we change our strategic direction or pursue an acquisition of new technologies, or if we determine that our sales, marketing or research and development expenses must increase to achieve our goals, we will be required to raise additional capital or further reduce the scale of our operations, or both.

The table below reflects our estimated fixed obligations and commitments as of September 30, 2006:

Description	Payments Due by Period Total (in Thousands)	Less Than One Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Obligations under license and collaborative agreements	$ 5,508	$ 788	$ 630	$ 630	$ 3,460
Operating lease obligations	3,803	953	1,990	860	
Retention bonus obligations in connection with employment agreements	1,300	200	1,100		
Purchase obligations	259	259			
Total	$ 10,870	$ 2,200	$ 3,720	$ 1,490	$ 3,460

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with leased facilities in Marlborough, Massachusetts. Retention bonus obligations represent commitments to our remaining employees following our October 2006 restructuring, as well as obligations under our employment agreement with Don Hardison, our President and Chief Executive Officer. Purchase obligations primarily represent commitments associated with our research and development activities. We do not have any special purpose entities or any other off balance sheet financing arrangements.

Our future capital requirements include, but are not limited to, continued funding of our research and development efforts, product development and potential FDA submissions, potential clinical studies required for such FDA submissions, sales and marketing efforts associated with the commercialization of stool-based DNA screening technologies, purchases of laboratory equipment and continued investment in our intellectual property estate. Our future capital requirements may depend on many factors, including the following:

- the inclusion of stool-based DNA screening in colorectal cancer screening guidelines of major guidelines organizations (including the American Cancer Society, the American College of Gastroenterology, the American Gastroenterological Association and the U.S. Preventative Services Task Force) and the timing thereof;

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

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

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

- a determination that additional studies surrounding our technologies are needed;

- a sustained level of interest and commitment by LabCorp in the commercialization of 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;

- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies; and

- a shift in our strategic direction or entry into new markets.

Until such time as some or all of the factors outlined above are in place, we do not expect material revenue growth. Moreover, if stool-based DNA screening is not included in colorectal cancer screening guidelines of one or more major organizations issuing guidelines

recommendations, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected and our business direction may change. In such event, we would likely be required to further significantly curtail our operations.

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

Off-Balance Sheet Arrangements

As of September 30, 2006, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company s exposure to market risk is principally confined to its 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 United States 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, 2006, 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

From time to time we update, revise and supplement the risk factors described under the title Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. 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, 2005 other than the deletion of a risk factor entitled If Effipure technology is replaced in commercial use by new or improved technologies, existing Effipure inventories could become obsolete, which could require the write off of existing inventory that would negatively impact our gross margins and profitability, the addition of a risk factor entitled If stool-based DNA screening is not included in colorectal cancer screening guidelines of the major organizations issuing guidelines recommendations, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected, and a change to the risk factors below entitled 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, We may never successfully commercialize any of our technologies or become profitable, Our business is substantially dependent on the success of our strategic agreement with LabCorp and The loss of key members of our senior management team could adversely affect our business. These sections have been updated to reflect recent developments with the U.S. Food and Drug administration and recent changes in management and agreements with management, respectively. In addition, we have updated several of our risk factors to reflect the proposed elimination in 2006 by LabCorp of its use of Effipure in processing PreGen-Plus tests.

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks which may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. 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 following risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

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

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

In addition, following its June 2006 meeting, the ACS-MSTF requested certain information from us relating primarily to our Version 2.0 next generation colorectal cancer technology. It is possible that ACS-MSTF may reject stool-based DNA screening or defer a recommendation regarding such screening for a number of reasons, including until such time as our Version 2.0 colorectal cancer screening technology is fully developed and adequately supported by clinical data, which could take several years, if it happens at all. Moreover, even if a recommendation is made to include stool-based DNA screening in guidelines, such inclusion could involve a recommendation for only a narrow screening purpose or subset of the population, or for some other limited purpose or application of stool-DNA screening that does not provide for broad use of stool-DNA screening. If stool-based DNA screening is not included in colorectal cancer screening guidelines for broad and sufficiently frequent use within the population at the next anticipated meeting of the ACS-MSTF, or if inclusion or notification of inclusion in such screening guidelines is significantly delayed, our business, financial condition and results of operations would be materially adversely affected and our business direction may change. In such event, we could be required to further significantly curtail our operations. In addition, an adverse guidelines determination could result in the impairment of the recorded value of our patent portfolio ($0.8 million at September 30, 2006) or our fixed assets.

We may never successfully commercialize any of our technologies or become profitable.

We have incurred losses since we were formed and have had only modest product and royalty fee revenues since the commercial launch of PreGen-Plus in August 2003. From our date of inception on February 10, 1995 through September 30, 2006, we have accumulated a total deficit of approximately $148.3 million. We expect that our losses will continue for at least the next several years and, depending upon our strategic direction, we may need to invest significant funds toward an FDA-approved test. Moreover, to achieve material demand for PreGen-Plus, or other stool-based DNA testing services utilizing our technologies, we believe that substantial funds will likely need to be invested in sales and marketing efforts over the next several years. Given our current levels of cash and revenues, and without raising additional capital, we will not be able to spend the amounts that we believe will likely be necessary to fund these investments and there can be no assurance that LabCorp will invest sufficient amounts in sales and marketing activities for PreGen-Plus. In addition, while we believe we are permitted, from a regulatory standpoint, to promote stool-based DNA testing services generically, our inability to market the brand PreGen-Plus under current FDA regulations, may limit our return on amounts that EXACT has invested or may invest in sales and marketing activities. If our revenue does not grow significantly, we will not be profitable. We cannot assure you that the revenue from the sale of any of our technologies will be sufficient to make us profitable.

Our future revenues will depend, in large part, upon whether PreGen-Plus is broadly ordered by medical practitioners and requested by patients. We believe that our ability to achieve the foregoing may be affected by the following:

- the inclusion of stool-based DNA screening in colorectal cancer screening guidelines of major guidelines organizations (including the American Cancer Society, the American College of Gastroenterology, and the American Gastroenterological Association);

- the regulatory requirements for PreGen-Plus and the timing of any required regulatory filing and approval process;

- whether LabCorp continues to offer PreGen-Plus commercially;

- material investment in sales and marketing;

- material investment in product development;

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

- whether payors issue favorable coverage policy for stool-based DNA screening if it is included in the screening guidelines of one or more, but not all, of the major guidelines organizations;

- effective LabCorp sales and sales management personnel and processes to educate physician staffs regarding PreGen-Plus and patient compliance;

- effective EXACT personnel to educate third-party payors, managed care organizations, and technology assessment groups regarding stool-based DNA screening;

- patient acceptance of PreGen-Plus, including its novel sample collection process;

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

- the quality and service of the LabCorp testing process.

Many of these factors are outside our control and, accordingly, we cannot assure you that one or more of the foregoing will occur in the near term, or at all. Failure to achieve one or more of the foregoing events could substantially impair our ability to generate revenues and achieve profitability and will negatively impact the successful commercialization of PreGen-Plus or other stool-based DNA testing services utilizing our

technologies.

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.

On January 13, 2006, the FDA sent correspondence to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure component used in processing PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device and that the device cannot be commercially distributed without an appropriate pre-market determination from the FDA. Pursuant to our and LabCorp s subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, we and LabCorp agreed, among other things, to revise our promotional activities with respect to LabCorp s PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests by the end of 2006. Based on the actions outlined above and our communications with the FDA, we believe that LabCorp intends to continue to market, sell and process the PreGen-Plus test as a homebrew testing service. Since the commercial launch of PreGen-Plus, LabCorp has offered the testing service as an in-house developed laboratory test, or homebrew testing service. The U.S. Food and Drug Administration (the FDA) has historically exercised enforcement discretion with regard to such homebrew tests, by not requiring FDA pre-market clearance or approval for such testing services. On September 7, 2006, however, the FDA issued a Draft Guidance Document in which the FDA said that homebrew tests were subject to FDA regulation as devices, and that the FDA would not exercise enforcement discretion with respect to laboratories that offer certain types of homebrew tests involving the use of algorithms and scoring of results. Although we do not

believe that the PreGen-Plus test represents the type of algorithm-based or scoring test to which this Draft Guidance Document refers, we cannot assure you that the FDA will view LabCorp s PreGen-Plus testing service, in whole or in part, as exempt from pre-market approval requirements. If the FDA does not view LabCorp s PreGen-Plus testing service as exempt from pre-market approval, LabCorp s use of PreGen-Plus could be delayed, halted or prevented and enforcement action could be initiated which could involve criminal or civil penalties, any of which would impair the commercialization of PreGen-Plus and materially harm our business.

Moreover, if the FDA were to determine that any of our technologies or other materials that we provide in used in connection with LabCorp s PreGen-Plus testing service require pre-market approval or clearance, we would be subject to a number of FDA requirements, including compliance with the September 7, 2006 Draft Guidance Document or restrictions regarding performance claims as well as the FDA s Quality System Regulation, which establishes extensive regulations for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement action against us, our partners, or our contract manufacturers. Adverse FDA action in any of these areas, including, for example, requiring pre-market approval or clearance for PreGen-Plus or any element that comprises PreGen-Plus, could cause material interruption in LabCorp s ability to continue offering the PreGen-Plus testing service and could significantly increase our expenses and limit our revenue and profitability.

Our ability to generate revenue depends on LabCorp s commercial sales of PreGen-Plus.

Our current operating revenue is dependent upon LabCorp s commercial sales of PreGen-Plus. We cannot assure you that LabCorp will be successful in achieving sufficient sales of PreGen-Plus for us to become profitable, nor can we be certain that LabCorp, in light of FDA regulatory action or otherwise, will keep PreGen-Plus on the market.

If LabCorp is unsuccessful in increasing sales of PreGen-Plus, our revenues will be limited and our ability to become profitable will be materially adversely affected. Moreover, given the number of products that LabCorp sells, we cannot assure you that LabCorp will devote the substantial level of resources and attention necessary to make PreGen-Plus commercially successful. Any failure of the LabCorp sales force to give continued and sustained focus to PreGen-Plus could harm the demand creation for PreGen-Plus and, in turn, could materially adversely affect our revenues and delay any performance-based payments for which we might otherwise be eligible, based on substantial sales volumes, under our strategic agreement with LabCorp. Any change in the senior management or organizational structure within LabCorp or us, could also negatively impact our ability to successfully commercialize PreGen-Plus.

Further, laboratory operating factors incurred at LabCorp such as turnaround times for the testing process, possible pre- and post-analytical sample and sample processing deficiencies and efforts to obtain third-party reimbursement all influence the rate of market adoption of PreGen-Plus. If LabCorp encounters difficulty performing PreGen-Plus tests on an accurate and timely basis or has difficulty obtaining reimbursement, our revenue could be materially and adversely affected. Future demand for the PreGen-Plus test may require LabCorp to further optimize operational and quality assurance processes to support commercial testing. No assurance can be given that such improvements will be successfully implemented by LabCorp, and failure to do so could adversely affect our ability to generate revenues.

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

We have a strategic alliance with LabCorp, under which we licensed to LabCorp certain of our technologies, including improvements to such technologies, that are required for the commercialization of PreGen-Plus. The license to LabCorp is exclusive within the United States and Canada for a five-year term followed by a non-exclusive license for the life of the underlying patents. LabCorp has the ability to terminate this agreement for, among other things, a material breach by us. If LabCorp were to terminate the agreement, fail to meet its obligations under the agreement or otherwise decrease its commitment to PreGen-Plus, our revenues would be materially adversely affected, the commercialization of PreGen-Plus would be interrupted and we could become insolvent. We cannot guarantee that we would be able to enter into a similar agreement with another company to commercialize this technology. Moreover, if we do not achieve certain milestones, or LabCorp does not achieve certain revenue and performance thresholds within the time periods prescribed in the agreement, we may not fully realize the expected benefits of the agreement.

In January 2004, we and LabCorp amended our license agreement to, among other things, restructure certain product development milestones. Although this amendment did not change the $45 million of total milestone payments that we may be eligible to receive under the agreement, it modified the targets set for achievement of these milestones and, as such, made it more difficult for us to fully realize these payments if LabCorp is unable to achieve significant revenue thresholds with respect to its sales of PreGen-Plus or if we are unable to obtain clinical guideline acceptance and policy-level reimbursement approvals for PreGen-Plus. In addition, we are currently in discussions that could result in an amendment to the license agreement. We cannot assure you that our prior amendment, these recent discussions or other strategic initiatives with LabCorp will accomplish the long-term goals of either party. If one or more additional amendments to our agreement with LabCorp become necessary as a result of the continuing evolution of PreGen-Plus, developments in our relationship with LabCorp or otherwise, we cannot assure you that any such amendment could be entered into on favorable terms, if at all.

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

If Medicare and other third-party payors, including managed care organizations, do not issue positive policy decisions approving reimbursement for PreGen-Plus, the commercial success of PreGen-Plus would be compromised.

Many physicians may decide not to order colorectal cancer screening tests using our technologies unless the tests are adequately reimbursed by third-party payors, including Medicare. There is significant uncertainty concerning third-party reimbursement for the use of tests incorporating new technology. Reimbursement by a third-party payor may depend on a number of factors, including a payor s determination that tests using our technologies are: sensitive for colorectal cancer; not experimental or investigational; approved by the major guidelines organizations; reliable, safe and effective, medically necessary; appropriate for the specific patient and cost-effective. Currently, no third-party payors have issued broad formal policy approving payment for stool-based DNA testing. Furthermore, the Centers for Medicare and Medicaid Services (CMS) have not yet approved stool-based DNA testing for colorectal cancer for payment, CMS has not yet accepted our request for a National Coverage Determination and CMS has sought additional information regarding the FDA regulatory status of PreGen-Plus and the performance and protocol relating to the PreGen-Plus assay, which has delayed our application s acceptance.

Neither we nor LabCorp has secured any broad-based policy-level reimbursement approval from Medicare or a sufficient amount of third-party payors to ensure the long-term commercial success of PreGen-Plus. For example, although PreGen-Plus received a favorable review from the California Technology Assessment Forum (CTAF), a unit of the Blue Shield of California Foundation, in March 2005, this review has not resulted in any policy-level reimbursement approval by Blue Shield of California. Moreover, several Blues plans across the country have declined to issue positive reimbursement policy for PreGen-Plus at this time.

If we or LabCorp are unable to obtain a positive policy decision from CMS or other third-party payors, including managed care organizations, approving reimbursement for PreGen-Plus, the commercial success of PreGen-Plus would be compromised and our revenues would be significantly limited.

Our business would suffer if we, or LabCorp, are unable to license certain technologies or obtain raw materials and components or if certain of our licenses were terminated.

LabCorp s current configuration of PreGen-Plus requires access to certain technologies and supplies of raw materials, including elements relating to the Effipure microtiter plates, for which licensing and supply agreements are required. Similarly, the commercialization of the next generation of our stool-based DNA screening technology, or Version 2.0, will require that we or LabCorp license certain third-party intellectual property. There can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, if at all. Although LabCorp recently indicated to the FDA that it is working on changes to PreGen-Plus to eliminate the use of Effipure in processing PreGen-Plus tests by the end of 2006, we cannot assure that it will be able to replace Effipure in such time or that any substitute technology will have comparable performance. There also can be no assurance that existing Effipure inventory levels will be sufficient to support the processing of PreGen-Plus tests for the period of time necessary for LabCorp to replace Effipure in commercial use. Failure to transition to a new and effective DNA capture technology could have a material adverse affect on the processing of PreGen-Plus and on our business. In the event LabCorp is able to identify a new DNA capture technology for use in connection with PreGen-Plus, any such technology may require us or LabCorp to pay additional royalties or other fees to third parties, which would have an adverse affect on our revenues or gross margin. Furthermore, there can be no assurance that any current contractual arrangements between us and third parties, us and LabCorp, LabCorp and vendors in the DNA capture component supply chain, or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we or LabCorp will be able to enter into any future relationships necessary to the continued commercial sale of PreGen-Plus or necessary to our realization of material revenues. Any failure to obtain necessary technologies or raw materials could require PreGen-Plus to be re-configured which could interrupt the testing service entirely, negatively impact its commercial sale and increase the costs associated with PreGen-Plus, any one of which could have a material adverse affect on our revenues and gross margin, respectively.

In addition, LabCorp currently maintains a license with a third party for access to certain genes that are integrated as part of the PreGen-Plus testing process. Under the terms of our amended license agreement with LabCorp, we are contingently liable to reimburse LabCorp for a portion of certain fixed, third-party royalty payments made by LabCorp to this third party based on sales

volume of PreGen-Plus over the exclusive period of the license agreement, which terminates on August 13, 2008. As of September 30, 2006, the potential reimbursement to LabCorp was $2.2 million. Although a significant increase in PreGen-Plus test sales volumes through August 13, 2008, would reduce this obligation, potentially to zero, test volumes consistent with historical PreGen-Plus sales levels would increase the amounts payable to LabCorp. LabCorp has not requested reimbursement of any amounts under the license agreement and we are currently in discussions with LabCorp regarding the terms of the license agreement, including our contingent liability for such reimbursement. There can be no assurance that sales volumes will increase to a level necessary to materially reduce this obligation to LabCorp nor can there be any assurance that we will be able to successfully negotiate an amendment to the license agreement that would eliminate our contingent liability to pay the amounts described above.

If our clinical studies do not prove the superiority, reliability, or effectiveness of stool-based DNA testing, we may experience reluctance or refusal on the part of guidelines writers to include stool-based DNA testing within screening guidelines as well as a reluctance or refusal on the part of physicians to order, and third-party payors to pay for tests based on PreGen-Plus.

If the results of our research and clinical studies do not convince third party payors, physicians, thought leaders and colorectal cancer screening guideline writers of the clinical value of PreGen-Plus or other stool-based DNA testing services utilizing our technologies, we and LabCorp may never successfully commercialize such testing services and, as a consequence, we may not be able to remain a viable business.

In 2006 we completed a research study on the performance of a new marker panel for our stool-based DNA screening technology for colorectal cancer. There were 40 cancers analyzed in this study and the results showed 88% sensitivity (95% Confidence Interval: 77% - 98%, meaning that the study showed, with 95% certainty, that the study sensitivity results could have fallen anywhere within this range) and 82% specificity for colorectal cancer detection. These 40 cancer samples were from post-colonoscopy patients, while the samples used in our multi-center study in 2003, were samples derived from asymptomatic, average risk individuals prior to colonoscopy. There can be no assurance that the results that we realized in this blinded, 2006 study will be viewed as persuasive for purposes of medical acceptance or guidelines inclusion.

In 2003, we completed our multi-center study of our prototype technology that included approximately 5,500 asymptomatic, average-risk patients aged 50 and older from over 80 academic and community-based medical practices. The point sensitivity from our multi-center study was lower than that seen in our previous research and clinical studies. Accordingly, we and LabCorp may experience reluctance or refusal on the part of third-party payors to pay for tests using our technologies which could slow the demand for LabCorp s commercial PreGen-Plus testing service and adversely and materially impact revenues and profitability.

In October 2001, Mayo Clinic initiated a three year study of the prototype bead-based version of our technology that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. Subsequently, we and the Mayo Clinic sought to include the Effipure technology in the study to improve DNA yield, rather than relying solely on the prototype technology alone. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while our prototype technology was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia, Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, our prototype technology in the detection of cancer among the thirteen cancer samples collected in the study. We believe that the sample collection protocols used in this study, which were the same as those used in our multi-center study, resulted in DNA degradation that, in turn, resulted in lower sensitivity of our technology. Thought-leading gastroenterologists, guidelines organizations, primary care physicians, payors and others may, despite the small sample size referenced above, assign significance to this preliminary data, especially if published by the NCI or Mayo Clinic, which may significantly adversely affect continued commercialization of the testing service.

If the results of our research and clinical studies, including the results of the Mayo Clinic study (especially in contrast to the results of the 2003 multi-center study referenced above), do not convince thought-leading gastroenterologists, guidelines organizations, primary care physicians, third party payors and patients that tests using our technologies are reliable, effective and/or superior to existing screening methods, including Hemoccult II and Hemoccult Sensa, or show that our technologies are superior but not by a large enough margin to affect prevailing clinical practice, we may experience reluctance or refusal on the part of screening guidelines writers to include stool-based DNA screening in such guidelines (including within the guidelines of the American Cancer Society, the American College of Gastroenterology, and the American Gastroenterological Association) as well as a reluctance or refusal on the part of physicians to order, and third-party payors to pay for tests using our technologies, which could slow the demand for, and successful commercialization of, PreGen-Plus.

If PreGen-Plus cannot be effectively sold at a price acceptable to the market or acceptable to the writers of screening guidelines, the successful commercialization of PreGen-Plus would be materially harmed.

The success of PreGen-Plus, and future versions of PreGen-Plus depends, in material part, on the ability of LabCorp to price the test at a level acceptable to consumers, physicians, third-party payors, and the writers of colorectal cancer screening guidelines. Currently, screening for colorectal cancer using our technologies is more expensive than FOBT because it is labor-intensive and uses

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highly complex processes and expensive reagents. The price differential between stool-based DNA testing and FOBT, when compared with the performance differential between the two screening modalities, may be viewed as too significant to endorse stool-based DNA screening for guidelines inclusion. In order to make PreGen-Plus less costly and more commercially attractive to consumers, physicians, third party payors, and guidelines writers, LabCorp will need to reduce the costs of tests using our technologies through significant automation of key operational processes or other cost savings procedures. There can be no assurance that such parties, including Medicare, will pay for PreGen-Plus at levels that will enable us to earn a profit, if at all and there can be no assurance that stool-based DNA testing will be included within screening guidelines, regardless of the performance of the technology. If LabCorp fails to create and improve technologies that sufficiently reduce costs, LabCorp s sales of PreGen-Plus and, as a result, our revenues may be limited. Moreover, if LabCorp is unable to sell a sufficient number of tests at favorable pricing levels, we will not be successful and we may not be able to remain viable as a company.

If our or LabCorp s technological advancements do not increase the performance of PreGen-Plus in a cost effective manner, the demand for PreGen-Plus may be negatively impacted.

We continue to work to improve the performance characteristics of stool-based DNA testing through research on technical innovations. However, there can be no assurance that future generations of PreGen-Plus, or the commercial version of the PreGen-Plus test currently offered by LabCorp will have sufficient sensitivity and specificity or performance to be commercially successful. There also can be no assurance that the sample handling protocols employed by LabCorp for PreGen-Plus are adequate to prevent DNA degradation and resulting negative impacts on test performance.

In a recent research study that we conducted, designed to test the efficacy of technological advances to enhance colorectal cancer detection in stool, Version 2.0 of our stool-based DNA screening technology demonstrated sensitivity and specificity results of 88% and 82%, respectively for detecting colorectal cancer. While previous published studies for stool-based DNA screening have generally shown specificity above 90%, the specificity results of 82%, may not be deemed clinically or commercially acceptable. There can be no assurance that the overall performance characteristics, or that the design of the Version 2.0 research study, will be viewed favorably by thought-leaders, physicians, and consumers or that LabCorp will be able to achieve similar levels of performance in future versions of its PreGen-Plus testing service. The blinded study was designed to test the efficacy of technological advances to enhance colorectal cancer detection in stool. This study involved the analysis of cancer samples from individuals whose colonoscopy results were positive for colorectal cancer. By contrast, our multi-center study, published in the New England Journal of Medicine in 2004, was comprised of cancer samples from an asymptomatic population. There can be no assurance that the population from which the cancer samples were obtained for the Version 2.0 study will be viewed as sufficient to support clinical or market acceptance of the Version 2.0 research study results. In addition, the Version 2.0 research study has not yet been accepted for publication in a peer-reviewed journal and there can be no assurance that the Version 2.0 study will be accepted for publication by a peer-reviewed journal, or by a peer-reviewed journal of a caliber necessary to support clinical or market acceptance of the Version 2.0 study results.

If the current commercial version or future generations of the PreGen-Plus test do not demonstrate a sufficiently significant increase in the sensitivity or performance over that of the prototype technology in a cost effective manner, sufficient demand for our stool-based DNA screening technologies may never be realized or such demand could be significantly reduced, either of which would have a material adverse affect on our revenues.

If an insufficient number of medical practitioners order and reorder tests using our technologies, our revenue and profitability will be limited.

If a sufficient number of medical practitioners are not convinced to order and reorder PreGen-Plus, we will not become profitable. An important element to the successful commercialization of PreGen-Plus is the inclusion of stool-based DNA testing in colorectal cancer screening guidelines (the guidelines of the American Cancer Society, the American College of Gastroenterology, and the American Gastroenterological Association). Gastroenterologists and primary care physicians will have to be made aware of the benefits of stool-based DNA testing through published papers, presentations at scientific conferences, favorable results from clinical studies and obtaining reimbursement from insurers. Our failure to be successful in these efforts or to be included within colorectal cancer screening guidelines would make it difficult to convince medical practitioners to order and reorder PreGen-Plus for their patients which would limit our revenues and materially adversely affect our business.

We may experience limits on our revenue if only a small number of people decide to be screened for colorectal cancer using our technologies.

Even if our technologies are superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and we convince medical practitioners to order tests using our technologies, only a small number of people may decide to be screened for colorectal cancer. Despite the availability of current colorectal cancer screening methods as well as the recommendations of the American Cancer Society that all Americans over the age of 50 be screened for colorectal

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cancer, a majority of these individuals do not complete a colorectal cancer screening test. If only a small portion of the recommended population is regularly screened for colorectal cancer or decides to utilize colorectal cancer screening tests using our technologies, we will, despite our efforts, experience limits on our revenue and our business would be materially harmed.

Our inability to raise additional capital on acceptable terms in the future may limit our growth.

If our capital resources become insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. Moreover, if we modify our business strategy to pursue other initiatives or technologies and are required to invest material amounts in the acquisition of these technologies, our current cash and cash equivalents could be reduced significantly. Our inability to raise capital would seriously harm our business and development efforts. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operations. These funds may not be available on favorable terms, or at all. If adequate funds are not available on attractive terms, we may have to restrict our operations significantly or obtain funds by entering into agreements on unattractive terms. 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 dilution to our stockholders.

We may be subject to substantial costs and liability or be prevented from licensing our technologies for cancer detection as a result of litigation or other proceedings relating to patent rights.

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners, or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the non-invasive early detection of colorectal cancer and is designed to maximize our patent protection against third parties in the U.S. and, potentially, in certain foreign countries. We have filed patent applications that we believe cover methods we have designed to help detect colorectal cancer and other cancers. In order to protect or enforce our patent rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming, and divert our management and key personnel from our business. Additionally, such actions could result in challenges to the validity or applicability of our patents. Because the U.S. Patent & Trademark Office maintains patent applications in secrecy until a patent application publishes or the patent is issued, others may have filed patent applications covering technology used by us or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any of these suits or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of PreGen-Plus, which would have a material adverse affect on our business, financial condition and results of operations.

Also, patents and applications owned by us may become the subject of interference proceedings in the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

As of September 30, 2006 we have 37 issued patents and 19 pending patent applications in the United States and we also have 70 issued foreign patents and 59 pending foreign patent applications. We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for such patents to be issued. Further, we cannot assure you that other parties will not challenge any patents issued to us, or that courts or regulatory agencies will hold our patents to be valid or enforceable. A third party has opposed one of our issued European patents relating to the enumerative analysis of nucleic acids in biological samples. A third-party institution is a co-owner of one of our issued patents relating to pooling patient samples in connection with our loss of heterozygosity detection method. We cannot guarantee you that we will be successful in defending challenges made in connection with our patents and patent applications. Any successful third-party challenge to our patents could result in co-ownership of such patents with a third party or the unenforceability or invalidity of such patents. In addition, we have jointly filed and jointly own, with a third party institution, a pending US patent application and a PCT patent application that has been nationalized and is pending in Canada, Europe, and Japan, which patent applications relate to the use of various DNA markers, including one of our detection methods, to detect cancers of the lung, pancreas,

esophagus, stomach, small intestine, bile duct, naso-oro-pharyngeal

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airways, liver, and gall bladder in stool. As joint owners of these patent applications, both we and the third party institution have the rights provided to joint owners under applicable patent law, including the right to use, transfer, and license the patent rights.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and employees to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights.

We cannot guarantee that the patents issued to us will be broad enough to provide any meaningful protection nor can we assure you that one of our competitors may not develop more effective technologies, designs or methods to test for colorectal cancer or any other common cancer without infringing our intellectual property rights or that one of our competitors might not design around our proprietary technologies.

Other companies may develop and market novel or improved methods for detecting colorectal cancer, which may make our technologies less competitive, or even obsolete.

The market for colorectal cancer screening is large, approximating 80 million Americans age 50 and above, of which we believe over at least 42 million fail to follow the American Cancer Society s screening guidelines. As a result, the colorectal cancer screening market has attracted competitors, some of which have significantly greater resources than we have. Currently, we face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and virtual colonoscopy, a procedure being performed in which a radiologist views the inside of the colon through a scanner, as well as from existing guaic based fecal occult blood testing (FOBT) and improved screening tests such as immunochemical FOBT. In addition, some companies and institutions are developing serum-based tests, or screening tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are produced by colon cancer. These and other companies may also be working on additional methods of detecting colon cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources and stronger business relationships.

We rely on third-party contract manufacturers and suppliers and may experience a scarcity of raw materials and components.

We have historically relied on contract manufacturers and suppliers for certain components for our technologies. We believe that there are relatively few manufacturers that are currently capable of supplying commercial quantities of the raw materials and components necessary for certain elements used in LabCorp s PreGen-Plus testing service, including Effipure. Although we have identified suppliers that we believe are capable of supplying these raw materials and components in sufficient quantity today, there can be no assurance that we, or LabCorp, will be able to enter into or maintain these agreements and relationships with such suppliers on a timely basis on acceptable terms, if at all. Furthermore, prior to August 2003, stool-based DNA testing had never been offered on a commercial scale, and there can be no assurance that the raw materials and components necessary to meet demand will be available in sufficient quantities or on acceptable terms, if at all. If we, or LabCorp, should encounter delays or difficulties in securing the necessary raw materials and components for LabCorp s PreGen-Plus testing service, LabCorp may need to reconfigure its PreGen-Plus testing service which would result in delays in commercialization or an interruption in sales and would materially adversely impact our revenues.

If we or our partners fail to comply with regulatory requirements, we may be subject to stringent penalties and our business may be materially adversely affected.

The marketing and sale of PreGen-Plus is subject to various state, federal and foreign regulations. We cannot assure you that we or our strategic partners will be able to comply with applicable regulations and regulatory guidelines. If we or our partners fail to comply with any such applicable regulations and guidelines, we could incur significant liability and/or our partners could be forced to cease offering PreGen-Plus in certain jurisdictions. Also, conforming the marketing and sale of our technologies to any applicable regulations and guidelines could substantially increase our operating expenses. In addition, LabCorp and any other laboratory that uses PreGen-Plus is subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CLIA is a federal law which regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the U.S. by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. If LabCorp were to lose its CLIA certification, it may no longer be able to offer PreGen-Plus, which would have a material adverse affect on our business.

Moreover, healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. Development of the existing commercialization strategy for PreGen-Plus has been based on existing healthcare policies. Changes in healthcare policy could substantially interrupt the sales of PreGen-Plus, increase costs, and divert

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management s attention. We cannot predict what changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

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

Our success depends largely on the skills, experience and performance of key members of our senior management team, including Don M. Hardison, our President and Chief Executive Officer. We have recently entered into an employment agreement with Mr. Hardison with an initial term through June 27, 2008, which provides for certain retention bonuses for his continued employment with the Company through such term. Notwithstanding this agreement, Mr. Hardison may terminate his relationship with us at any time. The efforts of Mr. Hardison will be critical to us as we continue to pursue our business goals.

In March 2006, Anthony Shuber, our Chief Technology Officer, resigned his employment with us. Mr. Shuber has been critical to our research and development goals and technology improvements, and there can be no assurance that we will be able to pursue and effectively accomplish our research and development goals without Mr. Shuber. In addition, in April 2006, Harry W. Wilcox, our Senior Vice President, Chief Financial Officer and Treasurer, resigned his employment with us. In addition, in October 2006 we reduced our workforce by 21 employees, or 48% of our staff. Although we are in the process of entering into retention agreements with our remaining officers and employees following the restructuring, if we were to lose any of these remaining officers or key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

If we are unable to attract the expertise necessary to develop and seek regulatory approval for an in vitro diagnostic kit, we may not be able to bring more advanced technologies to market.

Recently we announced research results on Version 2.0 of our stool-based DNA screening technology that was realized utilizing a marker panel comprised of only two markers. We may seek to configure this test as an in vitro diagnostic kit and seek regulatory approval with the FDA. There can be no assurance that we will be able to hire the personnel necessary to develop this product, that we will have the clinical data necessary and sufficient to support an FDA filing, or that an FDA filing on such a product will ultimately be approved. If we cannot execute successfully in these areas, our introduction and commercialization of Version 2.0 of our technology may be delayed or may never occur. Moreover, transferring Version 2.0 from the laboratory to the commercial setting will require the negotiation and licensing of necessary third-party intellectual property as well as the likelihood of additional technical and clinical validations of the technology. There can be no assurance that such clinical or technical validations will be consistent with the above research results, that the Version 2.0 technology will perform equally well in all patient populations and segments, or that such technical and clinical validations will support the commercial introduction of Version 2.0. Moreover, there can be no assurance that the third-party intellectual property that is needed to commercially launch Version 2.0 can be obtained on favorable terms, if at all.

Our stock price may be volatile.

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

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

- whether stool-based DNA screening is included in colorectal cancer screening guidelines and the timing of any such inclusion;
- FDA regulation of our or LabCorp s products and services;
- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to the PreGen-Plus test, stool-based DNA testing in general, or technologies of our competitors;
- stool DNA screening becoming a standard of care among prescribing physicians;
- reimbursement decisions by Medicare and other third party payors;

- the establishment of collaborative partnerships;
- health care legislation;
- intellectual property disputes and other litigation;
- additions or departures of key personnel;
- the performance characteristics of our technologies;
- general market conditions;
- the rate of market acceptance of PreGen-Plus; and
- sales of our common stock or debt securities.

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

Our operating results may fluctuate, which may adversely affect our share price.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by physicians and consumers for PreGen-Plus;
- new technology introductions;
- reimbursement acceptance success;
- changes in our agreement with LabCorp;
- the number and timing of milestones that we achieve may under collaborative agreements;
- impairment of our intellectual property;
- the level of our development activity conducted for, and our success in commercializing these developments; and
- the level of our spending on PreGen-Plus commercialization efforts, licensing and acquisition initiatives, clinical studies, and internal research and development.

Variations in the timing of our future revenue and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, The NASDAQ Global Market in general, and the market for biotechnology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

If we lose the support of our key scientific collaborators, it may be difficult to establish tests using our technologies as a standard of care for colorectal cancer screening, which may limit our revenue growth and profitability.

We have established relationships with leading scientists, including members of our scientific advisory board, and research and academic institutions, such as Mayo Clinic and John Hopkins University, that we believe are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. If our collaborators determine that colorectal cancer screening tests using our technologies are not appropriate options for colorectal cancer screening, or superior to available colorectal cancer screening tests, or that alternative technologies would be more effective in the early detection of colorectal cancer, we would encounter significant difficulty establishing tests using our technologies as a standard of care for colorectal cancer screening, which would limit our revenue growth and profitability.

Our inability to apply our proprietary technologies successfully to detect other common cancers may limit our future revenue growth and profitability.

While, to date, we have focused substantially all of our research and development efforts on colorectal cancer, we have used our technologies to detect cancers of the lung, pancreas, esophagus, stomach and gall bladder. In the future, we intend to evaluate and potentially extend our technology platform to the development of screening tests for these or other common cancers. To do so, we may need to overcome technological challenges to develop reliable screening tests for these cancers. There can be no assurance that our technologies will be capable of reliably detecting cancers, beyond colorectal cancer, with the sensitivity and specificity necessary to be clinically and commercially useful for such other cancers, or that we can develop such technologies at all. We may never realize any commercial benefit from our research and development activities.

Product liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Certain provisions of our charter, by-laws and Delaware law may make it difficult for you to change our management and may also make a takeover difficult.

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include a staggered board of directors, limitations on persons authorized to call a special meeting of stockholders and advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders. These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our board of directors.

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

On July 21, 2006, at our annual meeting of stockholders, the stockholders elected as Class III directors, each to serve for a three-year term, the following individuals: Sally W. Crawford (22,792,442 shares for; 220,787 shares withheld) and Edwin M. Kania (22,715,424 shares for; 298,805 shares withheld). The term of office for each of Patrick Zenner, Lance Willsey, Connie Mack, III and Don M. Hardison 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 2006 was approved (22,920,952 shares for, 87,755 shares against and 5,520 abstained)

Item 5. Other Information

On July 26, 2006, the Company elected to make a matching contribution in the form of common stock pursuant to the Company s qualified 401(k) retirement saving plan (the 401(k) Plan) and issued an aggregate of 85,800 shares of its common stock to the 401(k) Plan for the benefit of its employees for the plan year ended December 31, 2005. The 401(k) Plan paid no consideration for the shares. The shares were valued at $2.14 per share, the closing price of the Company s common stock on July 26, 2006. The shares will be allocated pursuant to the terms of the 401(k) Plan. The issuance of shares was exempt from registration under the Securities Act of 1933, as amended (the Act), as the contribution of the shares to the 401(k) Plan for the benefit of the Company s employees, without payment of consideration by the 401(k) Plan or employees, does not constitute a sale of the common stock for purposes of the Act.

Item 6. Exhibits

Exhibit Number	**Description**
10.1*	Employee Retention Agreement between the registrant and Jeffrey R. Luber dated as of October 23, 2006.
10.2*	Employee Retention Agreement between the registrant and Charles R. Carelli, Jr. dated as of October 23, 2006.
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.

* 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 9, 2006

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

Date: November 9, 2006

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

EXHIBIT INDEX

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