

EXACT SCIENCES CORP
Form 10-Q
November 02, 2012
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012

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)

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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)

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 October 30, 2012, the registrant had 63,767,680 shares of common stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

| | Page Number |
|---|------------------------|
| <u>Part I - Financial Information</u> | |
| Item 1. Financial Statements | |
| <u>Condensed Balance Sheets (Unaudited) as of September 30, 2012 and December 31, 2011</u> | 4 |
| <u>Condensed Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2012 and 2011</u> | 5 |
| <u>Condensed Statements of Comprehensive Loss (Unaudited) for the Three and Nine Months Ended September 30, 2012 and 2011</u> | 6 |
| <u>Condensed Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2012 and 2011</u> | 7 |
| <u>Notes to Condensed Financial Statements (Unaudited)</u> | 8 |
| Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 18 |
| Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 25 |
| Item 4. <u>Controls and Procedures</u> | 25 |
| <u>Part II - Other Information</u> | |
| Item 1. <u>Legal Proceedings</u> | 25 |
| Item 1A. <u>Risk Factors</u> | 25 |
| Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 26 |
| Item 3. <u>Defaults Upon Senior Securities</u> | 26 |
| Item 4. <u>Mine Safety Disclosures</u> | 26 |
| Item 5. <u>Other Information</u> | 26 |
| Item 6. <u>Exhibits</u> | 27 |
| <u>Signatures</u> | 28 |
| <u>Exhibit Index</u> | 29 |

Table of Contents

Part I Financial Information

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Balance Sheets****(Amounts in thousands, except share data - unaudited)**

| | September 30, 2012 | December 31, 2011 |
|---|-----------------------|----------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 12,660 | \$ 35,781 |
| Marketable securities | 105,912 | 57,580 |
| Prepaid expenses and other current assets | 1,252 | 1,034 |
| Total current assets | 119,824 | 94,395 |
| Property and Equipment, at cost: | | |
| Laboratory equipment | 3,955 | 2,314 |
| Office and computer equipment | 825 | 729 |
| Leasehold improvements | 283 | 288 |
| Furniture and fixtures | 28 | 23 |
| | 5,091 | 3,354 |
| Less Accumulated depreciation | (1,462) | (796) |
| | 3,629 | 2,558 |
| | \$ 123,453 | \$ 96,953 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 1,030 | \$ 765 |
| Accrued expenses | 4,084 | 3,069 |
| Capital lease obligation, current portion | 355 | |
| Deferred license fees, current portion | 4,143 | 4,143 |
| Total current liabilities | 9,612 | 7,977 |
| Long-term debt | 1,000 | 1,000 |
| Long-term accrued interest | 57 | 42 |
| Capital lease obligation, less current portion | 796 | |
| Deferred license fees, less current portion | 1,331 | 4,439 |
| Commitments and contingencies | | |
| Stockholders' Equity: | | |
| Preferred stock, \$0.01 par value | | |
| Authorized 5,000,000 shares | | |
| Issued and outstanding no shares at September 30, 2012 and December 31, 2011 | | |
| Common stock, \$0.01 par value | | |
| Authorized 100,000,000 shares | | |
| Issued and outstanding 63,753,363 and 56,624,763 shares at September 30, 2012 and December 31, 2011 | 638 | 566 |
| Additional paid-in capital | 370,184 | 304,767 |
| Other comprehensive income (loss) | 92 | (14) |
| Accumulated deficit | (260,257) | (221,824) |
| Total stockholders' equity | 110,657 | 83,495 |
| | \$ 123,453 | \$ 96,953 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | | | | |
|---|----------------------------------|----------|---------------------------------|----------|----------|----------|----|----------|
| | 2012 | 2011 | 2012 | 2011 | | | | |
| Revenue: | | | | | | | | |
| Product royalty fees | \$ | \$ | 4 | \$ | 14 | | | |
| License fees | | 1,036 | 1,035 | 3,108 | 3,107 | | | |
| | | 1,036 | 1,039 | 3,108 | 3,121 | | | |
| Cost of revenue: | | | | | | | | |
| Product royalty fees | | | 6 | | 18 | | | |
| Gross profit | | 1,036 | 1,033 | 3,108 | 3,103 | | | |
| Operating expenses: | | | | | | | | |
| Research and development | | 10,491 | 6,110 | 31,692 | 14,296 | | | |
| General and administrative | | 2,547 | 1,951 | 7,085 | 5,931 | | | |
| Sales and marketing | | 1,006 | 815 | 2,931 | 1,763 | | | |
| | | 14,044 | 8,876 | 41,708 | 21,990 | | | |
| Loss from operations | | (13,008) | (7,843) | (38,600) | (18,887) | | | |
| Investment income | | 67 | 75 | 188 | 131 | | | |
| Interest expense | | (11) | (5) | (21) | (15) | | | |
| Net loss | \$ | (12,952) | \$ | (7,773) | \$ | (38,433) | \$ | (18,771) |
| Net loss per share basic and diluted | \$ | (0.21) | \$ | (0.15) | \$ | (0.66) | \$ | (0.36) |
| Weighted average common shares outstanding basic and diluted | | 60,531 | 52,443 | 58,104 | 52,129 | | | |

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Statements of Comprehensive Loss**

(Amounts in thousands - unaudited)

| | Three Months September 30, | | Nine Months September 30, | |
|---|----------------------------|------------|---------------------------|-------------|
| | 2012 | 2011 | 2012 | 2011 |
| Net loss | \$ (12,952) | \$ (7,773) | \$ (38,433) | \$ (18,771) |
| Other comprehensive income (loss), net of tax: | | | | |
| Unrealized gain (loss) on securities: | | | | |
| Unrealized holding gain (loss) on marketable securities | 39 | (38) | 106 | (51) |
| Comprehensive loss | \$ (12,913) | \$ (7,811) | \$ (38,327) | \$ (18,822) |

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Statements of Cash Flows****(Amounts in thousands, except share data - unaudited)**

| | Nine Months Ended September 30, | |
|--|--|-------------|
| | 2012 | 2011 |
| Cash flows from operating activities: | | |
| Net loss | \$ (38,433) | \$ (18,771) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation of property and equipment | 666 | 262 |
| Stock-based compensation | 4,024 | 2,707 |
| Amortization of deferred license fees | (3,108) | (3,107) |
| Warrant licensing expense | 152 | 80 |
| Restricted stock licensing expense | 1,000 | |
| Amortization of premium on short-term investments | 359 | 250 |
| Changes in assets and liabilities: | | |
| Prepaid expenses and other current assets | (218) | (621) |
| Accounts payable | 265 | (51) |
| Accrued expenses | 1,483 | 596 |
| Accrued interest | 15 | 15 |
| Net cash used in operating activities | (33,795) | (18,640) |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (90,408) | (71,202) |
| Maturities of marketable securities | 41,823 | 17,128 |
| Purchases of property and equipment | (586) | (1,599) |
| Net cash used in investing activities | (49,171) | (55,673) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of common stock options and stock purchase plan | 2,090 | 556 |
| Proceeds from sale of common stock, net of issuance costs | 57,755 | |
| Net cash provided by financing activities | 59,845 | 556 |
| Net decrease in cash and cash equivalents | (23,121) | (73,757) |
| Cash and cash equivalents, beginning of period | 35,781 | 78,752 |
| Cash and cash equivalents, end of period | \$ 12,660 | \$ 4,995 |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Unrealized gain (loss) on available-for-sale investments | \$ 106 | \$ (51) |
| Issuance of 32,872 and 27,872 shares of common stock to fund the Company's 401(k) matching contribution for 2011 and 2010, respectively | \$ 274 | \$ 169 |
| Conversion of accrued expenses into 34,336 and 27,110 shares of common stock in connection with the Company's Employee Stock Purchase Plan for 2012 and 2011, respectively | \$ 194 | \$ 148 |
| Laboratory equipment acquired with a capital lease | \$ 1,151 | \$ |

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Condensed Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

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

Basis of Presentation

The accompanying condensed 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, 2011 included in the Company's Annual Report on Form 10-K (the 2011 Form 10-K). These condensed financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2011 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

Marketable Securities

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost 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 straight-line 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.

Table of Contents

At September 30, 2012 and December 31, 2011, the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2012. Realized losses for the nine months ended September 30, 2011 were \$477. Realized gains for the nine months ended September 30, 2012 were \$4,168. There were no realized gains for the nine months ended September 30, 2011. Unrealized gains or losses on investments are recorded in other comprehensive income.

Available-for-sale securities at September 30, 2012 consist of the following:

| (In thousands) | Amortized Cost | September 30, 2012 | | Estimated Fair Value |
|-------------------------------------|-------------------|---|--|-------------------------|
| | | Gains in Accumulated Other Comprehensive Income | Losses in Accumulated Other Comprehensive Income | |
| U.S. government agency securities | \$ 43,414 | \$ 33 | \$ | \$ 43,447 |
| Corporate bonds | 51,630 | 41 | | 51,671 |
| Certificates of deposit | 9,179 | 18 | | 9,197 |
| Commercial paper | 1,597 | | | 1,597 |
| Total available-for-sale securities | \$ 105,820 | \$ 92 | \$ | \$ 105,912 |

Available-for-sale securities at December 31, 2011 consist of the following:

| (In thousands) | Amortized Cost | December 31, 2011 | | Estimated Fair Value |
|-------------------------------------|-------------------|---|--|-------------------------|
| | | Gains in Accumulated Other Comprehensive Income | Losses in Accumulated Other Comprehensive Income | |
| U.S. government agency securities | \$ 28,004 | \$ | \$ (10) | \$ 27,994 |
| Corporate bonds | 19,124 | | (2) | 19,122 |
| Certificates of deposit | 9,467 | | (2) | 9,465 |
| Commercial paper | 999 | | | 999 |
| Total available-for-sale securities | \$ 57,594 | \$ | \$ (14) | \$ 57,580 |

Table of Contents**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 due to the Company's losses.

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) | 2012 | September 30, 2011 |
|--|-------|-----------------------|
| Shares issuable upon exercise of stock options | 6,282 | 6,678 |
| Shares issuable upon exercise of outstanding warrants (1) | 325 | 325 |
| Shares of restricted stock awards outstanding | 945 | 504 |
| Shares issuable upon the vesting of restricted stock awards related to a licensing agreement | 73 | |
| | 7,625 | 7,507 |

(1) At September 30, 2012 and September 30, 2011, represents warrants to purchase 250,000 shares of common stock issued under a licensing agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement.

Revenue Recognition

License fees. License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period. As more fully described in the 2011 Form 10-K, in connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including its obligation to deliver through licenses certain intellectual property improvements to Genzyme, if improvements are made during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and is amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company received the first holdback amount of \$962,000, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$934,250, which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme purchased 3,000,000 shares of common stock on January 27, 2009 for \$2.00 per share, 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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

for the CLP Agreement. Accordingly, the Company deferred the aggregate \$1.53 million premium and is amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

Table of Contents

The Company recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme, during each of the three months ended September 30, 2012 and September 30, 2011. The Company recognized approximately \$3.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the nine months ended September 30, 2012 and September 30, 2011.

Reclassifications

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

(3) MAYO LICENSE 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) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the license 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 is also required to make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the License Agreement. In addition to the license to intellectual property owned by MAYO, the Company receives 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 obligated 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.

In March of 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 86,596 shares leaving it with a net amount of 113,404 shares.

In September of 2010, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 300,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares.

Table of Contents

In June of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 60,246 shares leaving it with a net amount of 189,754 shares.

In September of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 56,641 shares leaving it with a net amount of 193,359 shares. Following this exercise, the warrant covering 1,000,000 shares was fully exercised.

Royalty Payments

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

Other Payments

Other payments under the MAYO agreement include an upfront payment of \$80,000, a milestone payment of \$250,000 on the commencement of patient enrollment in FDA trials for the Company's Cologuard pre-cancer and cancer screening test, and a \$500,000 payment upon FDA approval of the Company's Cologuard test. The upfront payment of \$80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. The Company began enrollment in its FDA trial in June of 2011 and the milestone payment of \$250,000 was made in June of 2011 and expensed to research and development in the second quarter of 2011. It is uncertain as to when the FDA will approve the Company's pre-cancer and cancer screening test. Therefore, the \$500,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial.

In addition, the Company is making payments to MAYO for research and development efforts. During the three and nine months ended September 2012, the Company made payments of \$0.3 million and \$0.6 million, respectively. At September 30, 2012 the Company recorded an estimated liability in the amount of \$0.2 million for research and development efforts. During the three and nine months ended September 2011, the Company made payments of \$0.3 million and \$1.0 million and at September 30, 2011 the Company recorded an estimated liability in the amount of \$0.3 million for research and development efforts.

May 2012 Amendment

In May 2012 the Company expanded its relationship with MAYO through an amendment to the License Agreement. As part of the amendment, the Company's license was expanded to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool- and blood-based testing. As consideration, the Company granted MAYO 97,466 shares of restricted stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. The Company recognized \$1.0 million in licensing expense during the nine months ended September 30, 2012 in connection with the restricted stock grant.

As part of the amendment, the Company is required to make additional restricted stock grants to MAYO as certain milestones are met with respect to the commercial launch of the Company's second and third licensed products. Additionally, the Company will make milestone payments once certain sales levels are reached on the second and third licensed products. It is uncertain as to when these milestones will be met; therefore, the milestone payments have not been recorded as liabilities. The Company periodically evaluates the status of the milestone payments.

(4) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

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

Table of Contents

Stock-Based Compensation Expense

The Company recorded \$1.5 million and \$4.0 million in stock-based compensation expense during the three and nine months ended September 30, 2012 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$1.2 million and \$2.7 million in stock-based compensation expense during the three and nine months ended September 30, 2011 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees and non-employee directors.

The estimated fair value of stock options and restricted stock and restricted stock unit awards is recognized to expense using the straight-line method over the vesting period.

Determining Fair Value

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

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 life. Using this method, the expected life is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility - Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.

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

Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------|-------------------------------------|---------------|------------------------------------|--------------|
| | 2012 | 2011 | 2012 | 2011 |
| Option Plan Shares | | | | |
| Risk-free interest rates | 0.81% - 0.89% | 1.12% - 1.52% | 0.81% - 0.89% | 1.12% - 2.3% |

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

| | | | | |
|--|---------|-----------|---------------|---------------|
| Expected term (in years) | 6 | 6 | 6 | 6 |
| Expected volatility | 86% | 91% - 92% | 86% - 92% | 91% - 92% |
| Dividend yield | 0% | 0% | 0% | 0% |
| Weighted average fair value per share of options granted during the period | \$ 7.47 | \$ 5.92 | \$ 6.90 | \$ 4.76 |
| ESPP Shares | | | | |
| Risk-free interest rates | (1) | (1) | 0.19% - 0.27% | 0.22% - 0.61% |
| Expected term (in years) | (1) | (1) | 0.5 - 2 | 0.5 - 2 |
| Expected volatility | (1) | (1) | 40% - 55% | 48% - 63% |
| Dividend yield | (1) | (1) | 0% | 0% |
| Weighted average fair value per share of options granted during the period | (1) | (1) | \$ 3.47 | \$ 2.88 |

Table of Contents

(1) The Company did not issue stock purchase rights under its 2010 Purchase Plan during the respective period.

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

Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2012 is as follows:

| Options (Aggregate intrinsic value in thousands) | September 30, 2012 Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (1) |
|--|-------------------------------------|--|--|--|
| Outstanding, January 1, 2012 | 6,453,644 | \$ 2.27 | 7.2 | |
| Granted | 489,148 | \$ 9.19 | | |
| Exercised | (598,904) | \$ 3.49 | | |
| Forfeited | (61,875) | \$ 8.56 | | |
| Outstanding, September 30, 2012 | 6,282,013 | \$ 2.63 | 6.8 | \$ 52,763 |
| Exercisable, September 30, 2012 | 4,520,667 | \$ 1.77 | 6.3 | \$ 41,879 |
| Vested and expected to vest, September 30, 2012 | 6,275,263 | \$ 2.62 | 6.8 | \$ 52,751 |

(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 \$11.00 market price of the Company's common stock at September 30, 2012. The total intrinsic value of options exercised during the three and nine months ended September 30, 2012 was \$0.4 million and \$3.8 million, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2011 was \$1.2 million and \$1.6 million, respectively.

As of September 30, 2012, there was \$10.7 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all Stock Plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.57 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2012 is as follows:

Table of Contents

| | Restricted Stock | | Weighted Average Grant Date Fair Value |
|---------------------------------|---------------------|----|--|
| Outstanding, January 1, 2012 | 401,490 | \$ | 6.24 |
| Granted | 587,268 | \$ | 9.48 |
| Released | (44,225) | \$ | 4.86 |
| Forfeited | (4,687) | \$ | 7.69 |
| Outstanding, September 30, 2012 | 939,846 | \$ | 8.32 |

During the first quarter of 2012, the Company granted a total of 262,500 restricted stock units to certain executives that will vest based upon the satisfaction of certain service and performance conditions. The Company performed an evaluation of internal and external factors, and determined the number of shares that are most likely to vest based on the probability of what performance conditions will be met. The expense for the fair value of the awards that are expected to vest, is being recognized ratably over the vesting period.

(5) FAIR VALUE MEASUREMENTS

The FASB has issued authoritative guidance which requires 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 establishes and 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:

- 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.

Fixed-income securities and mutual funds are valued using a third party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period. The estimated fair value of our long-term debt based on a market approach was approximately \$1.0

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Table of Contents

million as of September 30, 2012 and December 31, 2011 and represent Level 2 measurements. When determining the estimated fair value of our long-term debt, we used market-based risk measurements, such as credit risk.

The following table presents the Company's fair value measurements as of September 30, 2012 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

| Description | Fair Value at September 30, 2012 | Fair Value Measurement at September 30, 2012 Using: | | |
|---|-------------------------------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Cash equivalents (1) | \$ 10,166 | \$ 10,166 | \$ | \$ |
| Available-for-Sale Marketable securities | | | | |
| U.S. government agency securities | 43,447 | | 43,447 | |
| Corporate bonds | 51,671 | | 51,671 | |
| Certificates of deposit | 9,197 | | 9,197 | |
| Commercial paper | 1,597 | | 1,597 | |
| Total | \$ 116,078 | \$ 10,166 | \$ 105,912 | \$ |

(1) The \$10.2 million of cash equivalents above is included in the cash and cash equivalents balance of \$12.7 million at September 30, 2012.

The following table presents the Company's fair value measurements as of December 31, 2011 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

| Description | Fair Value at December 31, 2011 | Fair Value Measurement at December 31, 2011 Using: | | |
|---|------------------------------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Cash equivalents (1) | \$ 35,385 | \$ 35,385 | \$ | \$ |
| Available-for-Sale Marketable securities | | | | |
| U.S. government agency securities | 27,994 | | 27,994 | |
| Certificates of deposit | 9,465 | | 9,465 | |
| Corporate bonds | 19,122 | | 19,122 | |
| Commercial paper | 999 | | 999 | |
| Total | \$ 92,965 | \$ 35,385 | \$ 57,580 | \$ |

Table of Contents

(1) The \$35.4 million of cash equivalents above is included in the cash and cash equivalents balance of \$35.8 million at December 31, 2011.

(6) EQUITY

On August 13, 2012, the Company completed an underwritten public offering of 6,325,000 shares of common stock at a price of \$9.75 per share to the public. The Company received approximately \$57.8 million of net proceeds from the offering, after deducting \$3.9 million for the underwriting discount and other stock issuance costs paid by the Company.

(7) CAPITAL LEASE

The Company entered into a lease agreement during the three months ended September 30, 2012, which is accounted for as a capital lease. The leased equipment is recorded at \$1,151,000 and is included in the balance sheet as laboratory equipment at September 30, 2012. The cost of the leased equipment is depreciated over the three year lease term, and the expense is recorded as depreciation expense. Accumulated depreciation of the leased equipment at September 30, 2012 was approximately \$32,000. The Company is required to make payments of approximately \$32,000 per month over the three year term of the lease agreement.

The future minimum lease payments required under the capital lease and the present value of the net minimum lease payments as of September 30, 2012 are as follows (in thousands):

| | | |
|--|----|-------|
| Year Ending December 31, | | |
| 2012 | \$ | 127 |
| 2013 | | 381 |
| 2014 | | 381 |
| 2015 | | 368 |
| Total lease obligations | \$ | 1,257 |
| Less imputed interest | | (106) |
| Present value of minimum lease payments | | 1,151 |
| Less current maturities of capital lease obligations | | (355) |
| Long term capital lease obligations | \$ | 796 |

(8) RELATED PARTY TRANSACTIONS

During the three months ended September 30, 2012, the Company entered into a one year consulting agreement with a non-employee director under which the director will provide advisory services in support of the Company's commercialization activities. In accordance with the

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

agreement, the Company granted a restricted stock award for 4,873 shares of common stock that vests over one year, and will make cash payments totaling \$60,000 over the one year term of the agreement.

Table of Contents

(9) INCOME TAXES

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

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

A valuation allowance to reduce the deferred tax assets is reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has incurred significant losses since its inception and due to the uncertainty of the amount and timing of future taxable income, management has determined that a full valuation allowance at September 30, 2012 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company's effective tax rate.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At September 30, 2012 the Company had no unrecognized tax benefits, nor are there any tax positions where it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the 12 months following September 30, 2012.

(10) RECENT ACCOUNTING PRONOUNCEMENTS

Presentation of Comprehensive Income

In June 2011, the FASB issued an accounting standard update which requires the presentation of components of other comprehensive income with the components of net income in either (1) a continuous statement of comprehensive income that contains two sections, net income and other comprehensive income, or (2) two separate but consecutive statements. This accounting standard update eliminates the option to present components of other comprehensive income as part of the statement of stockholders' equity, and is effective for interim and annual periods beginning after December 15, 2011, and shall be applied retrospectively. Other than a change in presentation, the implementation of this accounting pronouncement did not have a material impact on our financial statements.

Amendments to Fair Value Measurements

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

In May 2011, the FASB issued an accounting standard update that amends the accounting standard on fair value measurements. The accounting standard update provides for a consistent definition and measurement of fair value, as well as similar disclosure requirements between GAAP and International Financial Reporting Standards (IFRS). The accounting standard update changes fair value measurement principles, clarifies the application of existing fair value measurement, and expands the fair value disclosure requirements, particularly for Level 3 fair value measurements. The amendments in this accounting standard update are to be applied prospectively and are effective for interim and annual periods beginning after December 15, 2011. The adoption of this accounting standard update did not have a material effect on our financial statements.

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 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, 2011, which has been filed with the SEC (the 2011 Form 10-K).

Table of Contents

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, anticipated timing and results of our pivotal clinical trial, 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 our 2011 Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

Exact Sciences Corporation is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal cancer.

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

- develop and refine our non-invasive Cologuard stool-based DNA (sDNA) colorectal pre-cancer and cancer screening test;
- advance our Cologuard test through U.S. Food and Drug Administration (FDA) clinical trials; and
- commercialize an FDA-cleared product that detects colorectal pre-cancer and cancer.

Our Cologuard test includes DNA markers, which in published studies have been shown to be associated with colorectal cancer. In addition to DNA markers, our test will also include a protein marker to detect blood in stool, utilizing an antibody-based fecal immunochemical test (FIT).

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Our current focus is on seeking FDA clearance or approval for our Cologuard test. We also are in the process of developing our strategy for the ultimate commercialization of our Cologuard test. We believe obtaining FDA clearance or approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. Product performance, throughput and cost are among the elements that will need to be addressed in the design and development of a commercial product based on our technology.

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who come in for routine colorectal cancer screening. We are designing our test with a goal of detecting both pre-cancers and cancers.

For our Cologuard test, the target sensitivity rate for cancer detection is equal to or greater than 85 percent at a specificity of 90 percent. In preliminary validation studies our Cologuard test was able to detect cancers at or above this target sensitivity rate and we were also able to demonstrate strong pre-cancer detection. On October 16, 2012, we released new study data for our Cologuard test at the International Conference on Frontiers in Cancer Prevention Research, a meeting

Table of Contents

of the American Association for Cancer Research. The primary purpose of the study was to establish the analytical performance of the test methodology in advance of completion of the Company's pivotal clinical trial for the test (known as the DeeP-C trial). The study demonstrated 98% sensitivity for cancer. It also demonstrated promising results for detecting the pre-cancers most likely to develop into colon cancer, with 83% sensitivity for high grade dysplasia and 57% for pre-cancer equal to or greater than 1 cm. All sensitivities were reported at a specificity of 90%. A total of 1,003 patient samples were analyzed in the study.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 10-15 years to progress from a pre-cancerous lesion or polyp to metastatic cancer and death. However, it is the second-leading cause of cancer death in the United States, killing almost 50,000 people each year.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Approximately 47 percent of those who should be screened for colorectal cancer are not screened according to current guidelines.

Poor screening compliance has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 62 percent and 8 percent, respectively.

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

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

The competitive landscape is favorable to sDNA-based screening. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. Colonoscopy is uncomfortable and expensive. A 2010 study showed that seven out of 10 people age 50 and older who were told they should get a colonoscopy did not do so primarily due to fears. Fecal blood testing suffers from poor compliance and poor sensitivity, including 66 percent detection rates for cancer and 27 percent detection rates for pre-cancers. Blood-based DNA testing also is disadvantaged by its low sensitivity for cancer and its inability to reliably detect pre-cancer. Data from a validation study of one blood-based test was released in late 2011. It demonstrated only 68 percent sensitivity across all stages of cancer at 80 percent specificity, with little sensitivity for pre-cancer.

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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Our intellectual property portfolio positions us to be the leading player to develop and market tests for the detection of colorectal cancer from stool samples. Our portfolio of issued and pending patents broadly protects our position from competitors and we believe that we have broad freedom to operate in this market. We have continued to invest in our intellectual property filings. We have intellectual property pertaining to: sample type, sample preparation, sample preservation, biomarkers, and related methods and formulations. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic and licensed Invader detection technology from Hologic, which we plan to incorporate into our Cologuard test. In 2012 we further expanded our relationship with Mayo to include licenses to all gastrointestinal cancers and diseases, and new cancer screening applications of stool- and blood-based testing. We have an extensive license to markers, digital PCR, and other technologies applicable to the detection of colorectal cancer from Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome Sciences) and Case Western Reserve University.

Table of Contents

We have generated limited operating revenues since inception and, as of September 30, 2012, we had an accumulated deficit of approximately \$260.3 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

2012 Priorities

In 2012 we will devote significant time and resources on the FDA clinical trial for our Cologuard test and preparing our FDA submissions. Our goal is to complete the clinical trial and submit the manufacturing module of a Premarket Approval Application (PMA) to the FDA by the end of 2012. We expect to release top line results from our clinical trial in the first quarter of 2013, and subsequently make a submission of the final clinical and analytical modules of the PMA to the FDA. If for any reason this trial is not successful or is substantially delayed, if the FDA does not approve our PMA or such approval is substantially delayed or if for any other reason we are unable to successfully commercialize our Cologuard test, our business and prospects would likely be materially adversely impacted.

With the goal of expediting receipt of a favorable coverage decision, we are working with the Centers for Medicare and Medicaid (CMS) to coordinate our clinical trial with the CMS coverage review process for our Cologuard test.

We are also focusing on manufacturing preparations and developing the market for our Cologuard test during 2012. This includes working to develop an FDA compliant quality management system, as well as completing a healthcare/cost effectiveness study, publishing scientific papers regarding our sDNA colorectal cancer screening technologies and continuing our outreach to physicians, third-party payors and advocates.

Financial Overview

Revenue. Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to Genzyme and product royalty fees on tests sold by LabCorp utilizing our technology. We expect that product royalty fees and license fees for 2012 will be consistent with amounts recorded in 2011.

Our Cost Structure. Our selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

Critical Accounting Policies and Estimates

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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, tax positions and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of our condensed financial statements included in the 2011 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition.

License fees. License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period.

In connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a

Table of Contents

holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the CLP Agreement), as described below, including our obligation to deliver certain intellectual property improvements to Genzyme, if improvements are made 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. We received the first holdback amount of \$962,000, which included accrued interest due, from Genzyme during the first quarter of 2010 and the second holdback amount of \$934,250, which included accrued interest, due from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

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

In total, we recognized approximately \$3.1 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme during each of the nine months ended September 30, 2012 and 2011 and approximately \$1.0 million for each of the three months ended September 30, 2012 and 2011.

Stock-Based Compensation. In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units and shares purchased under an employee stock purchase plan (ESPP) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The estimated fair value of stock options and restricted stock unit awards is recognized to expense using the straight-line method over the vesting period. The following assumptions are used in determining fair value for stock options, restricted stock and ESPP shares:

- **Valuation and Recognition** - The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in Note 4 to our condensed financial statements.
- **Expected Term** - The Company uses the simplified calculation of expected life, described by 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 on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

- **Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates.

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

Results of Operations

Revenue. Total revenue was \$1.0 million for each of the three months ended September 30, 2012 and September 30, 2011. Total revenue was \$3.1 million for each of the nine months ended September 30, 2012 and September 30, 2011. Total revenue is primarily composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The unamortized Genzyme up-front payment and holdback

Table of Contents

amounts are being amortized on a straight-line basis over the initial Genzyme collaboration period, which ends in January 2014. Revenues also include royalties on LabCorp's sales of ColoSure.

Research and development expenses. Research and development expenses increased to \$10.5 million for the three months ended September 30, 2012 from \$6.1 million for the three months ended September 30, 2011, and increased to \$31.7 million for the nine months ended September 30, 2012 from \$14.3 million for the same period in 2011. The increase for the three months ended September 30, 2012 was primarily due to an increase of \$4.3 million in clinical trial related expenses, \$0.6 million in compensation expenses, \$0.4 million of lab expenses, \$0.2 million in other research and development costs, \$0.1 million in stock-based compensation expenses compared to the same period in 2011 offset by a decrease of \$1.0 million in professional fees and \$0.2 million in research collaborations. The increase for the nine months ended September 30, 2012 was primarily due to an increase of \$12.5 million in clinical trial related expenses, \$2.2 million of lab expenses, \$1.6 million in compensation expenses, \$0.7 million in license and royalty fees, \$0.5 million in stock-based compensation expenses, \$0.4 million in other research and development expenses compared to the same period in 2011 offset by a decrease of \$0.4 million in professional fee expenses and \$0.1 million in research collaborations. The increase in these categories was the result of increased research and development activities in support of our efforts to develop and seek FDA approval for our Cologuard test, which included hiring additional research and development personnel and administering our clinical trial. As a result of these efforts, we expect research and development costs in 2012 to continue to be higher than 2011 levels.

General and administrative expenses. General and administrative expenses increased to \$2.5 million for the three months ended September 30, 2012, compared to \$2.0 million for the same period in 2011, and increased to \$7.1 million for the nine months ended September 30, 2012 from \$5.9 million for the same period in 2011. The increase for the three months ended September 30, 2012 was primarily due to an increase of \$0.6 million in other general and administrative expenses and \$0.1 million in legal and professional fees compared to the same period in 2011 offset by a decrease of \$0.2 million in stock-based compensation expenses. The increase for the nine months ended September 30, 2012 was primarily due to an increase of \$1.0 million in other general and administrative expenses and \$0.2 million in legal and professional fees.

Sales and marketing expenses. Sales and marketing expenses increased to \$1.0 million for the three months ended September 30, 2012 from \$0.8 million for the same period in 2011, and increased to \$2.9 million for the nine months ended September 30, 2012 from \$1.8 million in the same period in 2011, as a result of increased sales and marketing efforts in support of our efforts to develop and commercialize our Cologuard test which included hiring additional personnel and increased market research activities.

Investment income. Investment income decreased to \$67,000 for the three months ended September 30, 2012 from \$75,000 for the same period in 2011, and increased to \$188,000 for the nine months ended September 30, 2012 from \$131,000 for the same period in 2011. The decrease for the three months ended September 30, 2012 is due to a lower average cash and investment balance during the quarter compared to the same period in 2011. The increase for the nine months ended September 30, 2012 is primarily due to a higher average cash and investment balance during the nine months ended September 30, 2012 compared to the same period in 2011.

Interest expense. Interest expense increased to \$11,000 for the three months ended September 30, 2012 from \$5,000 for the three months ended September 30, 2011, and increased to \$21,000 for the nine months ended September 30, 2012 from \$15,000 for the same period in 2011. This increase is primarily due to interest expense recognized for our capital lease during the three and nine months ended September 30, 2012 which did not occur in the prior period.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our common stock, cash received from LabCorp in connection with our license agreement with LabCorp, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of September 30, 2012, we had approximately \$12.7 million in unrestricted cash and cash equivalents and approximately \$105.9 million in marketable securities.

Table of Contents

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

Net cash used in operating activities was \$33.8 million for the nine months ended September 30, 2012 as compared to \$18.6 million for the nine months ended September 30, 2011. The principal use of cash in operating activities for the nine months ended September 30, 2012 and 2011 was to fund our net loss which increased primarily due to increased research and development activities which included hiring additional research and development personnel and administering our clinical trial.

Net cash used in investing activities was \$49.2 million for the nine months ended September 30, 2012 as compared to \$55.7 million for the nine months ended September 30, 2011. The decrease in cash used in investing activities for the nine months ended September 30, 2012 compared to the same period in 2011 was primarily the result of the timing of purchases and maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities consisted of purchases of property and equipment of \$0.6 million for the nine months ended September 30, 2012 and \$1.6 million for the same period in 2011. The decrease in property and equipment purchases during the nine months ended September 30, 2012 was primarily the result of equipment purchases totaling \$1.2 million during 2012 being financed through a capital lease.

Net cash provided by financing activities was \$59.8 million for the nine months ended September 30, 2012, as compared to \$0.6 million for the nine months ended September 30, 2011. The increase in cash provided by financing activities for the nine months ended September 30, 2012 was due to the receipt of \$57.8 million of cash from our August 2012 common stock offering and \$2.1 million of cash inflows from stock option exercises during the nine months ended September 30, 2012 compared to \$0.6 million of cash inflows from stock option exercises for the same period in 2011.

We expect that cash and cash equivalents on hand at September 30, 2012, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since we have no current sources of material ongoing revenue, we expect that we will need to raise additional capital to fully fund our current strategic plan, the primary goal of which is developing and commercializing an FDA-cleared/approved non-invasive sDNA colorectal pre-cancer and cancer screening test. 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 our operations. Even if we successfully raise sufficient funds to complete our plan, we cannot assure you that our business will ever generate sufficient cash flow from operations to become profitable.

For the remainder of 2012, we expect to spend approximately \$5.0 million to \$6.0 million on the clinical trial for our Cologuard test, including costs for personnel, consultants, lab testing and clinical trial sites, the majority of which will be spent on completing patient enrollment in our clinical trial. We estimate that we need to spend an additional \$4.0 million to \$5.0 million in 2013 to complete the clinical trial and to complete our FDA submissions. These costs will include costs for personnel, lab testing, data management and supporting activities not provided by our full-time employees. We believe we have enough cash on hand to fund these planned expenditures in addition to our current operations.

Contractual Obligations

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

During the quarter ended September 30, 2012 we entered into a capital lease agreement for the purchase of certain laboratory equipment. As a result of the agreement, our capital lease obligations have changed as follows (in thousands):

Table of Contents

| | Payments Due by Period | | | | |
|---|------------------------|---------------------------|---------------|---------------|------------------------|
| | Total | Fourth Quarter 2012 | 2013- 2014 | 2015- 2016 | 2017 and thereafter |
| Pre-agreement capital lease obligation | \$ | \$ | \$ | \$ | \$ |
| Increase in obligation | 1,257 | 127 | 762 | 368 | |
| Post-agreement capital lease obligation | \$ 1,257 | \$ 127 | \$ 762 | \$ 368 | \$ |

Off-Balance Sheet Arrangements

As of September 30, 2012, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, which, as of September 30, 2012 were classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

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

Item 4. Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15e promulgated under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2012, our disclosure controls and procedures were effective. Disclosure controls and procedures enable 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 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.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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

Part II - Other Information

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in

Table of Contents

this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, Item 1A. Risk Factors in our most recent Annual Report on Form 10-K. There have been no material changes to the risk factors described in that report.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Table of Contents

Item 6. Exhibits

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

Table of Contents

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 2, 2012

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

President and Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2012

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

Chief Operating Officer, Chief Financial Officer, and Secretary
(Principal Financial Officer and Principal Accounting Officer)

Table of Contents

EXHIBIT INDEX

| Exhibit Number | Description |
|---------------------------|---|
| 10.1 | Consulting Agreement dated August 27, 2012 between the Registrant and James P. Connelly |
| 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. |
| 101 | Interactive Data Files |