SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2005

OR

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

Commission File Number: 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**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 ☒ No ☐

Indicate by checkmark whether or the registrant is an accelerated filer (as defined in the Exchange Act Rule 12b-2).

Yes ☒ No ☐

As of July 29, 2005, the Registrant had 26,265,063 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, 2004	June 30, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,092	$ 17,625
Marketable securities	37,188	22,916
Prepaid expenses and other current assets	1,835	1,945
Total current assets	52,115	42,486
Property and Equipment, at cost:		
Laboratory equipment	4,242	4,122
Office and computer equipment	1,383	1,400
Leasehold improvements	1,482	1,254
Furniture and fixtures	299	299
	7,406	7,075
Less—Accumulated depreciation and amortization	(5,452)	(5,623)
	1,954	1,452
Patent Costs and Other Assets, net of accumulated amortization of approximately $1,718 and $1,948 at December 31, 2004 and June 30, 2005, respectively	2,042	1,830
	$ 56,111	$ 45,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 365	$ 339
Accrued expenses	2,034	1,405
Deferred license fees, current portion	4,459	4,383
Total current liabilities	6,858	6,127
Deferred License Fees, less current portion	11,270	9,089
Commitments and contingencies		
Stockholders' Equity:		
Common stock, $0.01 par value		
Authorized—100,000,000 shares		
Issued and outstanding—26,285,067 and 26,350,613 shares at December 31, 2004 and June 30, 2005, respectively	263	264
Additional paid-in capital	161,356	162,340
Treasury stock, 85,550 shares at December 31, 2004 and June 30, 2005	(97)	(97)
Notes receivable	(5)	(5)
Deferred compensation	(89)	(15)
Other comprehensive loss	(115)	(69)
Accumulated deficit	(123,330)	(131,866)
Total stockholders' equity	37,983	30,552
	$ 56,111	$ 45,768

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Operations
(Amounts in thousands, except per share data - unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
Revenue:				
Product royalty fees	$ 35	$ 46	$ 57	$ 114
License fees	1,129	498	2,257	1,626
Product	58	79	85	130
	1,222	623	2,399	1,870
Cost of revenue:				
Product royalty fees	3	3	4	7
Product	57	129	88	173
	60	132	92	180
Gross profit	1,162	491	2,307	1,690
Operating Expenses:				
Research and development	2,640	1,875	5,774	4,156
Sales and marketing	1,392	1,619	2,719	3,218
General and administrative	1,461	1,157	3,428	2,378
Restructuring	—	—	—	626
Stock-based compensation (1)	120	52	246	355
	5,613	4,703	12,167	10,733
Loss from operations	(4,451)	(4,212)	(9,860)	(9,043)
Interest income	172	261	290	507
Net loss	$ (4,279)	$ (3,951)	$ (9,570)	$ (8,536)
Net loss per share—basic and diluted	$ (0.16)	$ (0.15)	$ (0.39)	$ (0.33)
Weighted average common shares outstanding—basic and diluted	26,081	26,251	24,515	26,227

(1) The following summarizes the departmental allocation of stock-based compensation:

Research and development	$ 53	$ 19	$ 106	$ 80
Sales and marketing	—	—	—	58
General and administrative	67	33	140	217
Total	$ 120	$ 52	$ 246	$ 355

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Cash Flows
(Amounts in thousands - unaudited)

	Six Months Ended June 30,	
	2004	**2005**
Cash flows from operating activities:		
Net loss	$ (9,570)	$ (8,536)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	635	436
Amortization	246	266
Restructuring	—	282
Stock-based compensation	246	355
Amortization of deferred license fees	(2,257)	(2,257)
Non-cash revenue reduction recorded in connection with warrant extension	—	630
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(671)	(110)
Accounts payable	(78)	(26)
Accrued expenses	404	(629)
Net cash used in operating activities	(11,045)	(9,589)
Cash flows from investing activities:		
Purchases of marketable securities	(47,767)	(8,701)
Maturities of marketable securities	14,936	23,020
Purchases of property and equipment	(245)	(216)
Increase in patent costs and other assets	(66)	(54)
Net cash (used in) provided by investing activities	(33,142)	14,049
Cash flows from financing activities:		
Net proceeds from sale of common stock	43,305	—
Proceeds from exercise of common stock options and stock purchase plan	162	73
Repayment of notes receivable	365	—
Net cash provided by financing activities	43,832	73
Net (decrease) increase in cash and cash equivalents	(355)	4,533
Cash and cash equivalents, beginning of period	14,200	13,092
Cash and cash equivalents, end of period	$ 13,845	$ 17,625
Supplemental disclosure of non-cash investing and financing activities:		
Repurchase of restricted stock through forgiveness of notes receivable	$ 83	$ —
Forgiveness of notes receivable and accumulated interest	$ 228	$ —

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 on February 10, 1995. The Company is an applied genomics company that 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, 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 DNA-based 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 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, 2004, 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, 2004 and June 30, 2005, approximately $1.0 million of the Company's cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's corporate headquarters. Cash equivalents primarily consist of money market funds at December 31, 2004 and June 30, 2005.

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 Securitie* s. Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date.

Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

All of the Company's investments are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sale of available-for sale securities during the three and six months ended June 30, 2004 and 2005.

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 us. 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 six months ended June 30, 2004 and 2005 because they had an antidilutive effect due to net losses for such periods:

	June 30,	
(In thousands)	**2004**	**2005**
Shares issuable upon exercise of stock options	3,956	4,904
Shares issuable upon vesting of restricted common stock	66	1
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,022	5,905

Accounting for Stock-Based Compensation

The Company accounts for its stock-based compensation plan under Accounting Principal Bulletin Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB Opinion No. 25"). SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"), establishes the fair-value-based method of accounting for stock-based compensation plans. The Company has adopted the disclosure-only alternative for options granted to employees and directors under SFAS No. 123, which requires disclosure of the pro forma effects on earnings as if SFAS No. 123 had been adopted, as well as certain other information. Options granted to scientific advisory board members and other non-employees are recorded at fair value based on the fair value measurement criteria of SFAS No. 123. The Company recorded stock-based compensation expense of $25,000 and $10,000 during the three months ended June 30, 2004 and 2005, respectively, in connection with options granted to non-employees, computed using the Black-Scholes option pricing model. During the six months ended June 30, 2004 and 2005, the Company recorded stock-based compensation expense of

$47,000 and $19,000, respectively, in connection with options granted to non-employees, computed using the Black-Scholes option pricing model.

The Company has computed the pro forma disclosures required under SFAS No. 123 for all stock options granted to employees and directors of the Company for the three and six months ended June 30, 2004 and 2005 using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The effect of applying SFAS No. 123 would be as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except per share data)	**2004**	**2005**	**2004**	**2005**
Net loss as reported	$ (4,279)	$ (3,951)	$ (9,570)	$ (8,536)
Add: Stock-based compensation included in reported net loss	120	52	246	355
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(1,816)	(2,015)	(3,638)	(4,328)
Pro forma net loss - SFAS 123	$ (5,975)	$ (5,914)	$ (12,962)	$ (12,509)
Basic and diluted net loss per share:				
As reported	$ (0.16)	$ (0.15)	$ (0.39)	$ (0.33)
Pro forma net loss - SFAS 123	$ (0.23)	$ (0.23)	$ (0.53)	$ (0.48)

The assumptions used for the three and six months ended June 30, 2004 and 2005 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 (1)	**2005**	**2004**	**2005**
Risk-free interest rates	—	3.94%	1.69 - 1.81%	3.94 - 4.00%
Expected lives	—	7 years	7 years	7 years
Expected volatility	—	100%	100%	100%
Dividend yield	—	0%	0%	0%
Weighted average fair value per share of options granted during the period	—	$ 2.41	$ 6.37	$ 3.50

(1) The company did not grant options during the quarter ended June 30, 2004.

In December 2004, the FASB issued Statement of Financial Standards No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, and amends FASB Statement No. 95, *Statement of Cash Flows* . Generally, the approach to accounting for share-based payments in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Pro forma disclosure of the fair value of share based payments is no longer an alternative to financial statement recognition. SFAS No. 123(R) is effective for public companies (excluding small business issuers) at the beginning of their next fiscal year that begins after June 15, 2005.

The Company expects the adoption of SFAS No. 123(R) to have a material effect on its financial statements, in the form of additional compensation expense, on a quarterly and annual basis. It is not possible to precisely determine the expense impact of adoption since a portion of the ultimate expense that is recorded will likely relate to awards that have not yet been granted, but are likely to be granted prior to the January 1, 2006 adoption date. The expense associated with these future awards can only be determined based on factors such as the price of the Company's common stock, volatility of the Company's stock price and risk free interest rates as measured at the grant date. However, the pro forma disclosures related to SFAS No. 123 included in the Company's historic financial statements are relevant data points for gauging the potential level of expense that might be recorded in future periods.

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.

Royalty fees earned on PreGen-Plus tests performed by LabCorp are based upon the customer's remittance to LabCorp, not the amount billed by LabCorp. Until such time that estimates utilized are supported by measurable, historical remittance data, the Company will recognize royalties as LabCorp customers make payments. The timing of customer payments to LabCorp is uncertain because of the number of parties involved in the reimbursement process.

Product revenue from the sale Effipure™ to LabCorp is recognized upon shipment of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

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

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income* , establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and six months ended June 30, 2004 and 2005 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2004**	**2005**	**2004**	**2005**
Net loss	$ (4,279)	$ (3,951)	$ (9,570)	$ (8,536)
Unrealized (loss) gain on marketable securities	(158)	62	(184)	46
Comprehensive loss	$ (4,437)	$ (3,889)	$ (9,754)	$ (8,490)

(3) RESTRUCTURING

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

Pursuant to the restructuring plan, the Company accrued charges of $626,000 in the quarter ended March 31, 2005. As of June 30, 2005 all liabilities related to the restructuring had been paid out. The table below summarizes the restructuring activities during the six months ended June 30, 2005. Amounts included in the table are in thousands.

Type of Liability	**Balance, December 31, 2004**	**Charges**	**Cash Payments**	**Non-cash Write-downs**	**Balance, June 30, 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. The Company's 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 $282 (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 the Company's corporate headquarters.

(4) EXTENSION OF WARRANT EXPIRATION DATE

In June 2002, in connection with our collaboration, the Company issued a warrant to LabCorp (the "LabCorp Warrant") to purchase 1,000,000 shares of its common stock, at an exercise price of $16.09 per share. At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, the Company 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 the Company's license agreement with LabCorp. All other terms of the LabCorp Warrant were unaffected. The Company assigned a value to the LabCorp Warrant extension of $630,000 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," the Company recorded the cost of the LabCorp Warrant extension as a one-time, non-cash reduction in license fee revenue of $630,000 in the quarter ended June 30, 2005.

(5) EFFIPURE INVENTORY CONTINGENCY

The Company has historically been responsible for the procurement and supply chain management of Effipure components until they are delivered to LabCorp, which uses Effipure in processing PreGen-Plus tests. The Company is currently in discussions with LabCorp to transition the procurement and supply chain management of Effipure to LabCorp. As of this date, the Company can not estimate the costs associated with this potential transfer, but such costs may include write downs of current inventory, costs to transfer on-hand inventory to LabCorp and costs associated with the transfer or cancellation of certain contracts in the current supply chain. As of June 30, 2005, the carrying value of the Company's Effipure inventory was $733,000 and was recorded under the caption "Prepaid expenses and other current assets" in the Company's consolidated balance sheets.

(6) RECLASSIFICATIONS

Certain prior period amounts have been reclassified to conform to the current period presentation.

(6) SUBSEQUENT EVENT

During the quarter ended March 31, 2005, the Company recorded $208,000 of stock-based compensation expense in connection with common stock awards granted to executives pursuant to the Company's 2004 Executive Incentive Plan. On July 21, 2005, the Compensation Committee of the Board of Directors approved an amendment to the Company's 2004 Executive Incentive Plan providing that the stock awards previously authorized for issuance under the 2004 Executive Incentive Plan be paid in cash, in the aggregate amount of $208,000, in lieu of shares of the Company's common stock. Accordingly, in the quarter ended September 30, 2005, the Company will reclassify the $208,000 from a stock-based expense to a cash based expense within the appropriate research and development, sales and marketing and general and administrative line items of the Company's consolidated statements of operations.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of the financial condition and results of operations of EXACT Sciences Corporation should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this 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, 2004, which has been filed with the Securities and Exchange Commission (the "SEC"). This 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, and are subject to the "safe harbor" created by those sections. Some of the forward-looking statements can be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "could," "seek," "intends," "plans," "estimates," "anticipates" or other comparable terms. Forward-looking statements involve inherent risks and uncertainties. A number of important factors could cause actual results to differ materially from those in the forward-looking statements. We urge you to consider the risks and uncertainties discussed at the end of this section under "Factors That May Impact Future Results of Operations" in evaluating our forward-looking statements. We have no plans to update our forward-looking statements to reflect events or circumstances after the date of this report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Overview

We are an applied genomics company that 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, 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 DNA-based testing service for the detection of colorectal cancer in the average-risk population. Colorectal cancer is the second leading cause of cancer death in the U.S. and the leading cause of cancer death among non-smokers. 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;
- hiring research and clinical personnel, sales personnel, management and other support personnel;
- raising capital;
- licensing our proprietary technologies to LabCorp;
- working with LabCorp on activities in support of the commercialization of PreGen-Plus and
- sales and marketing efforts in support of PreGen-Plus.

We have generated limited operating revenues since our inception and, as of June 30, 2005, we had an accumulated deficit of approximately $131.9 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, and more recently, the initiation of new 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. Our future revenues will depend, in large part, upon whether our technologies are broadly ordered by medical practitioners, requested by patients, and ultimately reimbursed by third-party payors.

We believe that the market demand for our colorectal cancer detection technologies is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- effective sales and sales management personnel and processes to educate physicians and their office staffs to facilitate patient compliance;
- patient acceptance of PreGen-Plus, including its novel sample collection process;
- stool-based DNA screening becoming a standard of care among prescribing physicians;

- the impact that the publication of our multi-center and other study results and accompanying editorials in a peer-reviewed journal have on market acceptance of PreGen-Plus and
- the quality and service of the LabCorp testing process.

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 account for PreGen-Plus royalty fees on a cash basis and will 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. 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 third-party reimbursement all influence 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. We expect that product royalty fees and product revenue for 2005 will be substantially consistent with amounts recorded in 2004. License fee revenue for 2005 is expected to be lower than license fee revenue recorded in 2004 due to the one time, non-cash reduction in revenue of $630,000 recorded in the quarter ended June 30, 2005 in connection with the extension of a warrant issued to Labcorp. See complete discussion of the accounting treatment of the LabCorp warrant extension in the "Revenue" section of "Results of Operations" below.

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. We intend to focus our research and development efforts in 2005 primarily on improving the sensitivity and other performance aspects of our technologies and, accordingly, we expect research and development expenses to decrease in 2005 from 2004 levels.

Sales and marketing expenses include salaries, benefits and travel costs for sales and marketing personnel as well as professional fees for promotional and marketing activities. We expect higher sales and marketing expenses in 2005 as compared to 2004 as we complement the direct sales efforts of LabCorp and implement additional marketing initiatives in certain regions of the U.S.

General and administrative expenses consist primarily of salaries and benefits, office expenses and professional fees. We expect general and administrative expenses to decrease in 2005 from 2004 as a result of lower headcount and professional fees in 2005 as compared to 2004.

Stock-based compensation expense, a non-cash expense, primarily represents the value of common stock awards granted to employees as well as charges resulting from common stock awards and stock options granted to non-employees, which are recorded at fair value based on the fair value measurement criteria of Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock Based Compensation* . Stock-based compensation expense also includes the difference between the exercise price and deemed fair value of common stock on the date of grant for certain options granted prior to our initial public offering. The stock-based compensation expense related to options granted prior to our initial public offering is being amortized on an accelerated method over the vesting period of the applicable options, which is generally 60 months, and will end in 2005. The amount of stock-based compensation expense that we record each quarter in connection with options granted to non-employees may fluctuate with changes in our stock price.

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* , and amends FASB Statement No. 95, *Statement of Cash Flows* . Generally, the approach to accounting for share-based payments in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Pro forma disclosure of the fair value of share based payments is no longer an alternative to financial statement recognition once SFAS No. 123(R) becomes effective. SFAS No. 123(R) is effective for public companies (excluding small business issuers) at the beginning of the first fiscal year commencing after June 15, 2005.

We expect the adoption of SFAS No. 123(R) to have a material effect on our financial statements, in the form of additional compensation expense, on a quarterly and annual basis. It is not possible to precisely determine the expense impact of adoption since a portion of the ultimate expense that is recorded will likely relate to awards that have not yet been granted, but are likely to be granted prior to the January 1, 2006 adoption date. The expense associated with these future awards can only be determined based on factors such as the price of our common stock, the volatility of our stock price and risk free interest rates as measured at the grant date. However, the pro forma disclosures related to SFAS No. 123 included in our historic financial statements are relevant data points for gauging the potential level of expense that might be recorded in future periods.

Critical Accounting Policies

The notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2004, 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.

Royalty fees earned on PreGen-Plus tests performed by LabCorp are based upon the customer's remittance to LabCorp, not the amount billed by LabCorp. Until such time that estimates utilized are supported by measurable, historical remittance data, we will recognize royalties as LabCorp customers make payments. The timing of customer payments to LabCorp is uncertain because of the number of parties involved in the reimbursement process.

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

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

Patent Costs . Patent costs, which consist of related legal fees and disbursements and purchases of intellectual property, are capitalized as incurred and are amortized beginning when patents are issued in the United States over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, or 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 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.

Results of Operations

Revenue. Revenue decreased to $623,000 for the three months ended June 30, 2005 from $1.2 million for the three months ended June 30, 2004 and decreased to $1.9 million for the six months ended June 30, 2005 from $2.4 million for the six months ended June 30, 2004. 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 license period.

The decrease in revenue for the three and six months ended June 30, 2005 as compared to the same periods for the prior year was primarily the result of a one-time, non-cash reduction in revenue of $630,000 recorded in June 2005 in connection with the amendment of a warrant originally 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 $630,000 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 $630,000 in the quarter ended June 30, 2005.

Cost of revenue . Cost of revenue increased to $132,000 for the three months ended June 30, 2005 from $60,000 for the three months ended June 30, 2004. Cost of revenue increased to $180,000 for the six months ended June 30, 2005 as compared to $92,000 for the six months ended June 30, 2004. The increase in the cost of revenue for the three and six months ended June 30, 2005 as compared to the three and six months ended June 30, 2004 was primarily the result of the write-off in June 2005 of $96,000 in excess Effipure inventory, partially offset by a decrease in Effipure shipments to LabCorp. The cost of product revenue includes pass-through costs to contract manufacturers and others while the cost of product royalty fees represents royalties owed to third-parties for intellectual property used in connection with our stool-based DNA technologies. We have contractual commitments to certain Effipure contract manufacturers which require us to pay minimum aggregate dollar amounts over the life of the commitments, which expire in April 2006. As we fulfill these minimum purchase commitments, if test volumes do not keep pace with Effipure inventory levels (the

components of which have a finite useful life, after which time they must be discarded), or if Effipure is replaced in commercial use by LabCorp, we may need to make additional provisions for excess or obsolete inventory.

We have historically been responsible for the procurement and supply chain management of Effipure components until they are delivered to LabCorp, who uses Effipure in processing PreGen-Plus tests. We are currently in discussions with LabCorp to transition the procurement and supply chain management of Effipure to LabCorp. As of this date, we can not estimate the costs associated with this potential transfer, but such costs may include write downs of current inventory, costs to transfer on-hand inventory to LabCorp and costs associated with the transfer or cancellation of certain contracts in the current supply chain. As of June 30, 2005, the carrying value of our Effipure inventory was $733,000 and was recorded under the caption "Prepaid expenses and other current assets" in our consolidated balance sheets.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, decreased to $1.9 million for the three months ended June 30, 2005 from $2.6 million for the three months ended June 30, 2004 and decreased to $4.2 million from $5.8 million for the six months ended June 30, 2004. The decrease in research and development expenses for the three and six months ended June 30, 2005 as compared to the three and six months ended June 30, 2004 was primarily the result of actions taken in February 2005 to focus research and development efforts on improving the sensitivity and other performance aspects of our technologies and associated cost reductions. As described under the heading "Restructuring" below, the Company discontinued certain research efforts and reduced its workforce by ten employees, principally in the research and development functions. Included in the net decrease in research and development expenses for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 were decreases of $312,000 in laboratory expenses, $273,000 in personnel-related expenses, $118,000 related to laboratory space, $104,000 in clinical study expenses and an increase of $42,000 in professional fees and expenses. Included in the decrease in research and development expenses for the six months ended June 30, 2005 as compared to the six months ended June 30, 2004 were decreases of $708,000 in personnel-related expenses, $364,000 in laboratory expenses, $265,000 related to laboratory space, $254,000 in clinical study expenses and $26,000 in professional fees and expenses.

Sales and marketing expenses. Sales and marketing expenses, excluding departmental allocations of stock-based compensation, increased to $1.6 million for the three months ended June 30, 2005 from $1.4 million for the three moths ended June 30, 2004. Sales and marketing expenses, excluding departmental allocations of stock-based compensation, increased to $3.2 million for the six months ended June 30, 2005 from $2.7 million for the six moths ended June 30, 2004. The increase in sales and marketing expenses for the three and six months ended June 30, 2005 as compared to the same periods of 2004 was primarily due to increases of $199,000 and $346,000, respectively, in sales personnel and related costs as a result of the expansion of our sales force to complement the direct sales efforts of LabCorp as well as increases of $ 37,000 and $169,000, respectively, in marketing expenses as we implement marketing initiatives in certain regions of the U.S.

General and administrative expenses. General and administrative expenses, excluding departmental allocations of stock-based compensation, decreased to $1.2 million for the three months ended June 30, 2005 from $1.5 million for the three months ended June 30, 2004. The decrease for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 was primarily the result of a decrease in professional fees of $204,000 as well as a decrease in personnel related expenses of $92,000, due to lower headcount. General and administrative expenses, excluding departmental allocations of stock-based compensation, decreased to $2.4 million for the six months ended June 30, 2005 from $3.4 million for the six months ended June 30, 2004. The decrease for the six months ended June 30, 2005 as compared to the same period of 2004 was primarily due to $611,000 in severance costs recorded in the six months ended June 30, 2004 in connection with the departure of certain executives. There was also a decrease in professional fees of $345,000 as well as a decrease in personnel related expenses of $131,000, due to lower headcount, in the six months ended June 30, 2005 as compared to the same period of 2004.

Stock-based compensation . Stock-based compensation, which is a non-cash expense, decreased to $52,000 for the three months ended June 30, 2005 from $120,000 for the three months ended June 30, 2004. The decrease in stock-based compensation for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 was due to a decrease in the amortization of the difference between the exercise price and fair value of common stock on the date of grant for certain options granted prior to our initial public offering. Stock-based compensation increased to $355,000 for the six months ended June 30, 2005 from $246,000 for the six months ended June 30, 2004. The increase in stock-based compensation for the six months ended June 30, 2005 as compared to the same period of the prior year was primarily the result of $208,000 in stock-based compensation recorded in connection with common stock awards granted to executives during the quarter ended March 31, 2005, which was partially offset by a decrease in the amortization of the difference between the exercise price and fair value of common stock on the date of grant for certain options granted prior to our initial public offering.

During the quarter ended March 31, 2005, we recorded $208,000 of stock-based compensation expense in connection with common stock awards granted to executives pursuant to our 2004 Executive Incentive Plan. On July 21, 2005, the Compensation Committee of the Board of Directors approved an amendment to our 2004 Executive Incentive Plan providing that the

stock awards previously authorized for issuance under the 2004 Executive Incentive Plan be paid in cash, in the aggregate amount of $208,000, in lieu of shares of our common stock. Accordingly, in the quarter ended September 30, 2005, we will reclassify the $208,000 from a stock-based expense to a cash based expense within the appropriate research and development, sales and marketing and general and administrative line items of our consolidated statements of operations.

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 technologies 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 that facility from approximately 56,000 square feet to approximately 37,000 square feet.

Pursuant to the restructuring plan, we accrued charges of $626,000 in the quarter ended March 31, 2005. As of June 30, 2005 all liabilities related to the restructuring had been paid out. The table below summarizes the restructuring activities during the six months ended June 30, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, June 30, 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* ("SFAS No. 144"). As a result of performing the impairment evaluations, asset impairment charges of $282,000 (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 increased to $261,000 for the three months ended June 30, 2005 from $172,000 for the three months ended June 30, 2004 and increased to $507,000 for the six months ended June 30, 2005 from $290,000 for the six months ended June 30, 2004. This increase was due to an increase in interest rates on investments held during the three and six months ended June 30, 2005 as compared to the same periods from the prior year partially offset by lower average cash, cash equivalents and marketable securities balances held during the three and six months ended June 30, 2005 as compared to the three and six months ended June 30, 2004.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, our initial public offering of common stock in February 2001, cash received from LabCorp in connection with our strategic alliance and a public offering of 6.9 million shares of common stock in February 2004. As of June 30, 2005, we had approximately $40.5 million in cash, cash equivalents and marketable securities, of which approximately $1.0 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 $9.6 million for the six months ended June 30, 2005 as compared to $11.0 million for the six months ended June 30, 2004. The principal use of cash in operating activities in the six months ended June 30, 2005 and 2004 was to fund our net loss. Cash flows from operations can vary significantly due to various factors including changes in prepaid expenses, accounts payable and accrued expenses.

Net cash provided by investing activities was $14.1 million for the six months ended June 30, 2005, as compared to net cash used in investing activities of $33.1 million in the six months ended June 30, 2004. Included in the net cash used in investing activities for the six months ended June 30, 2004 were net purchases of $32.8 million in marketable securities, which were made with the a portion of the proceeds from the sale of 6.9 million shares of our common stock in February 2004. Excluding the impact of purchases and

maturities of marketable securities, net cash used in investing activities was $270,000 and $311,000 in the six months ended June 30, 2005 and 2004, respectively.

Purchases of property and equipment of $216,000 during the six months ended June 30, 2005 were materially consistent with purchases of property and equipment of $245,000 during the six months ended June 30, 2004. We expect that purchases of property and equipment during 2005 will be substantially consistent with amounts spent in 2004. We continued to invest in our patent portfolio for the six months ended June 30, 2005 and 2004 and we expect that investments made in our patent portfolio in 2005 will be substantially consistent with amounts invested in 2004. Patent costs, which have historically consisted of related legal fees, are capitalized as incurred and are amortized beginning when patents are issued in the United States over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, or 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.

Net cash provided by financing activities was $73,000 for the six months ended June 30, 2005 and represented proceeds from the issuance of common stock under our employee stock option and purchase plans. Net cash provided by financing activities for the six months ended June 30, 2004 was $43.8 million and was primarily due to the offering of 6.9 million shares of our common stock in February 2004, which generated net proceeds to us of approximately $43.3 million, as well as $365,000 in repayment of notes receivable and $162,000 in proceeds from issuances of common stock under our stock option and employee stock purchase plans.

We expect that cash, cash equivalents and short-term investments currently on hand at June 30, 2005 will be sufficient to fund our operations for at least the next two years, based upon our current operating outlook. Product royalty fee payments and milestone payments from LabCorp may supplement our liquidity position. However, given that stool-based DNA testing is not yet included within colorectal cancer screening guidelines, the Centers for Medicare and Medicaid Services (CMS) have not approved stool-based DNA testing for colorectal cancer for payment, CMS has not yet accepted our request for a National Coverage Determination (NCD) (and has sought additional information in connection with the NCD submission which has delayed our application's acceptance) and that only a limited number of payors have issued formal policy approving payment for stool-based DNA testing, we cannot forecast how rapidly sales of PreGen-Plus and, consequently, royalty payments from LabCorp, will increase, if at all. Further, milestone and other performance-based payments from LabCorp for which we may be eligible under our strategic agreement may supplement our liquidity position. However, the timing and receipt of milestone and performance-based payments is similarly 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 guideline acceptance and policy-level reimbursement approvals that, in large part, depend upon decisions to be made by third parties, and $30 million relates to the achievement of certain significant cumulative LabCorp revenue thresholds that depend upon LabCorp's success with respect to its sales of PreGen-Plus and are not expected for the next several years, if at all. As such, no assurance can be given that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. If revenue and other payments from LabCorp are insufficient to meet our liquidity needs, we will be required to raise additional capital or reduce the scale of our operations, or both.

Our shelf registration statement on Form S-3 filed with the SEC was declared effective on September 26, 2003 and permits us to offer, from time to time, any combination of common stock, preferred stock, debt securities and warrants to purchase each of the foregoing, up to an aggregate of $100 million. On February 10, 2004, we completed an offering of 6.9 million shares of common stock under this shelf registration statement which generated net proceeds of $43.3 million. 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.

The table below reflects our estimated fixed obligations and commitments as of June 30, 2005:

		Payments Due by Period			
	Total	Less Than One Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
		(in Thousands)			
Operating lease obligations	$ 5,019	$ 972	$ 1,929	$ 2,032	$ 86
Purchase obligations	718	718	—	—	—
Obligations under license and collaborative agreements	5,579	1,281	530	530	3,238
Total	$ 11,316	$ 2,971	$ 2,459	$ 2,562	$ 3,324

Operating leases reflect remaining obligations associated with leased facilities in Marlborough and Maynard, Massachusetts. Purchase obligations primarily represent purchase commitments associated with the manufacture and production of Effipure. 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. 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, sales and marketing efforts associated with the commercialization of PreGen-Plus, continued funding of our research and development efforts, purchases of laboratory equipment and continued investment in our intellectual property estate. Our future capital requirements will depend on many factors, including the following:

- the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, and acceptance of the testing service by physicians as standard of care;
- the scope and breadth of the business strategy we decide to pursue;
- formal acceptance 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;
- the scope of and progress made in our research and development activities and
- the successful commercialization and sales growth of PreGen-Plus.

We cannot assure you that our business will generate sufficient cash flow from operations, or that we will be able to liquidate our investments or obtain financing when needed or desirable. An inability to fund our operations would have a material adverse effect on our business, financial condition and results of operations.

Factors That May Affect Future Results

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.

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 product introduction in August 2003. From our date of inception on February 10, 1995 through June 30, 2005, we have accumulated a total deficit of approximately $131.9 million. We expect that our losses will continue for the next several years as a result of continuing research and development expenses, as well as increased sales and marketing expenses. If our revenue does not grow significantly to offset these expenses, 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, is included within colorectal cancer screening guidelines, is approved for payment by Medicare, is requested by patients, and is reimbursed by other third-party payors. We believe that the market demand for PreGen-Plus is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- effective sales and sales management personnel and processes to educate physicians and their office staffs to facilitate patient compliance;
- patient acceptance of PreGen-Plus, including its novel sample collection process;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the impact that the publication of our multi-center and other study results and accompanying editorials in a peer-reviewed journal have on market acceptance of PreGen-Plus 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.

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

Pursuant to our exclusive license agreement with LabCorp, our current operating revenue is dependent upon LabCorp's commercial sales of PreGen-Plus. We cannot assure you that we or LabCorp will be successful in achieving sufficient sales of PreGen-Plus for us to become profitable. Initiatives in support of the commercialization of PreGen-Plus include the following:

- physician and consumer education and demand;
- implementation of marketing and sales initiatives and programs;
- patient adherence and compliance programs;
- broad-based reimbursement initiatives;
- advocacy development;
- sales force training and
- contracting with manufacturers and suppliers.

If we or LabCorp are unsuccessful in our efforts with respect to one or more of the foregoing initiatives, our revenues could be materially adversely affected. Moreover, given the number of products that LabCorp sells, we cannot assure you that LabCorp will devote the resources and attention necessary to make PreGen-Plus commercially successful. Any failure of the LabCorp sales force or our sales and marketing employees, in whole or in part, to give continued and sustained focus to PreGen-Plus would harm the demand creation for PreGen-Plus and, in turn, could materially adversely effect our revenues and delay any performance-based payments for which we might otherwise be eligible under our strategic agreement with LabCorp. Any change in the senior management or organizational structure within LabCorp or EXACT Sciences, 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 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. Further, 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 to us.

In January 2004, we and LabCorp amended our license agreement to, among other things, restructure certain product development milestones. Although this amendment does not change the $45 million of total milestone payments that we may be eligible to receive under the agreement, the amendment makes 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. Moreover, we cannot assure you that this amendment 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.

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 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 effect 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.

Our business would suffer if we 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. There can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, if at all. In addition we are currently in the process of transitioning management of the supply chain to LabCorp and there can be no assurance that LabCorp will be able to negotiate commercially acceptable agreements with the third-party vendors in this supply chain, nor that LabCorp will be able to enter into such agreements at all. Failure to transition this supply chain successfully could have a material adverse affect on the supply of raw materials necessary for LabCorp to perform the PreGen-Plus testing service which could interrupt the sale and delivery of the testing service and materially affect our revenues. In the event LabCorp is able to enter into these third-party agreements, any such licenses or supply agreements may require us or LabCorp to pay royalties or other fees to third parties, which would have an adverse effect 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 Effipure 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 for Effipure or the PreGen-Plus testing service overall would 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 effect on our revenues and gross margin, respectively.

If our clinical studies do not prove the superiority of PreGen-Plus, we may experience 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, we may never successfully commercialize PreGen-Plus and, as a consequence, we may not be able to remain a viable business.

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 goal of this study was to provide additional data supporting the superiority of tests utilizing our prototype technology versus the most widely used brand of FOBT, Hemoccult II®, in detecting colorectal cancer in this average-risk population. Although this study achieved its primary endpoint of showing that the prototype version of our technology was more sensitive than Hemoccult II, 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 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. This three-year study was designed to compare the results of our prototype technology with those of the Hemoccult II, a common first-line colorectal cancer screening option. The Mayo study was principally powered for the detection of screen relevant neoplasia (a category that includes high grade dysplasia, invasive cancer, and adenomas $\geq$1cm) rather than invasive cancers as a stand alone category. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. 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. While 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 than that demonstrated in our prior published studies, this preliminary data is susceptible to varying interpretations that could negatively impact the market acceptance of our technologies. Moreover, although we believe that the preliminary data from the Mayo Clinic study is clinically inconclusive given the small sample size of significant colorectal lesions and the DNA degradation that resulted from the sample collection methods used in the study, thought-leading gastroenterologists and primary care physicians may be reluctant to order tests using our technologies based on this preliminary data, which would materially harm our business and materially adversely affect our revenues. There is additional risk that thought-leading gastroenterologists, guidelines organizations, primary care

physicians and others may, despite the small sample size referenced above, assign disproportionate significance to this preliminary data, especially if published by the NCI and/or Mayo Clinic, which may significantly adversely affect commercialization.

If the results of our clinical studies, including the results of a 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 superior to existing screening methods, including Hemoccult II and Hemoccult Sensa, or show that our tests are superior but not by a large enough margin to affect prevailing clinical practice, we may experience 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 Medicare and other third-party payors, including managed care organizations, do not provide adequate reimbursement for PreGen-Plus, the commercial success of PreGen-Plus could 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, and covered by managed care organizations. There is significant uncertainty concerning third-party reimbursement for the use of any test 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; medically necessary; appropriate for the specific patient or cost-effective. 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 (NCD), CMS has sought additional information in connection with our NCD submission which has delayed our application's acceptance, and only a limited number of payors have issued formal policy approving payment for stool-based DNA testing. While we and LabCorp have had some success in obtaining reimbursement from third-party payors for tests performed to date, 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.

If PreGen-Plus cannot be effectively sold at a price acceptable to the market, we may not be able to successfully commercialize PreGen-Plus.

The success of PreGen-Plus depends, in material part, on the ability of LabCorp to price the test at a level acceptable to consumers, physicians, and third-party payors. Currently, screening for colorectal cancer using our technology is more expensive than FOBT because it is labor-intensive and uses highly complex processes and expensive reagents. In order to make PreGen-Plus less costly and more commercially attractive to consumers, physicians and third party payors, 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. 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 the Effipure technology and our or LabCorp's other 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 PreGen-Plus through research on technical innovations such as Effipure technology. 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, which incorporates Effipure and other technology improvements, will have sufficient sensitivity or performance to be commercially successful. We have conducted studies of the PreGen-Plus test, which included Effipure technology. These studies, which have consisted of cohorts from previously conducted clinical studies, including the multi-center study, have shown that the PreGen-Plus test that includes Effipure detected cancer in additional samples that the original bead-based version of our technology did not. However, the number of samples in each of these studies has been small and the ranges of sensitivity improvement with Effipure have been broad, thus making it difficult to definitively quantify the increased sensitivity with Effipure, as compared to the prototype test. If future generations of the PreGen-Plus test, or the commercial version of the PreGen-Plus test with Effipure, do not demonstrate a sufficiently significant increase in the sensitivity or performance over that of the prototype technology in a cost effective manner, we may never achieve the expected demand for tests using our technologies or such demand could be significantly reduced, either of which would have a material adverse effect on our revenues.

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

If we, or LabCorp, fail to convince a sufficient number of medical practitioners to order and reorder tests using our technologies, or if we or LabCorp are unable to generate adequate product loyalty among physicians, we will not be able to create sufficient demand for tests using our technologies in sufficient volume for us to 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. We and LabCorp will need to make gastroenterologists and primary care physicians 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 for us, or LabCorp, to convince medical practitioners to order and reorder colorectal cancer screening tests using our technologies for their patients which could materially adversely affect our revenues.

We may experience limits on our revenue and profitability 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 cancer, most 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 profitability.

If we or LabCorp fail to comply with U.S. Food and Drug Administration ("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.

The FDA regulates laboratory tests that are developed and used by a laboratory to conduct in-house testing. However, the FDA has historically exercised enforcement discretion in this area when such testing services are developed and offered by high-complexity, CLIA-approved laboratories. In addition, the FDA exempts from pre-market review certain specific "analyte specific reagents" and certain general purpose laboratory equipment, some of which are used in connection with LabCorp's PreGen-Plus testing service. For instance, we are a registered specification developer with the FDA for the Effipure microtiter plates that are used in connection with LabCorp's PreGen-Plus testing service. The microtiter plates are comprised of certain membranes with embedded strands of DNA that are manufactured by third-parties and then bonded by a third party to these microtiter plates. The microtiter plates are used by LabCorp in connection with the PreGen-Plus testing service for the recovery of DNA from biological samples. We believe that the Effipure microtiter plates are general purpose laboratory equipment that are exempt from pre-market review under current FDA regulation. We further believe that the strands of DNA and membranes manufactured by third-parties are also exempt from such pre-market review under current regulations. However, if the FDA determines that Effipure, in whole or in part, or that the commercial testing service as currently provided by LabCorp requires pre-market approval, commercial sales of PreGen-Plus could be delayed, halted or prevented and enforcement action could be initiated which could involve criminal or civil penalties. Finally, any analyte specific reagent or general purpose laboratory equipment that we provide in connection with LabCorp's PreGen-Plus testing service will be subject to a number of FDA requirements, including compliance with 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 could significantly increase our expenses and limit our revenue and profitability.

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 effect 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 June 30, 2005, we have 35 issued patents, 2 allowed patent applications and 25 pending patent applications in the United States and we also have 54 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 and a third-party institution have filed a joint patent application that is co-owned by us and that third-party institution relating 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-pharyngeal, liver and gall bladder in stool under the Patent Cooperation Treaty. This patent application designates the United States, Japan, Europe and Canada. Co-ownership of a patent allows the co-owner to exercise all rights of ownership, including the right to use, transfer and license the rights protected by the applicable patent.

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 over 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 new procedure being performed in which a radiologist views the inside of the colon through a scanner, as well as existing and possibly improved traditional screening tests such as immunochemical FOBT. In addition, some companies are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colon cancer in the blood including proteomics in which protein patterns are analyzed for links to disease. 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 rely 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, maintain, or effectively transition 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 the Effipure technology is replaced in commercial use by new or improved technologies, our existing Effipure inventories could become obsolete, which could require the write-off of existing inventory that would negatively impact our gross margins and profitability.

We purchase certain Effipure components from contract manufacturers pursuant to minimum purchase commitments. We carry Effipure components purchased pursuant to these minimum purchase commitments in our inventory until they are shipped to LabCorp for use in processing PreGen-Plus tests. During calendar 2004 and the six months ended June 30, 2005, we purchased approximately $1.3 million in Effipure components under these purchase commitments. As of June 30, 2005, our future minimum purchase commitment in connection with Effipure contract manufacturers was approximately $319,000. As we fulfill these minimum purchase commitments, if test volumes do not keep pace with Effipure inventory levels (the components of which have a finite useful life, after which time they must be discarded), or if Effipure is replaced in commercial use by LabCorp, we may need to make additional provisions for excess or obsolete inventory, which would have a negative impact on our gross margins and profitability.

We have historically been responsible for the procurement and supply chain management of Effipure components until they are delivered to LabCorp, who uses Effipure in processing PreGen-Plus tests. We are currently in discussions with LabCorp to transition the procurement and supply chain management of Effipure to LabCorp. As of this date, we can not estimate the costs associated with this potential transfer, but such costs may include write downs of current inventory, costs to transfer on-hand inventory to LabCorp and costs associated with the transfer or cancellation of certain contracts in the current supply chain. As of June 30, 2005, the carrying value of our Effipure inventory was $733,000 and was recorded under the caption "Prepaid expenses and other current assets" in our consolidated balance sheets.

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 or be forced to cease offering PreGen-Plus in certain jurisdictions. Also, conforming the marketing and sale of our products 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 effect 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 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 and Anthony P. Shuber, our Executive Vice President and Chief Technology Officer. Anthony P. Shuber has been critical to the development of our technologies and business. Although Messrs. Hardison and Shuber have each signed a non-disclosure and assignment of intellectual property agreement and a non-compete agreement, they have no employment agreements currently in place. We also have a severance agreement with each of Messrs. Hardison and Shuber that provides for twelve months severance under certain circumstances. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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.

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. 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.

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.

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 National Market under the symbol "EXAS." Factors affecting our stock price may include:

- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to the PreGen-Plus test or technologies of our competitors;
- inclusion of stool DNA screening in colorectal cancer screening guidelines;
- stool DNA screening becoming a standard of care among prescribing physicians;
- reimbursement decisions by Medicare and other third party payors;
- FDA regulation of our products and services;
- 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 National 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.

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

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

Item 4. Controls And Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer, our Senior Vice President, Chief Financial Officer and Treasurer and our Controller and Principal Accounting 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 President and Chief Executive Officer, our Senior Vice President, Chief Financial Officer and Treasurer and our Controller and Principal Accounting Officer concluded that, as of June 30, 2005, 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 5. Other Information

On July 21, 2005, the Compensation Committee of the Board of Directors approved an amendment to our 2004 Executive Incentive Plan (the "Incentive Plan") to provide that certain stock awards previously authorized for issuance under the Incentive Plan be paid in cash in lieu of our common stock. The Incentive Plan establishes cash and stock bonus awards that may be earned by senior management approved for participation in the Incentive Plan, including each of our executive officers, based on their individual performance and on our achievement of certain corporate goals during fiscal 2004. As amended, the Incentive Plan provides that the value of the total stock bonus awards earned under the Incentive Plan that are based upon fiscal 2004 corporate performance will be awarded 50% in cash, in the aggregate amount of $208,000, on the date of the amendment and, provided that we meet certain accession rate targets for the 2005 fiscal year, 50% in shares of the Company's common stock.

Item 6. Exhibits

Exhibit Number	Description
10.1	Executive Incentive Plan.
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.
31.3	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: August 2, 2005

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

Date: August 2, 2005

By: /s/ Harry W. Wilcox
Harry W. Wilcox
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Date: August 2, 2005

By: /s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Controller and Principal Accounting Officer
(Principal Accounting Officer)

EXHIBIT INDEX

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32.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Executive Incentive Plan

Adopted, as amended,
July 29, 2005

Overview

The EXACT Sciences Executive Incentive Plan has been designed to be an effective management tool that will bring focus to the company's, fiscal year objectives and incentivize performance to not just meet, but accelerate and overachieve the accomplishment of those objectives. The plan is based on specific and measurable objectives for both the company and each individual participant, with performance against those to be weighted equally. As a financial incentive, each executive will have a significant percentage of their annual total compensation tied to meeting the corporate and individual objectives that have been established for the year with the opportunity to receive greater payouts for overachievement.

Participation

In order to be eligible to participate in the Executive Incentive Plan for a given plan year, an executive must meet the following criteria:

- Be an employee of EXACT Sciences and hold the position of CEO or Vice President
- Have a hire date not later than July 1 st for such year and have worked at least 1040 hours of a given plan year
- Be an employee in good standing as of December 31 st of a given plan year
- Executives hired between February 1 st and June 30 th of a given plan year will have bonus amounts earned, if any, prorated to the number of full months of employment during the plan year
- If an executive does not meet the preceding criteria, they may still be allowed to participate in the plan under any such terms as approved by the Compensation Committee

Methodology

Objectives

The EXACT Executive Incentive plan includes setting objectives for both the corporation and for each executive individually. The Board of Directors reviews and approves corporate objectives for the fiscal year. Achievement of these objectives drives the corporate component of the plan. Working with the CEO, each executive will prepare their individual functional unit objectives using a similar form and will be a key basis for any cash payments under the plan. It is understood that plans and objectives may change

dynamically and need to be updated and that key achievements may occur that were not initially envisioned. Such factors will be considered as the plan is reviewed at year-end.

Performance Assessment

Each quarter, the Board of Directors will review overall corporate performance against objectives, with the Compensation Committee doing biannual reviews of individual executive performance. After the end of each fiscal year, the Compensation Committee working with the full Board will make a determination of the level of corporate performance for the year. The CEO will assess the performance of each executive and make a recommendation regarding a payout under this plan to the Compensation Committee for approval. CEO performance will be determined by the Compensation Committee and the Board of Directors. Individual performance is determined both against written functional area objectives and by subjective performance assessment.

Payouts

In order to achieve any payouts under the plan, it is first necessary for the company to hit approximately 70% of its corporate objectives. Upon achieving this threshold, payouts are then divided into two distinct, but related components. The Compensation Committee may recommend to the full Board to vary payout formulae to reflect corporate accomplishments as they determine appropriate. Specifically, the Compensation Committee may determine that despite achieving or not achieving any number of individual corporate objectives, the overall performance or status of the Company is such that payouts may be increased, reduced or eliminated altogether.

Corporate Performance

For assessment, corporate performance is divided into three levels of approximately 70%, 85% or 100% of objectives achieved.

Payouts for corporate performance may be made in cash or common stock at the discretion of the Compensation Committee. The amount of the payout for corporate performance will be based on a value calculated as a multiple of an executive's individual performance cash payout according to the following matrix:

Performance Level Corporate	**Calculation for Value of Payout**
100% (i.e., 6/6 objectives achieved)	2.5 times Individual Cash Payout
85% (i.e., 5/6 objectives achieved)	2.0 times Individual Cash Payout
70% (i.e., 4/6 objectives achieved)	No Multiplier of Cash Payout

In the event that that the Compensation Committee determines to use common stock for payouts for corporate performance, the stock grants will be made pursuant to the corporation's stock option and incentive plan as follows: 50% immediately and 50% on the first anniversary thereafter. The formula to calculate the number of shares to be granted on each applicable date is as follows: Total Value of Grant ÷ 2 ÷ closing price of the Corporation's common stock on the date of the grant. It is intended that there be

no restrictions upon the sale of the stock except for quiet periods and other restrictions that may be imposed by applicable securities laws. If an employee terminates his or her employment before the date of grant of any stock or cash award, the stock or cash award is forfeited.

Individual Performance

For assessment, individual performance is divided into three levels: Outstanding, Above Expectations, and Effective. Under the plan, an individual must perform to be rewarded and no incentive payouts will be made to individuals who do not achieve at least an effective level of performance regardless of the level of corporate performance.

Payouts for individual performance are made in cash according the following matrix:

Performance Level Individual	CEO	EVP	VP
Outstanding	$60-$70	$40-$50	$30-$35
Above	$50-$55	$30-$35	$20-$25
Effective	$15-$35	$7.5-$25	$5-$15

* all amounts in '000's

Total Compensation

The following table shows the range of total compensation available under the plan:

Performance Level		CEO			EVP			VP		
Corp	Individual	Ind. Award $	Corp. award $	Total $	Ind. Award $	Corp Award $	Total $	Ind. Award $	Corp Award $	Total $
	Outstanding	60-70	150-175	210-245	40-50	100-125	140-175	30-35	75-87.5	105-122.5
100%	Above	50-55	125-137.5	175-193	30-35	75-87.5	105-122.5	20-25	50-62.5	70-87.5
	Effective	15-35	37.5-87.5	52.5-122.5	7.5-25	18.8-62.5	26-87.5	5-15	12.5-37.5	17.5-52.5
	Outstanding	60-70	120-140	180-210	40-50	80-100	120-150	30-35	60-70	90-105
85%	Above	50-55	100-110	150-165	30-35	60-70	90-105	20-25	40-50	60-75
	Effective	15-35	30-70	45-105	7.5-25	15-50	22.5-75	5-15	10-30	15-45
	Outstanding	60-70	0	60-70	60-70	0	60-70	30-35	0	30-35
70%	Above	50-55	0	50-55	50-55	0	50-55	20-25	0	20-25
	Effective	15-35	0	15-35	15-35	0	15-35	5-15	0	5-15

* all amounts in '000's

The following example shows a potential total compensation calculation for a Vice President assuming that corporate performance awards are made in common stock:

Assumptions:	Company achieves 85% of objectives Individual performance is rated as Outstanding at highest end of cash payout range Common stock price on first vest date is $10.00 Common stock price on second vest date is $20.00	
Cash Payout:	$35,000	
Stock Payout:	$70,000 Total Value	
Total Compensation:	$105,000	
# of Shares Granted:	3,500 on first vest date 1,750 on second vest date	($70,000 ÷ 2 ÷ $10.00) ($70,000 ÷ 2 ÷ $20.00)

Timing

It is anticipated that the Compensation Committee will review corporate and individual performance under this plan with the Board of Directors at its January meeting. After that review and pending final approval of awards by the Committee, cash awards under this plan, if any, will be made as of the third Thursday in February of the year following the applicable fiscal year. Awards made in stock will have a first vesting date of the third Thursday in February of the year following the applicable fiscal year and a second vesting date of the third Thursday in February of the following year. Share amounts will be calculated using the closing price of EXACT Sciences common stock on the day previous to the vesting date. The Compensation Committee may elect to alter this schedule at it deems appropriate.

Plan Changes

At any time in any given plan year, the CEO with the approval of the Compensation Committee or the Compensation Committee acting in its sole discretion may alter any terms of the Executive Incentive Plan. In particular, if the financial resources of the company are inadequate to support the plan regardless of performance, payouts may be restructured using equity, deferred to such future date when financial resources can appropriately accommodate them or eliminated altogether.

Exhibit 31.1

I, Don M. Hardison, certify that:

1. I have reviewed this report on Form 10-Q of EXACT Sciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2005

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

Exhibit 31.2

I, Harry W. Wilcox, III, certify that:

1. I have reviewed this report on Form 10-Q of EXACT Sciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2005

By: /s/ Harry W. Wilcox, III
Harry W. Wilcox, III
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 31.3

I, Charles R. Carelli, Jr., certify that:

1. I have reviewed this report on Form 10-Q of EXACT Sciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2005

By: /s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Controller and Principal Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of EXACT Sciences Corporation (the "Company") on Form 10-Q for the period ending June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Don M. Hardison, Chief Executive Officer of the Company, Harry W. Wilcox, III, Senior Vice President, Chief Financial Officer and Treasurer of the Company and Charles R. Carelli, Jr., Controller and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Don M. Hardison

Don M. Hardison
President, Chief Executive Officer and Director
August 2, 2005

/s/ Harry W. Wilcox, III

Harry W. Wilcox, III
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)
August 2, 2005

/s/ Charles R. Carelli, Jr.

Charles R. Carelli, Jr.
Controller and Principal Accounting Officer
August 2, 2005