

Accelerate Diagnostics, Inc
Form 10-Q
August 01, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

or

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

For the transition period from ____ to ____

Commission File Number: 001-31822

ACCELERATE DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

84-1072256

(I.R.S. Employer Identification No.)

3950 South Country Club, Suite 470
Tucson, Arizona 85714
(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code:

(520) 365-3100

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 | Smaller reporting company |

(Do not check if a 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 July 28, 2014, there were 44,583,092 shares of the registrant's common stock outstanding.

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PART I – FINANCIAL INFORMATION**Item 1. Financial Statements (unaudited)**ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
BALANCE SHEETS

Unaudited

(in thousands, except share data)

| | June 30, 2014 | December 31, 2013 |
|---|------------------|-------------------------|
| Current assets: | | |
| Cash and cash equivalents | \$65,212 | \$30,029 |
| Investments | 13,800 | 11,960 |
| Trade accounts receivable | 40 | 24 |
| Prepaid expenses and other | 616 | 130 |
| Total current assets | \$79,668 | \$42,143 |
| Property and equipment, net | 1,933 | 1,047 |
| Intellectual property, net | 203 | 241 |
| Total Assets | \$81,804 | \$43,431 |
| Current liabilities: | | |
| Accounts payable | \$1,302 | \$540 |
| Accrued compensation and other liabilities | 727 | 515 |
| Deferred revenue and income | 76 | 82 |
| Capital lease obligation | 145 | — |
| Total current liabilities | \$2,250 | \$1,137 |
| Long-term deferred income | 763 | 777 |
| Long-term capital lease obligation | 87 | — |
| Total liabilities | \$3,100 | \$1,914 |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value; 55,000,000 common shares authorized 44,583,092 (as of June 30, 2014) and 41,649,521 (as of December 31, 2013) shares issued and outstanding | \$45 | \$42 |
| 5,000,000 preferred shares authorized and none outstanding as of June 30, 2014 and December 31, 2013 | — | — |
| Contributed capital | 126,469 | 75,937 |
| Accumulated deficit | (47,838) | (34,484) |
| Accumulated other comprehensive income | 28 | 22 |
| Total stockholders' equity | \$78,704 | \$41,517 |
| Total liabilities and stockholders' equity | \$81,804 | \$43,431 |

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Unaudited

(in thousands, except per share data)

| | Three-month period ended | | Six-month period ended | |
|--|-------------------------------------|-----------------|-----------------------------------|-----------------|
| | June 30, | June 30, | June 30, | June 30, |
| | 2014 | 2013 | 2014 | 2013 |
| Revenues: | | | | |
| Licensing and royalty revenues | \$ 13 | \$ 7 | \$ 27 | \$ 23 |
| Total revenues | \$ 13 | \$ 7 | \$ 27 | \$ 23 |
| Costs and expenses: | | | | |
| Research and development | \$ 4,562 | \$ 2,461 | \$ 8,125 | \$ 4,343 |
| Sales, general and administrative | 3,447 | 1,234 | 5,491 | 1,864 |
| Amortization | 19 | 19 | 38 | 38 |
| Depreciation | 150 | 71 | 285 | 107 |
| Total costs and expenses | \$ 8,178 | \$ 3,785 | \$ 13,939 | \$ 6,352 |
| Loss from operations | \$(8,165) | \$(3,778) | \$(13,912) | \$(6,329) |
| Other expense | \$(3) | \$(1) | \$(3) | \$(1) |
| Interest and dividend income | 16 | 2 | 34 | 4 |
| Total other income | \$ 13 | \$ 1 | \$ 31 | \$ 3 |
| Net loss before income taxes | \$(8,152) | \$(3,777) | \$(13,881) | \$(6,326) |
| Benefit from income taxes | — | — | 527 | — |
| Net Loss | \$(8,152) | \$(3,777) | \$(13,354) | \$(6,326) |
| Net loss per share: Basic and diluted net loss per share | \$(0.19) | \$(0.10) | \$(0.31) | \$(0.19) |
| Weighted average shares outstanding | 43,477 | 38,941 | 42,637 | 34,128 |
| Other comprehensive loss: | | | | |
| Net loss | \$(8,152) | \$(3,777) | \$(13,354) | \$(6,326) |
| Net unrealized gain on available-for-sale investments | 2 | — | 6 | — |
| Comprehensive loss | \$(8,150) | \$(3,777) | \$(13,348) | \$(6,326) |

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENT OF CASH FLOWS

Unaudited

(in thousands)

| | Six-month period ended | |
|---|---------------------------|------------------|
| | June 30, 2014 | June 30, 2013 |
| Cash flows from operating activities: | | |
| Net loss | \$(13,354) | \$(6,326) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 285 | 107 |
| Amortization of intangible assets | 38 | 38 |
| Amortization of investment discount | 124 | — |
| Stock-based compensation | 4,931 | 1,605 |
| Increase in assets: | | |
| Accounts receivable | (16) | (54) |
| Prepaid expense and other | (486) | (105) |
| Increase (decrease) in liabilities: | | |
| Accounts payable | 496 | 22 |
| Accrued liabilities | 197 | 42 |
| Deferred revenue and income | (20) | 495 |
| Net cash used in operating activities | \$(7,805) | \$(4,176) |
| Cash flows from investing activities: | | |
| Purchases of equipment and capitalized patents | \$(729) | \$(897) |
| Purchase of available-for-sale securities | (4,079) | — |
| Sales of available-for sale securities | 121 | — |
| Maturity of available-for-sale securities | 2,000 | — |
| Net cash used in investing activities | \$(2,687) | \$(897) |
| Cash flows from financing activities: | | |
| Issuance of common stock and warrants | \$44,980 | \$— |
| Exercise of warrants and options | 730 | 20,177 |
| Payments on capital lease obligations | (35) | — |
| Net cash provided by financing activities | \$45,675 | \$20,177 |
| Increase (decrease) in cash and cash equivalents | \$35,183 | \$15,104 |
| Cash and cash equivalents, beginning of period | 30,029 | 12,069 |
| Cash and cash equivalents, end of period | \$65,212 | \$27,173 |

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. ORGANIZATION AND NATURE OF BUSINESS; BASIS OF PRESENTATION

Accelerate Diagnostics, Inc. (“Accelerate” or the “Company”) is a Delaware corporation focused on developing and commercializing innovative instrumentation for the rapid identification and antibiotic susceptibility testing of infectious pathogens. The Company’s ID/AST instrument utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, (“U.S. GAAP”), and applicable rules and regulations of the United States Securities and Exchange Commission (“SEC”), regarding interim financial reporting. Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Therefore, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

The condensed consolidated balance sheet as of December 31, 2013 included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by U.S. GAAP.

The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, but are not necessarily indicative of the result of operations to be anticipated for the entire year ending December 31, 2014 or any future period.

All amounts are rounded to the nearest thousand dollars unless otherwise indicated.

Use of Estimates

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

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09 *Revenue from Contracts with Customers*, which will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. We are carefully evaluating our existing revenue recognition practices to determine whether any contracts in the scope of the guidance will be affected by the new requirements. The effects may include identifying performance obligations in existing arrangements, determining the transaction price and allocating the transaction price to each separate performance obligation. We will also establish practices to determine when a performance obligation has been satisfied, and recognize revenue in accordance with the new requirements. The new standard is effective for us on January 1, 2017. Early adoption is not permitted. The standard allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. We are currently evaluating the transition method that will be elected.

In July 2013, the FASB issued ASU 2013-11, which requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013. The adoption of ASU 2013-11 did not have a material impact on the Company’s consolidated financial statements.

In March 2013, the FASB issued ASU 2013-04, which provides guidance on the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. The update requires an entity to measure obligations resulting from joint and several liability obligations for which the total amount of the obligation within the scope of the update is fixed at the reporting date, as the sum of the amount the reporting entity agreed to pay on the basis of its arrangements among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. The amendments in ASU 2013-04 are effective for fiscal years and interim periods within those years, beginning on or after December 15, 2013 and must be applied retrospectively. The adoption of ASU 2013-04 did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of financial instruments such as cash equivalents, restricted cash, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company may invest its excess cash into financial instruments that are readily convertible into cash, such as marketable securities, money market funds and certificates of deposit with original maturities of three months or less at the date of purchase. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company has established guidelines to maintain safety and liquidity for our financial instruments, and the cost of securities sold is based on the specific identification method.

ASC Topic 820, Fair Value Measurements and Disclosures has redefined fair value and required the Company to establish a framework for measuring fair value and expand disclosures about fair value measurements. The framework requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

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The following tables represent the financial instruments measured at fair value on a recurring basis on the consolidated financial statements of the Company subject to *ASC Topic 820, Fair Value Measurements and Disclosure*, and the valuation approach applied to each class of financial instruments at June 30, 2014 and December 31, 2013 (in thousands):

June 30, 2014

(in thousands)

| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|--|--|---|---|--------------|
| Assets: | | | | |
| Money market funds (cash equivalents) | \$12,295 | \$— | \$— | \$12,295 |
| Corporate notes and bonds | — | 13,421 | — | 13,421 |
| Asset-backed securities | — | 379 | — | 379 |
| Total assets measured at fair value | \$12,295 | \$13,800 | \$— | \$26,095 |

December 31, 2013

(in thousands)

| | Quoted Prices in Active Markets for Identical Assets | Significant Other Observable Inputs | Significant Unobservable Inputs | Total |
|--|---|--|--|--------------|
| | (Level 1) | (Level 2) | (Level 3) | |
| Assets: | | | | |
| Money market funds (cash equivalents) | \$27,096 | \$— | \$— | \$27,096 |
| Corporate notes and bonds | — | 11,460 | — | 11,460 |
| Asset-backed securities | — | 500 | — | 500 |
| Total assets measured at fair value | \$27,096 | \$11,960 | \$— | \$39,056 |

Level 2 available-for-sale securities are priced using quoted market prices for similar instruments or nonbinding market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs. There were no significant transfers between levels during the six-month period ended June 30, 2014.

NOTE 4. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at June 30, 2014 (in thousands):

| | Amortized Costs | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---------------------------|----------------------------|---------------------------------------|--|-------------------|
| Asset-backed securities | \$379 | \$— | \$— | \$379 |
| Corporate notes and bonds | 13,393 | 29 | (1) | 13,421 |
| Total | \$13,772 | \$29 | \$(1) | \$13,800 |

The following table summarizes the maturities of the Company's available-for-sale securities at June 30, 2014 (in thousands):

| | Amortized Cost | Fair Value |
|-------------------------|---------------------------|-------------------|
| Due in less than 1 year | \$10,241 | \$10,246 |
| Due in 1-3 years | 3,531 | 3,554 |
| Total | \$13,772 | \$13,800 |

NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at June 30, 2014 and December 31, 2013 (in thousands):

| Property and Equipment (in thousands) | June 30, 2014 | December 31, 2013 |
|---|------------------|-------------------------|
| Computer equipment | \$574 | \$ 567 |
| Laboratory and scientific equipment | 943 | 791 |
| Furniture and fixtures | 206 | 37 |
| Manufacturing equipment | 6 | — |
| Leasehold improvements | 302 | 279 |
| Capital lease – leasehold improvements | 266 | — |
| Capital projects in progress | 548 | — |
| Total property and equipment | \$2,845 | \$ 1,674 |
| Accumulated amortization – capital lease | (67) | — |
| Accumulated depreciation – other | (845) | (627) |
| Net property and equipment | \$1,933 | \$ 1,047 |

Depreciation expense, which includes amortization of capital lease assets, for the three-month periods ended June 30, 2014 and 2013 was \$150,000 and \$71,000 respectively, and for the six-month periods ended June 30, 2014 and 2013, was \$285,000 and \$107,000, respectively.

NOTE 6. INTELLECTUAL PROPERTY

Intellectual property consisted of the following at the dates indicated (in thousands):

| Intellectual Property (in thousands) | June 30, 2014 | December 31, 2013 |
|--|------------------------------|----------------------------------|
| Technologies | \$ 193 | \$ 193 |
| Patents | 210 | 210 |
| Subtotal | \$403 | \$ 403 |
| Accumulated amortization | (200) | (162) |
| Net intellectual property | \$203 | \$ 241 |

Future amortization expense for the intangible assets is estimated as follows (in thousands):

| Intangible Assets Future Amortization Years Ending December 31 (in thousands) | |
|---|-------|
| Remaining in 2014 | \$25 |
| 2015 | 8 |
| 2016 | 8 |
| 2017 | 8 |
| 2018 | 8 |
| Thereafter | 146 |
| Total future amortization | \$203 |

Intellectual properties are recorded at cost and are being amortized on a straight-line basis over their estimated useful lives of 20 years or the patent application life specific to each capitalized patent. Amortization expense for the

three-month periods ended June 30, 2014 and 2013 was \$19,000 and \$19,000, respectively, and for the six-month periods ended June 30, 2014 and 2013 was \$38,000 and \$38,000, respectively. The Company routinely evaluates the recoverability of its long-lived assets based upon estimated future cash flows from and estimated fair value of such long-lived assets. If in management's judgment, the anticipated undiscounted cash flows or estimated fair value are insufficient to recover the carrying amount of the long-lived asset, the Company will determine the amount of the impairment and the value of the asset will be written down. There were no amounts recognized as losses due to impairments of intangible assets for the three-month periods ending June 30, 2014 and 2013 for the for the six-month periods ending June 30, 2014 and 2013.

NOTE 7. LICENSE AGREEMENTS AND GRANTS

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program ("DMRDP") recommended \$2 million of funding for a proposed 35-month project of which the Company estimates it will receive direct monies for internal research and development of \$650,000. The joint proposal became the sole recipient under the Military Infectious Diseases Applied Research Award program for rapid detection of serious antibiotic-resistant infections. The project will apply the Company's ID/AST instrument to wound infections and other serious infections secondary to trauma. The Company has invoiced a cumulative total of \$258,000 under this grant which is recorded as an offset to research and development expenses. The amount invoiced for the three-month periods ended June 30, 2014 and 2013 was \$60,000 and \$43,000, respectively, and for the six-month periods ended June 30, 2014 and 2013 was \$100,000 and \$54,000, respectively.

On August 22, 2012, the Company entered into a Grant Agreement (the “Grant Agreement”) with the Arizona Commerce Authority, an agency of the State of Arizona (the “Authority”), pursuant to which the Authority will provide certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the “Project”). Pursuant to the Grant Agreement, the Authority agreed to provide a total grant in the amount of \$1,000,000 (the “Grant”) for the use by the Company in the advancement of the Project. The Grant is payable out of an escrow account in four installments, upon the achievement of the following milestones:

Milestone 1 – Relocation of Company’s operations and corporate headquarters to Arizona and creation of 15 Qualified Jobs (as defined below).

Milestone 2 – Creation of 30 Qualified Jobs (including Qualified Jobs under Milestone 1).

Milestone 3 – Creation of 40 Qualified Jobs (including Qualified Jobs under Milestones 1 and 2).

Milestone 4 – Creation of 65 Qualified Jobs (including Qualified Jobs under Milestones 1, 2 and 3) and capital investment of at least \$4,520,000.

For purposes of the Grant Agreement, a “Qualified Job” is a job that is permanent, full-time, new to Arizona, and for which the Company pays average (across all Qualified Jobs identified by the Company in its discretion) annual wages of at least \$63,000 and offers health insurance benefits and pays at least 65% of the premiums associated with such benefits. The amount of each installment payment will be determined in accordance with a formula specified in the Grant Agreement. The Grant Agreement also contains other customary provisions, including representations, warranties and covenants of both parties. As of June 30, 2014 the Company has collected \$750,000 of the \$1,000,000 in milestones. The full amount is recorded in long-term deferred income until the economic development provisions of the grant have been satisfied in full, as there are “claw-back” provisions which would require repayment of certain amounts received if employment levels are not sustained during the term of the arrangement. Once the “claw-back” provisions expire, we will recognize the grant as other non-operating income. Further details are included in Note 8, Deferred Revenue and Income.

NOTE 8. DEFERRED REVENUE AND INCOME

Deferred revenue consists of amounts received for products or services not yet delivered or earned. Deferred income consists of amounts received for commitments not yet fulfilled. If we anticipate that the revenue or income will not be earned within the following twelve months, the amount is reported as long-term deferred income. A summary of the balances as of June 30, 2014 and December 31, 2013 follow (in thousands):

Deferred Revenue and Income (in thousands)

| June 30, 2014 | December 31, 2013 |
|------------------------------|----------------------------------|
|------------------------------|----------------------------------|

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| | | |
|---|-------|--------|
| Prepaid royalties | \$63 | \$ 69 |
| Fisher agreement | 13 | 13 |
| Total current deferred revenue and income | \$76 | \$ 82 |
| Arizona Commerce Authority Grant (see Note 7) | \$750 | \$ 750 |
| Fisher agreement | 13 | 27 |
| Total long-term deferred income | \$763 | \$ 777 |

Deferred revenue includes prepaid royalty fees. In September 2011, \$100,000 of prepaid royalty fees was received of which \$2,000 and \$5,000 were recognized during the three-month periods ended June 30, 2014 and 2013, respectively, and \$6,000 and \$12,000 were recognized during the six-month periods ended June 30, 2014 and 2013, respectively. Recognized amounts are reflected as licensing and royalty revenue.

Deferred income includes a \$40,000 payment received from Fisher Scientific in July 2013, of which \$13,000 and \$0 has been recognized as an offset against research and development expenses in the three-month periods ended June 30, 2014 and 2013, respectively, and \$13,000 and \$0 has been recognized as an offset against research and development expenses in the six-month periods ended June 30, 2014 and 2013, respectively. We anticipate earning \$13,000 of the remaining amount in the next twelve months and the final \$13,000 in future years.

Through June 30, 2014, \$750,000 in milestone payments from the Arizona Commerce Authority were received of which none has been recognized in income and we do not anticipate earning any of it in the next fiscal year. Further details regarding the Arizona Commerce Authority agreement are included in Note 7, License Agreements and Grants.

NOTE 9. STOCK PURCHASE

On April 20, 2012, we entered into a Securities Purchase Agreement with Abeja Ventures, LLC (“Abeja”), pursuant to which the Company agreed to sell and issue to Abeja at a purchase price of \$1.03 per share for an aggregate purchase price of \$14,420,000; (i) 14,000,000 shares of the Company’s common stock (“Common Stock”); (ii) a warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share (the “\$1.03 Warrant”); and (iii) another warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (the “\$2.00 Warrant”), with each warrant exercisable prior to the fifth anniversary of the closing of the transactions contemplated by the Securities Purchase Agreement (collectively, the “Investment”). The purchase of Common Stock and warrants pursuant to the Investment, which was consummated on June 26, 2012, qualified for equity treatment under U.S. GAAP. The respective values of the warrants and Common Stock were calculated using their relative fair values and both are classified under Contributed Capital. The value therefore recorded for the warrants was \$5,896,000 and for the Common Stock was \$8,524,000.

Both warrants were exercisable until June 26, 2017, which was the fifth anniversary of the date on which the warrants were issued. Other significant terms and conditions of the warrants are as follows:

the warrants provide for partial exercises, but they do not provide for a “cashless” exercise feature (i.e., they may only be exercised for cash);

the warrants do not contain anti-dilution provisions that would trigger exercise price or other adjustments as a result of subsequent issuances of the Company’s equity securities, but they do contain customary provisions for equitable adjustments in connection with stock dividends, stock splits or reclassifications of Common Stock;

following certain types of fundamental transactions involving the Company (e.g., a transaction resulting in a change in control of the Company), the holder of the warrants would continue to be entitled to exercise the warrants in exchange for the equity securities or alternate consideration receivable by a holder of Common Stock as a result of the fundamental transaction; and

the holder of the warrants is entitled to certain demand and piggy-back registration rights, including for shelf registrations, with respect to the shares of Common Stock issuable upon its exercise of the warrants.

On March 6, 2013, Abeja exercised in full its warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share. On the same date, Abeja also exercised the 92% of its warrant to purchase an additional 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (Abeja exercised such warrant for 6,428,840 shares, leaving 571,160 shares unexercised). The Company received aggregate funds of \$20,068,000 in connection with such exercises. Shares issued by the Company in connection with the warrant exercises were issued directly to the members of Abeja on a pro rata basis in accordance with their membership interests and written exercise instructions provided to the Company by Abeja. Immediately after giving effect to the warrant exercises, Abeja also distributed in kind to its members (on a pro rata basis in accordance with their membership interests) the remaining shares of Common Stock held by that entity.

NOTE 10. RIGHTS OFFERING

On April 7, 2014, the Company commenced a rights offering to raise \$45 million to fund continued operations, clinical trials, and product commercialization efforts. Under the terms of the rights offering, the Company distributed, at no charge to the holders of its Common Stock as of 5:00 p.m., New York City time, on March 14, 2014, which was established as the record date for the rights offering, 0.063921 non-transferable subscription rights for each share of Common Stock owned on the record date. Each whole subscription right allowed the holder to subscribe to purchase one share of Common Stock at a subscription price of \$16.80 per share. In the aggregate, the Company intended to issue 2,678,571 shares of Common Stock in connection with the rights offering. The purpose of the rights offering was to raise equity capital in a cost-effective manner that gives all of the Company's existing stockholders the opportunity to participate on a pro rata basis.

In connection with the rights offering, the Company received standby commitments from the Jack W. Schuler Living Trust and the Schuler Family Foundation. The standby purchasers agreed to purchase any and all shares of Common Stock that were not subscribed for by stockholders in connection with the rights offering. On May 1, 2014, the Company entered into an Assignment and Assumption Agreement with the standby purchasers, Oracle Institutional Partners, L.P. and Oracle Partners, L.P., pursuant to which each standby purchaser assigned and transferred its respective rights, responsibilities, liabilities and obligations under the Standby Purchase Agreement to purchase 297,619 shares of Common Stock not subscribed for by the Company's stockholders in connection with the rights offering to (i) Oracle Institutional Partners, L.P., with respect to 119,047 shares of such Common Stock, and (ii) Oracle Partners, L.P., with respect to the remaining 178,572 shares of such Common Stock.

The rights offering period expired at 5:00 p.m., New York City time, on April 28, 2014, and the transactions contemplated by the rights offering and the Standby Purchase Agreement described above (including the Company's issuance of an aggregate of 2,678,571 shares of its Common Stock to the rights offering participants and standby purchasers) were completed on May 19, 2014. The Company received gross proceeds of \$45,000,000 before costs associated with the transactions which totaled \$126,000, \$106,000 of which hasn't been paid as of June 30, 2014.

Because the exercise price of the rights offering of \$16.80 was less than the fair value of the Company's shares of Common Stock at the expiration of the offering, there is a bonus element that is treated akin to a stock dividend. The weighted average shares outstanding, as well as the basic and diluted loss per share for the three- and six-month periods ended June 30, 2013 have been revised for those effects.

NOTE 11. EARNINGS PER SHARE

The Company follows *ASC 260, Earnings Per Share*, which requires companies to present basic earnings per share and diluted earnings per share. Basic earnings (loss) per share includes no dilution and is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding for the period.

The Company's net loss for the periods presented caused the inclusion of certain outstanding warrants and options to purchase our Common Stock to be antidilutive. As of June 30, 2014 and December 31, 2013, there were Common Stock options and warrants exercisable for 6,109,600 (571,160 warrants and 5,538,440 options) and 5,731,246 (571,160 warrants and 5,160,086 options) shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

Weighted average shares outstanding for the three and six-month periods ended June 30, 2014 have been revised for the effects of the rights offering (See Note 10, Rights Offering).

NOTE 12. EMPLOYEE STOCK-BASED COMPENSATION

At the Company's 2014 Annual Meeting of Stockholders held on May 29, 2014, stockholders approved an amendment to the Company's 2012 Omnibus Equity Incentive Plan increasing the number of shares of Common Stock reserved and available for grant thereunder by 4,000,000 to 9,500,000 shares.

The following table summarizes stock-based compensation expense in the condensed consolidated statements of operations for the periods indicated (in thousands):

| | Stock-Based Compensation Expense | | | |
|--|---|-----------------|------------------------|-----------------|
| | (in thousands) | | | |
| | Three-month period ended | | Six-month period ended | |
| | June 30, | June 30, | June 30, | June 30, |
| | 2014 | 2013 | 2014 | 2013 |
| Research and development | \$1,288 | \$417 | \$2,112 | \$677 |
| Sales, general and administrative | 1,883 | 751 | 2,819 | 928 |
| Total stock-based compensation expense | \$3,171 | \$1,168 | \$4,931 | \$1,605 |

The following table summarizes option activity under all plans during the six-month period that ended on June 30, 2014:

Stock Option Activity

| | Number of Shares | Weighted Average Exercise Price per Share |
|---------------------------------------|-----------------------------|--|
| Options Outstanding December 31, 2013 | 5,160,086 | \$3.45 |
| Granted | 644,325 | \$15.58 |
| Cancelled | (10,971) | \$13.53 |
| Exercised | (255,000) | \$2.86 |
| Expired | — | — |
| Options Outstanding June 30, 2014 | 5,538,440 | \$4.87 |

The following table summarizes relevant information for options outstanding and options exercisable at June 30, 2014:

Stock Option Supplemental Information

| | Options Outstanding | Options Exercisable |
|--|----------------------------|----------------------------|
| Number of options | 5,538,440 | 1,575,651 |
| Weighted average remaining contractual term (in years) | 8.38 | 7.94 |
| Weighted average exercise price | \$4.87 | \$2.07 |
| Weighted average fair value | \$3.74 | \$1.36 |
| Aggregate intrinsic value (in thousands) | \$117,038 | \$37,711 |

The following table summarizes the weighted average assumptions used in determining the fair value of the Company's stock options granted to employees during the three-month periods ending June 30, 2014 and 2013:

Fair Value Assumptions for Stocks Issued
During the Quarter
(weighted average)

| | June 30, 2014 | June 30, 2013 |
|--------------------------|--------------------------|------------------------------|
| Expected term (in years) | 5.72 | 5.92 |
| Volatility | 97 % | 98 % |
| Expected dividends | — | — |

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| | | |
|--------------------------|---------|--------|
| Risk free interest rates | 1.93 % | 1.00 % |
| Estimated forfeitures | 3 % | 15 % |
| Fair value per share | \$15.40 | \$5.23 |

As of June 30, 2014, unrecognized share-based compensation cost related to unvested stock options was \$10,421,000.

NOTE 13. INCOME TAXES

Deferred tax assets and liabilities are recorded for the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets. The change in deferred tax assets and liabilities for the period represents the deferred tax provision or benefit for the period. Effects of changes in enacted tax laws in deferred tax assets and liabilities are reflected as an adjustment to the tax provision or benefit in the period of enactment.

The Company follows the provisions of *ASC 740, Income Taxes*, to account for any uncertainty in income taxes with respect to the accounting for all tax positions taken (or expected to be taken) on any income tax return. This guidance applies to all open tax periods in all tax jurisdictions in which the Company is required to file an income tax return. Under U.S. GAAP, in order to recognize an uncertain tax benefit the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon resolution of the benefit. The Company determined that no uncertain tax positions have been taken or are expected to be taken that could have a material effect on the Company's income tax liabilities. Interest and penalties, if any, would be recorded to general and administrative expenses.

On January 8, 2014, we were notified by the Arizona Commerce Authority ("Authority") that we meet the program requirements to receive a "Certificate of Qualification" and, therefore, are eligible for a partial refund of research and development investments. Our research and development tax credit for 2013 is \$703,000 which made us eligible to claim a partial refund of 75% or \$527,000. We claimed this partial refund and, by doing so, irrevocably forfeited the remaining 25% tax credit amount along with any additional tax credits that might become available if our qualifying expenses increase or income tax liability decreases. The "Certificate of Qualification" does not guarantee the receipt of tax incentives; nor does it obligate the Arizona Department of Revenue to issue the refund. Furthermore, if qualifying expenses decrease or income tax liability increases, the refund amount may be less than the \$527,000. If the amount received for this tax credit is later determined to be incorrect or invalid, the excess may be treated as a tax deficiency. As of March 31, 2014 we recorded the \$527,000 partial refund as a non-operating benefit from income taxes. Payment of this amount was received in April and deposited in May 2014.

NOTE 14. COMMITMENTS

Operating & Capital Lease Obligations

On August 20, 2012, the Company entered into a Lease Agreement ("Lease") with Pima County, a political subdivision of the State of Arizona ("Landlord"), pursuant to which the Company will lease approximately 15,096 square feet of office space located in Tucson, Arizona for a period of three years (the "Initial Term"), which may be extended by the Company for up to three additional one-year periods (each a "Renewal Term"). The Lease also provides that the Company has the option, with six months prior notice to Landlord, to lease either or both of two additional areas with an aggregate size of approximately 7,920 square feet.

Pursuant to the Lease, the Company agreed to: (i) pay rent equal to \$9.25 per usable square foot per year (approximately \$139,600 per year) during the Initial Term and \$19.80 per usable square foot per year (approximately \$298,900 per year) during any Renewal Term; (ii) relocate its corporate offices to the Tucson area and begin operations within 30 days of the date that the tenant improvements are substantially completed (the "Commencement Date"); and (iii) within 18 months of the Commencement Date, employ at least 30 individuals with a median salary of at least \$70,000, which median salary must be maintained throughout the term of the Lease. If the Company fails to

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satisfy the condition described in clause (iii) of the preceding sentence, the rental rate under the Lease will be increased by a percentage that is twice the percentage by which the Company's annual payroll has fallen short of the specified goal (subject to a cap equal to \$19.80 per usable square foot per year). The Lease also provides that Landlord will pay for tenant improvements (up to a cap of \$1,400,000) as well as certain repairs, utilities and insurance. As of February 1, 2013, we relocated our headquarters into the above described leased space in Tucson, Arizona.

On October 15, 2013, the Company executed the First Amendment to the Lease with Pima County to exercise its option and to expand its lease premises by 4,551 s