

EXACT SCIENCES CORP  
Form 10-Q  
November 12, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2009

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)

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**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**02-0478229**

(I.R.S. Employer  
Identification Number)

**441 Charmany Drive, Madison WI**  
(Address of principal executive offices)

**53719**  
(Zip Code)

**(608) 284-5700**

(Registrant's telephone number, including area code)

**505 S. Rosa Road, Suite 123, Madison, WI**

(Former name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 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  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 November 12, 2009, the registrant had 35,598,690 shares of Common Stock outstanding.

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## Part 1 Financial Information

**EXACT SCIENCES CORPORATION****Condensed Consolidated Balance Sheets**

(Amounts in thousands, except share data - unaudited)

|  | September 30,<br>2009 | December 31,<br>2008 |
|--|-----------------------|----------------------|
| <b>ASSETS</b>  |                       |                      |
| Current Assets:  |                       |                      |
| Cash and cash equivalents  | \$ 22,779             | \$ 4,937             |
| Marketable securities  | 4,165                 |                      |
| Prepaid expenses and other current assets  | 405                   | 190                  |
| Total current assets   | 27,349                | 5,127                |
| Property and Equipment, at cost:   |                       |                      |
| Laboratory equipment   | 184                   | 174                  |
| Office and computer equipment  | 62                    | 13                   |
| Leasehold improvements   | 13                    |                      |
| Furniture and fixtures   | 16                    |                      |
|  | 275                   | 187                  |
| Less Accumulated depreciation and amortization   | (155)                 | (111)                |
|  | 120                   | 76                   |
| Patent costs, net of accumulated amortization of \$2,820 at December 31, 2008  |                       | 95                   |
| Restricted cash  | 500                   | 600                  |
|  | \$ 27,969             | \$ 5,898             |
| <b>LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY</b>   |                       |                      |
| Current Liabilities:   |                       |                      |
| Accounts payable   | \$ 203                | \$ 683               |
| Accrued expenses   | 1,158                 | 1,498                |
| Third party royalty obligation   | 1,000                 | 1,500                |
| Deferred revenue   | 4,986                 | 1,350                |
| Total current liabilities  | 7,347                 | 5,031                |
| Third party royalty obligation, less current portion   | 965                   | 1,950                |
| Deferred revenue   | 12,408                | 1,350                |
| Commitments and contingencies  |                       |                      |
| Stockholders (Deficit) Equity:   |                       |                      |
| Preferred stock, \$0.01 par value; 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2009 and December 31, 2008                            |                       |                      |
| Common stock, \$0.01 par value; 100,000,000 shares authorized; 35,595,866 and 27,522,931 shares issued and outstanding at September 30, 2009 and December 31, 2008 | 355                   | 275                  |
| Additional paid-in capital   | 186,725               | 169,854              |
| Treasury stock, at cost, 85,550 shares   | (97)                  | (97)                 |
| Other comprehensive income   | 5                     |                      |
| Accumulated deficit  | (179,739)             | (172,465)            |
| Total stockholders (deficit) equity  | 7,249                 | (2,433)              |

\$ 27,969 \$ 5,898

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

Table of Contents**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, |                   |
|---|----------------------------------|-------------------|---------------------------------|-------------------|
|   | 2009                             | 2008              | 2009                            | 2008              |
| <b>Revenue:</b>   |                                  |                   |                                 |                   |
| Product royalty fees  | \$ 9                             | \$ (1,000)        | \$ 27                           | \$ (1,787)        |
| License fees  | 1,247                            | 337               | 3,487                           | 1,013             |
| Product   |                                  |                   |                                 | 16                |
|   | 1,256                            | (663)             | 3,514                           | (758)             |
| <b>Cost of revenue:</b>   |                                  |                   |                                 |                   |
| Product royalty fees  | 5                                |                   | 13                              | 1                 |
| <b>Gross profit (loss)</b>  | <b>1,251</b>                     | <b>(663)</b>      | <b>3,501</b>                    | <b>(759)</b>      |
| <b>Operating expenses:</b>  |                                  |                   |                                 |                   |
| Research and development (1)  | 837                              | 577               | 2,960                           | 1,964             |
| General and administrative (1)  | 1,478                            | 1,271             | 7,884                           | 4,601             |
| Sales and marketing   | 12                               |                   | 52                              |                   |
| Restructuring (1)   |                                  | 539               | (3)                             | 532               |
|   | 2,327                            | 2,387             | 10,893                          | 7,097             |
| <b>Loss from operations</b>   | <b>(1,076)</b>                   | <b>(3,050)</b>    | <b>(7,392)</b>                  | <b>(7,856)</b>    |
| Interest income   | 35                               | 36                | 118                             | 224               |
| <b>Net loss</b>   | <b>\$ (1,041)</b>                | <b>\$ (3,014)</b> | <b>\$ (7,274)</b>               | <b>\$ (7,632)</b> |
| <b>Net loss per share - basic and diluted</b>                         | <b>\$ (0.03)</b>                 | <b>\$ (0.11)</b>  | <b>\$ (0.23)</b>                | <b>\$ (0.28)</b>  |
| <b>Weighted average common shares outstanding - basic and diluted</b> | <b>34,932</b>                    | <b>27,233</b>     | <b>31,902</b>                   | <b>27,184</b>     |

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

|                            |        |       |        |       |
|----------------------------|--------|-------|--------|-------|
| Research and development   | \$ 118 | \$ 16 | \$ 168 | \$ 85 |
| General and administrative | 505    | 246   | 1,790  | 707   |
| Restructuring              |        | 3     |        | 3     |

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

Table of Contents**EXACT SCIENCES CORPORATION****Consolidated Statements of Cash Flows****(Amounts in thousands-unaudited)**

|   | <b>Nine Months Ended September 30,</b> |             |
|---|--|-------------|
|   | <b>2009</b>                            | <b>2008</b> |
| <b>Cash flows from operating activities:</b>  |  |             |
| Net loss  | \$ (7,274)                             | \$ (7,632)  |
| Adjustments to reconcile net loss to net cash used in operating activities:                           |  |             |
| Depreciation and amortization   | 139                                    | 494         |
| Restructuring   |  | 281         |
| Stock-based compensation  | 1,958                                  | 795         |
| Warrant expense for license fees  | 1,753                                  |             |
| Changes in assets and liabilities:  |  |             |
| Prepaid expenses and other current assets   | (215)                                  | 20          |
| Amortization of deferred revenue  | (3,487)                                | (1,013)     |
| Accounts payable  | (480)                                  | (9)         |
| Accrued expenses  | (308)                                  | (1,232)     |
| Third party royalty obligation  | (1,485)                                | 1,800       |
| Net cash used in operating activities   | (9,399)                                | (6,496)     |
| <b>Cash flows from investing activities:</b>  |  |             |
| Purchases of marketable securities  | (17,634)                               | (3,458)     |
| Maturities of marketable securities   | 13,474                                 | 11,536      |
| Purchases of property and equipment   | (88)                                   | (4)         |
| Increase in patent costs and other assets   |  | (101)       |
| Net cash (used in) provided by investing activities   | (4,248)                                | 7,973       |
| <b>Cash flows from financing activities:</b>  |  |             |
| Proceeds from Genzyme Collaboration, License and Purchase Agreement                                   | 16,650                                 |             |
| Proceeds from sale of common stock to Genzyme   | 6,000                                  |             |
| Proceeds from sale of common stock, net of issuance costs   | 8,062                                  |             |
| Proceeds from exercise of common stock options and stock purchase plan                                | 727                                    | 6           |
| Decrease in restricted cash   | 100                                    | 100         |
| Payment to repurchase stock options   | (50)                                   |             |
| Net cash provided by financing activities   | 31,489                                 | 106         |
| Net increase in cash and cash equivalents   | 17,841                                 | 1,583       |
| Cash and cash equivalents, beginning of period  | 4,937                                  | 4,486       |
| Cash and cash equivalents, end of period  | \$ 22,778                              | \$ 6,069    |
| <b>Supplemental disclosure for non-cash investing and financing activities:</b>                       |  |             |
| Unrealized gain on available-for-sale investments   | \$ 5                                   | \$          |
| Issuance of 24,430 shares of common stock to fund the Company's 401(k) matching contribution for 2008 | \$ 32                                  | \$          |
| Issuance of 27,660 shares of common stock to fund the Company's 401(k) matching contribution for 2007 | \$                                     | \$ 59       |

*The accompanying notes are an integral part of these 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 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. Effective April 2, 2009 the Company s board of directors appointed Kevin T. Conroy as president and chief executive officer, and Maneesh K. Arora as senior vice president and chief financial officer. Prior to joining Exact, Mr. Conroy and Mr. Arora served as president and chief executive officer, and chief financial officer, respectively, of Third Wave Technologies Inc through its sale in July 2008. On August 1, 2009 the Company hired Dr. Graham Lidgard as senior vice president and chief science officer. Dr Lidgard brings more than 3 decades of clinical diagnostic experience to Exact. His experience covers both immunoassay and molecular diagnostics, from pioneering chemiluminescent magnetic particle immunoassay at Ciba Corning, to leading the research and development for the Procleix HIV/HCV blood screening assays , the APTIMA Combo 2 STD assays and the TIGRIS automated nucleic acid Instrument at Gen-Probe. On August 1, 2009 the Company entered into a new employment agreement with Dr. Barry Berger as the Company s senior vice president and chief medical officer. Dr. Berger is Board Certified in Anatomic Clinical and Cytologic Pathology and has a visiting teaching appoint at Brigham and Women s Hospital (Boston, MA) and Harvard Medical School. He joined Exact in 1999 as VP of Laboratory Medicine following a long career as the Director of Pathology and Laboratory Medicine for a million member MCO, Harvard Pilgrim Healthcare (Boston, MA).

**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, 2008 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 financial statements and footnotes thereto included in our audit for the year ended December 31, 2008.

**(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. Cash equivalents primarily consist of money market funds.

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**Restricted Cash**

At September 30, 2009 and December 31, 2008, \$0.5 and \$0.6 million, respectively of the Company's cash was pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's facility in Marlborough Massachusetts.

**Fair Value of Financial Instruments**

Financial instruments consist of cash, cash equivalents, marketable securities and accounts payable. Marketable securities are carried at fair value. The estimated fair value of all other financial instruments approximates their carrying values due to their short-term maturity

**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 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, 2009, the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. At December 31, 2008, the Company held no marketable securities. 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 gains for the three and nine months ended September 30, 2009 were \$5,464. There were no realized gains or losses on the sale of available-for-sale securities during the nine months ended September 30, 2008. Unrealized gains or losses on investments are recorded in other comprehensive income.

**Patent Costs**

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. The capitalized patents 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 either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the three and nine months ended September 30, 2009 should be expensed and not capitalized as the future economic benefit derived from the transactions was indeterminate.

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As more fully described in Note 3 below, in connection with the Genzyme Strategic Transaction the Company sold its then-remaining capitalized intellectual property to Genzyme on January 27, 2009, and accordingly, wrote off the remaining unamortized capitalized patent costs at that time. There are no capitalized patent costs recorded in the Company's financial statements as of September 30, 2009.

The following table summarizes activity with respect to the Company's capitalized patents for the nine months ended September 30, 2009 and 2008. Amounts included in the table are in thousands.

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|   | Nine Months<br>Ended September 30,<br>2009 | Nine Months<br>Ended September 30,<br>2008 |
|---|--|--|
| Patents, net of accumulated amortization, Beginning of period | \$ 95                                      | \$ 432                                     |
| Patent costs capitalized                                      |  | 101  |
| Amortization of patents                                       |  | (67)                                       |
| Write-offs of patents   | (95)                                       | (253)                                      |
| Patents, net of accumulated amortization, End of period       | \$   | \$ 213                                     |

**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:

| (In thousands)  | 2009  | September 30,<br>2008 |
|---|-------|-----------------------|
| Shares issuable upon exercise of stock options        | 6,271 | 3,685                 |
| Shares issuable upon exercise of outstanding warrants | 1,250 |                       |
|   | 7,521 | 3,685                 |

**Accounting for Stock-Based Compensation**

In accordance with GAAP, the Company 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.

**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

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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 Note 3 below, in connection with the Genzyme Strategic Transaction, the Company 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. The Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, 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 will amortize that up-front payment on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. Receipt of any holdback amounts, as defined below, will similarly be deferred and 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 will amortize that amount on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company recognized approximately \$0.9 million and \$2.5 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the three and nine months ended September 30, 2009.

**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 is potentially obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 6 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 condensed consolidated statements of operations.

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

**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, 2009 and 2008 was as follows:

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| (In thousands)                           | Three Months Ended September 30, |            | Six Months Ended September 30, |            |
|--|----------------------------------|------------|--------------------------------|------------|
|  | 2009                             | 2008       | 2009                           | 2008       |
| Net loss                                 | \$ (1,041)                       | \$ (3,014) | \$ (7,274)                     | \$ (7,632) |
| Unrealized gain on marketable securities | (33)                             | (1)        | 5                              | (23)       |
| Comprehensive loss                       | \$ (1,074)                       | \$ (3,015) | \$ (7,269)                     | \$ (7,655) |

**(3) GENZYME STRATEGIC TRANSACTION**

**Transaction summary**

On January 27, 2009, the Company entered into a Collaboration, License and Purchase Agreement (the "CLP Agreement") with Genzyme Corporation ("Genzyme"). Pursuant to the CLP Agreement, the Company (i) assigned to Genzyme all of its intellectual property applicable to the fields of prenatal and reproductive health (the "Transferred Intellectual Property"), (ii) granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of the Company's remaining intellectual property (the "Retained Intellectual Property") in the fields of prenatal and reproductive health (the "Genzyme Core Field"), and (iii) granted Genzyme an irrevocable, perpetual, non-



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exclusive, worldwide, fully-paid, royalty-free license to use and sublicense the Retained Intellectual Property in all fields other than the Genzyme Core Field and other than colorectal cancer detection and stool-based disease detection (the Company Field ). Following the Genzyme Transaction, Exact retains rights in its intellectual property to pursue only the fields of colorectal cancer detection and stool-based detection of any disease or condition. As part of the transaction on January 27, 2009, the Company entered into an Assignment, Sublicense, Consent and Eighth Amendment (the JHU Amendment ) to License Agreement with Genzyme and The Johns Hopkins University ( JHU ) (collectively, with the licenses and assignment described herein, the Genzyme Strategic Transaction ), whereby the Company assigned its rights under the license agreement between the Company and JHU dated March 25, 2003, as amended (the JHU Agreement ) to Genzyme. Pursuant to the JHU Amendment, Genzyme sublicensed to the Company the intellectual property subject to the JHU Agreement for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. Under the JHU Amendment, the Company and Genzyme will share in the royalty and annual payment obligations to JHU.

Also as part of the Genzyme Strategic Transaction, the Company entered into an Amended and Restated License Agreement (the Restated License ) with Genzyme on January 27, 2009, which amends and restates the License Agreement between the parties dated March 25, 1999, effective as of January 27, 2009. Pursuant to the Restated License, Genzyme granted to the Company a non-exclusive license to use technology related to the use of certain genes, specifically APC and p53, and methodologies related thereto. In exchange for the license, which continues until the expiration of the last to expire licensed patent, the Company has agreed to pay Genzyme royalties based on net revenues received from performing tests that incorporate the licensed technology and sales of reagents and diagnostic test kits that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Pursuant to the Genzyme Strategic Transaction, Genzyme agreed to pay an aggregate of \$18.5 million to the Company, of which \$16.65 million was paid at closing and \$1.85 million (the Holdback Amount ) is subject to a holdback by Genzyme to satisfy certain potential indemnification obligations of the Company. Subject to the terms and conditions of the CLP Agreement, one-half of the Holdback Amount will be released to the Company in January 2010 and one-half will be released in July 2010. Genzyme also agreed to pay a double-digit royalty to the Company on income received by Genzyme as a result of any licenses or sublicenses to third parties of the Transferred Intellectual Property or the Retained Intellectual Property in any field other than the Genzyme Core Field or the Company Field.

The Company's on-going performance obligations to Genzyme under the CLP, including the 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 the License Fee Revenue line item in its statements of operations over the initial five year collaboration period. Receipt of any Holdback Amounts will similarly be deferred and amortized on a straight line basis into the License Fee Revenue line item in the Company's statements of operations over the remaining term of the collaboration at the time of receipt.

In addition, the Company entered into a Common Stock Subscription Agreement with Genzyme (the Purchase Agreement ) on January 27, 2009, which provided for the private issuance and sale to Genzyme of 3,000,000 shares (the Shares ) of the Company's common stock, \$0.01 par value per share ( Common Stock ), at a per share price of \$2.00, for an aggregate purchase price of \$6.0 million. The price paid by Genzyme for the Shares represented 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 included as a part of the total consideration for the CLP. Accordingly, the Company deferred the aggregate \$1.53 million premium and is amortizing that amount on a straight line basis into the License Fee Revenue line item in the Company's statements of operations over the initial five-year collaboration period. The Company recognized approximately \$0.9 million and \$2.5 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the three and nine months ended September 30, 2009.

**(4) 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

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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 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 shares was immediately exercisable and the grant to purchase 250,000 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 will be 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%  |
| Yield                      |    | 0%     |
| Fair value per warrant     | \$ | 1.72   |

**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.

**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 human cancer screening clinical, and a \$500,000 payment upon FDA approval of the Company's cancer screening test. The upfront payment of \$80,000 was made in the third quarter of 2009. In addition, the Company will pay a minimum of \$659,516 to MAYO

over the next 12 months for research and development efforts.

**(5) CHANGES IN SENIOR MANAGEMENT AND EMPLOYMENT AGREEMENTS**

**Former Chief Executive Officer and Former Chief Financial Officer**

Effective April 2, 2009, Jeffrey R. Lubber resigned as the Company's President and Chief Executive Officer and member of the Company's Board of Directors, and Charles R. Carelli, Jr. resigned as the Company's Chief Financial Officer. Mr. Carelli remained employed by the Company as a non-executive employee through April 30, 2009. The expenses related to these departures were recorded in the quarter ended March 31, 2009.

In connection with their departure, Messrs. Lubber and Carelli were entitled to receive severance benefits pursuant to their previously disclosed retention agreements, including salary continuation of \$472,500 and \$287,500, which is equal

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to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, the Company entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of the Company, for the accelerated payment of the salary continuation obligations. In addition, the release agreements also provided for the repurchase by the Company of options held by Messrs. Luber and Carelli for an aggregate of 804,026 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements. The Company paid Messrs. Luber and Carelli approximately \$39,000 and \$11,000, respectively, to repurchase Mr. Luber's options to purchase 553,333 shares and Mr. Carelli's options to purchase 250,693 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009 and was recorded as a reduction to additional paid-in-capital. Messrs. Luber and Carelli retained the balance of their existing options, the vesting of which was accelerated by nine months.

In connection with the repurchase of options from Messrs. Luber and Carelli, the Company recorded non-cash stock-based compensation charges of approximately \$0.2 million in the quarter ended March 31, 2009. In addition, the Company recorded non-cash stock-based compensation charges of approximately \$60,000 in the quarter ended March 31, 2009 in connection with modifications in vesting and period of exercise for options being retained by Messrs. Luber and Carelli.

A summary of options repurchased from Mr. Luber and options retained subsequent to Mr. Luber's termination is below.

### Options Repurchased

| Option Grant Date | Grant Price | Number of Securities Underlying Unexercised Options As of March 31, 2009 |               | Total Options | Total Options Repurchased | Total Options Forfeited |
|-------------------|-------------|--|---------------|---------------|---------------------------|-------------------------|
|                   |             | Exercisable  | Unexercisable |               |                           |                         |
| 11/18/2002        | \$ 14.33    | 50,000   |               | 50,000        | 50,000                    |                         |
| 2/11/2004         | \$ 7.72     | 80,000   |               | 80,000        | 80,000                    |                         |
| 12/23/2004        | \$ 3.61     | 60,000   |               | 60,000        | 60,000                    |                         |
| 2/17/2005         | \$ 4.22     | 20,000   |               | 20,000        | 20,000                    |                         |
| 2/16/2006         | \$ 2.61     | 55,000   |               | 55,000        | 55,000                    |                         |
| 4/11/2006         | \$ 3.07     | 29,166   | 834           | 30,000        | 30,000                    |                         |
| 2/15/2007         | \$ 2.77     | 52,083   | 22,917        | 75,000        | 70,833                    | 4,167                   |
| 9/4/2007          | \$ 2.90     | 125,000  | 125,000       | 250,000       | 187,500                   | 62,500                  |
|                   |             | 471,249  | 148,751       | 620,000       | 553,333                   | 66,667                  |

### Options Retained

| Option Grant Date | Grant Price | Number of Options Retained | Expiration Date |
|-------------------|-------------|----------------------------|-----------------|
| 2/21/2008         | \$ 1.83     | 80,207                     | 1/2/2011        |

A summary of options repurchased from Mr. Carelli and options retained subsequent to Mr. Carelli's termination is below.

**Options Repurchased**

| Option Grant Date | Grant Price | Number of Securities Underlying Unexercised Options As of March 31, 2009 |               | Total Options | Total Options Repurchased | Total Options Forfeited |
|-------------------|-------------|--|---------------|---------------|---------------------------|-------------------------|
|                   |             | Exercisable  | Unexercisable |               |                           |                         |
| 11/9/2004         | \$ 3.28     | 20,000   |               | 20,000        | 20,000                    |                         |
| 7/29/2005         | \$ 2.65     | 27,499   | 2,501         | 30,000        | 30,000                    |                         |
| 2/16/2006         | \$ 2.61     | 25,000   |               | 25,000        | 25,000                    |                         |
| 4/11/2006         | \$ 3.07     | 24,305   | 695           | 25,000        | 25,000                    |                         |
| 2/15/2007         | \$ 2.77     | 52,083   | 22,917        | 75,000        | 72,916                    | 2,084                   |
| 9/4/2007          | \$ 2.90     | 50,000   | 50,000        | 100,000       | 77,777                    | 22,223                  |
|                   |             | 198,887  | 76,113        | 275,000       | 250,693                   | 24,307                  |

**Options Retained**

| Option Grant Date | Grant Price | Number of Options Retained | Expiration Date |
|-------------------|-------------|----------------------------|-----------------|
| 2/21/2008         | \$ 1.83     | 43,124                     | 1/31/2011       |

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**New Chief Executive Officer and Chief Financial Officer**

On March 18, 2009, the Company's Board of Directors appointed Kevin T. Conroy as President and Chief Executive Officer of the Company, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of the Corporate Governance and Nominating Committee, the Board of Directors elected Mr. Conroy to the Board. In connection with his appointment, Mr. Conroy entered into an employment agreement with the Company on March 18, 2009 (the Conroy Agreement). Under the terms of the Conroy Agreement, Mr. Conroy serves as President and Chief Executive Officer of the Company at a base salary of \$340,000 and is eligible to earn up to 50% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Conroy Agreement, Mr. Conroy was granted options to purchase 2.5 million shares of the common stock of the Company, par value \$0.01 per share (the Common Stock), at a price per share of \$0.83, which is equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the shares underlying the stock options become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

On March 18, 2009, the Company's Board of Directors appointed Maneesh K. Arora as Senior Vice President and Chief Financial Officer of the Company, effective April 2, 2009. In connection with his appointment, Mr. Arora entered into an employment agreement with the Company on March 18, 2009 (the Arora Agreement). Under the terms of the Arora Agreement, Mr. Arora serves as Senior Vice President and Chief Financial Officer of the Company at a base salary of \$240,000 and is eligible to earn up to 40% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Arora Agreement, Mr. Arora was granted options to purchase 1.25 million shares of Common Stock, at a price per share of \$0.83, which is equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the shares underlying the stock options become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

**(6) CONTINGENCIES**

**Third Party Royalty Obligation**

Pursuant to the terms of the Second Amendment to the Company's license agreement with LabCorp, the Company is 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 measurement period, as outlined in the table below. During the quarter ended March 31, 2009, the Company paid LabCorp approximately \$1.5 million related to its obligation for the first measurement period, which ended on December 31, 2008. The Company's future 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 two separate measurement periods, as defined below. A significant increase in such sales volumes during either measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation during such measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate future payments to LabCorp totaling up to \$2.0 million during the remaining 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. Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of March 31, 2009, the Company had accrued a total of \$1.97 million related to the total potential \$2.0 million remaining obligation to LabCorp. The Company recorded charges of \$2.25 million and \$1.2 million during the years ended December 31, 2008 and 2007, respectively, 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. 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.





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| Measurement period Start Date | Measurement period End Date | Payment Due Date for Measurement Period | Potential Minimum Third Party Royalty Obligation During Measurement Period | Potential Maximum Third Party Royalty Obligation During Measurement Period |
|-------------------------------|-----------------------------|---|--|--|
| January 1, 2009               | December 31, 2009           | January 30, 2010                        | \$   | \$ 1,000   |
| January 1, 2010               | December 31, 2010           | January 30, 2011                        | \$   | \$ 1,000   |
|                               |                             |   | \$   | \$ 2,000   |

**(7) RESTRUCTURING****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), in connection with the Company's revised corporate strategy of reducing costs to better preserve existing cash.

In connection with the 2008 Restructuring, the Company recorded restructuring charges of approximately \$0.5 million during the three months ended September 30, 2008, including \$0.2 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and \$0.3 million resulting from the write-off of leasehold improvements abandoned by the Company in connection with the reduction in force. The Company's decision to eliminate 67% of its workforce was deemed to be an impairment indicator. As a result of performing the impairment evaluations, non-cash asset impairment charges of \$0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees previously unvested stock options, with a weighted average exercise price of \$2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of \$4.50 per share, through August 1, 2009. Due to the nature of the transaction, the Company recorded one-time non-cash stock-based compensation charges of approximately \$3,000 in the Restructuring line item of the Company's condensed consolidated statements of operations during the quarter ended September 30, 2008.

During the fourth quarter of 2008, the Company entered into a sublease agreement (the 2008 Sublease Agreement) with QTEROS, Inc. (QTEROS) to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, is 20 months with a base rent of \$625,657 per year. Pursuant to the 2008 Sublease Agreement, QTEROS has no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS is required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to the Company in the amount of approximately \$52,000 naming the Company as beneficiary. The 2008 Sublease Agreement provides for the Company's employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS.

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In connection with the 2008 Sublease Agreement, the Company also recorded the following restructuring charges during the fourth quarter of 2008 (included opposite the caption "Facility consolidation costs" in the table below): approximately \$0.1 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2008 Sublease Agreement; approximately \$0.1 million in one time real estate transaction and laboratory decommissioning fees; 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 2008 Sublease Agreement. These charges were offset by cash receipts of approximately \$0.3 million received in connection with sales of fully depreciated fixed assets upon commencement of the 2008 Sublease Agreement. During the quarter ended March 31, 2009, certain of the cost estimates related to the 2008 Restructuring were adjusted, resulting in a credit of approximately \$3,000 to the restructuring line item in the Company's condensed consolidated statements of operations.

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Amounts remaining in the 2008 Restructuring accrual at September 30, 2009, which are expected to be paid out in cash 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 nine months ended September 30, 2009 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

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

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

| Type of Liability            | Balance,<br>June 30,<br>2008 | Charges | Cash<br>Payments | Non-cash<br>Write-offs | Balance,<br>September 30,<br>2008 |
|------------------------------|------------------------------|---------|------------------|------------------------|-----------------------------------|
| Employee separation costs    | \$                           | \$ 255  | \$ (102)         | \$                     | \$ 153                            |
| Facility consolidation costs |                              | 281     |                  | (281)                  |                                   |
| Total                        | \$                           | \$ 536  | \$ (102)         | \$ (281)               | \$ 153                            |

**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. 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.

Amounts remaining in the 2007 Restructuring accrual at September 30, 2009, 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 the 2007 Restructuring activities during the nine months ended September 30, 2009. Amounts included in the table are in thousands.

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

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The following table summarizes the 2007 Restructuring activities during the nine months ended September 30, 2008. Amounts included in the table are in thousands.

| Type of Liability            | Balance,<br>December 31,<br>2007 | Charges       | Cash<br>Payments | Balance,<br>September 30,<br>2008 |
|------------------------------|----------------------------------|---------------|------------------|-----------------------------------|
| Employee separation costs    | \$ 224                           | \$ (7)        | \$ (217)         | \$                                |
| Facility consolidation costs | 268                              |               | (84)             | 184                               |
| <b>Total</b>                 | <b>\$ 492</b>                    | <b>\$ (7)</b> | <b>\$ (301)</b>  | <b>\$ 184</b>                     |

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**(8) 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.

**Stock-Based Compensation Expense**

The Company recorded \$0.6 million and \$2.0 million in stock-based compensation during the three and nine months ended September 30, 2009, respectively, in connection with the amortization of restricted common stock awards and stock options granted to employees, non-employee directors and non-employee consultants as well as the modification of certain stock options. The Company recorded \$0.3 million and \$0.8 million, respectively, in stock-based compensation during the three and nine months ended September 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, as well as stock-based compensation expense of \$32,000 related to the Company's 2008 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 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 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 valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

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**Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. The Company did not estimate forfeitures for awards prior to 2009 because all such share based awards vest monthly. Awards granted in 2009 that vest annually are all expected to vest and no forfeiture rate was utilized. The Company does not have significant history to calculate a forfeiture rate for awards that vest annually and the Company's best estimate is that all of these awards will vest.

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

|  | Three Months Ended<br>September 30, |         | Nine Months Ended<br>September 30, |               |
|--|-------------------------------------|---------|------------------------------------|---------------|
|  | 2009                                | 2008    | 2009                               | 2008          |
| <b>Option Plan Shares</b>  |                                     |         |                                    |               |
| Risk-free interest rates   | 2.31%                               | 3.02%   | 1.76% - 2.54%                      | 2.80% - 3.02% |
| Expected term (in years)   | 6                                   | 6       | 6                                  | 6             |
| Expected volatility  | 92%                                 | 75%     | 85% - 92%                          | 70% - 75%     |
| Dividend yield   | 0%                                  | 0%      | 0%                                 | 0%            |
| Weighted average fair value per share of options granted during the period | \$ 2.08                             | \$ 0.48 | \$ 0.80                            | \$ 1.10       |

### Stock Option and Restricted Stock Activity

A summary of stock option and restricted stock activity under the 1995 Option Plan and the 2000 Option Plan during the nine months ended September 30, 2009 is as follows:

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| Options<br>(Aggregate intrinsic value in thousands) | Shares      | Average<br>Exercise<br>Price | Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic<br>Value (1) |
|---|-------------|------------------------------|--|-------------------------------------|
| Outstanding, January 1, 2009                        | 3,703,899   | \$ 3.99                      | 4.9                                      |                                     |
| Granted   | 5,196,127   | \$ 1.08                      |  |                                     |
| Exercised   | (516,585)   | \$ 1.41                      |  |                                     |
| Cancelled or redeemed                               | (2,112,888) | \$ 4.41                      |  |                                     |
| Outstanding, September 30, 2009                     | 6,270,553   | \$ 1.65                      | 8.8                                      | \$ 9,722                            |
| Exercisable, September 30, 2009                     | 999,633     | \$ 4.55                      | 5.2                                      | \$ 408                              |
| Vested and expected to vest, September 30, 2009     | 6,270,553   | \$ 1.65                      | 8.8                                      | \$ 9,722                            |

(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 \$2.78 market price of the Company's common stock at September 30, 2009.

The table above includes outstanding restricted stock awards of 401,127 shares as of September 30, 2009 reflected as options with an exercise price of \$0. The Company granted 401,127 shares of common stock pursuant to restricted stock awards during the nine months ended September 30, 2009. There were 139,054 common stock awards that vested and were no longer subject to restriction during the nine months ended September 30, 2009.

As of September 30, 2009, there was \$3.8 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 3.0 years.

**(9) FAIR VALUE MEASUREMENTS**

In September 2006, the FASB issued authoritative guidance which 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. The fair value hierarchy established 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 are as follows:

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- 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.

The following table presents the Company's fair value measurements as of September 30, 2009 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.



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## Fair Value Measurement at September 30, 2009 Using:

| Description           | Fair Value Measurement at September 30, 2009 Using: |  |   |  |
|-----------------------|---|--|---|--|
|                       | Fair Value at<br>September 30, 2009                 | Quoted Prices in Active<br>Markets for Identical Assets<br>(Level 1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| Cash equivalents      | \$ 22,779   | \$ 22,779  | \$  | \$   |
| Available-for-Sale    |   |  |   |  |
| Marketable Securities | 4,165   | 650  | 3,515   |  |
| Total                 | \$ 26,944   | \$ 23,429  | \$ 3,515  | \$   |

**(10) EQUITY FINANCING**

On June 11, 2009, the Company completed a private placement transaction pursuant to which the Company sold 4,315,792 shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs. Management intends to use the proceeds to fund future research and development efforts.

**(11) NEW ACCOUNTING PRONOUNCEMENTS**

In June 2009, the Financial Accounting Standards Board ( FASB ) issued FASB Accounting Standards Codification 105, Generally Accepted Accounting Principles. FASB ASC 105 approved the FASB Accounting Standards Codification ( ASC ) as the source of authoritative nongovernmental GAAP. All existing accounting standards have been superseded and all other accounting literature not included in the FASB ASC will be considered nonauthoritative. FASB ASC 105 is effective for financial statements issued for interim or annual periods ending after September 15, 2009. Accordingly, all references to accounting standards have been conformed to the new ASC hierarchy.

On April 9, 2009, the FASB issued FASB ASC 825 Financial Instruments and FASB ASC 270 Interim Reporting. FASB ASC 825 requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FASB ASC 825 also amends FASB ASC 270, Interim Reporting, to require those disclosures in summarized financial information at interim reporting periods. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results. See Note 2 for further information.

On May 28, 2009, the FASB issued FASB ASC 855, Subsequent Events ( FASB ASC 855 ). FASB ASC 855 establishes principles and requirements for subsequent events, in particular: (i) the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results. See Note 12 for further information.

In September 2009, the EITF issued their final consensus for EITF Issue 08-1 (EITF 08-1), *Revenue Arrangements with Multiple Deliverables*, as codified in ASC 605, *Revenue Recognition*. When vendor specific objective evidence or third party evidence of selling price for deliverables in an arrangement cannot be determined, EITF Issue 08-1 will require the Company to develop a best estimate of the selling price to separate

deliverables and allocate arrangement consideration using the relative selling price method. Additionally, this guidance eliminates the residual method of allocation. The new guidance is effective for fiscal years beginning after June 15, 2010. The adoption of this accounting pronouncement is not expected to have a material effect on the determination or reporting of our financial results.

**(12) SUBSEQUENT EVENTS**

During November 2009, the Company entered into a loan agreement with the Wisconsin Department of Commerce pursuant to which the Wisconsin Department of Commerce agreed to lend up to \$1 million to the Company subject to the Company's satisfaction of certain conditions. The terms of the loan are such that portions of the loan become forgivable if the Company meets certain job creation requirements. The loan bears an interest rate of 2%, which is subject to increase if the Company does not meet certain job creation requirements. Both principal and interest payments under the loan agreement are deferred for five years.

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During November 2009, the Company entered into a five year lease for a 17,500 sq. ft. laboratory and office facility in Madison, Wisconsin. See the table below for future commitments under the lease agreement. Amounts in the table are in thousands.

| <b>Calendar<br/>Year</b> |           | <b>Minimum<br/>Lease Payments</b> |              |
|--------------------------|-----------|-----------------------------------|--------------|
| 2009                     | \$        |                                   | 44           |
| 2010                     |           |                                   | 264          |
| 2011                     |           |                                   | 270          |
| 2012                     |           |                                   | 277          |
| 2013                     |           |                                   | 284          |
| Thereafter               |           |                                   | 241          |
| <b>Total</b>             | <b>\$</b> |                                   | <b>1,380</b> |

During October 2009, the Company entered into a technology license agreement with Hologic, Inc. and Third Wave Technologies, Inc., a wholly-owned subsidiary of Hologic (collectively referred to as Hologic). Under the license agreement, Hologic granted the Company an exclusive, worldwide license within the field of human stool based colorectal cancer and pre-cancer detection or identification with regard to certain Hologic patents and improvements, including Hologic's Invader detection chemistry. The Invader chemistry, which is being commercialized by Third Wave Technologies, is a highly accurate, easy-to-use and rapid molecular detection platform that is easily combined with polymerase chain reaction, or PCR. Under the license agreement, the Company is obligated to make commercially reasonable efforts to bring products covered by the licenses to market. In addition, the Company is required to make certain up-front, milestone and royalty payments to Hologic. The license agreement requires the Company to pay Hologic specified royalties based on sales of products or services covered by the licensed intellectual property.

We have evaluated and disclosed subsequent events through November 12, 2009, our filing date, as necessary.

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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, 2008, 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, 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, 2008. 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. Our 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. We believe that our proprietary methods and technologies have several advantages over other screening options that may ultimately lead to decreased mortality associated with colorectal cancer, which is the third leading cause of cancer death overall, the second leading cause of death from cancers that affect both men and women, and the leading cause of cancer death among non-smokers in the United States.

The American Cancer Society estimates that 80-90 million people in the United States are eligible for colorectal cancer screening. The Company will approach this market opportunity by remaining focused on key priorities. The Company's priorities for 2009 are: 1) product development, 2) clinical trial planning and 3) creating a performance culture. Currently, we license certain of our colorectal cancer screening technologies on an exclusive basis in the U.S. and Canada through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®. LabCorp has developed and commercially offers a non-invasive sDNA colorectal cancer screening service for the average-risk population, which is based on certain of our technologies.

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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 sDNA colorectal pre-cancer and cancer screening test;
- advance our product through U.S. Food and Drug Administration, or FDA, clinical trials;
- secure insurance coverage and reimbursement for our product; and

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

We believe obtaining FDA approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. In 2009, we intend to focus on further refining our product design to demonstrate the clinical superiority of the test to detect pre-cancer and adenomas while balancing its product attributes to enable ease of commercialization and widespread adoption. Additionally, we intend to finalize plans for clinical trials in 2009 with the goal of confirming our trial protocols with the FDA.

We have generated limited operating revenues since inception and, as of September 30, 2009, we had an accumulated deficit of approximately \$179.7 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.

**Recent Developments**

*Mayo Strategic Licensing Agreement*

On June 11, 2009, we entered into a strategic transaction with the MAYO Foundation for Medical Education and Research (MAYO) to obtain a world-wide exclusive license to certain intellectual property. As part of the licensing agreement, we granted MAYO two common stock purchase warrants for 1,000,000 and 250,000 shares of common stock, respectively. We will also make payments to MAYO for up-front fees, fees upon our attainment of certain milestones, and other payments as outlined in the agreement. In addition to the license to intellectual property owned by MAYO, we will receive product development and research and development efforts from MAYO personnel. We determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. In addition to such payments, we are obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

*New Senior Management Team*

Effective April 2, 2009, Jeffrey R. Luber resigned as our President, Chief Executive Officer and member of our board of directors and Charles R. Carelli, Jr. resigned as our Chief Financial Officer.

On March 18, 2009, our board of directors appointed Kevin T. Conroy as President and Chief Executive Officer, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of our corporate governance and nominating committee, the board of directors appointed Mr. Conroy to fill a vacancy on our board. Our board of directors also appointed Maneesh K. Arora as our Senior Vice President and Chief Financial Officer, effective April 2, 2009.

On August 1, 2009 the Company hired Dr. Graham Lidgard as Senior Vice President and Chief Science Officer. Dr Lidgard brings more than 3 decades of clinical diagnostic experience to Exact. His experience covers both immunoassay and molecular diagnostics, from pioneering chemiluminescent magnetic particle immunoassay at Ciba Corning to leading the research and development for the Procleix HIV/HCV blood screening assays , the APTIMA Combo 2 STD assays and the TIGRIS automated nucleic acid Instrument at Gen-Probe.

On August 1, 2009 the Company entered into a new employment agreement with Dr. Barry Berger as the Company's Senior Vice President and Chief Medical Officer. Dr. Berger is Board Certified in Anatomic Clinical and Cytologic Pathology and has a visiting teaching appoint at Brigham and Women's Hospital (Boston, MA) and Harvard Medical School. He joined Exact sciences in 1999 as VP of Laboratory Medicine following a long career as the Director of Pathology and Laboratory Medicine for a million member MCO, Harvard Pilgrim Healthcare (Boston, MA).

***Genzyme Strategic Transaction***

In January 2009, we completed a strategic transaction with Genzyme Corporation, pursuant to which we assigned to Genzyme all of our intellectual property applicable to the fields of prenatal and reproductive health and granted

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Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of our remaining intellectual property in all fields other than colorectal cancer detection and stool-based disease detection. We retained our rights in both the assigned and licensed intellectual property in the fields of colorectal cancer detection and stool-based disease detection. We and Genzyme also agreed to form a joint advisory committee to assist Genzyme in the achievement of product development goals related to the purchased intellectual property and to assist us with our regulatory goals.

Genzyme agreed to pay us an aggregate of \$18.5 million, of which \$16.65 million was paid at closing and \$1.85 million is subject to a holdback by Genzyme to satisfy certain of our potential indemnification obligations. Subject to terms of the strategic agreement, one-half of the holdback amount will be released to us in January 2010 and one-half will be released in July 2010. Genzyme also agreed to pay a double-digit royalty to us on income received by Genzyme as a result of any licenses or sublicenses to third parties of the assigned or licensed intellectual property in any field other than prenatal and reproductive health or colorectal cancer detection and stool-based disease detection.

In addition, we sold to Genzyme 3,000,000 shares of our common stock at a per share price of \$2.00, for a total purchase price of \$6.0 million.

***Messrs. Luber and Carelli Severance***

In connection with their departures in March 2009, Messrs. Luber and Carelli were entitled to receive severance benefits pursuant to their existing retention agreements, including salary continuation of \$472,500 and \$287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, we entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of us, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for the repurchase by us of certain options held by Messrs. Luber and Carelli for an aggregate of 804,026 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from their retention agreements. We paid Messrs. Luber and Carelli approximately \$39,000 and \$11,000, respectively, to repurchase Mr. Luber's options to purchase 553,333 shares and Mr. Carelli's options to purchase 250,693 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009. Messrs. Luber and Carelli retained options to purchase 80,207 and 43,124 shares respectively at an exercise price of \$1.83, following the termination of their employment.

***Private Placement Transaction***

On June 11, 2009, we completed a private placement transaction pursuant to which we sold 4,315,792 shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs. Management intends to use the proceeds to fund future research and development efforts.

**Significant Accounting Policies**



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

The notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2008 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 the following accounting policies and judgments are critical to fully understand and evaluate our reported financial results.

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**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, 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, we are amortizing the remaining deferred revenue balance resulting from our 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 under the heading "Genzyme Strategic Transaction" above, in connection with the Genzyme strategic transaction, we received an up-front payment of \$16.65 million on January 27, 2009 in exchange for the assignment and licensing of certain of our intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement, or 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. Receipt of any holdback amounts will similarly be deferred and 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 3.0 million shares purchased from us 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 our common stock on the date of the transaction of \$1.53 million was deemed to be a part of the total consideration for the CLP Agreement. Accordingly, we deferred the aggregate \$1.53 million premium and will amortize that amount on a straight line basis into revenue over the initial five year collaboration period ending in January 2014. We recognized approximately \$2.5 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the nine months ended September 30, 2009.

**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 sDNA colorectal cancer screening service for the average-risk population based on our 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, sDNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our intellectual property. 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.

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.

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Additionally, as described below under the heading **Critical Accounting Estimate – Third Party Royalty Obligation**, pursuant to the Second Amendment, we are potentially obligated to reimburse LabCorp for certain third-party royalty payments. 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 statements of operations.

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

**Patent Costs.** Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if we determine that there is some probable future economic benefit derived from the transaction. The capitalized patents

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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 us to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to us. We determined that all patent costs incurred during the three and nine months ended September 30, 2009 should be expensed and not be capitalized as the future economic benefit derived from the transactions was indeterminate. In connection with the Genzyme Strategic Transaction, we sold our then-remaining capitalized intellectual property to Genzyme on January 27, 2009, and accordingly, wrote off the remaining unamortized capitalized patent costs at that time.

**Stock-Based Compensation.** All stock-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 financial statements based on their fair values.

**Critical Accounting Estimate - Third Party Royalty Obligation**

Pursuant to the terms of the Second Amendment to our license agreement with LabCorp, we are 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 measurement period, as outlined in the table below. During the quarter ended March 31, 2009, we paid LabCorp approximately \$1.5 million related to our obligation for the first measurement period, which ended on December 31, 2008. Our future 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 two separate measurement periods, as defined below. A significant increase in such sales volumes during either measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation during such measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate future payments to LabCorp totaling up to \$2.0 million during the remaining 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 our statements of operations. Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of September 30, 2009, we have accrued a total of \$1.97 million related to the total potential \$2.0 million remaining obligation to LabCorp. Amounts included in the table are in thousands.

| Measurement period<br>Start Date | Measurement period<br>End Date | Payment Due Date<br>for Measurement<br>Period | Potential<br>Minimum<br>Third Party<br>Royalty<br>Obligation During<br>Measurement Period | Potential<br>Maximum<br>Third Party<br>Royalty<br>Obligation During<br>Measurement Period |
|----------------------------------|--------------------------------|---|---|---|
| January 1, 2009                  | December 31, 2009              | January 30, 2010                              | \$  | \$ 1,000  |
| January 1, 2010                  | December 31, 2010              | January 30, 2011                              |   | 1,000   |
|                                  |                                |   | \$  | \$ 2,000  |

**Recent Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board ( FASB ) issued FASB Accounting Standards Codification 105, Generally Accepted Accounting Principles. FASB ASC 105 approved the FASB Accounting Standards Codification ( ASC ) as the source of authoritative nongovernmental GAAP. All existing accounting standards have been superseded and all other accounting literature not included in the FASB ASC will be considered nonauthoritative. FASB ASC 105 is effective for financial statements issued for interim or annual periods ending after September 15, 2009. Accordingly, all references to accounting standards have been conformed to the new ASC hierarchy.

On April 9, 2009, the FASB issued FASB ASC 825 Financial Instruments and FASB ASC 270 Interim Reporting. FASB ASC 825 requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FASB ASC 825 also amends FASB ASC 270, Interim Reporting, to require those disclosures in summarized financial information at interim reporting periods. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results. See Note 2 to the accompanying financial statements for further information.

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On May 28, 2009, the FASB issued FASB ASC 855, *Subsequent Events* ( FASB ASC 855 ). FASB ASC 855 establishes principles and requirements for subsequent events, in particular: (i) the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results. See Note 12 to the accompanying financial statements for further information

In September 2009, the EITF issued their final consensus for EITF Issue 08-1 (EITF 08-1), *Revenue Arrangements with Multiple Deliverables*, as codified in ASC 605, *Revenue Recognition*. When vendor specific objective evidence or third party evidence of selling price for deliverables in an arrangement cannot be determined, EITF Issue 08-1 will require the Company to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, this guidance eliminates the residual method of allocation. The new guidance is effective for fiscal years beginning after June 15, 2010. The adoption of this accounting pronouncement is not expected to have a material effect on the determination or reporting of our financial results.

**Results of Operations**

**Revenue.** Net revenue is primarily composed of the amortization of up-front technology license fees 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 in January 2014. While we expect license fee revenue resulting from the amortization of the up-front license payment from LabCorp in 2009 to be consistent with amounts recorded in 2008, we expect that total license fee revenue for 2009 will be higher than amounts recorded in 2008 as a result of amortization of payments received from Genzyme in January 2009 in connection with the Genzyme strategic transaction.

Net revenue increased to \$1.3 million for the three months ended September 30, 2009, from (\$0.7) million for the same period in 2008 and increased to \$3.5 million for the nine months ended September 30, 2009 from (\$0.8) million for the same period in 2008. The increase in net revenue for the three and nine months ended September 30, 2009 when compared to the same periods of 2008, was primarily due to an increase of approximately \$0.9 million and \$2.5 million, respectively, for the three and nine months ended September 30, 2009 in license fee amortization as a direct result of the commencement of amortization of the upfront payment received from Genzyme in January 2009. In addition, product royalty revenues were higher for the three months and nine months ended September 30, 2009 when compared to the same period in 2008 due to product royalty revenue charges of \$1.0 million and \$1.8 million recorded during the three months and nine months ended September 30, 2008. These charges related to our third-party royalty reimbursement obligation to LabCorp, and resulted in negative product royalty revenue for the three and nine months ended September 30, 2008.

**Research and development expenses.** Research and development expenses increased to \$0.8 million for the three months ended September 30, 2009 from \$0.6 million for the three months ended September 30, 2008, and increased to \$3.0 million for the nine months ended September 30, 2009 from \$2.0 million for the nine months ended September 30, 2008. The increase for the three months ended September 30, 2009 was primarily due to an increase in stock based compensation of \$0.1 million when compared to the same period in 2008. The increase for the nine months ended September 30, 2009 is primarily due to the \$1.8 million non-cash charge incurred as a result of the issuance of warrants pursuant to the Mayo licensing agreement and a decrease of \$0.8 million in general research and development expenses when compared to the same time period in 2008.

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As a result of the activities anticipated in support of our objectives toward developing an FDA-approved in vitro diagnostic test, we expect research and development costs in 2009 to continue to be higher than 2008 levels.

**General and administrative expenses.** General and administrative expenses increased to \$1.5 million for the three months ended September 30, 2009, compared to \$1.3 million for the same period in 2008. The increase is primarily due to a \$0.3 million increase in non-cash stock-based compensation expense included in general and administrative expense in the quarter ended September 30, 2009 when compared to the same time period in 2008.

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General and administrative expenses increased to \$7.9 million for the nine months ended September 30, 2009, compared to \$4.6 million for the same period in 2008. This increase was primarily the result of \$1.9 million in transaction costs related to the Genzyme strategic transaction in January 2009, including legal, audit, and investment banking fees as well as approximately \$0.8 million in retention bonus payments made to employees pursuant to board-approved retention agreements. Non-cash stock-based compensation expense included in general and administrative expense for the nine months ended September 30, 2009 also increased by \$1.1 million compared to the same period in 2008. In addition, there was an increase in other G&A expenses of \$0.3 million when compared to the same period in 2008 primarily due to an increase in professional fees during the first quarter of 2009.

We expect general and administrative expenses in 2009 to continue to be higher than 2008 levels, primarily as a result of professional fees in connection with the Genzyme strategic transaction and the transition of our senior management team as described above.

**Interest income.** Primarily as a result of increased cash and investment balances offset by less favorable interest rates on investments held, interest income slightly decreased to \$35,000 for the three months ended September 30, 2009 from \$36,000 for the same period in 2008. The decrease to \$118,000 for the nine months ended September 30, 2009 from \$224,000 for the same period in 2008 was primarily due to less favorable interest rates on investments held.

**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 in connection with our license agreement, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction described above. On June 11, 2009, we completed a private placement transaction pursuant to which we sold 4,315,792 shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs. As of September 30, 2009, we had approximately \$22.8 million in unrestricted cash and cash equivalents, \$0.5 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, and approximately \$4.2 million in investments in marketable securities. All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale.

Net cash used in operating activities was \$9.4 million for nine months ended September 30, 2009 as compared to \$6.5 million for the nine months ended September 30, 2008. The principal use of cash in operating activities for the nine months ended September 30, 2009 and 2008 was to fund our net loss. The increase in net cash used in operating activities for the nine months ended September 30, 2009 as compared to the same period in 2008, was primarily due to the payment of the \$1.5 million to LabCorp to satisfy our third party royalty obligation for 2008, one-time transaction payments for professional fees in connection with the Genzyme strategic transaction of approximately \$1.1 million, one time retention bonus payments to employees pursuant to board-approved retention payments of approximately \$0.8 million, and one-time severance payments of approximately \$0.8 million to former executives, each as described elsewhere in this report. Cash flows from operations can vary significantly due to various factors, including changes in our operations, prepaid expenses, accounts payable and accrued expenses.

Net cash used in investing activities was \$4.2 million for the nine months ended September 30, 2009 and represented the investment of a portion of the funds received in January 2009 from the Genzyme strategic transaction. Net cash provided by investing activities was \$8.0 million for the nine months ended September 30, 2008 and primarily resulted from the maturity of marketable securities. Purchases of property and equipment were not material during the nine months ended September 30, 2009 and 2008. As a result of the cash received in January 2009 in connection with the Genzyme strategic transaction, and based on our plans for further development of our sDNA technology for colorectal cancer detection, we expect that purchases of property and equipment during 2009 will be higher than amounts invested in 2008.



Net cash provided by financing activities was \$31.5 million for the nine months ended September 30, 2009 and was comprised primarily of the receipt of \$22.6 million of cash in connection with the Genzyme strategic transaction and net proceeds after issuance costs of \$8.1 million from the issuance of common stock in our June 2009 private placement transaction. In addition cash inflows from stock option exercises were \$0.7 million during this time period. We also paid \$50,000 to repurchase outstanding options from former executives as described elsewhere in this report.

We expect that cash, cash equivalents and marketable securities on hand at September 30, 2009 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. This projection is based on our currently anticipated cost structure and operating assumptions and does not provide for the full funding of

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our current strategic plan, the centerpiece of which is the commercialization of our sDNA technology through completion of the development of an FDA-approved in vitro diagnostic test for sDNA colorectal pre-cancer and cancer screening. 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 believe that we will need to raise additional capital to complete our strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected and we may be required to delay the implementation of our plan and otherwise scale back operations. Even if we successfully raise sufficient funds to continue the implementation of our strategic 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, 2009, 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-15b 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, 2009, 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**

Other than the factor set forth below, there have been no material changes to the risk factors included in Part I, Item 1A, of the 2008 Form 10-K.

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

The market for colorectal cancer screening is large, approximating 89 million Americans age 50 and above, of which we believe approximately one-half fail to strictly follow the ACS's screening guidelines for colorectal cancer. As a result, the colorectal cancer screening market has attracted competitors, some of which have significantly greater resources than we have. Currently, we face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and virtual colonoscopy, a procedure being performed in which a radiologist views the inside of the colon through a scanner, as well as from existing guaic-based FOBT, and improved screening tests such as immunochemical FOBT. In addition, some companies and institutions are developing serum-based tests, or screening tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are produced by colon cancer. For example, it is our understanding that Epigenomics AG is currently conducting a large multi-center study to demonstrate the performance of its blood-based screening test for colorectal cancer. Additionally, we understand OncoMethylome Sciences is in the process of enrolling patients for a large blood-based colorectal cancer screening trial. These and other companies may also be working on additional methods of detecting colon cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources and stronger business relationships.

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

On July 17, 2009, at our annual meeting of stockholders, the stockholders elected as Class III directors, each to serve for a three-year term, the following individuals: Sally W. Crawford (21,905,152 shares for; 2,021,536 shares withheld) and Edwin M. Kania (22,295,418 shares for; 1,631,270 shares withheld). The term of office for each of James Connelly, Kevin T. Conroy, Connie Mack, III, Katherine Napier, Lance Willsey, MD and Patrick J. Zenner as directors of the Company continued following the annual meeting.

**Item 5. Other Information.**

*Loan Agreement with the Wisconsin Department of Commerce*

On November 10, 2009, we entered into a loan agreement (the *Loan Agreement*) with the Wisconsin Department of Commerce. Under the Loan Agreement, the Wisconsin Department of Commerce agreed to lend us up to \$1 million subject to our satisfaction of certain conditions. We expect to draw down the full amount available under the Loan Agreement at a closing expected to take place during the fourth quarter of 2009.

The term of the Loan Agreement ends October 1, 2019 and payments of principal and accrued interest on any amounts advanced under the Loan Agreement will be made in 59 equal monthly payments beginning November 1, 2014. Amounts advanced under the Loan Agreement will accrue interest at an annual rate of two percent provided this interest rate may be increased up to a maximum of six percent if we do not create at least 68 full-time positions in Madison, Wisconsin by June 30, 2015.

If we create at least 100 full-time positions in Madison, Wisconsin by June 30, 2015, and are otherwise in compliance with the Loan Agreement, the principal balance we owe will be subject to forgiveness at a rate equal to \$5,405 for each full-time position created.

*Lease Agreement with University Research Park*

On November 11, 2009, we entered into a lease agreement (the *Lease Agreement*) with University Research Park Incorporated ( *University Research Park* ). Under the Lease Agreement, we leased from University Research Park approximately 17,500 square feet of space for a five-year term beginning on November 1, 2009 (the *Term* ). We will use the space for general office, laboratory, and storage purposes. In addition, we have the option to extend the Term for one period of five (5) years. The annual rent for the first year is \$262,500.00 and will increase 2.5% each year during the Term.

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**Item 6. Exhibits**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 10                        | Employment Agreement by and between Graham Lidgard and the Company dated as of August 1, 2009.                          |
| 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. |

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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: November 12, 2009

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

President and Chief Executive Officer  
(Authorized Officer)

Date: November 12, 2009

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

Chief Financial Officer  
(Authorized Officer and Principal Financial Officer)

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