EXACT SCIENCES CORP
Form 10-Q
October 29, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2010

OR

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

Commission File Number: 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**02-0478229**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
441 Charmany Drive, Madison WI	**53719**
(Address of principal executive offices)	(Zip Code)

(608) 284-5700

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of October 26, 2010, the registrant had 40,503,516 shares of common stock outstanding.

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Part 1 Financial Information

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EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,815	$ 21,924
Marketable securities	14,026	2,404
Prepaid expenses and other current assets	339	484
Restricted cash		500
Total current assets	35,180	25,312
Property and Equipment, at cost:		
Laboratory equipment	826	492
Office and computer equipment	181	90
Leasehold improvements	89	12
Furniture and fixtures	20	20
	1,116	614
Less Accumulated depreciation and amortization	(323)	(156)
	793	458
	$ 35,973	$ 25,770
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 379	$ 155
Accrued expenses	1,690	1,385
Third party royalty obligation, current portion	988	
Deferred license fees, current portion	4,481	4,986
Total current liabilities	7,538	6,526
Third party royalty obligation, less current portion		988
Long term debt	1,000	1,000
Long term accrued interest	16	1
Deferred license fees, less current portion	9,618	11,161
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding no shares at September 30, 2010 and December 31, 2009		
Common stock, $0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 40,480,084 and 35,523,140 shares at September 30, 2010 and December 31, 2009	405	355
Additional paid-in capital	206,993	187,333
Other comprehensive loss	(21)	(1)
Accumulated deficit	(189,576)	(181,593)
Total stockholders equity	17,801	6,094
	$ 35,973	$ 25,770

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue:				
Product royalty fees	$ 5	$ 9	$ 24	$ 27
License fees	1,351	1,247	3,945	3,487
	1,356	1,256	3,969	3,514
Cost of revenue:				
Product royalty fees	6	5	18	13
Gross profit	1,350	1,251	3,951	3,501
Operating expenses:				
Research and development	2,635	837	6,553	2,960
General and administrative	1,796	1,478	4,647	7,884
Sales and marketing	315	12	754	52
Restructuring				(3)
	4,746	2,327	11,954	10,893
Loss from operations	(3,396)	(1,076)	(8,003)	(7,392)
Interest income, net	14	35	20	118
Net loss	$ (3,382)	$ (1,041)	$ (7,983)	$ (7,274)
Net loss per share basic and diluted	$ (0.08)	$ (0.03)	$ (0.21)	$ (0.23)
Weighted average common shares outstanding basic and diluted	40,155	34,932	38,293	31,902

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands - unaudited)

	Nine Months Ended September 30,	
	2010	**2009**
Cash flows from operating activities:		
Net loss	$ (7,983)	$ (7,274)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	167	44
Amortization and write-offs of patents		95
Stock-based compensation	1,675	1,958
Amortization of deferred license fees	(3,944)	(3,487)
Warrant licensing expense	80	1,753
Changes in assets and liabilities:		
Prepaid expenses and other current assets	145	(215)
Accounts payable	224	(480)
Accrued expenses	370	(308)
Accrued interest	15	
Third party royalty obligation		(1,485)
Net cash used in operating activities	(9,251)	(9,399)
Cash flows from investing activities:		
Purchases of marketable securities	(18,740)	(17,634)
Maturities of marketable securities	7,098	13,474
Purchases of property and equipment	(502)	(88)
Net cash used in investing activities	(12,144)	(4,248)
Cash flows from financing activities:		
Proceeds from Genzyme Collaboration, License and Purchase Agreement	1,896	16,650
Proceeds from sale of common stock to Genzyme		6,000
Proceeds from sale of common stock, net of issuance costs	17,597	8,062
Proceeds from exercise of common stock options and stock purchase plan	293	727
Decrease in restricted cash	500	100
Payment for repurchase of stock options		(50)
Net cash provided by financing activities	20,286	31,489
Net increase (decrease) in cash and cash equivalents	(1,109)	17,842
Cash and cash equivalents, beginning of period	21,924	4,937
Cash and cash equivalents, end of period	$ 20,815	$ 22,779
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized gain (loss) on available-for-sale investments	$ (20)	$ 5
Issuance of 15,460 and 24,430 shares of common stock to fund the Company s 401(k) matching contribution for 2009 and 2008, respectively	$ 65	$ 32

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (Exact, we, us or the Company) was incorporated in February 1995. Exact is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. The Company s non-invasive stool-based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre-cancer and cancer.

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 and notes as of and for the year ended December 31, 2009 included in the Company s Annual Report on Form 10-K. 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. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. 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 statements should be read in conjunction with the audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2009 (the 2009 Form 10-K).

(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. On September 16, 2009 the Company dissolved Exact Sciences Securities Corporation and all intercompany transactions and

balances were permanently eliminated.

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.

Marketable 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

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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.

At September 30, 2010 and December 31, 2009, the Company s investments were comprised of marketable debt securities and mutual funds and all were deemed available-for-sale. The objectives of the Company s investment strategy 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. Realized losses for the three and nine months ended September 30, 2010 were $3,792. Realized gains for the three and nine months ended September 30, 2009 were $5,464. Unrealized gains or losses on investments are recorded in other comprehensive income.

Net Loss Per Share

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:

	September 30,	
(In thousands)	**2010**	**2009**
Shares issuable upon exercise of stock options	6,241	5,870
Shares issuable upon exercise of outstanding warrants	825	1,250
Shares issuable upon the release of restricted stock awards	157	401
	7,223	7,521

Revenue Recognition

License fees. License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash 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.

As more fully described in the Company s Annual Report on Form 10-K for the year ended December 31, 2009, in connection with our strategic transaction with Genzyme, Genzyme agreed to pay us a total of $18.5 million, of which $16.65 million was paid on January 27, 2009 and

$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company s on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the CLP Agreement), including its obligation to deliver certain intellectual property improvements to Genzyme during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial $16.65 million in cash received at closing and is amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company received the first holdback amount of $962,000, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of $934,250, which included accrued interest due, from Genyzme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

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In addition, Genzyme paid $2.00 per share for the 3,000,000 shares of common stock purchased from the Company on January 27, 2009, representing a premium of $0.51 per share above the closing price of the Company s common stock on that date of $1.49 per share. The aggregate premium paid by Genzyme over the closing price of the Company s common stock on the date of the transaction of $1.53 million is deemed to be a part of the total consideration for the CLP Agreement. Accordingly, the Company deferred the aggregate $1.53 million premium and is amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

The Company recognized approximately $1.4 million and $3.9 million, respectively, in license fee revenue in connection with the amortization of the up-front payments from Genzyme and LabCorp during the three and nine months ended September 30, 2010. The Company recognized $1.2 million and $3.5 million, respectively, in license fee revenue in connection with the amortization of the up-front payments from Genzyme and LabCorp during the three and nine months ended September 30, 2009.

Critical Accounting Estimate Third Party Royalty Obligation

Pursuant to the terms of the agreement the Company has with LabCorp, we agreed to reimburse LabCorp up to $3.5 million for certain third party royalty payments. As of September 30, 2010 we have paid $2.5 million to LabCorp. We will be required to pay at a maximum the remaining $1.0 million balance in January of 2011. Based on anticipated sales volumes of ColoSure, as of September 30, 2010, we accrued a total of $988,000 related to the total potential remaining $1.0 million obligation to LabCorp. Charges to record or adjust the obligation were recorded under the caption Product royalty fees in our consolidated statements of operations. No charges were recorded during the nine months ended September 30, 2010 and 2009. Future increases or decreases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of our condensed consolidated statements of operations.

Comprehensive Loss

Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and nine months ended September 30, 2010 and 2009 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2010**	**2009**	**2010**	**2009**
Net loss	$ (3,382)	$ (1,041)	$ (7,983)	$ (7,274)
Unrealized gain (loss) on marketable securities	(18)	(33)	(20)	5
Comprehensive loss	$ (3,400)	$ (1,074)	$ (8,003)	$ (7,269)

(3) MAYO LICENSING AGREEMENT

Overview

On June 11, 2009, the Company entered into a license agreement (the License Agreement) with MAYO Foundation for Medical Education and Research (MAYO). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the Field) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) (the Proteomic Target) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The License Agreement grants the Company an option to include the Proteomic Target within the Field upon written notice by the Company to MAYO during the first year of the term. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the licenses to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of $1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company will also make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the agreement. In addition to the license to

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intellectual property owned by MAYO, the Company will receive product development and research and development efforts from MAYO personnel. The Company determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. The Company is also liable to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

Warrants

The warrants granted to MAYO were valued based on a Black-Scholes pricing model at the date of the grant. The warrants were granted with an exercise price of $1.90 per share of common stock. The grant to purchase 1,000,000 unregistered shares was immediately exercisable and the grant to purchase 250,000 unregistered shares vests and becomes exercisable over a four year period. The total value of the warrants was calculated to be $2.1 million and a non-cash charge of $1.7 million was recognized as research and development expense in the second quarter of 2009 and the remaining $0.4 million non-cash charge is being recognized straight-line over the four year vesting period. The assumptions for the Black-Scholes pricing model are represented in the table below.

Assumptions for Black-Scholes Pricing Model:

Exercise price	$	1.90
Stock price	$	1.99
Volatility		86.30%
Life of warrant (in years)		10
Treasury rate		3.88%
Dividend yield		0%
Fair value per warrant	$	1.72

In March of 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the agreement. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 86,569 shares leaving it with a net amount of 113,404 shares.

In September of 2010, MAYO partially exercised its warrant covering the remaining 800,000 shares by utilizing the cashless exercise provision contained in the agreement. As a result of this exercise for a gross amount of 300,000 shares, (1) in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares, and (2) the warrant now covers a total of 500,000 shares.

Royalty Payments

The Company will make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Minimum royalty payments will be $10,000 in 2012 and $25,000 per year thereafter through 2029, the year the last patent expires.

Other Payments

Other payments under the MAYO agreement include an upfront payment of $80,000, a milestone payment of $250,000 on the commencement of patient enrollment in a clinical trial in support of the Company s efforts to obtain FDA clearance for its sDNA colorectal cancer screening product, and a $500,000 payment upon FDA approval of such product. The upfront payment of $80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. It is uncertain as to when the FDA trial will begin and when the FDA will clear the Company s cancer screening test. Therefore, the $250,000 and $500,000 milestone payments have not been recorded as liabilities. The Company will periodically evaluate the status of the FDA trial.

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In addition, the Company is paying MAYO for research and development efforts. Through September 30, 2010, as part of the agreement, the Company has incurred charges of $1.4 million and has made payments of $0.9 million and at September 30, 2010 the Company has recorded an estimated liability in the amount of $0.5 million for research and development efforts. During the three months ended September 30, 2010, as part of the agreement, the Company has incurred charges of $0.3 million and has made payments of $0.2 million.

(4) RESTRUCTURING

2008 Restructuring

In July 2008, we took actions to reduce our cost structure to help preserve our cash resources, which we refer to as the 2008 Restructuring. These actions included suspending the clinical validation study of our Version 2 technology, eliminating eight positions, or 67 percent of our staff, and seeking the re-negotiation of certain fixed commitments. The remaining amounts in the 2008 Restructuring accrual were paid out in cash in July 2010. These amounts were 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 nine months ended September 30, 2010 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, September 30, 2010
Employee separation costs	$	$	$	$
Facility consolidation costs	73		(73)	
Total	$ 73	$	$ (73)	$

The following table summarizes changes made to the restructuring accrual during the nine months ended September 30, 2009, related to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, September 30, 2009
Employee separation costs	$ 16	$ (2)	$ (14)	$
Facility consolidation costs	165	(1)	(74)	90
Total	$ 181	$ (3)	$ (88)	$ 90

2007 Restructuring

During the third quarter of 2007, in connection with the Third Amendment to the LabCorp agreement, 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. The remaining amounts in the 2007 Restructuring accrual were paid out in cash in July 2010. These amounts were recorded under the caption Accrued expenses in the Company s condensed consolidated balance sheets. The following table summarizes the 2007 Restructuring activities during the nine months ended

September 30, 2010. Amounts included in the table are in thousands.

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Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, September 30, 2010
Employee separation costs	$	$	$	$
Facility consolidation costs	67		(67)	
Total	$ 67	$	$ (67)	$

The following table summarizes changes made to the restructuring accrual during the nine months ended September 30, 2009, related to the 2007 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, September 30, 2009
Employee separation costs	$	$	$	$
Facility consolidation costs	161		(69)	92
Total	$ 161	$	$ (69)	$ 92

(5) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, 1995 Stock Option Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase Plan (collectively, the Stock Plans).

Stock-Based Compensation Expense

The Company recorded $0.6 million and $1.6 million, respectively, in stock-based compensation expense during the three and nine months ended September 30, 2010 in connection with the vesting of restricted common stock awards and stock options granted to employees, non-employee directors and non-employee consultants. The Company recorded $0.6 million and $2.0 million, respectively, in stock-based compensation expense during the three and nine months ended September 30, 2009 in connection with the vesting of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants and certain stock option modifications.

Determining Fair Value

Valuation and Recognition - 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 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 term 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 stock volatility data over the expected term of the awards.

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

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Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. No forfeiture rate was utilized for awards granted prior to 2009 due to the monthly vesting terms of the options granted in that timeframe. Because of the vesting terms, the Company was, in effect, recording stock-based compensation only for those awards that were vesting and expected to vest and a forfeiture rate was not necessary. Awards granted in the nine months ended September 30, 2010 that vest annually are all expected to vest and no forfeiture rate was utilized.

The fair value of each restricted stock award is determined on the date of grant using the closing stock price on that day.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	**2009**	**2010**	**2009**
Option Plan Shares				
Risk-free interest rates	1.60% - 1.70%	2.31%	1.60% - 2.69%	1.76% - 2.54%
Expected term (in years)	6	6	6	6
Expected volatility	92%	92%	91% - 92%	85% - 92%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	$ 3.02	$ 2.08	$ 2.99	$ 0.80
ESPP Shares				
Risk-free interest rates	(1)	(1)	0.17% - 0.38%	(1)
Expected term (in years)	(1)	(1)	0.5 - 1	(1)
Expected volatility	(1)	(1)	53% - 127%	(1)
Dividend yield	(1)	(1)	0%	(1)
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1)	$ 1.07	(1)

(1) The Company did not issue stock purchase rights under its 2000 Employee Stock Purchase Plan or its 2010 Employee Stock Purchase Plan during the period indicated.

Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2010 is as follows:

		Weighted Average	Weighted Average Remaining	Aggregate

Options (Aggregate intrinsic value in thousands)	Shares	Exercise Price	Contractual Term (Years)	Intrinsic Value (1)
Outstanding, January 1, 2010	5,912,019	$ 1.76	8.6	
Granted	500,066	$ 3.92		
Exercised	(171,329)	$ 1.71		
Forfeited				
Outstanding, September 30, 2010	6,240,756	$ 1.93	8.1	$ 34,038
Exercisable, September 30, 2010	2,562,564	$ 2.39	7.3	$ 13,350
Vested and expected to vest, September 30, 2010	6,240,756	$ 1.93	8.1	$ 34,038

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(1) The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company s common stock for options that had exercise prices that were lower than the $7.24 market price of the Company s common stock at September 30, 2010.

As of September 30, 2010, there was $4.7 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.83 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2010 is as follows:

	Restricted Shares		Weighted Average Grant Date Fair Value
Outstanding, January 1, 2010	40,000	$	1.72
Granted	209,197	$	3.95
Released	(92,567)	$	2.97
Forfeited			
Outstanding, September 30, 2010	156,630	$	3.96

(6) EQUITY TRANSACTIONS

On April 19, 2010 the Company completed an underwritten public offering of 4.2 million shares of common stock at a price of $4.50 per share to the public. The Company received approximately $17.6 million of net proceeds from the offering, after deducting $1.3 million for the underwriting discount and other stock issuance costs paid by the Company. The Company expects to use the net proceeds from the offering for general corporate and working capital purposes, including the funding of strategic initiatives that the Company may undertake from time to time, for product development and the furtherance of the Company s efforts to obtain FDA clearance of its sDNA colorectal cancer screening product.

In April of 2010, we entered into a license agreement with MAYO Foundation for Medical Education and Research (MAYO) for market research services and rights to use certain intellectual property related to product development. As part of the license agreement, we issued to MAYO 11,186 shares of common stock for an initial payment under the agreement. If Exact utilizes the licensed intellectual property in the Company s final product design, Exact will be required to make an additional nonrefundable payment to Mayo in the form of unregistered shares of common stock with a fair market value of $65,000.

(7) FAIR VALUE MEASUREMENTS

The Company values its assets and liabilities using the fair value hierarchy outlined in the Accounting Standards Codification.

The three levels of the fair value hierarchy 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

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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.

The following table presents the Company s fair value measurements as of September 30, 2010 along with the level within the fair value hierarchy 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). Amounts in the table are in thousands.

		Fair Value Measurement at September 30, 2010 Using:		
Description	**Fair Value at September 30, 2010**	**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 debt securities	$ 4,026	$	$ 4,026	$
Mutual funds	10,000	10,000		
Total	$ 14,026	$ 10,000	$ 4,026	$

The following table presents the Company s fair value measurements as of December 31, 2009 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

		Fair Value Measurement at December 31, 2009 Using:		
Description	**Fair Value at December 31, 2009**	**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	$ 2,404	$ 650	$ 1,754	$
Total	$ 2,404	$ 650	$ 1,754	$

(8) INCOME TAXES

The Company is subject to taxation in the U.S. and various state jurisdictions. All of the Company s tax years are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses.

Under financial accounting standards, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or benefit represents the change in the deferred tax assets or liabilities from period to period.

A valuation allowance to reduce the deferred tax assets is reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has incurred significant losses since its inception and due to the uncertainty of the amount and timing of future taxable income, management has

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determined that a full valuation allowance at September 30, 2010 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company s effective tax rate.

In accordance with GAAP, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At September 30, 2010 the Company had no unrecognized tax benefits, nor are there any tax positions where it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the 12 months following September 30, 2010.

(9) RECENT ACCOUNTING PRONOUNCEMENTS

Other than those pronouncements issued and adopted during the first quarter of 2010 as discussed in the Consolidated Financial Statements (unaudited), there were no other recently issued accounting pronouncements that are expected to impact Exact Sciences Corporation.

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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, 2009, 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 believe, expect, may, will, should, could, seek, i estimate, anticipate or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, expected license fee revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management s Discussion and Analysis of Financial Condition and Results of Operations sections of this report and our Annual Report on Form 10-K for the year ended December 31, 2009. 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 is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal pre-cancer and cancer.

Our primary goal is to become the market leader for a patient-friendly diagnostic screening product for the early detection of colorectal pre-cancer and cancer. Our strategic roadmap to achieve this goal includes the following key components:

- develop and refine our non-invasive stool-based (sDNA) colorectal pre-cancer and cancer screening test;

- advance our product through the U.S. Food and Drug Administration, or FDA, clinical trials;

- secure insurance coverage and reimbursement for our product; and

- commercialize an FDA-cleared product that detects colorectal pre-cancer and cancer.

Our current focus is on the commercial development and seeking FDA clearance of our sDNA colorectal cancer screening product. We believe obtaining FDA clearance is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. As part of our product development efforts, we are exploring the marker combinations and platform requirements necessary for optimal performance of our technology based on market need. Objectives around performance, throughput and cost are among the elements that will need to be met in the design and development of a commercial product based on our technology.

We are designing our sDNA colorectal cancer screening product with a goal of detecting both pre-cancers and cancers, at target sensitivities of at least 50 percent and 85 percent, respectively. On October 28, 2010 we announced the results of a validation study involving a total of 1,178 stool samples. In this study, the current version of our sDNA cancer screening test was able to detect both pre-cancers and cancers at or above these target sensitivity rates. However, prior to commercialization of our sDNA colorectal cancer screening product, it will be necessary to obtain FDA approval or clearance, which will depend upon our ability to successfully complete a pivotal clinical trial.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 15 years to progress from a pre-cancerous lesion to metastatic cancer and death. However, it is the second-leading cause of cancer death in the United States, killing almost 50,000 people each year.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Approximately 40 percent of those who should be screened for colorectal cancer are not screened according to current guidelines.

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Poor compliance has meant that nearly two-thirds of colon cancer diagnoses are made in the disease s late stages. The five-year survival rates for stages 3 and 4 are 68 percent and 10 percent respectively.

Our sDNA screening test can detect pre-cancers and cancers early, and is expected to be a powerful, preventive tool. By detecting pre-cancers and cancers early with the sDNA-based test, affected patients can be referred to colonoscopy, during which the polyp or lesion can be removed. The sDNA screening model has the potential to significantly reduce colorectal cancer deaths. The earlier the pre-cancer or cancer can be detected, the greater the reduction in mortality.

The competitive landscape is favorable to sDNA-based screening. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. Colonoscopy is uncomfortable and expensive. Fecal blood testing suffers from poor sensitivity and poor compliance. Blood-based DNA testing also is disadvantaged by its sensitivity. Data from a clinical trial of one blood-based test was released earlier this year. It demonstrated 50-64 percent sensitivity across all stages of cancer, with little sensitivity for pre-cancer.

The competitive advantages of sDNA-based screening provide a massive market opportunity. Assuming a 30 percent test adoption rate and a three-year screening interval, we estimate the potential U.S. market for sDNA screening to be $1.2 billion, and the total available U.S. market is more than $5 billion.

The benefits of sDNA-based screening are clear. It detects both pre-cancers and cancers, at target sensitivities greater than 50 percent and 85 percent, respectively. sDNA-based screening is non-invasive and requires no bowel preparation or dietary restriction like other methods. The sample for sDNA-based screening can be collected easily at home and mailed to the appropriate laboratory, where the testing would be conducted. sDNA-based screening also is affordable, particularly relative to colonoscopy.

Our intellectual property portfolio positions us as the leader in the sDNA market. Our patent estate broadly protects our position in the market, including the platform technology, methods and biomarkers. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic. We had previously licensed on an exclusive basis Johns Hopkins digital PCR technologies for colon cancer detection, as well as Case Western s important Vimentin DNA methylation marker. In 2009, we also licensed Hologic, Inc. s Invader detection chemistry, which we plan to incorporate into our test. In July 2010 we obtained an exclusive license to certain DNA methylation biomarkers from Oncomethylome Sciences.

We have generated limited operating revenues since inception and, as of September 30, 2010, we had an accumulated deficit of approximately $189.6 million. 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, the build-out of our sales infrastructure to support the commercialization of sDNA screening. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

Financial Overview

Revenue. Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp and Genzyme and product royalty fees on tests sold by LabCorp utilizing our technology. We expect that product royalty fees for the full year 2010 will be consistent with amounts recorded in 2009. We expect that license fee revenue resulting from the amortization of the up-front license payment from LabCorp and Genzyme in 2010 will be higher than amounts recorded in 2009 as a result of a full year of revenue from the Genzyme transaction and from the receipt of holdback amounts from Genzyme during 2010.

Our Cost Structure. Our general and administrative expenses have consisted primarily of non-research personnel salaries, office expenses, professional fees and, non-cash stock-based compensation. In 2009 and 2010 we have incurred an increased amount of research and development expenses and sales and marketing expenses in support of developing an FDA-approved sDNA screening test for the detection and prevention of colon cancer.

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Critical Accounting Policies and Estimates

Management s discussion and analysis of our financial condition and results of operations is based on our condensed 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 stock-based compensation. 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.

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements included in this report, we believe 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 are amortizing 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.

In connection with our January 2009 strategic transaction with Genzyme we received an up-front payment of $16.65 million on January 27, 2009 in exchange for the assignment and licensing of certain intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the CLP Agreement), including our obligation to deliver certain intellectual property improvements to Genzyme during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, we deferred the initial $16.65 million in cash received at closing and are amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company received the first holdback amount of $962,000, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of $934,250, which included accrued interest due, in the third quarter of 2010. Both of the holdback amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme paid $2.00 per share for the 3,000,000 shares of our common stock purchased on January 27, 2009, representing a premium of $0.51 per share above the closing price of our common stock on that date of $1.49 per share. The aggregate premium paid by Genzyme over the closing price of our common stock on the date of the transaction of $1.53 million is deemed to be a part of the total consideration for the CLP Agreement. Accordingly, we deferred the aggregate $1.53 million premium and are amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

We recognized approximately $1.4 million and $3.9 million, respectively, in license fee revenue in connection with the amortization of the up-front payments from Genzyme and LabCorp during the three and nine months ended September 30, 2010. The Company recognized approximately $1.2 million and $3.5 million, respectively, in license fee revenue in connection with the amortization of the up-front payments from Genzyme and LabCorp during the three and nine months ended September 30, 2009.

Stock-Based Compensation. In accordance with GAAP, 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), are recognized in the consolidated financial statements based on their fair values. The following assumptions are used in determining the fair value of stock option grants:

- ***Valuation and Recognition*** - The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The estimated fair value of employee stock options is recognized to expense using the straight-line method over the vesting period.

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- ***Expected Term*** - The Company uses the simplified calculation of expected term 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 term 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 stock volatility data over the expected term of the awards.

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

- ***Forfeitures*** - The Company records stock-based compensation expense only for those awards that are expected to vest. No forfeiture rate was utilized for awards granted prior to 2009 due to the monthly vesting terms of the options granted in that timeframe. Because of the vesting terms, the Company was, in effect, recording stock-based compensation only for those awards that were vesting and expected to vest and a forfeiture rate was not necessary. Awards granted in the nine months ended September 30, 2010 that vest annually are all expected to vest and no forfeiture rate was utilized.

The fair value of each restricted stock award is determined on the date of grant using the closing stock price on that day. 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 Note 5 to our condensed consolidated financial statements.

Critical Accounting Estimate Third-Party Royalty Obligation

Pursuant to the terms of the agreement the Company has with LabCorp, we agreed to reimburse LabCorp up to $3.5 million for certain third party royalty payments. As of September 30, 2010 we have paid $2.5 million to LabCorp. We will be required to pay at a maximum the remaining $1.0 million balance in January of 2011. Based on anticipated sales volumes of ColoSure, as of September 30, 2010, we accrued a total of $988,000 related to the total potential remaining $1.0 million obligation to LabCorp. Charges to record or adjust the obligation were recorded under the caption Product royalty fees in our consolidated statements of operations. No charges were recorded during the nine months ended September 30, 2010 and 2009 respectively. Future increases or decreases 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.

Recent Accounting Pronouncements

Other than those pronouncements issued and adopted during the first quarter of 2010 as discussed in the Consolidated Financial Statements (unaudited), there were no other recently issued accounting pronouncements that are expected to impact us.

Results of Operations

Revenue. Total revenue increased to $1.4 million for the three months ended September 30, 2010 from $1.3 million for the three months ended September 31, 2009, and increased to $4.0 million for the nine months ended September 30, 2010 from $3.5 million for the same period in 2009. Total revenue is primarily composed of the amortization of up-front technology license fee payments associated with our amended license agreement with LabCorp and our collaboration, license and purchase agreement with Genzyme. The unamortized LabCorp up-front payment is being amortized on a straight-line basis over the remaining exclusive license period, which ends in December 2010. The unamortized Genzyme up-front payment is being amortized on a straight-line basis over the initial Genzyme collaboration period which ends January 2014.

Revenues also include royalties on LabCorp s sales of ColoSure as well as charges for our third-party royalty reimbursement obligations to LabCorp which are recorded as reductions to revenue under financial accounting guidance.

Research and development expenses. Research and development expenses increased to $2.6 million for the three months ended September 30, 2010 from $0.8 million for the three months ended September 30, 2009, and increased to $6.6 million for the nine months ended September 30, 2010 from $3.0 million for the same period in 2009. The increase for the three months ended September 30, 2010 was primarily due to an increase of $0.6 million in compensation

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expenses, $0.6 million of lab expenses, $0.3 million in professional fee expenses, and $0.3 million in other research and development expenses. The increase for the nine months ended September 30, 2010 was primarily due to an increase of $2.1 million in compensation expenses, $1.1 million of lab expenses, $0.9 million of research collaboration expenses, $0.7 million in professional fee expenses as well as $0.3 million in other research and development expenses when compared to the same period in 2009 offset by the non-recurrence of a one-time stock based licensing expense of $1.8 million related to warrants issued to the Mayo Clinic. The increase in these categories was the result of increased research and development activities in support of our efforts to obtain FDA clearance of our sDNA colorectal cancer screening product, which included hiring additional research and development personnel.

As a result of these efforts, we expect research and development costs in 2010 to continue to be higher than 2009 levels.

General and administrative expenses. General and administrative expenses increased to $1.8 million for the three months ended September 30, 2010, compared to $1.5 million for the same period in 2009, and decreased to $4.6 million for the nine months ended September 30, 2010 from $7.9 million for the same period in 2009. The increase for the three months ended September 30, 2010 was primarily due to an increase of $0.3 million in other general and administrative expenses consisting primarily of office expenses, facility costs and information technology expenses. The decrease for the nine months ended September 30, 2010 was primarily due to the non-recurrence of $1.9 million in transaction costs related to the Genzyme strategic transaction in January 2009, a reduction in compensation expenses of $1.6 million due primarily to severance and stock option expense incurred in connection with the management change in the prior year period and a reduction in legal and professional fees expenses of $0.2 million, offset by an increase of $0.4 million in other general and administrative expenses.

Sales and marketing expenses. Sales and marketing expenses increased to $0.3 million for the three months ended September 30, 2010 from $12,000 for the same period in 2009, and $0.8 million for the nine months ended September 31, 2010 from $52,000 for the same period in 2009 as a result of increased sales and marketing efforts and activities in support of our efforts to obtain FDA clearance of our sDNA colorectal cancer screening product.

Interest income. Interest income decreased to $14,000 for the three months ended September 30, 2010 from $35,000 for the same period in 2009, and decreased to $20,000 for the nine months ended September 30, 2010 from $118,000 for the same period in 2009. This decrease is primarily due to decreased yields on investments held resulting from less favorable interest rates.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our equity securities, cash received from LabCorp under our license agreement with LabCorp, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of September 30, 2010, we had approximately $34.8 million in cash equivalents and marketable securities. All of our investments in marketable securities are comprised of marketable debt securities and mutual funds 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. As of September 30, 2010 we had approximately $14.0 million in marketable securities.

On April 19, 2010, we completed an underwritten public offering of 4.2 million shares of common stock at a price of $4.50 per share to the public. We received approximately $17.6 million of net proceeds from the offering, after deducting the underwriting discount and other stock issuance costs paid by us.

Net cash used in operating activities was $9.3 million for the nine months ended September 30, 2010 as compared to $9.4 million for the nine months ended September, 2009. The principal use of cash in operating activities for the nine months ended September 30, 2010 and 2009 was to fund our net loss.

Net cash used in investing activities was $12.1 million for the nine months ended September 30, 2010 as compared to $4.2 million for the nine months ended September 30, 2009. The increase in cash used in investing activities for the nine months ended September 30, 2010 compared to the same period in 2009 was the result of purchase and maturity activity of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $0.5 million for the nine months ended September 30, 2010 and $88,000 for the nine months ended September 30, 2009. Purchases of property and equipment of approximately $0.5 million during the nine

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months ended September 31, 2010 were higher than purchases of property and equipment for the nine months ended September 30, 2009 as a result of increased research and development activities. Based on our plans for further development of our sDNA technology for colorectal cancer detection, we expect that purchases of property and equipment during 2010 will be higher than amounts invested in 2009.

Net cash provided by financing activities was $20.3 million for the nine months ended September 30, 2010 as compared to $31.5 million for the nine months ended September 30, 2009. For the nine months ended September 30, 2009 we received $22.6 million in connection with the Genzyme strategic transaction and $8.1 million from an issuance of common stock. During the nine months ended September 30, 2010, cash inflows consisted of $17.6 million of proceeds from sale of common stock in our underwritten public offering, and $1.9 million in connection with the receipt of the first and second Genzyme hold back amounts.

We expect that cash and cash equivalents on hand at September 30, 2010, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since we have no current sources of material ongoing revenue, we will need to raise additional capital to fully fund our current strategic plan, the centerpiece of which is the commercialization of our sDNA technology through completion of the development of an FDA-cleared in vitro diagnostic test for sDNA colorectal pre-cancer and cancer screening. Even if we successfully raise sufficient funds to complete our plan, we cannot assure you that our business will ever generate sufficient cash flow from operations to become profitable.

Off-Balance Sheet Arrangements

As of September 30, 2010, we had no off-balance sheet arrangements.

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-15e promulgated under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2010, 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 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

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 most recent Annual Report on Form 10-K and in any subsequent Quarterly Reports on Form 10-Q. Other than the factors set forth below, there have been no material changes to the risk factors described in those reports.

Although in our validation study the current version of our sDNA colorectal cancer screening test detected both pre-cancers and cancers at our target sensitivity rates of at least 50 percent and 85 percent, respectively, the FDA approval path for our colorectal cancer screening technology will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

We are designing our test with a goal of detecting both pre-cancers and cancers, at target sensitivities of at least 50 percent and 85 percent, respectively. On October 28, 2010 we announced the results of a validation study involving a total of 1,178 stool samples. In this study, the current version of our sDNA cancer screening test was able to detect both pre-cancers and cancers at or above these target sensitivity rates. However, prior to commercialization of our sDNA colorectal cancer screening product, it will be necessary to obtain FDA approval or clearance, which will depend upon our ability to successfully complete a pivotal clinical trial. We have only recently received the data from this study and plan to engage in extensive further analysis and review. Also, this was a feasibility study and did not use a final product to test patient samples under real-life, clinical conditions (rather, for example, using previously frozen and stored samples). The results achieved in future clinical trials and other studies may differ materially from our validation study results for a number of reasons. To ensure successful completion of an FDA clinical trial for our screening test we expect to need to continue refine the product. Additionally, we will need to develop FDA compliant manufacturing and quality control systems. There can be no assurance that we will be successful in these efforts or achieve our initial validation study results in future studies and even if we do the FDA approval path for our colorectal cancer screening technology will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed..

There can be no assurance that we will obtain FDA clearance and approval for our sDNA colorectal cancer screening test.

The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be subject to either a premarket notification clearance, known as a 510(k), or a premarket approval, known as a PMA. Our current focus is on the commercial development and seeking FDA clearance and approval of our sDNA colorectal cancer screening product. We believe obtaining FDA clearance is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. The 510(k) process means that the FDA will not require a PMA, a generally but not necessarily more time-consuming and costlier process than the 510(k) process, because the FDA finds that either (a) our product is substantially similar to a legally marketed product (a predicate device) or (b) in the absence of a predicate device that the FDA concludes that our product may use a process known as a de novo classification, which is reserved for low-risk products; however, the 510(k) process still involves substantial costs and time and may have to be repeated for any number of reasons, including but not limited to, the FDA s discretion or if the product is modified during the process. The PMA process, which is necessary when a device cannot be cleared through the 510(k) process, involves providing extensive data to the FDA to allow the FDA to find that the device is safe and effective for its intended use, which may also include providing additional data and updates to the FDA, the convening of expert panels, inspection of manufacturing facilities, and new or supplemented PMAs if the product is modified during the process. Even if granted, a 510(k) or PMA approval may place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including but not limited to registering manufacturing facilities, listing the products with the FDA, complying with labeling, and meeting reporting requirements. We currently expect to seek a PMA for our colorectal cancer screening product. We believe that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is the 510(k) process or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve any 510(k) request or approve any PMA submitted by us in a timely manner or at all.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In June 2009, we entered into a license agreement with MAYO Foundation for Medical Education and Research (MAYO) under which we acquired rights to use certain intellectual property. As part of the license agreement, we granted MAYO two common stock purchase warrants with an exercise price of $1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively.

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In March 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 86,569 shares leaving it with a net amount of113,404 shares.

In September 2010, MAYO partially exercised its warrant covering the remaining 800,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 300,000 shares, (1) in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares, and (2) the warrant now covers a total of 500,000 shares.

We believe that the offer and sale of the securities referenced were exempt from registration under the Securities Act by virtue of Section 4(2) of the Securities Act of 1933 (the Securities Act) and/or Regulation D promulgated thereunder as transactions not involving any public offering. Use of this exemption is based on the following facts:

- Neither we, nor any person acting on our behalf, solicited any offer to buy or sell securities by any form of general solicitation or advertising.

- At the time of the purchase, MAYO was an accredited investor, as defined in Rule 501(a) of the Securities Act.

- MAYO has had access to information regarding DARA and is knowledgeable about us and our business affairs.

In addition, we believe the issuance of shares on exercise of the warrants via cashless exercise was exempt from registration under the Securities Act by virtue of Section 3(a)(9) of thereof inasmuch as such issuances involved the issuance of shares to an existing security holder in exchange for other securities where no commission or other remuneration was paid or given for soliciting such exchange.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. (Removed and Reserved)

Item 5. Other Information

As of October 27, 2010, Dr. Barry Berger has moved into the role of Senior Vice President of Medical Affairs. In connection with this move, Dr. Berger s employment agreement has been amended to (1) change his duties and responsibilities from that of Chief Medical Officer to Senior Vice President of Medical Affairs, (2) reduce his time commitment to 4 days a week and (3) reduce his compensation and severance benefits in light of his reduced responsibilities.

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Item 6. Exhibits

The exhibits required to be filed as a part of this report are listed in the Exhibit Index.

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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: October 28, 2010

By: /s/ Kevin T. Conroy
Kevin T. Conroy

President and Chief Executive Officer
(Authorized Officer)

Date: October 28, 2010

By: /s/ Maneesh K. Arora
Maneesh K. Arora

Chief Financial Officer
(Authorized Officer and Principal Financial Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1	Exact Sciences Corporation 2010 Omnibus Long-Term Incentive Plan (previously filed as Appendix A to the Proxy Statement for the Company s 2010 Annual Meeting of Stockholders filed on April 30, 2010), which is incorporated herein by reference).
10.2	Exact Sciences Corporation 2010 Employee Stock Purchase Plan (previously filed as Appendix A to the Proxy Statement for the Company s 2010 Annual Meeting of Stockholders filed on April 30, 2010), 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.