

EXACT SCIENCES CORP
Form 10-Q
October 30, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

Commission File Number: 001-35092

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)

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 |
| Emerging growth company | |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 27, 2017, the registrant had 119,730,401 shares of common stock outstanding.

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Part I — Financial Information

EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

| | September 30, 2017 | December 31, 2016 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 50,837 | \$ 48,921 |
| Marketable securities | 411,684 | 262,179 |
| Accounts receivable, net | 24,553 | 8,526 |
| Inventory, net | 18,064 | 6,833 |
| Prepaid expenses and other current assets | 8,551 | 7,114 |
| Total current assets | 513,689 | 333,573 |
| Property and Equipment, at cost: | | |
| Computer equipment and computer software | 27,374 | 20,767 |
| Laboratory equipment | 20,352 | 14,749 |
| Leasehold improvements | 14,200 | 13,549 |
| Assets under construction | 20,868 | 6,711 |
| Buildings | 4,792 | 4,792 |
| Furniture and fixtures | 3,156 | 2,515 |
| | 90,742 | 63,083 |
| Less—Accumulated depreciation | (35,036) | (24,941) |
| Net property and equipment | 55,706 | 38,142 |
| Other long-term assets, net | 17,784 | 5,325 |
| Total assets | \$ 587,179 | \$ 377,040 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 8,774 | \$ 710 |
| Accrued liabilities | 38,390 | 28,106 |
| Debt, current portion | 180 | 174 |
| Other short-term liabilities | 2,345 | 1,702 |
| Total current liabilities | 49,689 | 30,692 |
| Long-term debt | 4,511 | 4,633 |
| Other long-term liabilities | 5,611 | 5,734 |
| Lease incentive obligation, less current portion | 224 | 686 |
| Total liabilities | 60,035 | 41,745 |
| Commitments and contingencies | | |
| Stockholders' Equity: | | |
| | — | — |

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| | | |
|--|------------|------------|
| Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2017 and December 31, 2016 | | |
| Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—119,590,733 and 110,236,127 shares at September 30, 2017 and December 31, 2016 | 1,196 | 1,102 |
| Additional paid-in capital | 1,365,112 | 1,080,432 |
| Accumulated other comprehensive loss | (314) | (418) |
| Accumulated deficit | (838,850) | (745,821) |
| Total stockholders' equity | 527,144 | 335,295 |
| Total liabilities and stockholders' equity | \$ 587,179 | \$ 377,040 |

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|--------------|
| | 2017 | 2016 | 2017 | 2016 |
| Laboratory service revenue | \$ 72,574 | \$ 28,115 | \$ 178,583 | \$ 64,135 |
| Cost of sales | 20,729 | 12,174 | 55,701 | 31,330 |
| Gross margin | 51,845 | 15,941 | 122,882 | 32,805 |
| Operating expenses: | | | | |
| Research and development | 11,725 | 7,625 | 29,464 | 26,391 |
| General and administrative | 30,763 | 20,292 | 75,442 | 55,400 |
| Sales and marketing | 37,768 | 26,308 | 113,297 | 82,320 |
| Total operating expenses | 80,256 | 54,225 | 218,203 | 164,111 |
| Loss from operations | (28,411) | (38,284) | (95,321) | (131,306) |
| Other income (expense) | | | | |
| Investment income | 1,334 | 535 | 2,612 | 1,426 |
| Interest expense | (51) | (54) | (155) | (161) |
| Total other income | 1,283 | 481 | 2,457 | 1,265 |
| Net loss before tax | (27,128) | (37,803) | (92,864) | (130,041) |
| Income tax benefit | 231 | — | 231 | — |
| Net loss | \$ (26,897) | \$ (37,803) | \$ (92,633) | \$ (130,041) |
| Net loss per share—basic and diluted | \$ (0.23) | \$ (0.36) | \$ (0.81) | \$ (1.30) |
| Weighted average common shares outstanding—basic and diluted | 119,215 | 104,807 | 114,246 | 100,006 |

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(Amounts in thousands - unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|--------------|
| | 2017 | 2016 | 2017 | 2016 |
| Net loss | \$ (26,897) | \$ (37,803) | \$ (92,633) | \$ (130,041) |
| Other comprehensive loss, net of tax: | | | | |
| Unrealized gain (loss) on available-for-sale investments | 49 | (145) | 7 | 410 |
| Foreign currency translation gain (loss) | 16 | (25) | 97 | (164) |
| Comprehensive loss | \$ (26,832) | \$ (37,973) | \$ (92,529) | \$ (129,795) |

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

| | Nine Months Ended September 30, | |
|---|------------------------------------|--------------|
| | 2017 | 2016 |
| Cash flows from operating activities: | | |
| Net loss | \$ (92,633) | \$ (130,041) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization of fixed assets | 10,507 | 8,237 |
| Loss on disposal of property and equipment | 301 | 101 |
| Deferred tax benefit | (231) | — |
| Stock-based compensation | 23,002 | 16,773 |
| Amortization of other liabilities | (1,199) | (713) |
| Amortization of deferred financing costs | 40 | 40 |
| Amortization of premium on short-term investments | 56 | 412 |
| Amortization of intangible assets | 645 | 150 |
| Changes in assets and liabilities, net of effects of acquisition: | | |
| Accounts receivable, net | (15,663) | (2,930) |
| Inventory, net | (11,231) | (989) |
| Prepaid expenses and other current assets | (1,391) | 1,702 |
| Accounts payable | 8,022 | (973) |
| Accrued liabilities | 9,306 | 5,453 |
| Other short-term liabilities | (29) | — |
| Lease incentive obligation | (462) | (159) |
| Net cash used in operating activities | (70,960) | (102,937) |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (345,039) | (151,456) |
| Maturities of marketable securities | 195,485 | 142,813 |
| Purchases of property and equipment | (24,442) | (12,166) |
| Business acquisition, net of cash acquired | (2,996) | — |
| Internally developed software | (25) | — |
| Purchased intangible assets | (8,442) | — |
| Net cash used in investing activities | (185,459) | (20,809) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of common stock options | 3,350 | 1,049 |
| Proceeds from sale of common stock, net of issuance costs | 253,389 | 144,247 |
| Payments on mortgage payable | (130) | (124) |
| Proceeds in connection with the Company's employee stock purchase plan | 1,629 | 1,048 |
| Net cash provided by financing activities | 258,238 | 146,220 |
| Effects of exchange rate changes on cash and cash equivalents | 97 | (164) |

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| | | |
|--|-----------|-----------|
| Net increase in cash and cash equivalents | 1,916 | 22,310 |
| Cash and cash equivalents, beginning of period | 48,921 | 41,135 |
| Cash and cash equivalents, end of period | \$ 50,837 | \$ 63,445 |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Property and equipment acquired but not paid | \$ 3,930 | \$ 549 |
| Unrealized gain on available-for-sale investments | \$ 7 | \$ 410 |
| Issuance of 158,717 and 341,507 shares of common stock to fund the Company's | | |
| 401(k) matching contribution for 2016 and 2015, respectively | \$ 3,008 | \$ 2,151 |
| Interest paid | \$ 151 | \$ 157 |

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (“Exact” or the “Company”) was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. The Company has developed an accurate, non-invasive, patient-friendly screening test called Cologuard® for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of tests for other types of cancer.

Basis of Presentation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, CG Growth, LLC, Sampleminded, Inc., Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities 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, 2016 included in the Company’s Annual Report on Form 10-K (the “2016 Form 10-K”). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2016 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

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company's wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, CG Growth, LLC, Sampleminded, LLC, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities. All significant intercompany transactions and balances have been eliminated in consolidation.

References to "Exact", "we", "us", "our", or the "Company" refer to Exact Sciences Corporation and its wholly owned subsidiaries.

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.

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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 loss. 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.

At September 30, 2017 and December 31, 2016, 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. Investments in which the Company has the ability and intent, if necessary, to liquidate, in order to support its current operations (including those with a contractual term greater than one year from the date of purchase), are classified as current. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2017 and 2016. Realized gains were \$17,000 and \$21,000 for the nine months ended September 30, 2017 and 2016, respectively.

We periodically review our investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, our intent not to sell the security, and whether it is more likely than not that we will have to sell the security before recovery of its cost basis. For the nine months ended September 30, 2017, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at September 30, 2017 consisted of the following:

September 30, 2017

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| (In thousands) | Amortized Cost | Gains in Accumulated Other Comprehensive Income | Losses in Accumulated Other Comprehensive Income | Estimated Fair Value |
|--------------------------------------|----------------|---|--|-------------------------|
| Corporate bonds | \$ 213,058 | \$ 27 | \$ (80) | \$ 213,005 |
| Asset backed securities | 101,167 | 2 | (56) | 101,113 |
| U.S. government agency securities | 64,972 | — | (103) | 64,869 |
| Commercial paper | 20,894 | 2 | (1) | 20,895 |
| Certificates of deposit | 11,800 | 2 | — | 11,802 |
| Total available-for-sale securities | \$ 411,891 | \$ 33 | \$ (240) | \$ 411,684 |

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Available-for-sale securities at December 31, 2016 consisted of the following:

| (In thousands) | December 31, 2016 | | Losses in Accumulated Other Comprehensive Income | Estimated Fair Value |
|--------------------------------------|-------------------|---|--|-------------------------|
| | Amortized Cost | Gains in Accumulated Other Comprehensive Income | | |
| Corporate bonds | \$ 137,013 | \$ 17 | \$ (93) | \$ 136,937 |
| Asset backed securities | 55,667 | 3 | (30) | 55,640 |
| U.S. government agency securities | 49,591 | 3 | (120) | 49,474 |
| Commercial paper | 19,069 | 8 | (1) | 19,076 |
| Certificates of deposit | 1,053 | — | (1) | 1,052 |
| Total available-for-sale securities | \$ 262,393 | \$ 31 | \$ (245) | \$ 262,179 |

Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) ("AOCI") for the nine months ended September 30, 2017 were as follows:

| (In thousands) | Cumulative Translation Adjustment | Unrealized Gain (Loss) on Securities | Accumulated Other Comprehensive Income (Loss) |
|--|---|--|--|
| Balance at December 31, 2016 | \$ (204) | \$ (214) | \$ (418) |
| Other comprehensive loss before reclassifications | 97 | (3) | 94 |
| Amounts reclassified from accumulated other comprehensive loss | — | 10 | 10 |
| Net current period change in accumulated other comprehensive loss | 97 | 7 | 104 |
| Balance at September 30, 2017 | \$ (107) | \$ (207) | \$ (314) |

The amounts recognized in AOCI for the nine months ended September 30, 2016 were as follows:

| Cumulative Translation | Unrealized Gain (Loss) | Accumulated Other Comprehensive |
|---------------------------|---------------------------|---------------------------------------|
|---------------------------|---------------------------|---------------------------------------|

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| (In thousands) | Adjustment | on Securities | Income (Loss) |
|--|------------|---------------|---------------|
| Balance at December 31, 2015 | \$ 11 | \$ (444) | \$ (433) |
| Other comprehensive (loss) income before reclassifications | (164) | 346 | 182 |
| Amounts reclassified from accumulated other comprehensive loss | — | 64 | 64 |
| Net current period change in accumulated other comprehensive (loss) income | (164) | 410 | 246 |
| Balance at September 30, 2016 | \$ (153) | \$ (34) | \$ (187) |

Amounts reclassified from AOCI for the nine months ended September 30, 2017 and 2016 were as follows:

| Details about AOCI Components (In thousands) | Affected Line Item in the Statement of Operations | Nine Months Ended | |
|--|---|--------------------|--------------------|
| | | September 30, 2017 | September 30, 2016 |
| Change in value of available-for-sale investments | | | |
| Sales and maturities of available-for-sale investments | Investment income | \$ 10 | \$ 64 |
| Total reclassifications | | \$ 10 | \$ 64 |

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Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of fixed assets are as follows:

| Asset Classification | Estimated Useful Life |
|--|--|
| Laboratory equipment | 3 - 5 years |
| Computer equipment and computer software | 3 years |
| Leasehold improvements | Lesser of the remaining lease term or useful life |
| Building Improvements | Lesser of the remaining building life or useful life |
| Furniture and fixtures | 3 years |
| Buildings | 30 years |

At September 30, 2017, the Company had \$20.9 million of assets under construction which consisted of \$10.0 million related to machinery and equipment, \$8.0 million related to buildings and leasehold improvements, \$2.7 million related to computer equipment and computer software projects and \$0.2 million related to furniture and fixtures. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional \$8.4 million to complete the machinery and equipment, \$11.9 million to complete the building and leasehold improvements, and minimal costs to complete the computer equipment and computer software projects and furniture and fixtures. These projects are expected to be completed in 2017 and 2018. There were no impairment losses for the periods ended September 30, 2017 and December 31, 2016.

Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line basis over the estimated useful life of the software.

Patent Costs and Intangible Assets

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 to be derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. 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 nine months ended September 30, 2017 should be expensed and not capitalized as the future economic benefit to be derived from the transactions cannot be determined.

Under a technology license and royalty agreement entered into with MDxHealth (“MDx”), dated July 26, 2010 (as subsequently amended, the “License Agreement”), the Company was required to pay MDx milestone-based royalties on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone occurred or was considered probable, an intangible asset and corresponding liability was reported in other long-term assets and accrued liabilities, respectively. The intangible asset is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The liability was relieved once the milestone was achieved and payment was made. Payment for all remaining milestones under the License Agreement was made as part of the Royalty Buy-Out agreement outlined below.

Effective April 25, 2017, the Company and MDx entered into a Royalty Buy-Out Agreement (“Royalty Buy-Out Agreement”), which terminated the License Agreement. Pursuant to the Royalty Buy-Out Agreement, the Company paid MDx a one-time fee of \$8.0 million in exchange for an assignment of certain patents covered by the License Agreement and the elimination of all ongoing royalties and other payments by the Company to MDx under the License

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Agreement. Also included in the Royalty Buy-Out Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, the Company entered into a Patent Purchase Agreement (“Patent Purchase Agreement”) with MDx under which it paid MDx an additional \$7.0 million in exchange for the assignment of certain other patent rights that were not covered by the License Agreement. The total \$15.0 million paid by the Company pursuant to the Royalty Buy-Out Agreement and Patent Purchase Agreement, net of liabilities relieved of \$6.6 million, was recorded as an intangible asset and is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The \$6.6 million of liabilities relieved were related to historical milestones and accrued royalties under the License Agreement.

As of September 30, 2017, an intangible asset of \$9.4 million related to historical milestone payments made under the License Agreement and intangible assets acquired as part of the Royalty Buy-Out Agreement and Patent Purchase Agreement is reported in other long-term assets. As of December 31, 2016, an intangible asset of \$1.6 million and a liability of \$1.3 million related to historical milestone payments made under the License Agreement, were reported in other long-term assets and accrued liabilities, respectively. Amortization expense was \$0.3 million and \$0.1 million for the three months ended September 30, 2017 and September 30, 2016, respectively. Amortization expense was \$0.6 million and \$0.2 million for the nine months ended September 30, 2017 and September 30, 2016, respectively.

The estimated remaining useful life of the intangible asset is seven years. The table below represents future amortization expense as of September 30, 2017:

| | |
|----------------|----------|
| (In thousands) | |
| 2017 | \$ 335 |
| 2018 | 1,338 |
| 2019 | 1,338 |
| 2020 | 1,338 |
| 2021 | 1,338 |
| Thereafter | 3,680 |
| | \$ 9,367 |

The Company reviews long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There were no impairment losses for the periods ended September 30, 2017 and December 31, 2016.

Goodwill and Other Intangible Assets

Goodwill

As more fully described in Note 11, during the third quarter of 2017, the Company recognized goodwill of \$2.0 million from the acquisition of Sampleminded, Inc., which was completed during the period. The Company will evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicate the carrying amount is in excess of the fair value.

Other Intangible Assets

As a result of the Sampleminded acquisition, the Company recorded an intangible asset of \$1.0 million which was comprised of developed technology acquired of \$0.9 million, customer relationships of \$0.1 million, and non-compete agreements of \$32,000. The intangible assets acquired are being amortized over the remaining useful life which was determined to be eight years for developed technology acquired, thirteen years for customer relationships, and five years for non-compete agreements. As of September 30, 2017, the Company recorded \$20,000 in amortization expense.

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The table below represents estimated future amortization expense of these intangible assets as of September 30, 2017:

| | |
|----------------|--------|
| (In thousands) | |
| 2017 | \$ 30 |
| 2018 | 118 |
| 2019 | 118 |
| 2020 | 118 |
| 2021 | 118 |
| Thereafter | 449 |
| | \$ 951 |

The Company reviews these identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

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:

| | | |
|---|---------------|--------|
| | September 30, | |
| (In thousands) | 2017 | 2016 |
| Shares issuable upon exercise of stock options | 4,042 | 5,080 |
| Shares issuable upon the release of restricted stock awards | 6,164 | 5,989 |
| | 10,206 | 11,069 |

Revenue Recognition

Laboratory Service Revenue. The Company's laboratory service revenues are generated by performing screening services using our Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. The Company recognizes revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. The Company recognizes revenue on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated aggregate reimbursement rate from payers and patients. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.

The estimates of amounts that will ultimately be collected require significant judgment by management, and the Company's judgments will continue to evolve as it gains payment experience with payers and patients. Historically, in the absence of the ability to reasonably estimate the amount that will ultimately be collected for services, revenue was recognized upon cash receipt. Effective during the first quarter of 2017, the Company determined that it had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, the Company now recognizes revenue on an accrual basis for all billed claims.

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The components of laboratory service revenue, as recognized upon accrual or cash receipt, for the three and nine months ended September 30, 2017 and 2016 were as follows:

| (In thousands) | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2017 | 2016 | 2017 | 2016 |
| Revenue recognized on an accrual basis | \$ 72,574 | \$ 24,510 | \$ 174,074 | \$ 57,592 |
| Revenue recognized when cash is received | — | 3,605 | 4,509 | 6,543 |
| Total | \$ 72,574 | \$ 28,115 | \$ 178,583 | \$ 64,135 |

Inventory

Inventory is stated at the lower of cost or market value (net realizable value). The Company determines the cost of inventory using the first-in, first out method (“FIFO”). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated net realizable value, and records a charge to cost of sales for such inventory, as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated net realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development.

Inventory consists of the following:

| (In thousands) | September 30, | December 31, |
|----------------------------------|---------------|--------------|
| | 2017 | 2016 |
| Raw materials | \$ 7,033 | \$ 2,408 |
| Semi-finished and finished goods | 11,031 | 4,425 |
| Total inventory | \$ 18,064 | \$ 6,833 |

Foreign Currency Translation

For the Company's international subsidiaries, the local currency is the functional currency. Assets and liabilities of these subsidiaries are translated into United States dollars at the period-end exchange rate or historical rates, as appropriate. Condensed consolidated statements of operations are translated at average exchange rates for the period. The cumulative translation adjustments resulting from changes in exchange rates are included in the condensed consolidated balance sheet as a component of accumulated other comprehensive loss in total Exact Sciences Corporation's stockholders' equity. Transaction gains and losses are included in the condensed consolidated statement of operations.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation in the condensed consolidated financial statements and accompanying notes to the condensed consolidated financial statements.

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(3) MAYO LICENSE AGREEMENT

Overview

As more fully described in the 2016 Form 10-K, in June 2009 the Company entered into a patent license agreement with MAYO Foundation for Medical Education and Research (“MAYO”). The Company’s license agreement with MAYO was amended and restated in February 2015 and further amended in January 2016. Under the license agreement, MAYO granted the Company an exclusive, worldwide license to certain MAYO patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain MAYO know-how. As expanded by the January 2016 amendment to the license agreement, the scope of the license includes any screening, surveillance or diagnostic tests or tools for use in connection with any type of cancers, pre-cancers, diseases or conditions.

Pursuant to the Company’s agreement with MAYO, the Company is required to pay MAYO a low-single-digit royalty on the Company’s net sales of products using the licensed MAYO intellectual property, with minimum annual royalty fees of \$25,000 each year through 2033, the year the last patent expires. The January 2016 amendment to the MAYO license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. As part of the amendment, the royalty rate on the Company’s net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase, but, pursuant to the terms of the January 2016 amendment, would remain a low-single-digit percentage of net sales.

In addition to royalties, the Company is required to pay MAYO cash of \$0.2 million, \$0.8 million and \$2.0 million upon each product using the licensed MAYO intellectual property reaching \$5.0 million, \$20.0 million and \$50.0 million in cumulative net sales, respectively.

As part of the February 2015 amendment and restatement of the license agreement, the Company agreed to pay MAYO an additional \$5.0 million, payable in five annual installments, through 2019. The Company paid MAYO the annual installment of \$1.0 million in the first quarter of each of 2015 and 2016. The Company paid MAYO the 2017 installment in December 2016. The Company records the \$1.0 million installments to prepaid expenses and other current assets and amortizes each installment over a twelve-month period commencing on February 1 of each year. For the three and nine months ended September 30, 2017 and 2016 the Company has recorded \$0.3 million and \$0.7 million in amortization of the installments, respectively.

In addition, the Company is paying MAYO for research and development efforts. As part of the Company’s research collaboration with MAYO, the Company incurred charges of \$1.1 million and \$3.2 million for the three and nine months ended September 30, 2017, respectively. The Company made payments of \$0.3 million and \$2.2 million for the three and nine months ended September 30, 2017, respectively. The Company recorded an estimated liability of

\$1.9 million for research and development efforts as of September 30, 2017. The Company incurred charges of \$0.8 million and \$2.6 million for the three and nine months ended September 30, 2016, respectively. The Company made payments of \$1.0 million and \$3.3 million for the three and nine months ended September 30, 2016, respectively. The Company recorded an estimated liability of \$0.5 million for research and development efforts as of September 30, 2016.

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(4) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2010 Employee Stock Purchase Plan, the 2015 Inducement Award Plan, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive Plan (collectively, the “Stock Plans”).

Stock-Based Compensation Expense

The Company records stock-based compensation expense 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 \$10.8 million and \$23.0 million in stock-based compensation expense during the three and nine months ended September 30, 2017, respectively. The Company recorded \$6.2 million and \$16.8 million in stock-based compensation expense during the three and nine months ended September 30, 2016, respectively.

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. The fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

Expected Term – Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants. Expected life of a market measure-based award is based on the applicable performance period.

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 and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

Forfeitures – Beginning in 2017, the Company adopted Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“Update 2016-09”). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the condensed consolidated balance sheet was a cumulative-effect adjustment of \$0.4 million, increasing opening accumulated deficit and additional paid-in capital.

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The fair value of each option and market measure-based award is based on the assumptions in the following table:

| | Three Months Ended September 30, 2017 | | 2016 | | Nine Months Ended September 30, 2017 | | 2016 | |
|--|--|----------|------|--|--|-------------|-------------|-------------|
| Option Plan Shares | | | | | | | | |
| Risk-free interest rates | 2.06% | (1) | | | 2.06% - | | 1.48% - | |
| Expected term (in years) | 6.56 | (1) | | | 2.13% - | 6.56 - 6.59 | 1.69% - | 6.25 - 6.74 |
| Expected volatility | 62.5% | (1) | | | 62.5% - | 62.9% | 58.9% - | 59.4% |
| Dividend yield | 0% | (1) | | | 0% | | 0% | |
| Weighted average fair value per share of options granted during the period | \$ 27.03 | (1) | | | \$ 25.18 | | \$ 3.17 | |
| Market Measure-Based Shares | | | | | | | | |
| Risk-free interest rates | (2) | 0.76% | (2) | | (2) | | 0.76% - | 0.91% |
| Expected term (in years) | (2) | 2.43 | (2) | | (2) | | 2.43 - 2.84 | 68.3% - |
| Expected volatility | (2) | 79.6% | (2) | | (2) | | 79.6% | |
| Dividend yield | (2) | 0% | (2) | | (2) | | 0% | |
| Weighted average fair value per share of stock purchase rights granted during the period | (2) | \$ 13.42 | (2) | | (2) | | \$ 3.77 | |
| ESPP Shares | | | | | | | | |
| Risk-free interest rates | (3) | (3) | | | 0.98% - | | 0.41% - | |
| Expected term (in years) | (3) | (3) | | | 1.28% | | 0.8% | |
| Expected volatility | (3) | (3) | | | 0.5 - 2.0 | | 0.5 - 2.0 | |
| Dividend yield | (3) | (3) | | | 66.4% - | | 70.1% - | |
| Weighted average fair value per share of stock purchase rights granted during the period | (3) | (3) | | | 85.5% | | 92.7% | |
| | | | | | 0% | | 0% | |
| | | | | | \$ 13.05 | | \$ 3.08 | |

(1) The Company did not grant options under its 2010 Stock Plan during the period indicated.

(2) The Company did not issue market measure-based shares during the respective period.

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

Stock Option and Restricted Stock Activity

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A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2017 is as follows:

| Options (Aggregate intrinsic value in thousands) | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value(1) |
|---|-----------|--|---|------------------------------------|
| Outstanding, January 1, 2017 | 3,505,481 | \$ 7.00 | 5.5 | |
| Granted | 942,997 | 21.68 | | |
| Exercised | (382,967) | 8.75 | | |
| Forfeited | (23,879) | 14.19 | | |
| Outstanding, September 30, 2017 | 4,041,632 | \$ 10.22 | 5.9 | \$ 149,127 |
| Exercisable, September 30, 2017 | 2,281,645 | \$ 5.81 | 3.6 | \$ 94,250 |

-
- (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 \$47.12 market price of the Company's common

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stock at September 30, 2017. The total intrinsic value of options exercised during the nine months ended September 30, 2017 and 2016 was \$11.2 million and \$5.6 million, respectively.

As of September 30, 2017, there was \$100.8 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 forfeitures. The Company expects to recognize that cost over a weighted average period of 3.0 years.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the nine months ended September 30, 2017 is as follows:

| | Restricted Shares | Weighted Average Grant Date Fair Value |
|---------------------------------|----------------------|--|
| Outstanding, January 1, 2017 | 5,601,316 | \$ 9.19 |
| Granted | 1,946,736 | 31.81 |
| Released | (1,075,538) | 14.14 |
| Forfeited | (308,471) | 18.60 |
| Outstanding, September 30, 2017 | 6,164,043 | \$ 15.16 |

(5) FAIR VALUE MEASUREMENTS

The Financial Accounting Standards Board 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 the Company's long-term debt based on a market approach was approximately \$4.5 million and \$4.6 million as of September 30, 2017 and December 31, 2016, respectively, and represent Level 2 measurements. When determining the estimated fair value of the Company's long-term debt, the Company used market-based risk measurements, such as credit risk.

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The following table presents the Company's fair value measurements as of September 30, 2017 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

| | Fair Value at September 30, 2017 | Fair Value Measurement at September 30, 2017 Using: | | |
|---|--|--|--|--|
| | | Quoted Prices Significant in Active Markets for Identical Assets (Level 1) | Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| (In thousands) | | | | |
| Cash and cash equivalents | | | | |
| Cash and money market | \$ 30,837 | \$ 30,837 | \$ — | \$ — |
| U.S. government agency securities Available-for-sale | 20,000 | — | 20,000 | — |