EXACT SCIENCES CORP

FORM 10-Q
(Quarterly Report)

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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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 April 29, 2005, the Registrant had 26,247,941 shares of Common Stock outstanding.

EXACT SCIENCES CORPORATION

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Part I - Financial Information

Part II - Other Information

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

	December 31, 2004	March 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,092	$ 9,333
Marketable securities	37,188	35,001
Prepaid expenses and other current assets	1,835	2,112
Total current assets	52,115	46,446
Property and Equipment, at cost:		
Laboratory equipment	4,242	4,071
Office and computer equipment	1,383	1,400
Leasehold improvements	1,482	1,133
Furniture and fixtures	299	299
	7,406	6,903
Less—Accumulated depreciation and amortization	(5,452)	(5,418)
	1,954	1,485
Patent Costs and Other Assets, net of accumulated amortization of approximately $1,718 and $1,833 at December 31, 2004 and March 31, 2005, respectively	2,042	1,922
	$ 56,111	$ 49,853
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 365	$ 99
Accrued expenses	2,034	1,399
Deferred license fees, current portion	4,459	4,421
Total current liabilities	6,858	5,919
Deferred License Fees, less current portion	11,270	10,180
Commitments and contingencies		
Stockholders' Equity:		
Common stock, $0.01 par value Authorized—100,000,000 shares Issued and outstanding—26,285,067 and 26,333,491 shares at December 31, 2004 and March 31, 2005, respectively	263	263
Additional paid-in capital	161,356	161,679
Treasury stock, 85,550 shares at December 31, 2004 and March 31, 2005	(97)	(97)
Notes receivable	(5)	(5)
Deferred compensation	(89)	(40)
Other comprehensive loss	(115)	(131)
Accumulated deficit	(123,330)	(127,915)
Total stockholders' equity	37,983	33,754
	$ 56,111	$ 49,853

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

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

	Three Months Ended March 31,	
	2004	2005
Revenue:		
Product royalty fees	$ 22	$ 68
License fees	1,128	1,128
Product	27	51
	1,177	1,247
Cost of revenue:		
Product royalty fees	1	4
Product	31	44
	32	48
Gross profit	1,145	1,199
Operating Expenses:		
Research and development	3,134	2,281
Sales and marketing	1,327	1,599
General and administrative	1,967	1,221
Restructuring	—	626
Stock-based compensation (1)	126	303
	6,554	6,030
Loss from operations	(5,409)	(4,831)
Interest income	118	246
Net loss	$ (5,291)	$ (4,585)
Net loss per share—basic and diluted	$ (0.23)	$ (0.17)
Weighted average common shares outstanding—basic and diluted	22,949	26,203

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

Research and development	$ 53	$ 61
Sales and marketing	—	58
General and administrative	73	184
Total	$ 126	$ 303

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)

	Three Months Ended March 31,	
	2004	2005
Cash flows from operating activities:		
Net loss	$ (5,291)	$ (4,585)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	336	210
Amortization	132	138
Restructuring	—	282
Stock based compensation	126	303
Amortization of deferred license fees	(1,128)	(1,128)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(512)	(277)
Accounts payable	129	(266)
Accrued expenses	344	(635)
Net cash used in operating activities	(5,864)	(5,958)
Cash flows from investing activities:		
Purchases of marketable securities	(36,777)	(6,340)
Maturities of marketable securities	9,168	8,511
Purchases of property and equipment	(30)	(23)
Increase in patent costs and other assets	(84)	(18)
Net cash (used in) provided by investing activities	(27,723)	2,130
Cash flows from financing activities:		
Net proceeds from sale of common stock	43,383	—
Proceeds from exercise of common stock options and stock purchase plan	160	68
Repayment of notes receivable	23	1
Net cash provided by financing activities	43,566	69
Net increase (decrease) in cash and cash equivalents	9,979	(3,759)
Cash and cash equivalents, beginning of period	14,200	13,092
Cash and cash equivalents, end of period	$ 24,179	$ 9,333
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 and commercializes proprietary DNA-based tests for the early detection of cancer. The Company has selected colorectal cancer as the first application of its technology platform. The Company has devoted the majority of its efforts to date on the research, development and commercialization of PreGen-Plus™, the Company's proprietary, non-invasive DNA-based technology for the early detection of colorectal cancer in the average-risk population, which is offered commercially through a license agreement with Laboratory Corporation of America® Holdings ("LabCorp®").

(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 March 31, 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 March 31, 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 months ended March 31, 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 approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is deemed to be no longer of value to 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 as of March 31, 2004 and 2005 because they had an antidilutive effect due to net losses for such periods:

	(In thousands) March 31,	
	2004	2005
Shares issuable upon exercise of stock options	4,246	5,292
Shares issuable upon vesting of restricted common stock	107	9
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,353	6,301

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. Compensation expense of $24,000 and $9,000 with respect to options granted to non-employees computed using the Black-Scholes option pricing model was recorded in the accompanying condensed consolidated statements of operations for the three months ended March 31, 2004 and 2005, respectively.

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 as of March 31, 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:

(In thousands, except per share data)	Three Months Ended March 31, 2004	2005
Net loss as reported	$ (5,291)	$ (4,585)
Add: Stock-based compensation included in reported net loss	126	303
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(1,822)	(2,313)
Pro forma net loss - SFAS 123	$ (6,987)	$ (6,595)
Basic and diluted net loss per share:		
As reported	$ (0.23)	$ (0.17)
Pro forma net loss - SFAS 123	$ (0.30)	$ (0.25)

The assumptions used for the three months ended March 31, 2004 and 2005 are as follows:

	Three Months Ended March 31, 2004	2005
Risk-free interest rates	1.69% - 1.75%	3.96% - 4.00%
Expected lives	7 years	7 years
Expected volatility	100%	100%
Dividend yield	0%	0%
Weighted average fair value per share of options granted during the period	$ 6.37	$ 3.54

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. Service revenue is recognized when services are performed (earned), amounts can be objectively determined (measurable), and collection is reasonably assured (collectible or realizable).

Product revenue from the sale of certain components of its Effipure™ technology 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 months ended March 31, 2004 and 2005 was as follows:

	Three Months Ended March 31,	
(In thousands)	2004	2005
Net loss	$ (5,291)	$ (4,585)
Unrealized loss on marketable securities	(26)	(16)
Comprehensive loss	$ (5,317)	$ (4,601)

(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 its 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 recorded the following charges and payments in the quarter ended March 31, 2005. Amounts remaining in the restructuring accrual at March 31, 2005 are expected to be paid out through June 2005 and are recorded under the caption “Accrued expenses” in the condensed consolidated balance sheets at March 31, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, March 31, 2005
Employee separation costs	$ —	$ 246	$ (227)	$ —	$ 19
Facility consolidation costs	—	380	—	(282)	98
Total	$ —	$ 626	$ (227)	$ (282)	$ 117

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) RECLASSIFICATIONS

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

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 and commercializes proprietary DNA-based tests for the early detection of cancer. Our first commercial test, PreGen-Plus™, is used for screening for colorectal cancer, 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 tests;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- conducting market studies and analyzing alternative approaches for commercializing our technologies;
- hiring research and clinical personnel, sales personnel, management and other support personnel;
- raising capital;
- licensing our proprietary technologies to Laboratory Corporation of America ("LabCorp");
- working with LabCorp on activities necessary for the commercialization, marketing and sale of PreGen-Plus and
- direct sales and marketing efforts related to PreGen-Plus.

We have generated limited operating revenues since our inception and, as of March 31, 2005, we had an accumulated deficit of approximately $127.9 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 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 PreGen-Plus, which is being sold through LabCorp, is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- effective sales 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 and
- the impact that the publication of our multi-center study results and accompanying editorials in a peer-reviewed journal have on market acceptance of PreGen-Plus.

Our revenue is comprised of product royalty fees on PreGen-Plus tests sold by LabCorp, product revenue from the sale to LabCorp of certain components of our Effipure™ technology, which is incorporated into the PreGen-Plus test, 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 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 will increase in 2005 on an aggregate basis as compared to 2004 due to the ongoing commercial sales of PreGen-Plus by LabCorp. License fee revenue for 2005 is expected to be consistent with license fee revenue recorded in 2004 due to the ratable recognition of upfront license fees received from LabCorp.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies. Our research and development efforts in 2005 will focus on improving the sensitivity and other performance aspects of PreGen-Plus 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 stock option grants 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. SFAS No. 123(R) is effective for public companies (excluding small business issuers) at the beginning of the first fiscal year 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. Service revenue is recognized when services are performed (earned), amounts can be objectively determined (measurable), and collection is reasonably assured (collectible or realizable).

Product revenue from the sale of certain components of our Effipure™ technology 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 was $1.2 million for the three months ended March 31, 2005 as well as for the comparable 2004 period. 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.

Cost of revenue . Cost of revenue increased to $48,000 for the three months ended March 31, 2005 from $32,000 for the three months ended March 31, 2004. The increase in the cost of revenue for the three months ended March 31, 2005 as compared to the three months ended March 31, 2004 was the result of an increase in the number of Effipure components shipped to LabCorp. The cost of product revenue includes the product costs of Effipure components while cost of product royalty fees represents royalties owed to third-parties for technology currently incorporated into PreGen-Plus. We have contractual commitments to certain of our Effipure contract manufacturers which require us to pay minimum aggregate dollar amounts over the life of the commitments, which expire in April 2006. During 2004, we recorded charges of approximately $239,000 to write-off excess and expired Effipure inventory units. A portion of the 2004 charges to write-off excess and expired Effipure inventory units was based upon payments related to these minimum purchase commitments. As we fulfill these minimum purchase commitments or if the Effipure technology is replaced in commercial use, we may need to make additional provisions for excess or obsolete inventory.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, decreased to $2.3 million for the three months ended March 31, 2005 from $3.1 million for the three months ended March 31, 2004. The decrease in research and development expenses for the three months ended March 31, 2005 as compared to the three months ended March, 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 PreGen-Plus 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 decrease in research and development expenses were decreases of $435,000 in personnel-related expenses, $68,000 in professional fees and expenses, $52,000 in laboratory expenses, $150,000 in clinical study expenses and $147,000 related to laboratory space.

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 March 31, 2005 from $1.3 million for the three moths ended March 31, 2004. The increase in sales and marketing expenses for the three months ended March 31, 2005 as compared to the same period of 2004 was primarily due to an increase of $147,000 in sales personnel and related costs as a result of the expansion of our sales force during the fourth quarter of 2004 to complement the direct sales efforts of LabCorp as well as an increase of $132,000 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 March 31, 2005 from $2.0 million for the three months ended March 31, 2004. The decrease for the three months ended March 31, 2005 as compared to the three months ended March 31, 2004 was primarily due $581,000 in severance costs recorded in the three months ended March 31, 2004 in connection with the departure of certain executives. There was also a decrease in personnel related expenses of $69,000, due to lower headcount, as well as a decrease in professional fees of $141,000 in the quarter ended March 31, 2005 as compared to the same quarter of 2004.

Stock-based compensation . Stock-based compensation, which is a non-cash expense, increased to $303,000 for the three months ended March 31, 2005 from $126,000 for the three months ended March 31, 2004. Stock-based compensation for the three months ended March 31, 2005 included: (i) $208,000 for common stock awards granted to employees; (ii) $47,000 in charges resulting from the valuation of stock option grants to non-employees, which are recorded at fair value based on the fair value measurement criteria of SFAS No. 123 and (iii) $48,000 related to 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 for the three months ended March 31, 2004 included: (i) $228,000 of stock-based compensation associated with our agreement to forgive an outstanding loan of a former executive officer; (ii) a reduction of $272,000 in stock-based compensation associated with the forfeitures of restricted stock and the cancellation of unvested stock options due to the departure of certain officers and employees during the first quarter of 2004; (iii) $145,000 related to 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 and (iv) $25,000 in charges resulting from the valuation of stock option grants to non-employees, which are recorded at fair value based on the fair value measurement criteria of SFAS No. 123.

Restructuring. In February 2005, we took steps to focus our research and development efforts primarily on improving the sensitivity and other performance aspects of PreGen-Plus 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 recorded the following charges and payments in the quarter ended March 31, 2005. Amounts remaining in the restructuring accrual at March 31, 2005 are expected to be paid out through June 2005 and are recorded under the caption "Accrued expenses" in the consolidated balance sheets at March 31, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, March 31, 2005
Employee separation costs	$ —	$ 246	$ (227)	$ —	$ 19
Facility consolidation costs	—	380	—	(282)	98
Total	$ —	$ 626	$ (227)	$ (282)	$ 117

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 $246,000 for the three months ended March 31, 2005 from $118,000 for the three months ended March 31, 2004. This increase was due to an increase in our average cash, cash equivalents and marketable securities balances during the three months ended March 31, 2005 as compared to the three months ended March 31, 2004 as well an increase in interest rates on investments held during the three months ended March 31, 2005 as compared to the same period from the prior year.

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 March 31, 2005, we had approximately $44.3 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 $6.0 million for the three months ended March 31, 2005 as compared to $5.9 million for the three months ended March 31, 2004. The principal use of cash in operating activities in the three months ended March 31, 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 $2.1 million for the three months ended March 31, 2005, as compared to net cash used in investing activities of $27.7 million in the three months ended March 31, 2004. Included in the net cash used in investing activities for the three months ended March 31, 2004 were net purchases of $27.6 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 $41,000 and $114,000 in the three months ended March 31, 2005 and 2004, respectively.

Purchases of property and equipment of $23,000 during the three months ended March 31, 2005 were consistent with purchases of property and equipment of $30,000 during the three months ended March 31, 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 three months ended March 31, 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 approved in the United States over an estimated useful life of five years.

Net cash provided by financing activities was $69,000 for the three months ended March 31, 2005 and included $68,000 in proceeds from the issuance of common stock under our employee stock option and purchase plans. Net cash provided by financing activities for the three months ended March 31, 2004 was $43.6 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 $160,000 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 March 31, 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, as we are in the early stage of commercialization of PreGen-Plus, 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 PreGen-Plus 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.

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 raise additional funds at an acceptable price level.

The table below reflects our estimated fixed obligations and commitments as of March 31, 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	$ 5,289	$ 998	$ 1,929	$ 2,018	$ 344
Purchase obligations	612	612	—	—	—
Obligations under license and collaborative agreements	5,604	1,154	530	530	3,390
Total	$ 11,505	$ 2,764	$ 2,459	$ 2,548	$ 3,734

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, capital expenditures primarily associated with the relocation of our administrative offices to smaller space in our corporate headquarters, 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;
- 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:
- 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 March 31, 2005, we have accumulated a total deficit of approximately $127.9 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 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 first commercial product, PreGen-Plus, a proprietary, non-invasive DNA-based screening test for the early detection of colorectal cancer in the average-risk population, which is being sold through LabCorp, is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- effective sales 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 and
- the impact that the publication of our multi-center study results and accompanying editorials in a peer-reviewed journal have on market acceptance of PreGen-Plus.

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 primarily dependent upon LabCorp's commercial sales of PreGen-Plus. Although we are actively working together with LabCorp on initiatives designed to promote our joint success with regard to 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. Such initiatives include the following:

- physician and consumer education and demand;
- implementation of marketing and sales initiatives and 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 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 effectively 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 commercialize the test ourselves. We cannot assure you that we would be able to license our technology to another commercial laboratory or otherwise successfully commercialize the technology, 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.

The current configuration of PreGen-Plus that we have commercialized with LabCorp requires access to certain technologies and supplies of raw materials, including components for our Effipure technology, 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. Any such licenses may require us 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, or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we or our strategic partners 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 would require PreGen-Plus to be re-configured which could negatively impact its commercial sale and increase the costs associated with PreGen-Plus, 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 PreGen-Plus 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 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 our original, bead-based DNA capture version of PreGen-Plus 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 the PreGen-Plus test and adversely and materially impact revenues and profitability.

In October 2001, Mayo Clinic initiated a study of the bead-based version of our PreGen-Plus test that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. This three-year study, similar to our multi-center study, was designed to compare the results of our bead-based technologies with those of the Hemoccult II, a common first-line colorectal cancer screening option. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. Subsequently, we and the Mayo Clinic sought to include EXACT Sciences' Effipure technology in the study, rather than our older, bead based technology. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while PreGen-Plus was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia (a category that includes high grade dysplasia, invasive cancer, and adenomas $\geq$ 1cm), Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, the older, bead-based version of our 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, 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. 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 our technologies less costly and more commercially attractive to consumers, physicians and third party payors, we or 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 we or LabCorp fail 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 we and LabCorp are unable to sell a sufficient number of tests at favorable pricing levels, we will not be successful and we may not be able to remain viable as a company.

If our 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 our 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 our 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 increase in sensitivity of the PreGen-Plus test including Effipure, as compared to the original bead-based 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 original bead-based 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 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 tests using our technologies, 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 the test in colorectal cancer screening guidelines. We and LabCorp will need to make gastroenterologists and primary care physicians aware of the benefits of tests using our technologies 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 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 our partners fail to comply with FDA requirements, we may be limited or restricted in our ability to market our products and services and may be subject to stringent penalties.

The FDA does not actively regulate laboratory tests that are developed and used by a laboratory to conduct in-house testing. The FDA does regulate specific reagents and certain components, some of which are used with our technologies and react with a biological substance including those designed to identify a specific DNA sequence or protein. For instance, a key component of our technologies includes our Effipure technology for the recovery of DNA from biological samples. The FDA's regulations provide that most such reagents, which the FDA refers to as analyte specific reagents, or ASRs, are exempt from the FDA's pre-market review requirements. We believe the ASRs that we provide currently fall within these exemptions. However, if the FDA were to decide to more actively regulate in-house developed laboratory tests, or significantly change the regulations for ASRs, commercial sales of PreGen-Plus and the sale of Effipure components to LabCorp could be delayed, halted or prevented. If the FDA were to view any of our or LabCorp's actions as non-compliant, it could initiate enforcement action, which could involve criminal or civil penalties. Moreover, while we believe that Effipure qualifies as an ASR, and is therefore exempt from the FDA's pre-market review requirements, there can be no assurance that the FDA or other regulatory bodies will agree with our assessment and the commercialization of our products and services could be impacted by being delayed, halted or prevented altogether. Finally, any ASRs that we provide 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 selling our screening tests for cancer 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 in foreign countries. We have filed patent applications that we believe cover methods we have designed to detect colorectal cancer and other cancers, including our testing process. 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 March 31, 2005, we have 32 issued patents, 5 allowed patent applications and 23 pending patent applications in the United States and we also have 34 issued foreign patents and 43 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 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 the current configuration of the PreGen-Plus test, including our Effipure technology. Although we have identified suppliers that we believe are capable of supplying these raw materials and components in sufficient quantity today, there can be no assurance that we, or LabCorp, will be able to enter into or maintain agreements with such suppliers on a timely basis on acceptable terms, if at all. Furthermore, prior to August 2003, PreGen-Plus 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 PreGen-Plus, we may need to reconfigure the PreGen-Plus test which would result in delays in commercialization or an interruption in sales and would materially adversely impact our revenues.

If our 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 quarter ended March 31, 2005, we purchased approximately $1 million in Effipure components under these purchase commitments. As of March 31, 2005, our future minimum purchase commitment in connection with Effipure contract manufacturers was approximately $510,000. If our Effipure technology is replaced in commercial use by new or improved technologies developed by us or third parties, we may need to write-off all or a portion of our existing Effipure inventories, which would have a negative impact on our gross margins and profitability.

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 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. We and LabCorp developed our commercialization strategy for PreGen-Plus 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 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.

The time and attention of our management team may be diverted from domestic sales and operational issues if opportunities in foreign markets are pursued.

Our license with LabCorp is exclusive in the United States and Canada and we have the ability to license our technologies for colorectal cancer screening in other markets beyond these territories. Our success materially depends upon our management team devoting adequate time and attention to sales and operational issues within the United States. In the event we enter into business relationships with entities abroad, there can be no assurance that our management team will be able to continue to devote the time and attention necessary to adequately manage and support domestic initiatives.

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 our test, 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 March 31, 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

In February 2005, we took steps to focus our research and development efforts primarily on improving the sensitivity and other performance aspects of PreGen-Plus and reduced our cost structure accordingly. On February 9, 2005, we reported on Form 8-K that we were reducing our workforce by ten employees, effective February 15, 2005, under a plan of termination described in paragraph 8 of SFAS No. 146. On February 25, 2005, we reported on Form 8-K that we had entered into an amendment of the lease for our corporate headquarters, effective as of January 20, 2005, pursuant to which we would vacate certain leased space, thereby reducing the total space occupied under the lease from approximately 56,000 square feet to approximately 37,000 square feet.

Pursuant to the restructuring plan, we recorded the following charges and payments in the quarter ended March 31, 2005. Amounts remaining in the restructuring accrual at March 31, 2005 are expected to be paid out through June 2005 and are recorded under the caption "Accrued expenses" in the consolidated balance sheets at March 31, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, March 31, 2005
Employee separation costs	$ —	$ 246	$ (227)	$ —	$ 19
Facility consolidation costs	—	380	—	(282)	98
Total	$ —	$ 626	$ (227)	$ (282)	$ 117

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. 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.

On May 3, 2005, the Compensation Committee of the Board of Directors amended certain stock options previously granted to Dr. Richard Barker, a member of our Board of Directors, in connection with his decision not to stand for re-election to the Board of Directors. The amended options consist of vested options to purchase an aggregate of 20,000 shares of our common stock which were granted at various times between January 31, 2001 and July 26, 2002, at exercise prices ranging between $10.74 and $14.00 per share. These options have been amended to extend the period during which they may be exercised, following Dr. Barker's cessation of service as a director, from 90 days to one year, consistent with the terms of stock options granted under the Company's current compensation policy for non-employee directors. Other than extending the exercise period for the above referenced options, the terms of all options granted to Mr. Barker remain unchanged.

Item 6 . Exhibits

Exhibit Number	Description
10.1	2000 Employee Stock Purchase Plan, as amended.
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: May 6, 2005

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

Date: May 6, 2005

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

Date: May 6, 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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Exhibit 10.1

EXACT SCIENCES CORPORATION

2000 EMPLOYEE STOCK PURCHASE PLAN

Article 1 - Purpose .

This 2000 Employee Stock Purchase Plan (the "Plan") is intended to encourage stock ownership by all eligible employees of Exact Corporation (the "Company"), a Delaware corporation, and its participating subsidiaries (as defined in Article 17) so that they may share in the growth of the Company by acquiring or increasing their proprietary interest in the Company. The Plan is designed to encourage eligible employees to remain in the employ of the Company and its participating subsidiaries. The Plan is intended to constitute an "employee stock purchase plan" within the meaning of Section 423(b) of the Internal Revenue Code of 1986, as amended (the "Code").

Article 2 - Administration of the Plan .

The Plan may be administered by a committee appointed by the Board of Directors of the Company (the "Committee"). The Committee shall consist of not less than two members of the Company's Board of Directors. The Board of Directors may from time to time remove members from, or add members to, the Committee. Vacancies on the Committee, howsoever caused, shall be filled by the Board of Directors. The Committee may select one of its members as Chairman, and shall hold meetings at such times and places as it may determine. Acts by a majority of the Committee, or acts reduced to or approved in writing by a majority of the members of the Committee, shall be the valid acts of the Committee.

The interpretation and construction by the Committee of any provisions of the Plan or of any option granted under it shall be final, unless otherwise determined by the Board of Directors. The Committee may from time to time adopt such rules and regulations for carrying out the Plan as it may deem best, provided that any such rules and regulations shall be applied on a uniform basis to all employees under the Plan. No member of the Board of Directors or the Committee shall be liable for any action or determination made in good faith with respect to the Plan or any option granted under it.

In the event the Board of Directors fails to appoint or refrains from appointing a Committee, the Board of Directors shall have all power and authority to administer the Plan. In such event, the word "Committee" wherever used herein shall be deemed to mean the Board of Directors.

Article 3 - Eligible Employees .

All employees of the Company or any of its participating subsidiaries whose customary employment is more than 20 hours per week and for more than five months in any calendar year and who have completed three months of service shall be eligible to receive options under

the Plan to purchase common stock of the Company, and all eligible employees shall have the same rights and privileges hereunder; provided, however, that with respect to the First Payment Period (as defined below), all employees of the Company or any of its participating subsidiaries employed on the first day of the First Payment Period and whose customary employment is more than 20 hours per week and for more than five months in any calendar year shall be eligible to receive options under the Plan to purchase common stock of the Company. Persons who are eligible employees on the first business day of any Payment Period (as defined in Article 5) shall receive their options as of such day. Persons who become eligible employees after any date on which options are granted under the Plan shall be granted options on the first day of the next succeeding Payment Period on which options are granted to eligible employees under the Plan. In no event, however, may an employee be granted an option if such employee, immediately after the option was granted, would be treated as owning stock possessing five percent or more of the total combined voting power or value of all classes of stock of the Company or of any parent corporation or subsidiary corporation, as the terms "parent corporation" and "subsidiary corporation" are defined in Section 424(e) and (f) of the Code. For purposes of determining stock ownership under this paragraph, the rules of Section 424(d) of the Code shall apply, and stock which the employee may purchase under outstanding options shall be treated as stock owned by the employee.

Article 4 - Stock Subject to the Plan .

The stock subject to the options under the Plan shall be shares of the Company's authorized but unissued common stock, par value $.01 per share (the "Common Stock"), or shares of Common Stock reacquired by the Company, including shares purchased in the open market. The aggregate number of shares which may be issued pursuant to the Plan is 300,000 , subject to adjustment as provided in Article 12. If any option granted under the Plan shall expire or terminate for any reason without having been exercised in full or shall cease for any reason to be exercisable in whole or in part, the unpurchased shares subject thereto shall again be available under the Plan.

Beginning February 1, 2002 and each February 1 thereafter (each, an "Adjustment Date"), the number of shares which may be issued pursuant to the Plan shall automatically increase by such number of shares as is equal to the greater of (i) 0.75% of the number of shares of Common Stock outstanding on the immediately preceding December 31, and (ii) the number of shares of Common Stock that has been made subject to options under the Plan during the year immediately preceding such Adjustment Date; provided, however, that the Board may provide for a lesser number of shares on any Adjustment Date by designating such lesser number by resolution adopted on or before such Adjustment Date; and provided further, however that the cumulative number of additional shares that may be issued pursuant to the Plan as a result of increases on all Adjustment Dates taken together may not exceed 1,000,000 shares (such number to be subject to adjustment in accordance with Article 12 below).

Article 5 - Payment Period and Stock Options .

The first Payment Period during which payroll deductions will be accumulated under the Plan shall commence on the effective date of the registration statement on Form S-1 registering

the shares to be offered in the initial public offering of the Common Stock (the "Offering") and shall end on July 31, 2001 (the "First Payment Period"). For the remainder of the duration of the Plan, Payment Periods shall consist of six-month periods commencing on February 1 and August 1 and ending on July 31 and January 31 of each calendar year.

Twice each year, on the first business day of each Payment Period, the Company will grant to each eligible employee who is then a participant in the Plan an option to purchase on the last day of such Payment Period, at the Option Price hereinafter provided for, a maximum of 1,000 shares, on condition that such employee remains eligible to participate in the Plan throughout the remainder of such Payment Period. The participant shall be entitled to exercise the option so granted only to the extent of the participant's accumulated payroll deductions on the last day of such Payment Period. If the participant's accumulated payroll deductions on the last day of the Payment Period would enable the participant to purchase more than the maximum number of shares provided herein except for the share limitation set forth herein, the excess of the amount of the accumulated payroll deductions over the aggregate purchase price of the maximum number of shares which many be purchased in accordance with this Article 5 shall be promptly refunded to the participant by the Company, without interest. The Option Price per share for each Payment Period shall be the lesser of (i) 85% of the average market price of the Common Stock on the first business day of the Payment Period and (ii) 85% of the average market price of the Common Stock on the last business day of the Payment Period, in either event rounded up to the nearest cent. Notwithstanding the foregoing, with respect to the First Payment Period, the Option Price shall be calculated as the lesser of (i) 85% of the price per share at which the Common Stock is sold to the underwriters in the Offering, without regard to any applicable discounts or commissions provided to such underwriters, and (ii) 85% of the average market price of the Common Stock on the last business day of the First Payment Period. The foregoing limitation on the number of shares subject to option and the Option Price shall be subject to adjustment as provided in Article 12.

For purposes of the Plan, the term "average market price" on any date means (i) the average (on that date) of the high and low prices of the Common Stock on the principal national securities exchange on which the Common Stock is traded, if the Common Stock is then traded on a national securities exchange; or (ii) the last reported sale price (on that date) of the Common Stock on the NASDAQ National Market, if the Common Stock is not then traded on a national securities exchange; or (iii) the average of the closing bid and asked prices last quoted (on that date) by an established quotation service for over-the-counter securities, if the Common Stock is not reported on the NASDAQ National Market; or (iv) if the Common Stock is not publicly traded, the fair market value of the Common Stock as determined by the Committee after taking into consideration all factors which it deems appropriate, including, without limitation, recent sale and offer prices of the Common Stock in private transactions negotiated at arm's length.

For purposes of the Plan, the term "business day" means a day on which there is trading on the NASDAQ National Market or the aforementioned national securities exchange, whichever is applicable pursuant to the preceding paragraph; and if neither is applicable, a day that is not a Saturday, Sunday or legal holiday in State of Massachusetts.

No employee shall be granted an option which permits the employee's right to purchase stock under the Plan, and under all other Section 423(b) employee stock purchase plans of the Company and any parent or subsidiary corporations, to accrue at a rate which exceeds $25,000 of fair market value of such stock (determined on the date or dates that options on such stock were granted) for each calendar year in which such option is outstanding at any time. The purpose of the limitation in the preceding sentence is to comply with Section 423(b)(8) of the Code. If the participant's accumulated payroll deductions on the last day of the Payment Period would otherwise enable the participant to purchase Common Stock in excess of the Section 423(b)(8) limitation described in this paragraph, the excess of the amount of the accumulated payroll deductions over the aggregate purchase price of the shares actually purchased shall be promptly refunded to the participant by the Company, without interest.

Article 6 - Exercise of Option .

Each eligible employee who continues to be a participant in the Plan on the last day of a Payment Period shall be deemed to have exercised his or her option on such date and shall be deemed to have purchased from the Company such number of full shares of Common Stock reserved for the purpose of the Plan as the participant's accumulated payroll deductions on such date will pay for at the Option Price, subject to the maximum share limit of the option and the Section 423(b)(8) limitation described in Article 5. If the individual is not a participant on the last day of a Payment Period, the he or she shall not be entitled to exercise his or her option. Only full shares of Common Stock may be purchased under the Plan. Unused payroll deductions remaining in a participant's account at the end of a Payment Period by reason of the inability to purchase a fractional share shall be carried forward to the next Payment Period.

Article 7 - Authorization for Entering the Plan .

An employee may elect to enter the Plan by filling out, signing and delivering to the Company an authorization:

A. Stating the percentage to be deducted regularly from the employee's pay;

B. Authorizing the purchase of stock for the employee in each Payment Period in accordance with the terms of the Plan; and

C. Specifying the exact name or names in which stock purchased for the employee is to be issued as provided under Article 11 hereof.

Such authorization must be received by the Company at least ten days before the first day of the next succeeding Payment Period and shall take effect only if the employee is an eligible employee on the first business day of such Payment Period; provided, however, that with respect to the First Payment Period, an option shall be granted to each eligible employee and such authorization to participate in the plan must be received no more than three weeks following the first day of the First Payment Period.

Unless a participant files a new authorization or withdraws from the Plan, the deductions and purchases under the authorization the participant has on file under the Plan will continue from one Payment Period to succeeding Payment Periods as long as the Plan remains in effect.

The Company will accumulate and hold for each participant's account the amounts deducted from his or her pay. No interest will be paid on these amounts.

Article 8 - Maximum Amount of Payroll Deductions .

An employee may authorize payroll deductions in an amount (expressed as a whole percentage) not less than one percent (1%) but not more than ten percent (10%) of the employee's total compensation, including base pay or salary and any overtime, bonuses or commissions.

Article 9 - Change in Payroll Deductions .

Deductions may not be increased or decreased during a Payment Period. However, a participant may withdraw in full from the Plan.

Article 10 - Withdrawal from the Plan .

A participant may withdraw from the Plan (in whole but not in part) at any time prior to the last day of a Payment Period by delivering a withdrawal notice to the Company.

To re-enter the Plan, an employee who has previously withdrawn must file a new authorization at least ten days before the first day of the next Payment Period in which he or she wishes to participate. The employee's re-entry into the Plan becomes effective at the beginning of such Payment Period, provided that he or she is an eligible employee on the first business day of the Payment Period.

Article 11 - Issuance of Stock .

Certificates for stock issued to participants shall be delivered as soon as practicable after each Payment Period by the Company's transfer agent.

Stock purchased under the Plan shall be issued only in the name of the participant, or if the participant's authorization so specifies, in the name of the participant and another person of legal age as joint tenants with rights of survivorship.

Article 12 - Adjustments .

Upon the happening of any of the following described events, a participant's rights under options granted under the Plan shall be adjusted as hereinafter provided:

A. In the event that the shares of Common Stock shall be subdivided or combined into a greater or smaller number of shares or if, upon a reorganization, split-up,

liquidation, recapitalization or the like of the Company, the shares of Common Stock shall be exchanged for other securities of the Company, each participant shall be entitled, subject to the conditions herein stated, to purchase such number of shares of Common Stock or amount of other securities of the Company as were exchangeable for the number of shares of Common Stock that such participant would have been entitled to purchase except for such action, and appropriate adjustments shall be made in the purchase price per share to reflect such subdivision, combination or exchange; and

B. In the event the Company shall issue any of its shares as a stock dividend upon or with respect to the shares of stock of the class which shall at the time be subject to option hereunder, each participant upon exercising such an option shall be entitled to receive (for the purchase price paid upon such exercise) the shares as to which the participant is exercising his or her option and, in addition thereto (at no additional cost), such number of shares of the class or classes in which such stock dividend or dividends were declared or paid, and such amount of cash in lieu of fractional shares, as is equal to the number of shares thereof and the amount of cash in lieu of fractional shares, respectively, which the participant would have received if the participant had been the holder of the shares as to which the participant is exercising his or her option at all times between the date of the granting of such option and the date of its exercise.

Upon the happening of any of the foregoing events, the class and aggregate number of shares set forth in Article 4 hereof which are subject to options which have been or may be granted under the Plan and the limitations set forth in the second paragraph of Article 5 shall also be appropriately adjusted to reflect the events specified in paragraphs A and B above. Notwithstanding the foregoing, any adjustments made pursuant to paragraphs A or B shall be made only after the Committee, based on advice of counsel for the Company, determines whether such adjustments would constitute a "modification" (as that term is defined in Section 424 of the Code). If the Committee determines that such adjustments would constitute a modification, it may refrain from making such adjustments.

If the Company is to be consolidated with or acquired by another entity in a merger, a sale of all or substantially all of the Company's assets or otherwise (an "Acquisition"), the Committee or the board of directors of any entity assuming the obligations of the Company hereunder (the "Successor Board") shall, with respect to options then outstanding under the Plan, either (i) make appropriate provision for the continuation of such options by arranging for the substitution on an equitable basis for the shares then subject to such options either (a) the consideration payable with respect to the outstanding shares of the Common Stock in connection with the Acquisition, (b) shares of stock of the successor corporation, or a parent or subsidiary of such corporation, or (c) such other securities as the Successor Board deems appropriate, the fair market value of which shall not materially exceed the fair market value of the shares of Common Stock subject to such options immediately preceding the Acquisition; or (ii) terminate each participant's options in exchange for a cash payment equal to the excess of (a) the fair market value on the date of the Acquisition, of the number of shares of Common Stock that the participant's accumulated payroll deductions as of the date of the Acquisition could purchase, at an option price determined with reference only to the first business day of the applicable Payment Period and subject to the maximum share limitation set forth in Article 5 hereof, Code

Section 423(b)(8) and fractional-share limitations on the amount of stock a participant would be entitled to purchase, over (b) the result of multiplying such number of shares by such option price.

The Committee or Successor Board shall determine the adjustments to be made under this Article 12, and its determination shall be conclusive.

Article 13 - No Transfer or Assignment of Employee's Rights .

An option granted under the Plan may not be transferred or assigned, except by will or the laws of descent and distribution, and shall be exercised, during the participant's lifetime, only by the participant.

Article 14 - Termination of Employee's Rights .

Whenever a participant ceases to be an eligible employee because of retirement, voluntary or involuntary termination, resignation, layoff, discharge, death or for any other reason, his or her rights under the Plan shall immediately terminate, and the Company shall promptly refund, without interest, the entire balance of his or her payroll deduction account under the Plan. Notwithstanding the foregoing, eligible employment shall be treated as continuing intact while a participant is on military leave, sick leave or other bona fide leave of absence, for up to 90 days, or for so long as the participant's right to re-employment is guaranteed either by statute or by contract, if longer than 90 days.

Article 15 - Termination and Amendments to Plan .

Unless terminated sooner as provided below, the Plan shall terminate on January 31, 2011. The Plan may be terminated at any time by the Company's Board of Directors but such termination shall not affect options then outstanding under the Plan. It will terminate in any case when all or substantially all of the unissued shares of stock reserved for the purposes of the Plan have been purchased. If at any time shares of stock reserved for the purpose of the Plan remain available for purchase but not in sufficient number to satisfy all then unfilled purchase requirements, the available shares shall be apportioned among participants in proportion to the amount of payroll deductions accumulated on behalf of each participant that would otherwise be used to purchase stock, and the Plan shall terminate. Upon such termination or any other termination of the Plan, all payroll deductions not used to purchase stock will be refunded, without interest.

The Committee or the Board of Directors may from time to time adopt amendments to the Plan provided that, without the approval of the stockholders of the Company, no amendment may (i) increase the number of shares that may be issued under the Plan; (ii) change the class of employees eligible to receive options under the Plan, if such action would be treated as the adoption of a new plan for purposes of Section 423(b) of the Code; or (iii) cause Rule 16b-3 under the Securities Exchange Act of 1934 to become inapplicable to the Plan.

Article 16 - Limits on Sale of Stock Purchased under the Plan .

The Plan is intended to provide shares of Common Stock for investment and not for resale. The Company does not, however, intend to restrict or influence any employee in the conduct of his or her own affairs. An employee may, therefore, sell stock purchased under the Plan at any time the employee chooses, subject to compliance with any applicable federal or state securities laws and subject to any restrictions imposed under Article 21 to ensure that tax withholding obligations are satisfied. **THE EMPLOYEE ASSUMES THE RISK OF ANY MARKET FLUCTUATIONS IN THE PRICE OF THE STOCK.**

Article 17 - Participating Subsidiaries .

The term "participating subsidiary" shall mean any present or future subsidiary of the Company, as that term is defined in Section 424 (f) of the Code, which is designated from time to time by the Board of Directors to participate in the Plan. The Board of Directors shall have the power to make such designation before or after the Plan is approved by the stockholders.

Article 18 - Optionees Not Stockholders .

Neither the granting of an option to an employee nor the deductions from his or her pay shall constitute such employee a stockholder of the shares covered by an option until such shares have been actually purchased by the employee.

Article 19 - Application of Funds .

The proceeds received by the Company from the sale of Common Stock pursuant to options granted under the Plan will be used for general corporate purposes.

Article 20 - Notice to Company of Disqualifying Disposition .

By electing to participate in the Plan, each participant agrees to notify the Company in writing immediately after the participant transfers Common Stock acquired under the Plan, if such transfer occurs within two years after the first business day of the Payment Period in which such Common Stock was acquired. Each participant further agrees to provide any information about such a transfer as may be requested by the Company or any subsidiary corporation in order to assist it in complying with the tax laws. Such dispositions generally are treated as "disqualifying dispositions" under Sections 421 and 424 of the Code, which have certain tax consequences to participants and to the Company and its participating subsidiaries.

Article 21 - Withholding of Additional Income Taxes .

By electing to participate in the Plan, each participant acknowledges that the Company and its participating subsidiaries are required to withhold taxes with respect to the amounts deducted from the participant's compensation and accumulated for the benefit of the participant under the Plan, and each participant agrees that the Company and its participating subsidiaries may deduct additional amounts from the participant's compensation, when amounts are added to

the participant's account, used to purchase Common Stock or refunded, in order to satisfy such withholding obligations. Each participant further acknowledges that when Common Stock is purchased under the Plan the Company and its participating subsidiaries may be required to withhold taxes with respect to all or a portion of the difference between the fair market value of the Common Stock purchased and its purchase price, and each participant agrees that such taxes may be withheld from compensation otherwise payable to such participant. It is intended that tax withholding will be accomplished in such a manner that the full amount of payroll deductions elected by the participant under Article 7 will be used to purchase Common Stock. However, if amounts sufficient to satisfy applicable tax withholding obligations have not been withheld from compensation otherwise payable to any participant, then, notwithstanding any other provision of the Plan, the Company may withhold such taxes from the participant's accumulated payroll deductions and apply the net amount to the purchase of Common Stock, unless the participant pays to the Company, prior to the exercise date, an amount sufficient to satisfy such withholding obligations. Each participant further acknowledges that the Company and its participating subsidiaries may be required to withhold taxes in connection with the disposition of stock acquired under the Plan and agrees that the Company or any participating subsidiary may take whatever action it considers appropriate to satisfy such withholding requirements, including deducting from compensation otherwise payable to such participant an amount sufficient to satisfy such withholding requirements or conditioning any disposition of Common Stock by the participant upon the payment to the Company or such subsidiary of an amount sufficient to satisfy such withholding requirements.

Article 22 - Governmental Regulations .

The Company's obligation to sell and deliver shares of Common Stock under the Plan is subject to the approval of any governmental authority required in connection with the authorization, issuance or sale of such shares.

Government regulations may impose reporting or other obligations on the Company with respect to the Plan. For example, the Company may be required to identify shares of Common Stock issued under the Plan on its stock ownership records and send tax information statements to employees and former employees who transfer title to such shares.

Article 23 - Governing Law .

The validity and construction of the Plan shall be governed by the laws of Delaware, without giving effect to the principles of conflicts of law thereof.

Article 24 - Approval of Board of Directors and Stockholders of the Company .

The Plan was adopted by the Board of Directors on October 17, 2000 and was approved by the stockholders of the Company on October 17, 2000. The Plan was subsequently amended by the Board of Directors, without the need for stockholder approval, on July 22, 2003.

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: May 6, 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: May 6, 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: May 6, 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 March 31, 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
May 6, 2005

/s/ Harry W. Wilcox, III

Harry W. Wilcox, III
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)
May 6, 2005

/s/ Charles R. Carelli, Jr.

Charles R. Carelli, Jr.
Controller and Principal Accounting Officer
May 6, 2005