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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2008

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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

As of August 4, 2008, the registrant had 27,243,568 shares of Common Stock outstanding.

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EXACT SCIENCES CORPORATION

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

	June 30, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,504	$ 4,486
Marketable securities	2,244	8,101
Prepaid expenses and other current assets	402	275
Total current assets	8,150	12,862
Property and Equipment, at cost:		
Laboratory equipment	3,730	3,730
Office and computer equipment	1,420	1,420
Leasehold improvements	1,161	1,161
Furniture and fixtures	299	299
	6,610	6,610
Less—Accumulated depreciation and amortization	(6,125)	(6,009)
	485	601
Patent costs, net of accumulated amortization of $2,837 and $3,019 at June 30, 2008 and December 31, 2007, respectively	200	432
Restricted cash	700	700
	$ 9,535	$ 14,595
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 350	$ 245
Accrued expenses	1,568	2,811
Third party royalty obligation	2,000	1,200
Deferred license fees, current portion	1,350	1,350
Total current liabilities	5,268	5,606
Deferred license fees, less current portion	2,025	2,701
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares Issued and outstanding—0 shares at June 30, 2008 and and December 31, 2007	—	—
Common stock, $0.01 par value Authorized—100,000,000 shares Issued and outstanding—27,274,118 and 27,225,541 shares at June 30, 2008 and December 31, 2007, respectively	273	273
Additional paid-in capital	169,407	168,813
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	1	23
Accumulated deficit	(167,342)	(162,724)
Total stockholders' equity	2,242	6,288
	$ 9,535	$ 14,595

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenue:				
Product royalty fees	$ (495)	$ 19	$ (787)	$ 45
License fees	338	1,091	676	2,182
Product	11	5	16	58
	(146)	1,115	(95)	2,285
Cost of revenue:				
Product royalty fees	—	1	1	3
Gross profit	(146)	1,114	(96)	2,282
Operating expenses:				
Research and development (1)	528	1,332	1,387	2,609
General and administrative (1)	1,495	1,447	3,330	3,095
Sales and marketing (1)	—	400	—	789
Restructuring	(5)	(2)	(7)	31
	2,018	3,177	4,710	6,524
Loss from operations	(2,164)	(2,063)	(4,806)	(4,242)
Interest income	64	238	188	497
Net loss	$ (2,100)	$ (1,825)	$ (4,618)	$ (3,745)
Net loss per share—basic and diluted	$ (0.08)	$ (0.07)	$ (0.17)	$ (0.14)
Weighted average common shares outstanding—basic and diluted	27,175	26,880	27,160	26,835

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

Research and development	$ 25	$ 357	$ 70	$ 431
General and administrative	204	274	460	524
Sales and marketing	—	90	—	174

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

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

	Six Months Ended June 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	$ (4,618)	$ (3,745)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and write-offs of fixed assets	116	110
Amortization and write-offs of patents	315	239
Stock-based compensation	530	1,129
Amortization of deferred license fees	(676)	(2,182)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(127)	30
Accounts payable	105	5
Accrued expenses	(1,185)	296
Third party royalty obligation	800	—
Net cash used in operating activities	(4,740)	(4,118)
Cash flows from investing activities:		
Purchases of marketable securities	(3,458)	(12,934)
Maturities of marketable securities	9,293	16,076
Purchases of property and equipment	—	(2)
Increase in patent costs and other assets	(83)	(33)
Net cash provided by investing activities	5,752	3,107
Cash flows from financing activities:		
Proceeds from exercise of common stock options and stock purchase plan	6	15
Net cash provided by financing activities	6	15
Net increase (decrease) in cash and cash equivalents	1,018	(996)
Cash and cash equivalents, beginning of period	4,486	4,831
Cash and cash equivalents, end of period	$ 5,504	$ 3,835
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of 27,660 shares of common stock to fund the Company’s 401(k) matching contribution for 2007	$ 58	$ —
Issuance of 34,030 shares of common stock to fund the Company’s 401(k) matching contribution for 2006	$ —	$ 103
Issuance of 56,675 shares of restricted common stock to collaborator in lieu of cash to settle semi-annual license obligation	$ —	$ 158

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

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

EXACT Sciences Corporation (the "Company") was incorporated in February 1995. The Company has developed proprietary DNA-based technologies for use in the detection of cancer. The Company has selected colorectal cancer as the first application of its technologies. The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to Laboratory Corporation of America® Holdings ("LabCorp®") for use in a commercial testing service for the detection of colorectal cancer developed by LabCorp. LabCorp's first generation testing service, "PreGen-Plus™," was a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population and was marketed by LabCorp from August 2003 through June 1, 2008. In July 2008, LabCorp began offering "ColoSure™", its new non-invasive laboratory developed stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. The Company has devoted the majority of its efforts to date on research and development and commercialization support of its colorectal cancer detection technologies.

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 assume that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business, and, in the opinion of management, include all normal and recurring adjustments which are necessary to present fairly the results of operations for the reported periods. These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting.

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.

The Company has generated limited operating revenues since its inception and, as of June 30, 2008, had an accumulated deficit of approximately $167.3 million. The Company's losses have historically resulted from costs incurred in conjunction with research, development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and, prior to August 31, 2007, costs related to its sales and marketing functions to support the commercialization of its stool-based DNA screening technology.

The audit opinion with respect to the Company's consolidated financial statements for the year ended December 31, 2007 issued by its independent registered public accounting firm included an explanatory paragraph to emphasize that there is substantial doubt about the Company's ability to continue as a going concern. The Company expects that its cash, cash equivalents and short-term investments on hand at June 30, 2008 will be sufficient to fund its current operations through the end of the second quarter of 2009. This projection is based on the Company's current cost structure and its current operating assumptions, which do not provide for any funding related to clinical validation and other studies for the Company's Version 2 technology. The Company has no current sources of material ongoing revenue and, accordingly, it will need to raise additional capital in the next ten months through a strategic transaction, debt or equity financing, or third-party collaboration, if any, or some combination of the foregoing, to continue operations beyond the end of the second quarter of 2009. If the Company is unable to obtain additional capital prior to the end of the second quarter of 2009, it will not be able to sustain its operations and would likely be required to cease its operations . In addition, if the Company's expenses exceed its current estimates, the Company will be required to obtain additional funds even sooner. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

As a result of the foregoing, the Company engaged an investment bank in the first quarter of 2008 to assist its board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, the Company announced that it revised its corporate strategy to take immediate actions to preserve existing cash while focusing on the pursuit of a strategic transaction for the business. To date,

the Company has not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith. The company's revised corporate strategy may not result in a strategic alternative in the near future, if at all.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, EXACT Sciences Securities Corporation, a Massachusetts securities corporation. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with maturities of 90 days or less at the time of acquisition to be cash equivalents. Cash equivalents primarily consist of money market funds.

Restricted Cash

At June 30, 2008 and December 31, 2007, $0.7 million of the Company's cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's corporate headquarters.

Marketable Securities

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

All of the Company's investments are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sale of available-for-sale securities during the three and six months ended June 30, 2008 and 2007.

Patent Costs

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred and are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is deemed to be no longer of value to the Company. As of June 30, 2008, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with its stool-based DNA colorectal cancer screening service.

The following table summarizes activity with respect to the Company's capitalized patents for the six months ended June 30, 2008 and 2007. Amounts included in the table are in thousands.

	Six Months Ended June 30, 2008	Six Months Ended June 30, 2007
Patents, net of accumulated amortization, Beginning of period	$ 432	$ 763
Patent costs capitalized	83	33
Amortization of patents	(62)	(86)
Write-offs of patents	(253)	(153)
Patents, net of accumulated amortization, End of period	$ 200	$ 557

In July 2008, the Company announced that it was taking certain actions to reduce its cost structure to preserve existing cash, including suspending the clinical validation study of its Version 2 technology and eliminating approximately eight positions. These cost reduction actions were deemed to be impairment indicators pursuant to SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS No. 144"). After performing the requisite impairment analysis, the Company wrote off approximately $253,000 in capitalized patents related specifically to one of the components of its Version 2 technology that is not used in LabCorp's current ColoSure testing service.

During the three months ended March 31, 2007, the Company determined that it would likely not pursue commercialization of certain technologies and, accordingly, wrote off approximately $121,000 in capitalized patents related to these technologies. Capitalized patents written off during the three months ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus. During the three months ended June 30, 2007, a capitalized pending patent application, which is not critical to LabCorp's PreGen-Plus testing service, was not approved by the U.S. Patent and Trademark Office, and, accordingly, the Company wrote off approximately $32,000 in connection with this patent application.

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

Net Loss Per Share

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

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

	June 30,	
(In thousands)	2008	2007
Shares issuable upon exercise of stock options	4,396	4,328
Shares issuable upon exercise of outstanding warrants	1,000	1,000
	5,396	5,328

Accounting for Stock-Based Compensation

The Company accounts for share-based payments to employees in accordance with SFAS No. 123(R), *Share-Based Payment* ("SFAS No. 123(R)"), which requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. Share-based payment transactions with parties other than employees are accounted for in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* .

Revenue Recognition

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

Product royalty fees — The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of the Company's intellectual property. The Company will be entitled to the same royalty and milestone structure on any sales of ColoSure as it was entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, the Company's product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to the Company each month by LabCorp. Subsequent to the effective date of the Second Amendment, the Company's product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, the Company records product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to the Company each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company's consolidated statements of operations.

Product revenue —Product revenue from the sale of certain components of the Company's Effipure™ technology to LabCorp is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable. LabCorp has indicated that Effipure is not used as a component in LabCorp's ColoSure offering.

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

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income* , establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and six months ended June 30, 2008 and 2007 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2008	2007	2008	2007
Net loss	$ (2,100)	$ (1,825)	$ (4,618)	$ (3,745)
Unrealized (loss) gain on marketable securities	(23)	7	(22)	6
Comprehensive loss	$ (2,123)	$ (1,818)	$ (4,640)	$ (3,739)

(3) FOURTH AMENDMENT TO LABCORP LICENSE AGREEMENT

On March 17, 2008, the Company entered into the fourth amendment (the "Fourth Amendment") to its exclusive license agreement with LabCorp. Among other things, the Fourth Amendment further clarified certain license rights of the parties, amended LabCorp's termination rights relating to the failure to launch the Company's Version 2 technology and restricted certain of the Company's termination rights in the event the U.S. Food and Drug Administration ("FDA") limits LabCorp's ability to market products that incorporate technology

licensed to LabCorp under the amended license agreement. In addition, the Fourth Amendment eliminated certain of the Company's termination rights for a specified period of time during which LabCorp is not marketing any stool-based DNA test for colorectal cancer as a result of preparing for a commercial launch of a stool-based DNA test for colorectal cancer based on certain of the Company's intellectual property.

(4) CONTINGENCIES

Third Party Royalty Obligation

Pursuant to the terms of the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. The Company's obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using the Company's technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp's sales of colorectal cancer screening tests using the Company's technology increase to a level that would reduce this potential maximum obligation, if ever, the Company intends to record its estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)* . Based on sales volumes of PreGen-Plus through June 1, 2008 and anticipated sales volumes of ColoSure, as of June 30, 2008, the Company's had accrued a total of $2.0 million related to the total potential $3.5 million obligation to LabCorp, including the total potential $1.5 million obligation related to the first measurement period, which ends in December 2008, as well as $500,000 of the total potential $1.0 million obligation related to the second measurement period, which ends in December 2009. The Company recorded charges of $0.5 million and $0.8 million, respectively, during the three and six months ended June 30, 2008 in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in the Company's consolidated statements of operations. This obligation is recorded in the Company's consolidated balance sheets under the caption "Third-party royalty obligation." Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of the Company's consolidated statements of operations. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	$ —	$ 1,500
January 1, 2009	December 31, 2009	—	1,000
January 1, 2010	December 31, 2010	—	1,000
		$ —	$ 3,500

Employee Severance and Retention Agreements

On April 18, 2008, the Company entered into amended and restated employee retention agreements (the "Agreements") with certain employees, including Jeffrey R. Luber, the Company's President and Chief Executive Officer, and Charles R. Carelli, Jr., the Company's Senior Vice President, Chief Financial Officer, Treasurer and Secretary. The Agreements supersede and replace the prior employee retention agreements entered into between the Company and Messrs. Luber and Carelli on October 23, 2006.

For personnel remaining employed by the Company after the July 2008 cost reduction initiations (described in Note 10 below), the total potential severance and other obligations upon the occurrence of certain triggering events, including a termination without cause following a change of control of the Company, was approximately $2.0 million at June 30, 2008. As of June 30, 2008, the Company has not recorded any amount related to the potential severance payments because no triggering events had occurred as of that date.

(5) RESTRUCTURING

On August 31, 2007, the Company entered into a third amendment (the "Third Amendment") to its exclusive license agreement with LabCorp that, among other things, added a potential $2.5 million milestone payment for which the Company may be eligible upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of ColoSure over a defined measuring period. The Third Amendment also provided that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp's stool-based DNA testing service, and provided that LabCorp would offer at-will employment to certain former personnel of the Company. In connection with the Third Amendment, the Company notified six employees of their termination from the Company (the "2007 Restructuring"). The 2007 Restructuring was principally designed to eliminate the Company's sales and marketing functions to reduce costs and help preserve the Company's cash resources. In connection with the 2007 Restructuring, the Company recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges associated with extending the period of exercise for vested stock option awards for terminated employees.

During the fourth quarter of 2007, the Company entered into a sublease agreement (the "Sublease Agreement") with INTRINSIX Corporation (the "Subtenant") to sublease to the Subtenant approximately 11,834 square feet of rentable area in the Company's corporate headquarters. In connection with the Sublease Agreement, the Company recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption "Facility consolidation costs" in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the Sublease Agreement. The Company's decision to enter into the Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million 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 Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at June 30, 2008, which are expected to be paid out through July 2010, are recorded under the caption "Accrued expenses" in the Company's condensed consolidated balance sheets.

The following table summarizes changes made to the restructuring accrual during the six months ended June 30, 2008 relating to the 2007 Restructuring and Sublease Agreement. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, June 30, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$ —	$ —
Facility consolidation costs	268	—	(62)	—	206
Total	$ 492	$ (7)	$ (279)	$ —	$ 206

As described in Note 10 below, the Company plans to record restructuring charges ranging from $200,000 to $300,000 during the third quarter of 2008 in connection with its July 2008 cost reduction initiatives. The Company is pursuing efforts to further reduce its costs and may record additional restructuring charges related to such reductions in future periods.

(6) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 1995 Stock Option Plan ("1995 Option Plan"), the 2000 Stock Option and Incentive Plan ("2000 Option Plan") and the 2000 Employee Stock Purchase Plan ("Employee Stock Purchase Plan"). Note 9 to the Company's consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the SEC, includes a description of the Company's stock-based compensation plans.

Stock-Based Compensation Expense

The Company recorded $0.2 million and $0.5 million, respectively, in stock-based compensation during the three and six months ended June 30, 2008 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants. The Company recorded $0.7 million and $1.1 million, respectively, in stock-based compensation during the three and six months ended June 30, 2007 in connection with the amortization of employee and non-employee director stock option awards, stock options granted to non-employee consultants, common stock issued to a collaborator, and stock-based compensation expense related to the Company's 2007 401(k) match.

Determining Fair Value

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

Expected Term **-** The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected life is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility **-** Expected volatility is based on the Company's historical volatility from the time of its initial public offering in January 2001 through the measurement date of the awards.

Risk-Free Interest Rate **-** The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Forfeitures - As required by SFAS No. 123(R), the Company records share-based compensation expense only for those awards that are expected to vest. The Company does not need to estimate forfeitures because all share based awards vest monthly.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Option Plan Shares				
Risk-free interest rates	(1)	(1)	2.80%	4.50%
Expected term (in years)	(1)	(1)	6	6
Expected volatility	(1)	(1)	70%	70%
Dividend yield	(1)	(1)	0%	0%
Weighted average fair value per share of options granted during the period	(1)	(1)	$1.17	$1.83
ESPP Shares				
Risk-free interest rates	(1)	(1)	(1)	5.10 - 5.17%
Expected term (in years)	(1)	(1)	(1)	0.5 - 2
Expected volatility	(1)	(1)	(1)	70%
Dividend yield	(1)	(1)	(1)	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1)	(1)	$1.08

(1) The Company did not issue stock options or stock purchase rights under its stock-based compensation plans during the periods indicated.

Stock Option Activity

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the six months ended June 30, 2008 is as follows:

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
Outstanding, January 1, 2008	3,996,688	$ 4.88	4.8	
Granted	498,600	$ 1.83		
Exercised	(14,666)	$ 0.39		
Cancelled	(84,373)	$ 6.16		
Outstanding, June 30, 2008	4,396,249	$ 4.52	4.9	$ 80
Exercisable, June 30, 2008	3,329,283	$ 5.19	3.5	$ 69
Vested and expected to vest, June 30, 2008	4,329,906	$ 4.52	4.9	$ 80

(1) The aggregate intrinsic value of options outstanding, as well as options vested and expected to vest, at June 30, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 54,204 options that had exercise prices that were lower than the $1.80 market price of our common stock at June 30, 2008. The aggregate intrinsic value of options exercisable at June 30, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 47,953 options that had exercise prices that were lower than the $1.80 market price of our common stock at June 30, 2008.

As of June 30, 2008, there was $1.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.7 years.

(7) COLORECTAL CANCER SCREENING GUIDELINES

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society ("ACS"), the American College of Gastroenterology and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, such recommendations consisted of colonoscopy, flexible sigmoidoscopy, double contrast barium enema and fecal occult blood testing (FOBT), as well as combinations of some of these methods. On March 5, 2008, the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine (the "MSTF-CRC"), and the American College of Radiology announced that non-invasive, stool-based DNA screening technology has been included in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and above. These new guidelines now divide colorectal cancer screening into two groups, one including non-invasive methods for the early detection of colorectal cancer and the other including invasive techniques for the prevention and early detection of colorectal cancer. Non-invasive technologies include fecal occult blood testing and stool-based DNA screening for individuals unwilling or unable to use invasive screening procedures. Invasive procedures include colonoscopy, flexible sigmoidoscopy, CT colonography, and double contrast barium enema and, according to the new guidelines, are designed to detect both early cancer and adenomatous polyps and should be encouraged if resources are available and patients are willing to undergo and invasive test. While the Company views inclusion of its stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for any stool-based DNA screening test for colorectal cancer, the Company believes that FDA clearance for its technologies, and reimbursement from the Centers for Medicare and Medicaid Services and other third-party payors will be necessary to achieve any significant increase in demand for its technologies. In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need only detect a majority of colorectal cancers in a screening population to meet guidelines criteria. The Company has not performed a stand-alone colorectal cancer screening study of LabCorp's ColoSure test and there can be no assurance that the guidelines groups will agree that existing studies using our Version 2 technologies, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of ColoSure in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on the Company's business.

(8) REGULATORY STATUS

From August 2003 through June 2008, LabCorp offered its PreGen-Plus testing service, which included the Effipure component from the Company, as an in-house developed laboratory test, or "homebrew" testing service. On October 11, 2007, the FDA sent the Company a warning letter (the "Warning Letter") with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. The Company's Version 1 technology was the basis for LabCorp's PreGen-Plus testing service. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In addition to the Company's Version 1 technology underlying the PreGen-Plus testing service that was offered by LabCorp, the Company has also developed a Version 2 colorectal cancer screening technology that it believes has greater sensitivity and is more cost-effective than Version 1. In April 2008, the Company began to focus its regulatory efforts on pursuing FDA clearance for Version 2 of its technology, a two-marker version that the Company believes offers greater sensitivity and is more cost-effective than its earlier, 23 marker Version 1 technology. In this regard, in April 2008, the Company submitted a pre-Investigational Device Exemption ("pre-IDE") request to the FDA for its Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for the Company's Version 2 technology and that the clinical and other studies proposed in its Version 2 pre-IDE submission would likely support such a *de novo* regulatory path.

On July 14, 2008, LabCorp announced that it would begin offering a new laboratory-developed test called ColoSure, a single-marker test that is based on certain of the Company's Version 2 intellectual property and that does not use the Effipure component. Also in July 2008, the Company confirmed with the FDA the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of its Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on its discussions with the FDA, the Company believes that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. The Company estimates that total costs to complete its Version 2 validation studies and the related regulatory submission process would range from $6.5 million to $8.5 million. The FDA may ultimately determine that a pre-market approval application ("PMA") is the appropriate path forward for the Company with respect to Version 2 of its stool-based DNA technology instead of a *de novo* pathway, or that additional samples, and a more expensive and time-consuming study or studies may be required for clearance or approval. The Company believes that the studies required in connection with any approval or clearance of its Version 2 technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve a *de novo* classification request or approve a PMA.

As described in Note 10, in July 2008, the Company further reduced its cost structure by suspending the clinical validation study and other studies for its Version 2 technology and eliminating eight positions within the Company. Because the Company does not currently have sufficient funds to complete any clinical validation or other FDA-related study of its Version 2 technology, it will need to raise additional capital through a strategic transaction, debt or equity financing, or third-party collaboration, if any, and/or some combination of any of the foregoing in order to fund any FDA regulatory clearance or approval process of its Version 2 technology. There can be no assurance that the Company will be successful in securing any additional capital to pursue the clinical validation study for its Version 2 technology under any potential strategic transaction or capital structure. If the Company is unable to finance the requisite clinical and other studies of its Version 2 technology, it will not be able to complete and submit its application to seek FDA approval or clearance of its Version 2 technology.

(9) FAIR VALUE MEASUREMENTS

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on its consolidated results of operations, financial position or cash flows.

SFAS 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established by SFAS 157 in order of priority are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

In accordance with the disclosure provisions of SFAS No. 157, the following table presents the Company's fair value measurements as of June 30, 2008 along with the level within the fair value hierarchy prescribed by SFAS No. 157 in which the fair value measurements in their entirety fall, segregating fair value measurements using quoted prices in active markets for identical assets or liabilities (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). Cash and cash equivalents are recorded at cost, which approximates fair value. Amounts in the table are in thousands.

		Fair Value Measurement at June 30, 2008 Using:		
Description	**Fair Value at June 30, 2008**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Available-for-Sale Marketable Securities	$ 2,244	$ —	$ 2,244	$ —
Total	$ 2,244	$ —	$ 2,244	$ —

(10) SUBSEQUENT EVENTS

July 2008 Restructuring

On July 16, 2008, the Company implemented certain cost reduction initiatives, including the suspension of the clinical validation study for its Version 2 technology and the elimination of eight positions, or 67% of the Company's workforce (the "2008 Restructuring") to preserve its existing cash. The severance costs incurred in connection with the workforce reduction will be accounted for in accordance with SFAS No. 146.

The Company estimates that the restructuring charges to be recorded in the third quarter of 2008 in connection with the workforce reduction will range from between $200,000 and $300,000 and relate to one-time employee termination benefits, including severance, outplacement and other fringe benefits. These estimated charges will result in future cash expenditures. In addition, as described in Note 2 above, these cost reduction actions were deemed to be impairment indicators pursuant to SFAS No. 144. After performing the requisite impairment analysis, the Company wrote off approximately $253,000 in capitalized patents during the quarter ended June 30, 2008. The Company is pursuing efforts to further reduce its costs and may record additional restructuring charges related to such reductions in future periods.

Delisting Notice from NASDAQ

As previously disclosed on July 11, 2008 via press release and a filing on Form 8-K, on July 10, 2008, the Company received notice from The NASDAQ Stock Market that it was not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), which requires a listed security to maintain a minimum $50.0 million market capitalization for continued listing on The NASDAQ Global Market.

In accordance with NASDAQ Marketplace Rule 4450(e)(4), the Company was provided a period of 30 calendar days, or until August 11, 2008, to regain compliance. Because the Company has not regained compliance by maintaining a minimum $50.0 million market value of its common stock for at least 10 consecutive business days before August 11, 2008, the Company expects to receive an additional notice of non-compliance from NASDAQ. The Company is currently evaluating its alternatives to resolve the listing deficiency, if any, and intends to request a hearing before a NASDAQ Listing Qualifications Panel (the "Panel") to address this

issue. The Company's common stock will remain listed on The NASDAQ Global Market pending the issuance of a decision by the Panel following the hearing. The delisting of the Company's common stock would significantly affect the ability of investors to trade the Company's securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of the Company's common stock could adversely affect its ability to enter into a strategic transaction or to raise capital on terms acceptable to the Company, or at all. Delisting from The NASDAQ Global Market could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

(11) NEW ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—including an amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for the company in 2008. The adoption of SFAS No. 159 in the first quarter of fiscal 2008 did not have any impact on the Company's financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. The Company adopted EITF 07-3 on January 1, 2008 and it did not have any impact on its consolidated results of operations, financial position or cash flows.

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

The following discussion of the financial condition and results of operations of EXACT Sciences Corporation should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the Securities and Exchange Commission, or SEC.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "could," "seek," "intends," "plans," "estimates," "anticipates" or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q include, among others, statements regarding the building of material market demand, the sufficiency of our capital resources, expected royalty fees and revenues, the potential costs and impact of U.S. Food and Drug Administration, or FDA, regulatory action on the marketing and sale of our DNA-based technologies, our expected actions with respect to continuing the listing of our common stock on the NASDAQ Global Market, expectations regarding third-party reimbursement of tests using our technology, expected restructuring charges, our expectations concerning our commercial strategy, and the effectiveness and market acceptance of our technologies and ColoSure. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, including those risks and uncertainties described in Item 1A of this report and our Annual Report on Form 10-K for the year ended December 31, 2007. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

EXACT Sciences Corporation develops proprietary DNA-based technologies for use in the detection of cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis in the United States and Canada through December 2010 to Laboratory Corporation of America ® Holdings, or LabCorp ®. LabCorp developed and commercially offered PreGen-Plus, its first generation non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure™, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our technologies. We are entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus. Since our inception in February 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;
- conducting clinical studies to validate our colorectal cancer screening technologies;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- pursuing reimbursement for stool-based DNA screening with third-party payors, including the Centers for Medicare and Medicaid Services, or CMS;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our proprietary technologies to LabCorp and others;
- working to further the adoption of stool-based DNA testing for colorectal cancer, including seeking inclusion of such technology in the guidelines of the major guidelines organizations;
- pursuing U.S. Food and Drug Administration, or FDA, clearance or approval, or exemptions therefrom for our stool-based DNA screening technology for colorectal cancer;
- working with LabCorp on activities in support of the commercialization of tests using our technology; and
- pursuing strategic alternatives for our business.

We have generated limited operating revenues since our inception and, as of June 30, 2008, we had an accumulated deficit of approximately $167.3 million. Our losses have historically resulted from costs incurred in conjunction with our research,

development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and, prior to August 31, 2007, the build-out of our sales infrastructure to support the commercialization of stool-based DNA screening. We expect that our losses will continue for the next several years and we may never achieve profitability.

From the date of commercial launch through June 2008, when LabCorp stopped commercially offering PreGen-Plus, LabCorp had accessioned approximately 14,900 PreGen-Plus samples, including approximately 500 in the six months ended June 30, 2008 and approximately 1,800, 3,700 and 4,000 samples during the years ended December 31, 2007, 2006 and 2005, respectively.

In addition to our Version 1 technology underlying the PreGen-Plus testing service formerly offered by LabCorp, we have also developed or licensed technologies related to a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. Our Version 2 technology includes two DNA markers, which in published studies have been shown to be associated with colorectal cancer. These markers include the aberrant methylation of the Vimentin gene promoter region, which we refer to as Vimentin, and DIA®, or long DNA. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University, or Case Western, under which we pay a royalty and certain other fees to Case Western in return for the right to use and sublicense the Vimentin technology. In a recent research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. On July 14, 2008, LabCorp began to commercially offer ColoSure™, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our technologies. LabCorp's ColoSure testing service relies solely on the Vimentin gene and does not use the DIA marker that is also included in our Version 2 technology.

Recent Developments

Regulatory Update

From August 2003 through June 2008, LabCorp offered its PreGen-Plus testing service, which included the Effipure component from us, as an in-house developed laboratory test, or "homebrew" testing service. On October 11, 2007, the FDA sent us a warning letter, or the Warning Letter, with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. Our Version 1 technology was the basis for LabCorp's PreGen-Plus testing service. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In addition to our Version 1 technology underlying the PreGen-Plus testing service that was offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost-effective than Version 1. In April 2008, we began to focus our regulatory efforts on pursuing FDA clearance for Version 2 of our technology, a two-marker version that we believe offers greater sensitivity and is more cost-effective than our earlier, 23 marker Version 1 technology. In this regard, in April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA for our Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a *de novo* regulatory path.

On July 14, 2008, LabCorp announced that it would begin offering a new laboratory-developed test called ColoSure, a single-marker test that is based on certain of our Version 2 intellectual property and that does not use the Effipure component. Also in July 2008, we confirmed with the FDA the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of our Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. We estimate that total costs to complete its Version 2 validation studies and the related regulatory submission process would range from $6.5 million to $8.5 million. The FDA may ultimately determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to Version 2 of our stool-based DNA technology instead of a *de novo* pathway, or that additional samples, and a more expensive and time-consuming study or studies may be required for clearance or approval. We believe that the studies required in connection with any approval or clearance of our Version 2 technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve a *de novo* classification request or approve a PMA.

As described under the heading "2008 Restructuring" below, in July 2008, we further reduced our cost structure by suspending the clinical validation study and other studies for our Version 2 technology and eliminating eight positions within the Company. Because we do not currently have sufficient funds to complete any clinical validation or other FDA-related study of our Version 2 technology, we will need to raise additional capital through a strategic transaction, debt or equity financing, or third-party collaboration, if any, and/or some

combination of any of the foregoing in order to fund any FDA regulatory clearance or approval process of our Version 2 technology. There can be no assurance that we will be successful in securing any additional capital to pursue the clinical validation study for our Version 2 technology under any potential strategic transaction or capital structure. If we are unable to finance the requisite clinical and other studies of its Version 2 technology, we will not be able to complete and submit our application to seek FDA approval or clearance of our Version 2 technology.

2008 Restructuring

In July 2008, we took actions to further reduce our cost structure to help preserve our cash resources, which we refer to as the 2008 Restructuring. These actions included including suspending the clinical validation study of our Version 2 technology, eliminating eight positions, or 67% of our staff, and seeking the re-negotiation of certain fixed commitments. We expect to record estimated restructuring charges ranging from approximately $200,000 to $300,000 in the third quarter of 2008 in connection with one-time employee termination benefits, including severance, outplacement and other fringe benefits. These estimated charges will result in future cash expenditures. In addition, after performing the requisite impairment analyses, we recorded non-cash impairment charges of approximately $253,000 related to our patent portfolio during the quarter ended June 30, 2008. We continue to assess our facility needs and other operating costs and, as a result, could incur additional restructuring charges in the event we undertake additional activities to reduce facility or other operating costs.

Delisting Notice from NASDAQ

As previously disclosed on July 11, 2008 via press release and a filing on Form 8-K, on July 10, 2008, we received notice from The NASDAQ Stock Market that we were not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), which requires a listed security to maintain a minimum $50.0 million market capitalization for continued listing on The NASDAQ Global Market.

In accordance with NASDAQ Marketplace Rule 4450(e)(4), we were provided a period of 30 calendar days, or until August 11, 2008, to regain compliance. Because we have not regained compliance by maintaining a minimum $50.0 million market value of our common stock for at least 10 consecutive business days before August 11, 2008, we expect to receive an additional notice of non-compliance from NASDAQ. We are currently evaluating alternatives to resolve the listing deficiency, if any, and intend to request a hearing before a NASDAQ Listing Qualifications Panel, or the Panel, to address this issue. Our common stock will remain listed on The NASDAQ Global Market pending the issuance of a decision by the Panel following the hearing. The delisting of our common stock would significantly affect the ability of investors to trade our securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could adversely affect our ability to enter into a strategic transaction or to raise capital on terms acceptable to us, or at all. Delisting from The NASDAQ Global Market could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

Colorectal Cancer Screening Guidelines

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society, or ACS, the American College of Gastroenterology and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, such recommendations consisted of colonoscopy, flexible sigmoidoscopy, double contrast barium enema, and fecal occult blood testing (FOBT), as well as combinations of some of these methods. On March 5, 2008, the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine, or MSTF-CRC, and the American College of Radiology announced that non-invasive, stool-based DNA screening technology has been included in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and above. These new guidelines now divide colorectal cancer screening into two groups, one including non-invasive methods for the early detection of colorectal cancer and the other including invasive techniques for the prevention and early detection of colorectal cancer. Non-invasive technologies include fecal occult blood testing and stool-based DNA screening for individuals unwilling or unable to use invasive screening procedures. Invasive procedures include colonoscopy, flexible sigmoidoscopy, CT colonography, and double contrast barium enema and, according to the new guidelines, are designed to detect both early cancer and adenomatous polyps and should be encouraged if resources are available and patients are willing to undergo and invasive test. While we view inclusion of our stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for any stool-based DNA screening test for colorectal cancer, we believe that FDA clearance for our technologies, and reimbursement from the Centers for Medicare and Medicaid Services and other third-party payors will be necessary to achieve any significant increase in demand for our technologies. In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need only detect a majority of colorectal cancers in a screening population to meet guidelines criteria. We have not performed a stand-alone colorectal cancer screening study of LabCorp's ColoSure test and there can be no assurance that the guidelines groups will agree that existing studies using our Version 2 technologies, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of ColoSure in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on our business.

Our Cost Structure

In addition to the 2008 Restructuring, in October 2006 and again in July 2007, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2006 Restructuring and the 2007 Restructuring, respectively, to help preserve our cash resources. The 2006 Restructuring eliminated 21 positions, or 48% of our staff at that time, across all departments. As part of the 2007 Restructuring, we eliminated our sales and marketing functions, terminated six employees, and subleased a portion of our leased space at our corporate headquarters.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies and, effective as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123 (revised 2004), *Share-Based Payment* , or SFAS No. 123(R). Although we have suspended the Version 2 clinical validation study, and took steps in 2006, 2007 and 2008 to lower research and development costs, we will still likely need to invest substantial funds in additional research, design and development, or clinical or other studies that may be required for FDA approval or clearance of our stool-based DNA screening technologies, to successfully commercialize our Version 2 technology, or any future versions of our technologies or products. In this regard, the costs of the clinical and related technical validation studies that we believe are required by the FDA in connection with any future *de novo* 510(k) pre-market clearance notice for our Version 2 technology, as well as any subsequent studies or filings for other versions of our technologies, are expected to be material. We do not have, and can make no assurance that we can raise or otherwise secure, the capital necessary to initiate the Version 2 clinical validation study or the related regulatory submission. As a result of the cost reduction actions taken in 2008, we expect research and development costs in 2008 to be lower than 2007 levels.

Selling, general and administrative expenses have consisted primarily of non-research personnel salaries, office expenses, professional fees and, as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123(R). As a result of the 2007 Restructuring, in which we eliminated our sales and marketing functions effective August 31, 2007, we do not expect to incur material sales and marketing operating expenses in 2008. We expect general and administrative expenses in 2008 to be higher than 2007 levels, primarily as a result of increased professional fees during 2008 in connection with our efforts through July 2008 to obtain FDA regulatory clearance or approval of our Version 2 technology.

Other Factors Affecting Potential Revenue Growth

We believe that substantial funds and managerial attention will likely need to be invested in sales and marketing efforts over the next several years for our stool-based DNA screening technologies to be commercially successful. We do not have, and we cannot assure you that LabCorp will devote, the funds or management resources that we believe are likely necessary to build sufficient demand for ColoSure. Despite the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, we do not expect material revenue growth from sales of ColoSure until such time as FDA clearance or approval is obtained, if ever, and reimbursement is provided by CMS and other third-party payors at an acceptable level. In addition, we believe our success will also depend upon a number of additional factors that are largely out of our control, including the following:

- the impact that the inclusion of stool-based DNA screening in guidelines will have on prescribing physicians, third-party payors, including CMS, and health care consumers;
- any regulatory restrictions placed upon ColoSure or any other product or testing service based on our technologies;
- success in educating third-party payors, including CMS, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- effective negotiation and contracting by us and LabCorp with CMS and other third-party payors for coverage at acceptable levels of reimbursement for stool-based DNA screening;
- patient acceptance of stool-based DNA screening, including its novel sample collection process;
- the absence of competing technologies that offer equal or better attributes than stool-based DNA screening;
- stool-based DNA screening becoming a standard of care among prescribing physicians; and
- the quality and service of the LabCorp testing process.

As a result of the foregoing, we engaged an investment bank in the first quarter of 2008 to assist our board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, we announced our revised corporate strategy to take immediate actions to preserve existing cash while focusing on the pursuit of a strategic transaction for the business. To date, we have not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all.

Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp under our strategic license agreement and product royalty fees on tests sold by LabCorp utilizing our technology, which has historically been based on PreGen-Plus sales but will now be based on ColoSure sales. We expect that product royalty fees for the full year 2008 will

be lower than amounts recorded in 2007 as a result of potential third-party royalty obligations in connection with our amended license agreement with LabCorp. In addition, as a result of the second amendment to our license agreement with LabCorp, which also extended the exclusive license period under our agreement with LabCorp, we expect that license fee revenue for 2008 will be lower than amounts recorded in 2007 as a result of the extended amortization period over which our remaining deferred revenue will be amortized.

Reimbursement

An important component of our reimbursement strategy is to obtain a National Coverage Determination, or NCD, from CMS for inclusion of our stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our stool-based DNA technology, as a laboratory developed test that was not cleared or approved by the FDA. The application was accepted by CMS on August 1, 2007. In October 2007, we received the Warning Letter from the FDA. Following our receipt of the Warning Letter, we sought to understand what impact the Warning Letter would have on the NCD given that LabCorp, the entity commercially offering the only available stool-based DNA test, did not receive a Warning Letter and that the commercially available test remained on the market. We also sought to subsequently withdraw the application for a NCD to preserve our options with CMS for reconsideration of our application. CMS subsequently issued a proposed and then, on April 28, 2008, a final decision memorandum regarding our application. In these memoranda, CMS decided to not provide national coverage for our Version 1 technology, in part because of the FDA's determination as set forth in the Warning Letter. However, the decision memoranda also indicated that CMS would reconsider our application for coverage of stool-based DNA screening for colorectal cancer following any such FDA clearance or approval of our DNA screening technology. Accordingly, we intend to submit our NCD application for reconsideration following any such FDA clearance or approval and our accumulation of other information and evidence that may be necessary for such submission. There can be no assurance that Version 2, or any subsequent versions of our technology, will be cleared or approved by the FDA. Even if cleared or approved by the FDA, there can be no assurance that CMS will reach a positive coverage decision regarding our request for an NCD on any version of our technologies. Moreover, even if CMS issues a positive coverage decision for any version of our stool-based DNA screening technology, such coverage does not guarantee adequate levels of reimbursement. We could incur significant costs, over an extended period of time, to obtain the necessary data for a positive coverage and reimbursement decisions from CMS. Additionally, despite the fact that our technology is included in the ACS and MSTF-CRC guidelines, the Warning Letter may have a similar impact on private third-party payors in that those payors may defer reimbursement policy decisions with respect to our technology until such time as we obtain FDA clearance for our technologies.

In addition, at its February 2008 meeting, the CPT Editorial Panel of the American Medical Association considered a request from gastroenterology specialty physician organizations to create a category III code for a stool-based DNA test. While the CPT Editorial Panel decided to postpone discussion on the issue, the application can be reconsidered at any future meeting, unless it is withdrawn. The CPT Editorial Panel meets three times each year; the final 2008 meeting is scheduled for October. Category III codes are temporary codes which are used to designate emerging technologies, services and procedures and are issued semi-annually unlike Category I codes which are issued annually. Payors typically do not cover services with Category III codes because they consider "emerging" technologies to be "investigational" services and are therefore not covered services. The creation of a Category III code for our stool-based DNA technology could limit the number of payors that reimburse stool-based DNA colorectal cancer screening, which would materially limit our revenues and adversely affect our operating results and financial position.

Significant Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, certain third party royalty obligations, and intangible assets. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2007, which has been filed with the SEC, include a summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements. As described below, we believe that that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition.

License fees - License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, we entered into an amendment to our exclusive license agreement with LabCorp, or the Second Amendment, which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we amortize the remaining deferred revenue balance at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees – We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's Version 1 technology, from August 2003 through June 2008. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our Version 2 technology. We will be entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, our product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, we recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to us each month by LabCorp. Subsequent to the effective date of the Second Amendment, our product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, we record product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 to the condensed consolidated financial statements located elsewhere in this quarterly report of Form 10-Q. To the extent we incur liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in our consolidated statements of operations.

Product revenue - Product revenue from the sale of certain components of our Effipure technology to LabCorp is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable. Effipure is not used as a component in LabCorp's ColoSure offering.

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

Patent Costs. Patent costs are capitalized as incurred and are amortized beginning when patents are issued over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, upon a decision by us to no longer pursue the patent, or when the related intellectual property is deemed to be no longer of value to us. As of June 30, 2008, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with its stool-based DNA colorectal cancer screening service.

The following table summarizes activity with respect to our capitalized patents for the six months ended June 30, 2008 and 2007. Amounts included in the table are in thousands.

	Six Months Ended June 30, 2008	Six Months Ended June 30, 2007
Patents, net of accumulated amortization, Beginning of period	$ 432	$ 763
Patent costs capitalized	83	33
Amortization of patents	(62)	(86)
Write-offs of patents	(253)	(153)
Patents, net of accumulated amortization, End of period	$ 200	$ 557

During the three months ended March 31, 2007, we determined that we would likely not pursue commercialization of certain technologies and, accordingly, wrote off approximately $121,000 in capitalized patents related to these technologies. Capitalized patents written off during the three months ended March 31, 2007 were unrelated to intellectual property licensed to LabCorp for PreGen-Plus. During the three months ended June 30, 2007, a capitalized pending patent application, which is not critical to LabCorp's stool-based DNA colorectal cancer screening service, was not approved by the U.S. Patent and Trademark Office, and, accordingly, we wrote off approximately $32,000 in connection with this patent application.

In July 2008, we took immediate actions pursuant to our revised corporate strategy to preserve existing cash while pursuing a strategic transaction for the business. Under this revised corporate strategy, we implemented cost reduction initiatives, including suspending the clinical validation study of our Version 2 technology and eliminating eight positions. These cost reduction actions were deemed to be impairment indicators pursuant to SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS No. 144. After performing the requisite impairment analysis, we wrote off approximately $253,000 in capitalized patents related specifically to one of the components of our Version 2 technology that is not used in LabCorp's current ColoSure testing service.

We apply SFAS No. 144, which requires us to continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles may warrant revision or that the carrying value of these assets may be impaired. Such events may include a change in the regulatory requirements for ColoSure.

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

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

Critical Accounting Estimate — Third-Party Royalty Obligation

Pursuant to the terms of the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. Our obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using our technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp's sales of colorectal cancer screening tests using our technology increase to a level that would reduce this potential maximum obligation, if ever, we intend to record our estimated obligation under this provision of the Second Amendment as a reduction in the

product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)* . Based on sales volumes of PreGen-Plus through June 1, 2008 and anticipated sales volumes of ColoSure, as of June 30, 2008, we had accrued a total of $2.0 million related to the total potential $3.5 million obligation to LabCorp, including the total potential $1.5 million obligation related to the first measurement period, which ends in December 2008, as well as $500,000 of the total potential $1.0 million obligation related to the second measurement period, which ends in December 2009. We recorded charges of $0.5 million and $0.8 million, respectively, during the three and six months ended June 30, 2008 in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in our consolidated statements of operations. This obligation is recorded in our consolidated balance sheets under the caption "Third-party royalty obligation." Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of our consolidated statements of operations. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	$ —	$ 1,500
January 1, 2009	December 31, 2009	—	1,000
January 1, 2010	December 31, 2010	—	1,000
		$ —	$ 3,500

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements* , or SFAS No. 157. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on our consolidated results of operations, financial position or cash flows.

SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established by SFAS No. 157 in order of priority are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect our assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

In accordance with the disclosure provisions of SFAS No. 157, the following table presents our fair value measurements as of June 30, 2008, along with the level within the fair value hierarchy prescribed by SFAS No. 157 in which the fair value measurements in their entirety fall, segregating fair value measurements using quoted prices in active markets for identical assets or liabilities (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). Cash and cash equivalents are recorded at cost, which approximates fair value. Amounts in the table are in thousands.

Description	Fair Value at June 30, 2008	Fair Value Measurement at June 30, 2008 Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-Sale Marketable Securities	$ 2,244	$ —	$ 2,244	$ —
Total	$ 2,244	$ —	$ 2,244	$ —

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—including an amendment of FASB Statement No. 115* , or SFAS No. 159. SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for us in 2008. The adoption of SFAS No. 159 in the first quarter of fiscal 2008 did not have any impact on our financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* , or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. We adopted EITF 07-3 on January 1, 2008 and it did not have any impact on our consolidated results of operations, financial position or cash flows.

Results of Operations

Revenue. Total revenue decreased to $(0.1) million for the three months ended June 30, 2008 from $1.1 million for the three months ended June 30, 2007, and decreased to $(0.1) million for the six months ended June 30, 2008 from $2.3 million for the six months ended June 30, 2007. Total revenue during these periods is primarily composed of the amortization of up-front technology license fees associated with our amended license agreement with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in December 2010 and, to a lesser extent, royalties on LabCorp's sales of PreGen-Plus, and sales of Effipure units to LabCorp.

The decrease in total revenue for the three and six months ended June 30, 2008 when compared to the same periods of 2007 was primarily the result of a decreases of approximately $0.8 million and $1.5 million for the three and six months ended June 30, 2008, respectively, in non-cash license fee amortization revenue resulting from the Second Amendment, which extended the exclusive period under our license agreement with LabCorp from August 2008 to December 2010. As a result of this extension, the remaining unamortized up-front license fees that LabCorp previously paid to us ($4.7 million at the time of the Second Amendment) are now being recognized over a longer period of time, resulting in lower non-cash license fee amortization as compared to prior periods.

In addition, product royalty revenues were $0.5 million and $0.8 million lower for the three and six months ended June 30, 2008, respectively, when compared to the same periods of 2007 due to charges of $0.5 million and $0.8 million recorded in the product royalty revenue line item of our consolidated statements of operations in the three and six months ended June 30, 2008, respectively, in connection with our third-party royalty reimbursement obligation to LabCorp. These charges to product royalty revenue were recorded pursuant to the Second Amendment and resulted in negative product royalty revenue for the three and six months ended June 30, 2008.

In June 2008, LabCorp stopped offering PreGen-Plus, the version of the stool-based DNA technology that has been the subject of FDA inquiry over the past several years. In July 2008, LabCorp began offering a new stool-based DNA test, which is different from our Version 2 technology and is based solely on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. Pursuant to our license agreement with LabCorp, we are entitled to the same royalty and milestone structure on sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Research and development expenses. Research and development expenses decreased to $0.5 million for the three months ended June 30, 2008 from $1.3 million for the three months ended June 30, 2007, and decreased to $1.4 million for the six months ended June 30, 2008 from $2.6 million for the six months ended June 30, 2007. The decrease in the three and six months ended June 30, 2008 as compared to the same periods of 2007 was primarily the result of the continuing effect of the cost reduction plans undertaken in 2006 and 2007 as described under the heading "Our Cost Structure" above. Included in the decrease in research and development

expenses for the quarter ended June 30, 2008, as compared to the quarter ended June 30, 2007, were decreases of $0.3 million in licensing costs, $0.1 million in personnel-related expenses and $0.1 million in other lab-related operating expenses and a decrease of $0.3 million on non-cash stock-based compensation resulting from the June 2007 issuance of 100,000 shares of our common stock to Oncomethylome Sciences S.A., or OMS, on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS. Included in the decrease in research and development expenses for the six months ended June 30, 2008, as compared to the six months ended June 30, 2007, were decreases of $0.3 million in licensing costs, $0.3 million in lab-related operating expenses, $0.2 million in personnel-related expenses and a decrease of $0.3 million on non-cash stock-based compensation resulting from the June 2007 issuance of our common stock to OMS.

General and administrative expenses. General and administrative expenses increased to $1.5 million for the quarter ended June 30, 2008, compared to $1.4 million for the quarter ended June 30, 2007. The increase was primarily the result of patent impairment charges of $0.3 million recorded in the quarter ended June 30, 2008 described under the heading "2008 Restructuring" above, which was offset by a reduction of $0.2 million in salary, benefit and other costs due to lower general and administrative headcount during the quarter ended June 30, 2008, as compared to the same quarter of 2007.

General and administrative expenses increased to $3.3 million for the six months ended June 30, 2008 from $3.1 million for the six months ended June 30, 2007. The increase was primarily the result of higher professional fees of $0.5 million in connection with our reimbursement efforts with CMS and our regulatory efforts with the FDA, as well as an increase of $0.1 million in patent write-offs. These increases were partially offset by a decrease of $0.4 million in salary, benefit and other costs due to lower general and administrative headcount during the six months ended June 30, 2008, as compared to the same period of 2007.

Sales and marketing expenses. Sales and marketing expenses decreased to $0 for the three and six months ended June 30, 2008 from $0.4 million and $0.8 million for the three and six months ended June 30, 2007 as a result of the elimination of our sales and marketing functions effective August 31, 2007, as described under the heading "Our Cost Structure" above.

2007 Restructuring. On August 31, 2007, we entered into a third amendment, or the Third Amendment, to our exclusive license agreement with LabCorp that, among other things, added a potential $2.5 million milestone payment for which we may be eligible upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of ColoSure over a defined measuring period. The Third Amendment also provided that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp's stool-based DNA testing service, and provided that LabCorp would offer at-will employment to certain of our former personnel. In connection with the Third Amendment, we terminated five employees and one employee effective August 31, 2007 and October 31, 2007, respectively, which we refer to as the 2007 Restructuring. The 2007 Restructuring was principally designed to eliminate our sales and marketing functions to reduce costs and help preserve our cash resources. In connection with the 2007 Restructuring, we recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007 primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges recorded in connection with certain stock option modifications.

During the fourth quarter of 2007, we entered into a sublease agreement, or the Sublease Agreement, to sublease approximately 11,834 square feet of rentable area in our corporate headquarters. In connection with the Sublease Agreement, we recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption "Facility consolidation costs" in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between our committed lease payments and the estimated sublease rental income under the Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned in connection with the Sublease Agreement. Our decision to enter into the Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million 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 Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at June 30, 2008, which are expected to be paid out through July 2010, are recorded under the caption "Accrued expenses" in our condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the six months ended June 30, 2008 relating to the 2007 Restructuring and Sublease Agreement. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, June 30, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$ —	$ —
Facility consolidation costs	268	—	(62)	—	206
Total	$ 492	$ (7)	$ (279)	$ —	$ 206

As described above under the heading “Our Cost Structure”, in July 2008, we initiated the 2008 Restructuring to further reduce our cost structure to help preserve our cash resources. We expect to record estimated restructuring charges ranging from approximately $200,000 to $300,000 in the third quarter of 2008 in connection with one-time employee termination benefits, including severance, outplacement and other fringe benefits. These estimated charges will result in future cash expenditures. We continue to assess our facility needs and other operating costs and, as a result, could incur additional restructuring charges in the event we undertake additional activities to reduce facility or other operating costs.

We account for restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* , or SFAS No. 146. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at its fair value in the period in which the liability is incurred, except for one-time termination benefits that meet specified requirements.

Interest income. Interest income decreased to $0.1 million for the three months ended June 30, 2008 from $0.2 million for the three months ended June 30, 2007. Interest income decreased to $0.2 million for the six months ended June 30, 2008 from $0.5 million for the six months ended June 30, 2007. These decreases were due to lower average cash, cash equivalents and marketable securities balances held during the three and six months ended June 30, 2008 as compared to the same periods of 2007, as well as less favorable interest rates on investments held during the three and six months ended June 30, 2008 as compared to the same period of 2007.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, public offerings of common stock in February 2001 and February 2004 and cash received from LabCorp in connection with our license agreement. As of June 30, 2008, we had approximately $7.7 million in unrestricted cash, cash equivalents and marketable securities and $0.7 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit in connection with the lease for our Marlborough, Massachusetts facility.

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

Net cash used in operating activities was $4.7 million for the six months ended June 30, 2008 as compared to $4.1 million for the six months ended June 30, 2007. The principal use of cash in operating activities for the six months ended June 30, 2008 and 2007 was to fund our net loss. The increase in net cash used in operating activities for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007, was primarily due to increased spending in connection with our ongoing regulatory efforts. Cash flows from operations can vary significantly due to various factors, including changes in our operations, prepaid expenses, accounts payable and accrued expenses.

Net cash provided by investing activities was $5.8 million for the six months ended June 30, 2008 compared to $3.1 million for the six months ended June 30, 2007. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $83,000 for the six months ended June 30, 2008 compared to $35,000 for the six months ended June 30, 2007.

Purchases of property and equipment were not material during the six months ended June 30, 2008 and 2007. We expect that purchases of property and equipment during 2008 will be consistent with amounts invested during 2007. We continued to invest in our capitalized patent portfolio during the six months ended June 30, 2008, primarily in the form of recurring maintenance fees on patents. We expect that investments made in our patent portfolio during 2008 will higher than amounts capitalized in 2008 as a result of the timing certain payments in connection with our patent portfolio.

Net cash provided by financing activities of $6,000 and $15,000 for the six months ended June 30, 2008 and 2007, respectively, represents proceeds received from the issuance of common stock under our employee stock option and purchase plans.

The audit opinion with respect to our consolidated financial statements for the year ended December 31, 2007 issued by our independent registered public accounting firm included an explanatory paragraph to emphasize there is substantial doubt about our ability to continue as a going concern. As a result of the 2008 Restructuring, we expect that cash, cash equivalents and short-term investments on hand at June 30, 2008 will be sufficient to fund our current operations through the end of the second quarter of 2009. This projection is based on our current cost structure and our current operating assumptions, which do not provide for any funding of our Version 2 clinical validation studies. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. Since we have no current sources of material ongoing revenue, we will have to raise additional capital during the next ten months through a strategic transaction, debt or equity financing, or third-party collaboration, if any, or some combination of the foregoing to continue operations beyond the end of the second quarter of 2009 . In addition, if our expenses exceed our current estimates, we will be required to obtain additional capital even sooner. We cannot assure you that any of these alternatives will be successful, or even available, or that our actual cash requirements will not be greater than anticipated. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of any financing or other strategic opportunities that may become available to us, we will be unable to sustain our operations, our results of operations and financial condition would be materially adversely affected and we may be required to cease our operations. Even if we successfully raise sufficient funds to continue our operations beyond the end of the second quarter of 2009, we cannot assure you that our business will ever generate sufficient cash flow from operations.

The table below reflects our estimated fixed obligations and commitments as of June 30, 2008:

		Payments Due by Period			
Description	**Total**	**Less Than One Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
			(in Thousands)		
Obligations under license and collaborative agreements	$ 8,307	$ 2,079	$ 2,768	$ 630	$ 2,830
Operating lease obligations	2,118	1,002	1,116	—	—
Purchase obligations	197	197	—	—	—
Total	$ 10,622	$ 3,278	$ 3,884	$ 630	$ 2,830

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. This category includes a potential obligation to reimburse LabCorp for a certain third-party royalty, up to an aggregate maximum of $3.5 million, during three defined measurement periods between June 28, 2007 and December 31, 2010. Although payment of this potential obligation is dependent upon LabCorp's sales levels of colorectal cancer screening tests using our technology during the measurement periods, the total potential $3.5 million obligation has been included in the table above based on historical sales levels of PreGen-Plus. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with leased facilities in Marlborough, Massachusetts. Purchase obligations represent outstanding purchase commitments associated with our research and development activities.

We do not have any special purpose entities or any other off-balance sheet financing arrangements.

Our anticipated future capital requirements include, but are not limited to, continued funding of our development efforts, including product development and FDA submissions, clinical and other studies required for such FDA submissions and resubmission of our CMS application for approval of our technologies, and continued investment in our intellectual property estate. Our future capital requirements may depend on many factors, including the following:

- the regulatory requirements for ColoSure, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- our ability to attract third parties to support the development of an FDA-cleared or approved product based on our technologies;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with LabCorp;
- a determination that additional studies surrounding our technologies are needed;

- a sustained level of interest and commitment by LabCorp in the commercialization of our technologies;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the scope of and progress made in our research and development activities;
- threats posed by competing technologies;
- new out-licensing arrangements relating to our technologies; and
- the successful commercialization and sales growth of ColoSure, or other stool-based DNA testing services utilizing our technologies.

Additionally, LabCorp could decide to stop offering ColoSure, or could decide to stop offering ColoSure until it has been approved or cleared by the FDA, if ever. Either of these situations will limit our revenue and materially adversely affect our business and cash reserves.

As a result of the foregoing, we engaged an investment bank in the first quarter of 2008 to assist our board of directors in evaluating strategic alternatives for the Company. On July 16, 2008, we announced our revised corporate strategy to take immediate actions to preserve existing cash while focusing on the pursuit of a strategic transaction. To date, we have not entered into any agreements or commitments for any specific strategic alternative or transaction in connection therewith. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all.

Off-Balance Sheet Arrangements

As of June 30, 2008, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

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

Item 4. Controls And Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15b promulgated under the Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2008, our disclosure controls and procedures were effective in enabling us to record, process, summarize and report information required to be included in our periodic SEC filings within the required time period. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1A. Risk Factors

Factors That May Affect Future Results

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. There are no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 other than the following: changes set forth in our Quarterly Report on Form 10-Q for the period ended March 31, 2008; changes as set forth below to update for recent developments; and changes to generally replace or supplement references to "PreGen-Plus" with references to "ColoSure," except where the context would make such reference inapplicable, to reflect that LabCorp ceased sales of PreGen-Plus in June 2008 and in July 2008 began offering ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer, which is based on certain of our technologies. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. If any of the foregoing risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern, and we may be unable to raise additional capital on acceptable terms in the future.

We have incurred substantial losses to date and we expect to incur substantial losses for the foreseeable future. As of June 30, 2008, we had an accumulated deficit of approximately $167.3 million. The audit opinion with respect to our consolidated financial statements for the year ended December 31, 2007 issued by our independent registered public accounting firm included an explanatory paragraph to emphasize there is substantial doubt about our ability to continue as a going concern. As a result of our most recent cost reduction initiatives, which include suspension of our clinical validation and related studies for our Version 2 technology and the elimination of eight positions within the Company, we expect that cash, cash equivalents and short-term investments on hand at June 30, 2008 will be sufficient to fund our current operations through the end of the second quarter of 2009. This projection is based on our current cost structure and our current operating assumptions, which do not include any funding for our Version 2 clinical validation study or related regulatory submission. Our future liquidity and capital requirements will depend upon numerous factors, including the following:

- our ability to find a strategic partner and/or to recapitalize the Company in a manner that allows us to continue operations;
- the successful commercialization and sales growth of ColoSure, or other stool-based DNA testing services utilizing our technologies;
- a sustained level of interest and commitment by LabCorp in the commercialization of our technologies;
- the regulatory requirements for ColoSure, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with Laboratory Corporation of America Holdings, or LabCorp;
- a determination that additional studies surrounding our technologies are needed;
- stool-based DNA screening becoming a standard of care among prescribing physicians; and
- the scope of and progress made in our collaborations on the research and development of stool-based DNA detection activities.

We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. Since we have no current sources of material ongoing revenue, we will have to raise additional capital before the end of the second quarter of 2009 through a strategic transaction, the sale of debt or equity securities, or strategic collaborations with third parties, if any, to continue our business operations beyond the end of the second quarter of 2009. In March 2008, we announced that we have engaged an investment bank to advise our Board of Directors in its evaluation of strategic alternatives for the business, including, but not limited to, the sale of the company or merger with another entity. We cannot assure you that our evaluation of strategic alternatives will result in such a transaction being successfully consummated or, if successful, that any such transaction would achieve our goal of maximizing the value of our business for our stockholders. We also cannot assure you that our actual cash requirements will not be greater than anticipated. In addition, the going concern explanatory paragraph included in our auditor's report on our consolidated financial statements could inhibit our ability to enter into license agreements or other collaborations or our ability to raise additional financing. If we are unable to obtain the required funds to enable us to fund our

operations through the completion of any financing or other strategic opportunities that may become available to us, we will be required to further reduce the scale of our operations and our business, our results of operation and financial condition would be materially adversely affected and we may be required to seek bankruptcy protection.

Additionally, even if we do enter into a strategic transaction and/or raise sufficient capital and generate revenues to support our operating expenses beyond the end of the second quarter of 2009, there can be no assurances that the revenue or capital infusion will be sufficient to enable us to develop our business to a level where it will generate profits and cash flows from operations. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, or grant licenses on terms that are not favorable to us. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations.

If we or LabCorp fail to comply with FDA requirements, we or LabCorp may be limited or prohibited in our ability to commercialize stool-based DNA testing for colorectal cancer and may be subject to stringent penalties.

From August 2003 through June 2008, LabCorp offered its PreGen-Plus testing service, which included the Effipure component from us, as an in-house developed laboratory test, or "homebrew" testing service. On October 11, 2007, the FDA sent us a warning letter, or the Warning Letter, with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. Our Version 1 technology was the basis for LabCorp's PreGen-Plus testing service. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In addition to our Version 1 technology underlying the PreGen-Plus testing service that was offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost-effective than Version 1. In April 2008, we began to focus our regulatory efforts on pursuing FDA clearance for Version 2 of our technology, a two-marker version that we believe offers greater sensitivity and is more cost-effective than our earlier, 23 marker Version 1 technology. In this regard, in April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA for our Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a *de novo* regulatory path.

On July 14, 2008, LabCorp announced that it would begin offering a new laboratory-developed test called ColoSure, a single-marker test that is based on certain of our Version 2 intellectual property and that does not use the Effipure component. Also in July 2008, we confirmed with the FDA the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of our Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. We estimate that total costs to complete its Version 2 validation studies and the related regulatory submission process would range from $6.5 million to $8.5 million. The FDA may ultimately determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to Version 2 of our stool-based DNA technology instead of a *de novo* pathway, or that additional samples, and a more expensive and time-consuming study or studies may be required for clearance or approval. We believe that the studies required in connection with any approval or clearance of our Version 2 technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve a *de novo* classification request or approve a PMA.

In July 2008, we further reduced our cost structure by suspending the clinical validation study and other studies for our Version 2 technology and eliminating eight positions within the Company. Because we do not currently have sufficient funds to complete any clinical validation or other FDA-related study of our Version 2 technology, we will need to raise additional capital through a strategic transaction, debt or equity financing, or third-party collaboration, if any, and/or some combination of any of the foregoing in order to fund any FDA regulatory clearance or approval process of our Version 2 technology. There can be no assurance that we will be successful in securing any additional capital to pursue the clinical validation study for our Version 2 technology under any potential strategic transaction or capital structure. If we are unable to finance the requisite clinical and other studies of its Version 2 technology, we will not be able to complete and submit our application to seek FDA approval or clearance of our Version 2 technology.

Our common stock may be delisted from The NASDAQ Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on The NASDAQ Global Market. On July 10, 2008, we received a letter from The NASDAQ Stock Market LLC, or NASDAQ, advising us that the market value of our listed securities was below the minimum $50,000,000 requirement for continued inclusion on The NASDAQ Global Market. NASDAQ also noted that we were not in compliance with the alternative condition, which requires total assets and total revenue of at least $50,000,000 each, for the most recently completed fiscal year or two of the three most recently completed fiscal years. NASDAQ provided us 30 calendar days, or until August 11, 2008, to regain compliance, which would have been achieved if the market value of our listed securities was $50,000,000 or more for a minimum of 10 consecutive business days. Because this compliance requirement has not been achieved, we expect to receive an additional notice of non-compliance from NASDAQ. We are currently evaluating alternatives to resolve the listing deficiency, if any, and intend to request a hearing before a NASDAQ Listing Qualifications Panel to address this issue. Our common stock will remain listed on The NASDAQ Global Market pending the issuance of a decision by the Panel following the hearing. If this request for continued listing is not granted, our common stock will be delisted from The NASDAQ Global Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to enter into a strategic transaction or to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Global Market, or the NASDAQ Stock Market generally, could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

We have recently revised our corporate strategy and our new strategy may not be successful.

On July 16, 2008, we announced that we revised our corporate strategy to take immediate actions to preserve existing cash while pursuing a strategic alternative for the business. Our revised corporate strategy may not result in a strategic alternative in the near future, if at all. For instance, the terms of our existing collaboration with LabCorp and other agreements to which we are a party may hinder any potential strategic transaction. In addition, any potential strategic transaction would likely require the cooperation of LabCorp, as well as the approval of our stockholders. We cannot assure you that we would be able to obtain such cooperation or approval. If we do not raise additional capital before the end of the second quarter of 2009 through a strategic transaction, the sale of debt or equity securities, or strategic collaborations with third parties, we will likely be unable to continue our business operations beyond the end of the second quarter of 2009 and we would likely be required to cease our operations.

The loss of any of our remaining employees could adversely affect our business.

Our success depends upon the continued services of our remaining employees. Although we have in the past entered, and may in the future enter, into retention agreements with our employees, including members of our management team, each of our employees, including our executive officers, could terminate his or her relationship with us at any time. For instance, in July 2007, Don M. Hardison resigned his position as our President and Chief Executive Officer. The loss of any member of our current management team could significantly delay or prevent the achievement of our business or development objectives and could materially harm our business. In addition, the loss of the other full-time employees would likely cause delays in our business operations, as his or her responsibilities would have to be reallocated among the few remaining employees, or the attention of our remaining employees would be diverted to hiring new personnel.

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

LabCorp's current configuration of ColoSure requires access to certain technologies and supplies of raw materials, including rights to the Vimentin gene, for which licensing or supply agreements are required. We cannot assure you that LabCorp has proper licensing or supply agreements in place for such technologies and raw materials, including the rights necessary for its ColoSure testing service. In addition, any future commercialization of our Version 2 stool-based DNA screening technology will require that we or LabCorp license certain third-party intellectual property. There can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, if at all. Furthermore, there can be no assurance that any current contractual arrangements between us and third parties, us and LabCorp, LabCorp and vendors in the DNA capture component supply chain, or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we or LabCorp will be able to enter into any future relationships necessary to the continued commercial sale of ColoSure or Version 2, or necessary to our realization of material revenues. Any failure to obtain necessary technologies or raw materials could require ColoSure or Version 2 to be re-configured which could interrupt the testing service entirely, negatively impact its commercial sale and increase the costs associated with ColoSure or Version 2, any one of which could materially harm our business and adversely affect our future revenues.

Item 5. Other Information

On May 15, 2008, we elected to make a matching contribution in the form of common stock pursuant to our qualified 401(k) retirement savings plan (the "401(k) Plan") and issued an aggregate of 27,660 shares of our common stock to the 401(k) Plan for the benefit of our employees for the plan year ended December 31, 2007. The 401(k) Plan paid no consideration for the shares. The shares were valued at $2.17 per share, the closing price of our common stock on May 15, 2008. The shares will be allocated pursuant to the terms of the 401(k) Plan. The issuance of shares was exempt from registration under the Securities Act of 1933, as amended (the "Act"), as the contribution of the shares to the 401(k) Plan for the benefit of our employees, without payment of consideration by the 401(k) Plan or employees, does not constitute a sale of the common stock for the purposes of the Act.

We have entered into a License Agreement with Case Western Reserve University, or Case Western, under which Case Western has granted us an exclusive license to use certain technology, including the aberrant methylation of the Vimentin gene promoter region in our stool-based DNA screening technologies for the detection of colorectal cancer. The License Agreement provides for us to pay royalties to Case Western for commercial sales of products containing the licensed technology. In addition, under the License Agreement we are obligated to pay up to an aggregate of $135,000 upon the achievement of certain milestones, as well as a minimum annual royalty following the launch of any product containing the licensed technology. The License Agreement provides us with the right to sublicense the licensed technology to third parties to help produce and market a commercial product. The License Agreement terminates at the expiration of the last to expire of the patents for the licensed technology, or upon certain uncured defaults of either party.

Item 6. Exhibits

Exhibit Number	Description
10.1**	License Agreement between the Registrant and Case Western Reserve University, dated as of July 18, 2005, as amended.
10.2†	Amended and Restated Employee Retention Agreement between the Registrant and Jeffrey R. Luber, dated as of April 18, 2008 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference).
10.3†	Amended and Restated Employee Retention Agreement between the Registrant and Charles R. Carelli, Jr., dated as of April 18, 2008 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference).
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

** *Confidential treatment has been requested for portions of this exhibit.*
† *Indicates a management contract or any compensatory plan, contract or arrangement.*

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: August 8, 2008

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

Date: August 8, 2008

By: /s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(Authorized Officer and Principal Financial Officer)

EXHIBIT INDEX

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

Exhibit 10.1

LICENSE AGREEMENT

Case Western Reserve University – Exact Sciences Corporation

This Agreement (hereinafter "this Agreement") entered into as of this 18th day of July, 2005 ("Effective Date") by and between Case Western Reserve University, an Ohio non-profit corporation, having a principal place of business at 10900 Euclid Avenue, Cleveland, Ohio 44106 ("CASE") and Exact Sciences Corporation, a Delaware corporation, having a principal place of business at 100 Campus Drive, Marlborough, MA 01752 ("Licensee").

WITNESSETH

WHEREAS, CASE has, subject to certain interests of Howard Hughes Medical Institute ("HHMI"), certain technology developed in the laboratory of Dr. Sanford Markowitz, a Howard Hughes Medical Institute Investigator at CASE, relating to HLTF and Vimentin Gene Methylation in Colon Cancer, and is interested in licensing same,

WHEREAS, CASE has right, by reason of its Intellectual Property Policy and assignment from HHMI, to license such technology, subject to the right of HHMI to review and approve of any such license;

WHEREAS, CASE's interest in such technology is subject to certain retained rights by the United States of America and HHMI;

WHEREAS, Licensee desires to acquire rights in and to the technology upon the terms and conditions herein set forth;

NOW THEREFORE, in consideration of the mutual covenants contained herein and intending to be legally bound hereby, the parties agree as follows:

1. DEFINITIONS

1.1 The term "Copyrights" shall mean CASE's and/or HHMI's copyrights in the Licensed Technology.

1.2 The term "Dispose" or "Disposition" shall mean the sale, lease or other transfer of Licensed Product(s).

1.3 The term "Dollar", "U.S. Dollar" and "U.S. $" shall mean lawful money of the United States of America.

1.4 The term "Field of Use" shall mean use of the Licensed Technology in detecting human colorectal cancer and tumors, including, without limitation, adenomas, in stool-based assays, and other products for the purposes of colorectal disease screening and detection, disease staging, disease monitoring, disease prognosis, and/or pharmacogenomic testing.

1.5 The term "Fiscal Quarter" or "Quarter" shall refer to the normal quarterly accounting periods of Licensee; if Licensee does not have normal quarterly accounting periods,

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

then “Fiscal Quarters” shall mean the calendar three months periods commencing with January of each year.

1.6 The term “Licensed Product” shall mean any product, service and/or process that constitutes, is based on, incorporates or uses, in whole or in part, Licensed Technology, including any mutant or altered form of the genetic material which is covered by the Patent Rights.

1.6.1 The term “Licensed Combination Product” shall mean a Licensed Product that includes one or more genes for which Licensee or a Product Sublicensee must pay royalties, upon Disposition, to one or more Third Party Licensors.

1.6.2 The term “Third Party Licensor” means an entity (other than CASE, Licensee or Sublicensee) that has entered a royalty-bearing license agreement with Licensee or a Product Sublicensee for one or more genes included in a Licensed Product.

1.7 The term “Licensed Technology” or “Technology” shall mean (i) the Patent Rights ; and (ii) the technology, trade secrets, know-how, improvements and other information and intellectual property of CASE identified in Attachment A.

1.8 The term “Licensee Net Sales” shall mean the total of [********] received by Licensee due to Dispositions of Licensed Products (other than Dispositions by Product Sublicensees), less the total of all:

[********]

No deduction shall be made for commissions paid to individuals whether they are individual sales agents or persons regularly employed by Licensee.

1.9 The term “Product Sublicensee Royalty Basis” shall mean the revenue or sales total used in a sublicense agreement between Licensee and a Product Sublicensee as the basis for computing royalties owed by such Product Sublicensee to Licensee due to Dispositions of Licensed Products. Product Sublicensee Royalty Basis, however, shall be no less than the value of Licensee Net Sales that would result from considering Revenues of Product Sublicensee to be Revenues of Licensee, unless CASE has agreed in advance to accept a particular definition of “Product Sublicensee Royalty Basis” for the computation of Royalties due to Dispositions by a Product Sublicensee.

1.10 The term “Patent Rights “ shall mean and include the United States patents and/or patent applications listed in Attachment A to this Agreement; United States patents issued from the applications listed in Attachment A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications described above; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications described above.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company’s application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

1.11 The term “Prime Rate” shall mean the interest rate per annum announced from time to time by Key Bank, Cleveland, Ohio, as its prime rate.

1.12 The term “Product Launch” shall mean the first commercial sale of Licensed Product(s).

1.13 The term “Product Sublicensee” shall mean an entity to which Licensee sublicenses rights to make, sell, distribute, manufacture, or otherwise convey or Dispose of Licensed Products pursuant to a sublicense agreement.

1.14 The term “Revenue” shall mean the U.S. Dollar value of all consideration realized from the Disposition of Licensed Product (s).

1.15 The term “Royalties” shall mean royalties calculated as a percentage of Net Sales and payable by Licensee to CASE under this Agreement.

1.16 The term “Year” refers to contract years of the License Agreement, *i.e* ., a 12-month period starting with the date (or anniversary) of the Effective Date of the License Agreement.

2. LICENSE GRANT

2.1 CASE hereby grants to Licensee, and Licensee hereby accepts, (i) an exclusive, royalty bearing, world-wide right and license under and to the Licensed Technology to make, have made, use and Dispose of Licensed Products in the Field of Use and (ii) a non-exclusive, world-wide, royalty free right and license under and to the Licensed Technology for internal research and development purposes in the Field of Use.

2.2 No right to sublicense the Licensed Technology is hereby granted to Licensee except that Licensee may sublicense to (i) Product Sublicensees to the extent necessary to enable Product Sublicensees to make and/or Dispose of Licensed Products within the Field of Use; (ii) customers to the extent necessary for their personal use of a Licensed Product; or (iii) other entities with the specific agreement of CASE.

2.2.1 Licensee understands that any sublicenses granted by Licensee to entities other than customers (even though the specific agreement by CASE to such a sublicense has been obtained) must provide that the obligations to CASE and HHMI (as a third-party beneficiary) under this Agreement, including but not limited to, Indemnification, Insurance, HHMI’s third party beneficiary status, and procedures for Dispute Resolution shall be binding upon such sublicensee as if it were a party to this Agreement and that the economic return to CASE from the Disposition of Licensed Products be not less than the economic returns would be if such Disposition had been by Licensee. In addition, any sublicense agreement shall provide for automatic assignment to CASE in the event of termination of Licensee’s license to the Licensed Technology (prior to expiration of this Agreement). Licensee shall be responsible for the acts or omissions of its sublicensees and shall not grant any rights which are inconsistent with the rights granted to and obligations of Licensee hereunder. Any act or omission of a sublicensee that would be a breach of this License Agreement if performed by Licensee shall be

deemed to be a breach of this License Agreement by Licensee if such breach is not cured before 180 days. Each sublicense agreement granted by Licensee shall include an audit right by CASE of the same scope as provided herein below with respect to Licensee. No such sublicense agreement shall contain any provision which would cause it to extend beyond the Team of this Agreement. Licensee shall give CASE prompt notification of the identity and address of each sublicensee with whom it concludes a sublicense agreement and shall supply CASE with a copy of each such sublicense agreement.

2.3 No provision of this Agreement shall restrict Licensee's, CASE's and/or HHMI's ability to conduct further research and development in the area of Licensed Technology or other areas.

2.4 All Licensed Products shall be manufactured, sold and performed by Licensee in compliance with all applicable governmental laws, rules and regulations. Licensee shall keep CASE fully informed of, and shall move expeditiously to resolve, any complaint by a governmental body relevant to Licensed Products, except for complaints subject to the Section of this Agreement entitled "Infringement."

2.5 CASE represents and warrants that CASE has the right to license the Patent Rights to Licensee under the terms provided in this Agreement and that CASE's obligations to HHMI do not conflict with the licenses provided hereunder. CASE retains the right to grant either exclusive or non-exclusive licenses for the Licensed Technology in fields of use other than the Field of Use for which the license hereunder is granted.

2.6 If Licensed Technology was supported under a United States Government funding agreement, then (a) the United States Government has been or will be granted licensing rights solely as required under the terms of those federal agreements, (b) all rights and obligations reserved to the United States Government and others under Public Law 96-517, and Public Law 98-620 and any applicable governmental rules and regulations, including but not limited to government purpose license and march-in rights and sharing of certain research materials, shall be respected and shall in no way be diminished by this Agreement and any right granted in this Agreement regarding Licensed Technology greater than that permitted under Public Law 96-517 or Public Law 98-620, and any applicable governmental rules and regulations, shall be subject to modification as may be required to conform to the provisions of those statutes, and (c) products using Licensed Technology sold or used in the United States will be manufactured substantially in the United States of America, unless a waiver has been obtained from the federal funding agency under whose funding agreement the Licensed Technology was generated.

2.7 Notwithstanding the license granted in this Agreement, CASE and HHMI and any health care institutions affiliated with either of them shall have and retain all rights to use, free of charge, the Licensed Technology for their non-commercial research, clinical research treatment (*i.e.* the treatment of patients as part of a clinical research effort to determine the effectiveness, safety or tolerability of Licensed Technology), educational or academic purposes, even in the Field of Use, but not for licensing to others. There is no restriction on licensing by CASE of Licensed Technology outside the Field of Use.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

2.8 CASE and HHMI may have in the past, and shall have the right in the future, to provide Licensed Technology to academic and/or non-profit health care institutions for non-commercial research, clinical research treatment, educational, or academic purposes. Nothing in this Agreement shall prohibit such conduct by CASE or HHMI or use for such purposes by academic or non-profit health care institutions receiving Licensed Technology from CASE or HHMI. For the avoidance of confusion, CASE may not, during the Term of this Agreement, permit any third party to use the Licensed Technology in the Field of Use for commercial purposes.

3. FIELD OF USE OPTION

CASE hereby grants to Licensee an option (the "Field of Use Option") for a term of twenty-four (24) months only, commencing on the Effective Date, (the "Option Period") to negotiate an amendment to the Agreement with CASE to expand the Field of Use for the Licensed Technology to include human blood-based assays for the purposes of colorectal disease screening and detection, disease staging, disease monitoring, disease prognosis, and/or pharmacogenomic testing. To exercise this Field of Use Option, Licensee must (i) provide a written statement, reasonably satisfactory to CASE, demonstrating Licensee's capability and intention to develop Licensed Products within the human blood-based assay field of use for public sale as soon as practicable, consistent with sound and reasonable business practices and judgment, and (ii) execute an amendment to this Agreement with CASE prior to expiration of the Option Period.

4. TERM OF THIS AGREEMENT

This Agreement shall expire at the end of its term (the "Term"), which extends from the Effective Date to the expiration of the last to expire of the Patent Rights. The Agreement may be terminated prior to expiration pursuant to other provisions of this Agreement.

5. DUE DILIGENCE

5.1 Licensee shall use its best commercially reasonable efforts to effect introduction of Licensed Technology into the commercial market as soon as reasonably practical; thereafter, until the termination of this Agreement, Licensee shall keep Licensed Technology reasonably available to the public. At a minimum, Licensee shall achieve Product Launch within thirty (30) months of the Effective Date.

5.2 Licensee's default in performance in accordance with Subsection 5.1 shall be grounds for CASE to terminate this Agreement.

6. LICENSE FEES AND ROYALTIES

6.1 For Dispositions of Licensed Products other than Licensed Combination Products, Licensee shall pay CASE a Royalty of [********] (hereinafter the "Royalty Rate") of the sum of Licensee Net Sales and Product Sublicensee Royalty Basis.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

6.2 For Dispositions of Licensed Combination Products, the Royalty Rate of [********] shall be reduced by the percentage, if any, of Licensee Net Sales and/or Product Sublicensee Royalty Basis payable as a royalty to the Third Party Licensor(s) who have contributed one or more genes to such Licensed Combined Products. Notwithstanding the foregoing, in no event shall the Royalty Rate be less than 1 percent.

6.3 The parties acknowledge that Licensee, in partial satisfaction of its fee obligations to CASE hereunder, paid CASE [********] on March 10, 2003. In addition to this amount, Licensee shall pay CASE non-refundable License Fees of (i) [********] due and payable [********]; (ii) [********] due and payable, if this Agreement is still in effect, upon the earlier of: (a) [********] or, (b) [********]; and (iii) [********] due and payable [********]. The License Fees described in this section 6.3 will be in addition to any other amounts due under this Agreement.

6.4 Licensee shall pay CASE a minimum royalty of [********] per year (" *Annual Minimum Royalty* "), commencing on the anniversary date of the Effective Date following the Product Launch, and payable on each anniversary of the Effective Date thereafter. The Annual Minimum Royalty shall be credited against the Royalties payable in a Year.

6.5 Annual Minimum Royalty payments are to be adjusted by the cumulative percentage change in the CPI-W Consumer Price Index between December 2004 and the December preceding the date on which the payment in question is payable.

7. PAYMENT TERMS

7.1 Royalties shall be paid by Licensee to CASE, as defined in the Section entitled "Royalties" for each Fiscal Quarter within sixty (60) days of the end of such Fiscal Quarter, until this Agreement expires or is terminated in accordance with this Agreement. If this Agreement terminates before the end of a Fiscal Quarter, the payment for that terminal fractional portion of a Fiscal Quarter shall be made within ninety (90) days of the date of termination of this Agreement.

7.2 All Royalties hereunder shall be paid in U.S. Dollars and shall be made by wire transfer to CASE's account No. [********] at Key Bank's Cleveland office, or by Licensee's check sent in accordance with the Section entitled "Notices".

7.3 All Royalties payable hereunder that are overdue shall bear interest until paid at a rate equal to the Prime Rate in effect at the date such Royalties were due plus four percent (4%) per annum, but in no event to exceed the maximum rate of interest permitted by applicable law. This provision for interest shall not be construed as a waiver of any rights CASE has as a result of Licensee's failure to make timely payment of any amounts.

8. REPORTS AND AUDITS

8.1 Licensee shall provide Quarterly reports of its progress in achieving Product Launch and shall notify CASE within ten (10) days of achieving Product Launch.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

8.2 Licensee shall maintain accurate books and records such that the Royalties due and payable hereunder can be easily ascertained. Such books and records shall be maintained at Licensee's principal place of business and shall be available for inspection by CASE or its representatives during the normal business day upon not less than ten (10) days prior written notice, provided that CASE or its representatives agree to protect the confidentiality of the informational Licensee.

8.3 Licensee shall make available Licensee's books and records for audit by an independent accounting firm of CASE's selection and Licensee agrees to cooperate fully in any such audit, provided that the auditors agree to protect the confidentiality of the information of Licensee. Any such audit shall not be more frequent than annually. In the event that such audit determines that the amount of Royalties paid to CASE was in error by the greater of [********] or [********], Licensee shall pay the costs of the audit.

9. IMPROVEMENTS

9.1 Discussion of technical matters with each other by the parties will not create in a party any rights to ownership of patents, copyrights, trade secrets or other intellectual property rights in solutions to the matters that are invented solely by employees or agents of the other party hereto.

9.2 Licensee will own all of the right, title and interest (including patents, copyrights, trade secrets and any other intellectual property rights) in and to any results developed solely by Licensee or on its behalf in connection with this Agreement, including the results of any collaboration between the parties that are invented solely by Licensee's employees or agents.

9.3 CASE will own all of the right, title and interest (including patents, Patent Rights, Copyrights, mask work rights, trade secrets and any other intellectual property rights) in and to any results developed solely by CASE or on its behalf in connection with this Agreement, including the results of any collaboration between the parties that are invented solely by CASE employees or agents.

9.4 All intellectual property that is a direct improvement of and is dominated by the Patent Rights and has been jointly invented by employees or agents of CASE and Licensee in connection with this Agreement and without use of Licensee's own intellectual property shall be owned by CASE and included as Patent Rights, provided that Licensee may use such jointly invented intellectual property pursuant to the terms of Section 2.1 of this License Agreement. CASE may issue licenses to others regarding such jointly invented property that result in Patent Rights, as long as such licenses do not violate any exclusive license to Licensee granted to Licensee under Section 2.1 (entitled "License Grant"). If any other intellectual property is jointly invented by employees or agents of CASE and Licensee in connection with this Agreement, CASE and Licensee shall jointly own (without any duty to account to the other for profits) all right, title and interest (including patents, copyrights, mask work rights, trade secrets, and other intellectual property rights) therein. If any such patentable invention which would not constitute a Patent Right or Licensed Technology arises out of such joint invention by employees or agents of CASE and Licensee, CASE and Licensee will negotiate in good faith on whether

and how to pursue patent, copyright or mask work protection of the invention in the U.S. and elsewhere.

9.5 Except as provided in this Section, nothing herein shall be deemed to grant any license or rights in any other technology in addition to the Licensed Technology.

10. PATENTS AND OTHER INTELLECTUAL PROPERTY

10.1 CASE Property. Intellectual property rights to Licensed Technology, such as Patent Rights, and Case's Copyrights, will remain the property of CASE. Trademarks owned by CASE existing on the Effective Date of this License Agreement related to the Licensed Technology belong to CASE.

10.2 Licensee shall bear all patenting costs for prosecution and maintenance of patents included in the Licensed Technology that are reasonably incurred or due prior to termination of this Agreement according to the following terms. Licensee will reimburse CASE for the following fees and expenses related to such patenting that have been incurred as of the Effective Date, as follows: (i) [********] of past fees and expenses shall be due within thirty (30) days of receipt of an invoice or bill from CASE, not to exceed [********], and (ii) [********] of past fees and expenses shall be due upon Product Launch, not to exceed [********]. Licensee shall reimburse CASE for all reasonable future fees and expenses related to the Patent Rights in those countries agreed upon by Licensee within thirty (30) days of the receipt of each invoice or bill. Should Licensed Technology be licensed to others, those patenting and other intellectual property protection costs which are incurred after that point shall be pro-rated among all licenses in proportion to the number of licenses in effect at the time the costs are incurred. CASE will use reasonable best efforts to manage efficiently patent prosecution and expenses and shall keep Licensee advised of such expenses. Licensee shall have reasonable input into consideration of issues relating to prosecution and maintenance of patents covering the Licensed Technology, but CASE shall retain ultimate control and decision-making authority with respect thereto.

10.3 CASE has applied for, and/or will apply for and prosecute Patent Rights, at Licensee's expense, in any country that is requested by Licensee, for any and all patent applications and patents listed in Attachment A, to the extent that such protection is reasonably obtainable. Licensee will not be responsible for patent costs associated with foreign prosecution unless such foreign pursuit has first been approved by Licensee in writing. If such written approval is not delivered to CASE within thirty (30) days of CASE's written request therefor, Licensee shall have no rights concerning those specific patent rights included in the Patent Rights in such country(ies).

10.4 CASE may, at its option and sole discretion and at its own expense, pursue patent, copyright and/or trademark rights for Licensed Technology in any country for which coverage has not been requested by Licensee in accordance with Subsection 10.3 above. If Licensee does not reimburse CASE for such fees within thirty (30) days of the receipt of a related invoice or bill, then Licensee shall have no rights under any of those specific patent rights included in the Patent Rights in that country and shall have no rights to practice under such patent in such country.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

11. MARKINGS, TRADEMARKS AND TRADE NAMES

11.1 Licensee shall have included in all sales, marketing literature and invoices relating to Licensed Product, a statement to the effect that "this product or portions thereof is manufactured under license from Case Western Reserve University" and, if applicable, either "Patent Pending" or, if applicable, "U.S. Patent Number ."

11.2 Licensee shall have marked the appropriate portions of all Licensed Product with any applicable United States of America and foreign patent numbers in accordance with the applicable laws of the countries in which the materials are intended to be used. Licensee shall neither register nor use any CASE trademarks or trade names.

11.3 Licensee and CASE each acknowledge that they do not have any rights or any title whatsoever in or to the other's technology, trade names or trademarks, except as expressly provided under this Agreement and except as expressly authorized in writing after the Effective Date of this Agreement and except as required by law. Any reference by Licensee to CASE beyond the above may only be done with express written permission of CASE's Associate Vice President for Technology Transfer.

12. TERMINATION

12.1 In the event that Licensee defaults in the payment in full of any amount required to be paid under this Agreement on the date such payment is due, in addition to using any other legal and/or equitable remedies, CASE shall have the right, following the applicable cure period described in 12.2 below, and by written notice to Licensee after such default either (i) to terminate the exclusivity, if any, of the license hereunder (by amending the word "exclusive" in the License Grant to read "non-exclusive") without any reduction in any of the payments due from Licensee or (ii) to terminate this Agreement.

12.2 In the event that either party to this Agreement defaults in the performance of any of its obligations hereunder and fails to cure such default within thirty (30) days after written notice of such default from such other party, the other party shall have the right by written notice to the defaulting party within sixty (60) days after the expiration of such thirty (30) day period to terminate this Agreement.

12.3 The termination of this Agreement, under any Section of the Agreement, shall not terminate (i) the obligation of Licensee to pay any amounts, which have accrued or which are otherwise to be paid by Licensee under the terms of this Agreement, or (ii) the obligations of either party arising prior to the date of termination under the Sections entitled "Reports and Audits," "Patents and Other Intellectual Property," "Termination," "Taxes," "Confidentiality and Trade Secrets," "Indemnification," "Insurance," "Dispute Resolution," and "Infringement" hereunder.

12.4 Upon termination of this Agreement, Licensee will immediately discontinue any further use of Licensed Technology and discontinue production of any Licensed Products.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

12.5 In the event of termination of the Agreement prior to expiration, any sublicenses entered by Licensees shall be automatically be assigned to CASE and shall operate thereafter as direct licenses from CASE. Notwithstanding the foregoing, CASE shall only be entitled under such sublicenses, to the receipt of amounts relating to the Licensed Technology and shall not be entitled to receive amounts from such sublicensees relating to Licensee's technologies, which shall continue to remain due and payable to Licensee directly.

12.6 Licensee shall have the right to terminate this Agreement upon notice to CASE if one or more of the Patent Rights do not issue.

13. TAXES

Licensee shall pay all taxes which may be assessed or levied on, or on account of, the Licensed Technology, Licensed Product made, used or Disposed of hereunder and all taxes (other than taxes imposed by the United States of America or the State of Ohio or jurisdictions within such State) levied on or on account of the amounts payable to, or for the account of, CASE under this Agreement, excluding income taxes.

14. NO WARRANTY

EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT: (A) ANY INFORMATION, MATERIALS, SERVICES, INTELLECTUAL PROPERTY OR OTHER PROPERTY OR RIGHTS GRANTED OR PROVIDED BY CASE PURSUANT TO THIS AGREEMENT ("DELIVERABLES") ARE ON AN "AS IS" BASIS, (B) NEITHER LICENSEE NOR CASE MAKE ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, OR MERCHANTABILITY, EXCLUSIVITY OR RESULTS OBTAINED FROM USE, NOR SHALL EITHER CASE OR LICENSEE BE LIABLE FOR CLAIMS FOR INDIRECT, SPECIAL, OR CONSEQUENTIAL DAMAGES SUCH AS LOSS OF PROFITS OR INABILITY TO USE SAID DELIVERABLES OR ANY APPLICATIONS AND DERIVATIONS THEREOF. EXCEPT AS PROVIDED IN THIS AGREEMENT, NEITHER CASE NOR LICENSEE MAKES ANY WARRANTY OF ANY KIND WITH RESPECT TO FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT, OR THEFT OF TRADE SECRETS. CASE DOES NOT ASSUME ANY LIABILITY HEREUNDER FOR ANY INFRINGEMENT OF ANY PATENT, TRADEMARK, OR COPYRIGHT ARISING FROM THE USE OF THE DELIVERABLES. NEITHER PARTY WILL MAKE ANY WARRANTY ON BEHALF OF THE OTHER, EXPRESSED OR IMPLIED, TO ANY THIRD PARTY.

15. COSTS

All costs and expenses incurred by Licensee in carrying out Licensee's obligations under this Agreement shall be paid by Licensee, and Licensee shall not be entitled to reimbursement from Royalties hereunder or otherwise therefore from CASE. Licensee shall possess or obtain at its own expense all necessary licenses and permits and shall comply with all laws, ordinances,

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rules or regulations affecting the exportation, use, and/or sale or transfer of the Licensed Product and/or Licensed Technology by Licensee..

16. CONFIDENTIALITY AND TRADE SECRETS

16.1 "Confidential Information" shall mean any information relating to the Licensed Technology, the terms of this Agreement (as from time to time amended), Patent Rights, or other non-public matters covered by this Agreement or information disclosed from one party to the other hereunder in the manner set forth hereinafter. All such information shall be Confidential Information, including information disclosed prior to the date of this Agreement, unless such information (i) was already in the receiving party's possession prior to the time of relevant disclosure thereof as provided in subsection (a) hereof; (ii) has been published or is published hereafter, unless such publication is a breach of this Agreement; (iii) is obtained by the receiving party from a third party not under an obligation of confidentiality with respect thereto; or (iv) is independently developed by the receiving party.

(a) In the event that such information shall be established to have been known to the receiving party prior to the disclosure thereof by reference to any publication thereof by the receiving party or by reference to any internal writing or other business record maintained by the receiving party in the ordinary course of business, such information shall not be deemed to be Confidential Information for purposes of this Agreement following notification to the other party under this Agreement of such fact.

(b) With respect to any information not related to the Licensed Technology or Licensee's assay and product development efforts which are deemed by the disclosing party to be Confidential Information subject to this Agreement, the disclosing party shall mark such information as "Confidential" prior to disclosing it to the other.

(c) With respect to any oral communication not related to the Licensed Technology or Licensee's assay and product development efforts which is deemed by the disclosing party to be Confidential Information subject to this Agreement, the disclosing party shall notify the receiving party of such fact and within thirty (30) days thereafter the disclosing party shall send a memorandum to the receiving party outlining the information deemed to be Confidential Information.

16.2 Each party shall maintain in confidence and shall not disclose to any person not a party hereto, nor shall either party use or exploit in any way without the other party's written agreement, any Confidential Information until three (3) years after the later of the date of the termination of this Agreement or the end of the term of the last to expire of the Patent Rights, unless such information ceases to be Confidential Information prior to the end of such period through no fault of the receiving party or the parties enter into an agreement authorizing same.

16.3 The receiving party shall exercise all reasonable precautions to prevent the disclosure of Confidential Information by its employees or representatives, and in any event shall maintain with respect to such Confidential Information a standard of care which is no less than

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that standard which such party maintains to prevent the disclosure of its own confidential information.

16.4 Upon termination of this Agreement, each party agrees to return at once to the other, without copying, all originals and copies of all materials (other than this Agreement) containing any Confidential Information and to make no further use thereof

17. INDEMNIFICATION

Licensee hereby agrees to defend, indemnify and hold harmless CASE and HHMI, and their respective trustees, officers, employees, attorneys and agents from and against any third party claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "Claims"), based upon, arising out of or otherwise relating to Licensee's actions or inactions under this Agreement or based upon, arising out of or otherwise relating to Licensee's and/or its sublicensee's use, conduct, or misconduct regarding Licensed Products , including but not limited to, any claims of product liability, personal injury, death, damage to property or violation of any laws or regulations.

18. INSURANCE

Before Licensed Technology is used to diagnose or treat human beings, Licensee shall obtain and maintain appropriate coverage of general liability, product liability, and public liability insurance in the amount of no less than Three Million Dollars to protect CASE and HHMI, and their respective trustees, officers, employees, attorneys and agents under the indemnification provided hereunder. CASE and HHMI, and their respective trustees, officers, employees, attorneys and agents shall be named as additional insureds on Licensee's insurance policies. CASE shall be provided appropriate certificates of insurance thereunder.

19. BREACH

No acquiescence in any breach of this Agreement by either party shall operate to excuse any subsequent or prior breach.

20. PRIOR AGREEMENT

Except for any confidential disclosure agreement executed by the parties, this Agreement supersedes all previous agreements relating to the subject matter hereof, whether oral or in a writing, and constitutes the entire agreement of the parties hereto and shall not be amended or altered in any respect except in a writing executed by the parties.

21. INTERPRETATION

This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Ohio, United States of America, without regard to conflict of law principles.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

22. DISPUTE RESOLUTION

22.1 Subject to Subsection 22.2, any controversy or dispute arising under or relating to this Agreement (including, but not limited to, the validity, scope and enforceability of this arbitration clause) shall be referred to and finally settled by arbitration in the City of Cleveland, Ohio, under the auspices of, and conducted in accordance with, the rules of the American Arbitration Association. All arbitration proceedings shall be before a board of three (3) arbitrators, for each of which each party shall select one (1) arbitrator and the selected arbitrators shall select the third arbitrator. The costs of the third arbitrator shall be divided equally between the parties, and each party shall pay the costs of the arbitrator selected by it. Any award of the arbitrators shall be final and conclusive on the parties to this Agreement, and judgment upon such award may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, any dispute affecting the rights or property of HHMI shall not be subject to the arbitration provisions above.

22.2 Either party may seek injunctive relief for: (a) violation by the other party of the Sections entitled “Reports and Audits,” “Markings, Trademarks and Trade Names,” “Confidentiality and Trade Secrets,” “Insurance” and “Dispute Resolution”; (b) for enforcement of any arbitration award; or (c) for enforcement of any non-arbitrable matter. The prevailing party shall be entitled to recover from the other all costs, including attorney’s fees, related to the action for injunctive relief.

22.3 Licensee hereby irrevocably and unconditionally:

(i) Agrees that any legal action, suit or proceeding relating to the Agreement and contemplated by this Section entitled “Dispute Resolution” hereof (collectively, “Related Litigation”) may be brought in any state or federal court of competent jurisdiction sitting in Cuyahoga County, Ohio, submits to the jurisdiction of such courts, and to the fullest extent permitted by law agrees that it will not bring any Related Litigation in any other forum (but nothing herein shall affect the right of CASE to bring any action, suit or proceeding in any other forum);

(ii) Waives any objection which it may have at any time to the laying of venue of any Related Litigation brought in any such court located in Cuyahoga County, Ohio, waives any claim that any such Related Litigation has been brought in an inconvenient forum, and waives any right to object, with respect to any Related Litigation brought in any such court, that such court does not have jurisdiction over Licensee; and

(iii) Consents and agrees to service of any summons, complaint or other legal process in any Related Litigation by registered or certified mail, postage prepaid, to Licensee at the address for notices described in the Section entitled “Notices” hereof, and consents and agrees that such service shall constitute in every respect valid and effective service (but nothing herein shall affect the validity or effectiveness of process served in any other manner permitted by law).

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company’s application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

23. INFRINGEMENT

23.1 Licensee shall have the right during the term of this Agreement to commence an action for infringement of the Patent Rights against any third party for any infringement occurring within the Field of Use, provided that Licensee shall provide CASE thirty (30) days' prior written notice of such infringement and of Licensee's intent to file such action. CASE shall have the right at its own expense to appear in such action by counsel of its own selection. If required by the jurisdictional laws of the forum that any such action be prosecuted in the name of the owner of the Patent Right, CASE shall voluntarily appear at Licensee's expense; provided that if such appearance subjects CASE to any unrelated action or claim of a third party or Licensee in such jurisdiction, then CASE shall have the right to decline such appearance. Settlement of any action brought by Licensee shall require the consent of CASE and Licensee, which neither shall unreasonably withhold from the other, and any settlement amount or recovery for damages shall be applied as follows: (i) first, to reimburse the parties for their expenses in connection with the litigation; and (ii) second, CASE shall receive compensation for the time of any CASE personnel involved in the action; and (iii) third, CASE shall receive [*********] of any monies remaining.

23.2 CASE shall have the right in its sole discretion during the term of this Agreement to commence an action for infringement of the Patent Rights against any third party for any infringement occurring anywhere in the world, provided that, before commencing any such action concerning products within the Field of Use, CASE shall provide Licensee with the first right to sue as provided in Section 23.1 and, if Licensee determines not to bring suit, with not less than thirty (30) days' prior written notice of such infringement and of CASE's intent to file such action. Licensee shall have the right at its own expense to appear in such action by counsel of its own selection. If CASE provides Licensee with such notice before instituting an action concerning products within the Field of Use and Licensee fails to initiate an action against such third party prior to the commencement of an action by CASE, then any settlement amount or recovery for damages shall belong entirely to CASE and CASE may settle said action without the consent of Licensee; provided, however, that the terms of any such settlement do not impose any obligations on Licensee or limit any rights Licensee would otherwise have under this Agreement.

23.3 Notwithstanding the pendency of any infringement (or other) claim or action by or against Licensee, Licensee shall have no right to terminate or suspend (or escrow) payment of any amounts required to be paid to CASE pursuant to this Agreement.

24. NOTICES

Any notice under any of the provisions of this Agreement shall be deemed given when deposited in the mail, postage prepaid, registered or certified first class mail and addressed to the applicable party at the address stated on the signature page hereof, or such other address as such party shall specify for itself by like notice to other party. Each party shall transmit to the other a facsimile copy of each such notice promptly after such deposit in the mail.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

25. ASSIGNMENT

Except in the instance of a merger of Licensee into another entity or the sale of the assets of Licensee to which this License Agreement relates, Licensee shall neither assign nor transfer this Agreement or any interest herein without the prior written consent of CASE.

26. THIRD PARTY BENEFICIARY

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

27. HEADINGS

The section headings contained in this Agreement are set forth for the convenience of the parties only, do not form a part of this Agreement and are riot to be considered a part hereof for the purpose of construction or interpretation hereof; or otherwise.

28. EXPORT CONTROLS

It is understood that CASE is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee shall not export data or commodities to certain foreign countries without prior approval of such agency. CASE neither represents that a license shall not be required nor that, if required, it shall be issued.

(The balance of this page is intentionally left blank)

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed in duplicate counterparts, each of which shall be deemed to constitute an original, effective as of the date first above written.

The undersigned verify subject to the penalties of Section 2921.13 of the Ohio Revised Code relating to unsworn falsification to authorities that they have the authority to bind to this Agreement the party on behalf of which they are executing below.

Case Western Reserve University

By: /s/ Mark E. Coticchia

Title: VP for Research & Technology Management

Date: 8/4/05

By: /s/ [illegible]

Title: CIO

Date: 8/5/05

Address for Notices:

Case Western Reserve University

10900 Euclid Avenue
Cleveland, Ohio 44106, USA
Attention: Assistant Vice President Biomedical Science
Facsimile: 216-368-0196

Exact Sciences Corporation

By: /s/ Don Hardison

Title: President and CEO

Date: 7/27/05

Address for Notices:

100 Campus Drive
Marlborough, MA 01752
Attention: President
Facsimile:(508) 683-1201

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

Attachment A

Description of Licensed Technology

1) [********]

2) [********]

Also, without limitation, any foreign filed patents and patent applications based on the subject matter included in (1) and (2) above not already listed above.

CASE has represented to Licensee that this Attachment A is a complete list of patent applications and patents owned or controlled by CASE as of the Effective Date that relate to HLTF Gene Methylation and/or Vimentin Gene Methylation that have application to the Field of Use. To the extent not already listed, this Attachment A therefore includes, without limitation, patent applications and patents owned or controlled by CASE as of the Effective Date that relate to HLTF Gene Methylation and/or Vimentin Gene Methylation and have application to the Field of Use, provided that Licensee may elect, upon disclosure of the patent rights by CASE to Licensee, to include or exclude any such patent application or patent from this Agreement.

To the extent not already listed, this Attachment A shall include, without limitation, any such patent application(s) and/or patent(s) that Licensee elects to include in the Patent Rights pursuant to Section 2.10 of this Agreement.

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

First Amendment to License Agreement
EXACT Sciences Corporation
and
Case Western Reserve University

This First Amendment (this "Amendment") is made effective as of December 31, 2007 (the "Amendment Effective Date"), by and between Case Western Reserve University ("CWRU") and EXACT Sciences Corporation ("EXACT").

WHEREAS, CWRU and EXACT entered into an Agreement dated July 18, 2005, (the "Agreement") and the parties desire to amend certain provisions of the Agreement.

NOW, THEREFORE, in partial consideration of entry of this Amendment by CWRU, Licensee shall pay to CWRU a non-refundable upfront fee of [*********] within 90 days of the Amendment Effective Date; this [*********] payment is separate and apart from the [*********] payment referenced below in paragraph 1. The parties agree to the following amendments to the Agreement, to be effective as of the Amendment Effective Date:

1. The last sentence of Section 5.1 of the Agreement shall be replaced with the following:

At a minimum, Licensee shall achieve Product Launch by December 31, 2008. If Licensee has not achieved Product Launch by December 31, 2008, it can extend the date for this requirement to December 31, 2009 by notifying CWRU in writing and paying a [*********] non-refundable fee to CWRU.

2. Except as expressly modified herein, the Agreement and all of its terms and conditions shall continue in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Amendment as of the date first above written.

Case Western Reserve University

By: /s/ Mark E. Coticchia

Printed Name: Mark E. Coticchia

Title: Vice President for Research and Technology Management

EXACT Sciences Corporation

By: /s/ Jeffrey Luber

Printed Name: Jeffrey Luber

Title: President

Case Western Reserve University

By: /s/ Robert Clarke Brown

Printed Name: Robert Clarke Brown

Title: Treasurer

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Exchange Act; [*] denotes omissions.

Exhibit 31.1

I, Jeffrey R. Luber, certify that:

1. I have reviewed this quarterly 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 officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 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 fiscal 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 officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 8, 2008

By: /s/ Jeffrey R. Luber
Jeffrey R. Luber
President and Chief Executive Officer

Exhibit 31.2

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

1. I have reviewed this quarterly 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 officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 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 fiscal 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 officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 8, 2008

By: /s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Senior Vice President, Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

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

In connection with the Quarterly Report of EXACT Sciences Corporation (the "Company") on Form 10-Q for the period ending June 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Jeffrey R. Luber, President and Chief Executive Officer of the Company and Charles R. Carelli, Jr., Senior Vice President, Chief Financial Officer, Treasurer and Secretary 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/ Jeffrey R. Luber
Jeffrey R. Luber
President and Chief Executive Officer

August 8, 2008

/s/ Charles R. Carelli, Jr.
Charles R. Carelli, Jr.
Senior Vice President, Chief Financial Officer, Treasurer and Secretary

August 8, 2008