

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Accelerate Diagnostics, Inc
Form 10-Q
November 06, 2018

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, 2018

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-31822

ACCELERATE DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

84-1072256

(State or other jurisdiction

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

of incorporation or organization)

3950 South Country Club Road, Suite 470

Tucson, Arizona

85714

(Address of principal executive offices)

(Zip Code)

(520) 365-3100

(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 every Interactive Data File required to be submitted 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 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 file ☐

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. ☐

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

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

As of November 2, 2018, there were 54,198,743 shares of the registrant's common stock outstanding.

1

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>23</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>29</u>
<u>Item 4. Controls and Procedures</u>	<u>29</u>

Part II - OTHER INFORMATION

<u>Item 1. Legal Proceedings</u>	<u>31</u>
<u>Item 1A. Risk Factors</u>	<u>31</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>32</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>32</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>32</u>
<u>Item 5. Other Information</u>	<u>32</u>
<u>Item 6. Exhibits</u>	<u>33</u>

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ACCELERATE DIAGNOSTICS, INC.
 CONDENSED CONSOLIDATED
 BALANCE SHEET
 (in thousands, except share data)

	September 30, 2018	December 31, 2017
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$61,622	\$28,513
Investments	118,982	80,648
Trade accounts receivable	1,440	1,946
Inventory	9,406	8,063
Prepaid expenses	940	850
Other current assets	494	468
Total current assets	192,884	120,488
Property and equipment, net	7,412	4,890
Intellectual property, net	119	134
Other non-current assets	241	—
Total assets	\$200,656	\$125,512
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$1,559	\$2,080
Accrued liabilities	3,518	3,636
Accrued interest	191	—
Deferred revenue and income	202	1,071
Total current liabilities	5,470	6,787
Other long term liabilities	26	21
Convertible notes	117,754	—
Total liabilities	\$123,250	\$6,808
Commitments and contingencies		
Stockholders' equity:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 75,000,000 common shares authorized with 54,196,876 shares issued and outstanding on September 30, 2018 and 75,000,000 common shares authorized with 55,673,810 shares issued and outstanding on December 31, 2017	54	56
Contributed capital	430,734	360,620
Treasury Stock	(45,067)	—
Accumulated deficit	(308,156)	(241,972)

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Accumulated other comprehensive loss	(159	)—
Total stockholders' equity	77,406	118,704
Total liabilities and stockholders' equity	\$200,656	\$125,512

See accompanying notes to condensed consolidated financial statements.

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

Unaudited

(in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September	September	September	September
	30,	30,	30,	30,
	2018	2017	2018	2017
Net sales	\$1,355	\$828	\$3,848	\$2,058
Cost of sales	680	191	1,889	352
Gross profit	675	637	1,959	1,706
Costs and expenses:				
Research and development	7,891	6,351	20,734	16,166
Sales, general and administrative	12,153	11,601	41,835	33,589
Total costs and expenses	20,044	17,952	62,569	49,755
Loss from operations	(19,369)	(17,315)	(60,610)	(48,049)
Other income (expense):				
Interest expense	(3,357)	—	(6,720)	—
Foreign currency exchange loss	(133)	(40)	(331)	(73)
Interest income	908	323	1,983	612
Other income (expense), net	—	2	(25)	(3)
Total other income (expense), net	(2,582)	285	(5,093)	536
Net loss before income taxes	(21,951)	(17,030)	(65,703)	(47,513)
Provision for income taxes	(147)	(45)	(432)	(220)
Net loss	\$(22,098)	\$(17,075)	\$(66,135)	\$(47,733)
Basic and diluted net loss per share	\$(0.41)	\$(0.31)	\$(1.21)	\$(0.89)
Weighted average shares outstanding	54,145	55,316	54,591	53,603
Other comprehensive loss:				
Net loss	\$(22,098)	\$(17,075)	\$(66,135)	\$(47,733)
Net unrealized (loss) gain on available-for-sale investments	1	(7)	(54)	(4)
Foreign currency translation adjustment	(26)	91	(105)	295
Comprehensive loss	\$(22,123)	\$(16,991)	\$(66,294)	\$(47,442)

See accompanying notes to condensed consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENTS OF CASH FLOWS
Unaudited
(in thousands)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
Cash flows from operating activities:		
Net loss	\$(66,135)	\$(47,733)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,734	1,595
Amortization of intangible assets	15	9
Amortization of investment discount	(413)	)298
Equity-based compensation	12,476	10,970
Amortization of debt discount and issuance costs	4,529	—
Loss on disposal of property and equipment	540	3
(Increase) decrease in assets:		
Accounts receivable	506	(1,077)
Inventory	(5,206)	)(7,079)
Prepaid expense and other	55	(392)
Other current assets	(26)	)(277)
Other non-current assets	(241)	)—
Increase (decrease) in liabilities:		
Accounts payable	(524)	)359
Accrued liabilities	(18)	)780
Accrued interest	191	—
Deferred revenue and income	(918)	)46
Deferred compensation	5	—
Net cash used in operating activities	(53,430)	)(42,498)
Cash flows from investing activities:		
Purchases of equipment	(842)	)(2,055)
Purchases of available-for-sale securities	(115,634)	)(68,423)
Sales of available-for-sale securities	3,000	9,522
Maturity of available-for-sale securities	74,496	30,049
Net cash used in investing activities	(38,980)	)(30,907)
Cash flows from financing activities:		
Issuance of common stock net of issuance costs	447	83,741
Exercise of options and warrants	3,710	4,562
Proceeds from issuance of convertible note	171,500	—
Prepayment of forward stock repurchase transaction	(45,069)	)—
Payment of debt issuance costs	(4,992)	)—
Net cash provided by financing activities	125,596	88,303
Effect of exchange rate on cash	(77)	)289
Increase in cash and cash equivalents	33,109	15,187
Cash and cash equivalents, beginning of period	28,513	19,244
Cash and cash equivalents, end of period	\$61,622	\$34,431
Non-cash investing activities:		

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Transfer of instruments from inventory to property and equipment	\$4,061	\$—
Supplemental cash flow information:		
Interest paid	\$2,001	\$—
Income taxes paid	\$435	\$—

See accompanying notes to condensed consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

NOTE 1. ORGANIZATION AND NATURE OF BUSINESS; BASIS OF PRESENTATION; PRINCIPLES OF CONSOLIDATION; SIGNIFICANT ACCOUNTING POLICIES

Accelerate Diagnostics, Inc. (“we” or “us” or “our” or “Accelerate” or “the Company”) is an in vitro diagnostics company dedicated to providing solutions that improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“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, 2017, as filed with the SEC on March 1, 2018.

The condensed consolidated balance sheet as of December 31, 2017 included herein was derived from the audited financial statements as of that date, but does not include all disclosures such as 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 presented, but are not necessarily indicative of the results of operations to be anticipated for the entire year ending December 31, 2018, or any future period.

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances.

Use of Estimates

The preparation of the Company’s consolidated financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions relate to accounts receivable, inventories, property and equipment, intangible assets, accruals, warranty liabilities, tax valuation accounts and stock-based compensation. Actual results could differ materially from those estimates.

Estimated Fair Value of Financial Instruments

The Company follows Accounting Standards Codification (“ASC”) Topic 820, Fair Value Measurements, which has defined fair value and requires the Company to establish a framework for measuring fair value and disclose 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).

The carrying amounts of financial instruments such as cash and cash equivalents, trade accounts receivable, prepaid expenses, other current assets, accounts payable, accrued liabilities, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments.

The estimated fair value of the Company's long-term debt represents a Level 2 measurement. See Note 11, Convertible Notes for further detail on the Company's long-term debt.

Cash and Cash Equivalents

All highly liquid investments with an original maturity of three months or less at time of purchase are considered to be cash equivalents. Cash and cash equivalents include overnight repurchase agreement accounts and other investments. As part of our cash management process, excess operating cash is invested in overnight repurchase agreements with our bank. Repurchase agreements and other investments classified as cash and cash equivalents are not deposits and are not insured by the U.S. Government, the FDIC or any other government agency and involve investment risk including possible loss of principal. We believe however, that the market risk arising from holding these financial instruments is minimal.

Investments

The Company invests excess funds in various investments which are primarily held in the custody of major financial institutions. Investments consist of certificates of deposit, debt securities in U.S. government and agency securities, commercial paper, asset-backed securities and corporate notes and bonds. Management classifies its investments as available-for-sale investments and records these investments in the condensed consolidated balance sheet at fair value. The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs. Unrealized gains or losses for available-for-sale securities are included in accumulated other comprehensive income (loss), a component of stockholders' equity. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

The Company assesses whether an other-than-temporary impairment loss has occurred due to declines in fair value or other market conditions when an investment's fair value remains less than its cost for more than twelve months. This assessment includes a determination of whether the investment is expected to recover in value and whether the Company has the intent and ability to hold the investment until the anticipated recovery in value occurs. When an investment is identified as having an other-than-temporary impairment loss, we adjust the cost basis of the investment down to fair value resulting in a realized loss. The new cost basis is not changed for subsequent recoveries in fair value and temporary future increases or decreases in fair value are included in other comprehensive income (loss).

Inventory

The Company writes down its inventory for estimated obsolescence or in an amount equal to the difference between the cost of inventory and the estimated net realizable value based upon assumptions about future demand, market conditions and, where applicable, product expiration.

Accounts Receivable

Accounts receivable consist of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. Allowances on accounts receivable are recorded when circumstances indicate collection is doubtful for a particular accounts receivable. Receivables are written off if reasonable collection efforts prove unsuccessful. The Company provides for allowances on a specific account basis.

The Company has not included an allowance for doubtful accounts as of September 30, 2018 and December 31, 2017, due to no circumstances arising that would indicate collection of any particular or grouping of customer accounts receivable is doubtful.

Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and expenditures for major improvements are capitalized. Gains and losses from retirement or replacement are included in costs and expenses. Depreciation of property and equipment is computed using the straight-line method over the estimated useful life of the assets, ranging from one to seven years. Leasehold improvements are depreciated over the remaining life of the lease or the life of the asset, whichever is less. Property and equipment includes diagnostic instruments used for sales demonstrations, evaluations, and instruments under rental agreements. The Company retains title to the instruments under these arrangements.

Long-lived Assets

Long-lived assets and certain identifiable intangibles to be held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company continuously evaluates the recoverability of its long-lived assets based on estimated future cash flows from and the estimated fair value of such long-lived assets, and provides for impairment if such undiscounted cash flows or the estimated fair value are insufficient to recover the carrying amount of the long-lived asset.

Warranty Reserve

Instruments are typically sold with a one year limited warranty, while kits and accessories are typically sold with a 60 days limited warranty. Accordingly, a provision for the estimated cost of the limited warranty repair is recorded at the time revenue is recognized. Our estimated warranty provision is based on historical and anticipated rates of warranty repairs. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary. The expense incurred for these provisions is included in cost of sales on the condensed consolidated statements of operations and comprehensive loss.

Warranty reserve activity for the three and nine months ended September 30, 2018 and 2017 is as follows (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Beginning balance	\$ 199	\$ 61	\$ 192	\$ 1
Provisions	128	62	394	143
Warranty incurred	(138)	(34)	(397)	(55)
Ending balance	\$ 189	\$ 89	\$ 189	\$ 89

Convertible Notes

The Company issued convertible notes that had conversion prices which resulted in an embedded beneficial conversion feature. The intrinsic value of the beneficial conversion feature was recorded as a debt discount with the corresponding amount recorded to contributed capital. The debt discount is amortized to interest expense over the life

of the convertible notes using the effective interest method.

Revenue Recognition

Effective January 1, 2018, the Company adopted the requirements of ASC 606, Revenue from Contracts with Customers, ("Topic 606") and recognizes revenue when control of the promised good or service is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Sales taxes are excluded from revenues.

We determine revenue recognition through the following steps:

- 1. Identification of the contract with a customer
- 2. Identification of the performance obligations in the contract
- 3. Determination of the transaction price
- 4. Allocation of the transaction price to the performance obligations
- 5. Recognition of revenue as we satisfy a performance obligation

Product revenue is derived from the sale or rental of our instruments and sales of related consumable products. When an instrument is sold, revenue is generally recognized upon installation of the unit consistent with contract terms, which do not include a right of return. When a consumable product is sold, revenue is generally recognized upon shipment. Invoices are generally issued when revenue is recognized.

Service revenue is derived from the sale of extended service agreements which are generally non-cancellable. This revenue is recognized on a straight-line basis over the contract term beginning on the effective date of the contract because the Company is standing ready to provide services. Invoices are generally issued annually and coincide with the beginning of individual service terms.

Our contracts with customers may include multiple performance obligations. For such arrangements, we allocate revenue to each performance obligation based on its relative standalone selling price. We generally determine relative standalone selling prices based on the price charged to customers for each individual performance obligation.

We also provide instruments to customers under bundled rental agreements. Under these agreements, we install the instrument in the customer's facility and provide service. The customer agrees to purchase consumable products at a stated price over the term of the agreement, which is typically five years or less. Contracts sometimes have renewal clauses but such clauses do not provide for a bargain renewal option or penalize the customer if they do not renew. The instrument remains the Company's property throughout the term of the agreement and there is no transfer of title upon expiration.

Our payment terms vary by the type and location of our customers and the product or services offered and typically range between 30 and 60 days.

Sales commissions earned by our sales force are considered incremental and recoverable costs of obtaining a contract with a customer. The Company has determined these costs would have an amortization period of less than one year and has elected to recognize them as an expense when incurred. Contract asset opening and closing balances were immaterial for the quarter ended September 30, 2018.

The Company adopted Topic 606 using the modified retrospective method applied to those contracts that were not fully performed by the Company as of January 1, 2018. We recorded a decrease to opening retained earnings and an increase in deferred revenue of \$49,000 as of January 1, 2018 due to the cumulative impact of adopting Topic 606. The impact to revenues for the three and nine months ended September 30, 2018 was not material as a result of applying Topic 606. The reported results for 2017 and prior were prepared and are presented under the guidance of ASC 605, Revenue Recognition.

Cost of Sales

Cost of sales consists of raw materials, depreciation, direct labor and stock-based compensation expense, manufacturing overhead, facility costs and warranty costs.

Shipping and Handling

Shipping and handling costs billed to customers are included as a component of revenue. The corresponding expense incurred with third party carriers is included as a component of sales, general and administrative costs on the condensed consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for leases in accordance with ASC 840, Leases, which requires leases to be classified as either operating or capital leases. In general, the Company classifies leases as capital leases when there is either a transfer of ownership at the end of the lease term, the lease contains a bargain purchase option, the lease term is seventy-five percent or more of the estimated economic life of the leased property or the minimum lease payments are ninety percent or more of the fair value of the leased property at lease inception. The Company has entered into bundled rental agreements that qualify as sales-type leases. In those instances, the present value of the minimum lease payments, computed at the interest rate implicit in the lease, is recorded as the sales price and a lease investment is recorded in current and non-current assets. Other leases are classified as operating leases.

Operating lease rent is recorded as an operating expense on a monthly basis. For capital leases, both an asset and liability are recorded at the inception of the lease based on the present value of lease payments. The asset is included with property and equipment on the condensed consolidated balance sheet and amortization is recorded on a straight-line basis over the term of the lease with the amortization expense included with depreciation on the statements of operations and comprehensive loss. For the liability, the amount due within the next year is recorded as a current liability and the amount due in more than a year is recorded as a long-term liability on the condensed consolidated balance sheet. Interest expense is recorded based on the implicit or explicit interest rate used in the lease and is included as non-operating interest expense on the statements of operations and comprehensive loss. As of September 30, 2018 and December 31, 2017, the Company did not carry any capital leases.

Equity-Based Compensation

The Company may award stock options, restricted stock units, performance-based options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period for each tranche (an accelerated attribution method) except for performance-based options. Performance-based stock options vest based on the achievement of performance targets. Compensation costs associated with performance-based option awards are recognized over the requisite service period based on probability of achievement. Performance-based stock options require management to make assumptions regarding the likelihood of achieving performance targets.

The Company estimates the fair value of service based and performance based stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

The Company records the fair value of restricted stock units or stock grants based on published closing market price on the day before the grant date.

Income Taxes and Deferred Tax Assets

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 condensed consolidated 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 determine it is more likely than not certain that its tax position will be sustained, and the measurement of the benefit is calculated as the largest amount that is more likely than not to be realized upon resolution of the position. Interest and penalties, if any, would be recorded within tax expense.

Foreign Currency Translation and Foreign Currency Transactions

The Company follows ASC 830, Foreign Currency Matters, which provides guidance on foreign currency transactions and translation of financial statements. Adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive income (loss) in the consolidated statements of stockholders' equity.

The Company has assets and liabilities, including receivables and payables, which are denominated in currencies other than their functional currency. These balance sheet items are subject to re-measurement, the impact of which is recorded in foreign currency exchange gain and loss, within the condensed consolidated statements of operations and comprehensive loss.

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. Diluted earnings per share are computed similarly to basic earnings (loss) per share except the denominator includes additional common shares that would have been outstanding if notes convertible at the balance sheet date were converted and share-based payments had been issued. Diluted earnings are not presented when the effect of adding such additional common shares is antidilutive.

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 modifies the disclosure requirements for fair value measurements. This ASU is effective for us on January 1, 2020, with early adoption permitted. We are currently assessing the impact this will have on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718); Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 simplifies the accounting for share-based payments made to nonemployees so the accounting for such payments is substantially the same as those made to employees. Under this ASU, share-based awards to nonemployees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to ASC 718 upon vesting, which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. We do not anticipate this update will have an effect on our consolidated financial statements because all share-based awards granted to nonemployees are fully vested.

In March 2018, the FASB issued ASU 2018-05, Income Taxes (Topic 740); Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. ASU 2018-05 provides guidance regarding the recording of tax impacts where uncertainty exists, in the period of adoption of the 2017 U.S. Tax Cuts and Jobs Act (the "Tax Act"). In accordance with this guidance, the Company's financial results reflect provisional amounts for those specific income tax effects of the Tax Act for which the accounting under ASC 740 is incomplete but a reasonable estimate could be determined. During the nine months ended September 30, 2018, the Company did not recognize any changes to the provisional amounts recorded in its 2017 Annual Report on Form 10-K in connection with the Tax Act. Additionally, the Company filed its 2017 U.S. income tax return in the fourth quarter of 2018.

In February 2018, the FASB issued ASU 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220); Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (AOCI). ASU 2018-02

allows a reclassification from accumulated other comprehensive income to retained earnings for tax effects resulting from the Tax Act that the FASB refers to as having been stranded in AOCI. This ASU is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2018, with early adoption permitted. The Company is evaluating the impact of the adoption of the ASU on our consolidated financial statements, though its effects are not expected to be material.

In March 2017, the FASB issued ASU 2017-08, Receivable - Nonrefundable Fees and Other Costs (Topic 310-20); Premium Amortization on Purchased Callable Debt Securities. ASU 2017-08 shortens the amortization period for certain callable debt securities held at a premium. Specifically, the amendment requires premiums to be amortized to the earliest call date. The amendments do not require an accounting change for securities held at a discount; the discount continues to be amortized to maturity. This ASU is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. If an entity early adopts in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments should be applied on a modified retrospective basis, with a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently assessing the impact this will have on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740); Intra-Entity Transfers of Assets Other Than Inventory. ASU 2016-16 is effective for periods after December 15, 2017 and eliminates the requirement that the Company recognize the income tax consequences of an intra-entity transfer of an asset upon transfer other than inventory, eliminating the current recognition requirement. The Company adopted this ASU on January 1, 2018. In adopting this ASU, the Company recorded no cumulative-effect adjustment to retained earnings at January 1, 2018. As the U.S. and the consolidated group are in a net operating loss position, no prepaid tax has been recorded.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments. ASU 2016-13 amends the guidance on measuring credit losses on financial assets (including trade accounts receivable and available for sale debt securities) held at amortized cost. Currently, an “incurred loss” methodology is used for recognizing credit losses which delays recognition until it is probable a loss has been incurred. The amendment requires assets valued at amortized cost to be presented at the net amount expected to be collected using an allowance for credit losses. Reversal of credit losses on available for sale debt securities will be recorded in the current period net income. This ASU is effective for us on January 1, 2020, with early adoption permitted. We do not anticipate this guidance will have a significant impact on our consolidated financial statements and plan to adopt on the effective date.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The FASB also issued several subsequent updates to provide improvements to ASC 842. ASC 842 amends the existing accounting standards for leases to increase transparency and comparability among organizations. The new guidance requires a lessee to recognize a lease right-of-use asset and related lease liability for most leases, including those classified as operating leases under current U.S. GAAP. ASC 842 also changes the definition of a lease and requires expanded quantitative and qualitative disclosures for both lessees and lessors. Accounting by lessors will remain largely similar to existing U.S. GAAP. The Company plans to adopt ASC 842 on January 1, 2019 using the modified retrospective approach, and the Company will recognize a cumulative-effect adjustment to the opening balance of retained earnings in the earliest period presented in its financial statements. The Company is in the process of evaluating the impact the adoption of ASC 842 will have on its financial statements, and the Company expects the most significant changes will be the recognition of right-of-use assets and lease liabilities on the Company’s consolidated financial statements for its facilities. We do not expect the new guidance to have any significant impact on our earnings or cash flows.

In January, 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Topic 825); Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-01 requires equity investments, with some exceptions, be measured at fair value with valuation changes recognized in net income, simplifies the impairment assessment of some equity investments, eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value for financial instruments measured at amortized cost, requires the use of the exit price notion when measuring the fair value of financial instruments, requires separate presentation of some changes in other comprehensive income, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets, and clarifies the need for a valuation allowance on some deferred

tax assets. The Company adopted this ASU on January 1, 2018, and the adoption did not have a material impact on the Company's consolidated financial statements.

NOTE 3. FDA CLEARANCE

On February 23, 2017, the U.S. Food and Drug Administration ("FDA") granted Accelerate's de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC Kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples.

Due to various factors, the Company manufactured inventory in advance of regulatory approval (“pre-launch inventory”). On January 1, 2017, the regulatory review process had progressed to a point that objective and persuasive evidence of approval was sufficiently probable, and a future economic benefit existed. On January 1, 2017, the Company started capitalizing pre-launch inventory.

NOTE 4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018			
	Quoted			
	Prices			
	in	Significant	Significant	
	Active	Other	Unobservable	Total
	Markets	Observable	Inputs	
	for	Inputs	(Level 3)	
	Identical	(Level 2)		
	Assets			
	(Level			
	1)			
Assets:				
Cash and cash equivalents:				
Money market funds	\$27,160	\$ —	\$	—\$27,160
Commercial paper	—	2,644	—	2,644
Asset-backed securities	—	3,001	—	3,001
Total cash and cash equivalents	\$27,160	\$ 5,645	\$	—\$32,805
Investments:				
Certificates of deposit	—	12,481	—	12,481
U.S. Treasury securities	34,268	—	—	34,268
U.S. Agency securities	—	7,951	—	7,951
Commercial paper	—	18,456	—	18,456
Asset-backed securities	—	11,967	—	11,967
Corporate notes and bonds	—	33,859	—	33,859
Total investments	34,268	84,714	—	118,982
Total assets measured at fair value	\$61,428	\$ 90,359	\$	—\$151,787

	December 31, 2017			
	Quoted			
	Prices			
	in	Significant	Significant	
	Active	Other	Unobservable	Total
	Markets	Observable	Inputs	
	for	Inputs	(Level 3)	
	Identical	(Level 2)		
	Assets			
	(Level			
	1)			

Assets:

Cash and cash equivalents:

Money market funds	\$7,832	\$ —	\$	—\$7,832
--------------------	---------	------	----	----------

Investments:

Certificates of deposit	—	13,441	—	13,441
U.S. Treasury securities	14,716	—	—	14,716
U.S. Agency securities	—	8,459	—	8,459
Commercial paper	—	9,171	—	9,171
Asset-backed securities	—	3,025	—	3,025
Corporate notes and bonds	—	31,836	—	31,836
Total investments	14,716	65,932	—	80,648
Total assets measured at fair value	\$22,548	\$ 65,932	\$	—\$88,480

Highly liquid investments with an original maturity of three months or less at time of purchase are included in

cash and cash equivalents on the condensed consolidated balance sheet.

Level 1 assets are priced using quoted prices in active markets for identical assets which include money market funds and U.S. Treasury securities as these specific assets are liquid.

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 transfers between levels during the nine months ended September 30, 2018.

On March 27, 2018, the Company issued \$150.0 million aggregate principal amount of 2.50% Convertible Senior Notes due 2023 ("Notes"). In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional \$22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in \$21.5 million of additional proceeds, for total proceeds of \$171.5 million, as described in Note 11, Convertible Notes. The calculated fair value of the Notes, of \$162.9 million, is highly correlated to the Company's stock price and as a result, significant changes to the Company's stock price will have a significant impact on the calculated fair value of the Notes. The fair value of the Notes are classified as Level 2 within the fair value hierarchy.

NOTE 5. CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable, including receivables from major customers.

The Company has financial institutions for banking operations that hold 10% or more of the Company's cash and cash equivalents. As of September 30, 2018, three of the Company's financial institutions held 57%, 31% and 12% of the Company's cash and cash equivalents, respectively. As of December 31, 2017, two of the Company's financial institutions held 82% and 12% of the Company's cash and cash equivalents, respectively.

The Company grants credit to domestic and international clients in various industries. Exposure to losses on accounts receivable is principally dependent on each client's financial position. The Company had two customers that accounted for 18% and 13% of the Company's net accounts receivable balance as of September 30, 2018, and one customer that accounted for 24% of the Company's net accounts receivable balance as of December 31, 2017.

Customers who represented 10% or more of the Company's total revenue for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2017		Three Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Company A	17%	*		*	*
Company B	18%	*		*	*
Company C	20%	*		*	*
Company D	*	10%		*	22%
Company E	*	12%		*	*

Company F *	16%	*	*
Company G *	19%	*	*
Company H *	20%	*	15%

* Less than 10% for the period indicated

NOTE 6. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	\$12,481	\$ —	\$ —	\$12,481
U.S. Treasury securities	34,390	—	(122)	34,268
U.S. Agency securities	8,017	—	(66)	7,951
Commercial paper	18,456	—	—	18,456
Asset-backed securities	11,968	—	(1)	11,967
Corporate notes and bonds	33,916	2	(59)	33,859
Total	\$119,228	\$ 2	\$ (248)	\$118,982

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	\$13,441	\$ —	\$ —	\$13,441
U.S. Treasury securities	14,787	—	(71)	14,716
U.S. Agency securities	8,510	—	(51)	8,459
Commercial paper	9,171	—	—	9,171
Asset-backed securities	3,026	—	(1)	3,025
Corporate notes and bonds	31,906	—	(70)	31,836
Total	\$80,841	\$ —	\$ (193)	\$80,648

The following table summarizes the maturities of the Company's available-for-sale securities at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018		December 31, 2017	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	\$93,971	\$93,825	\$55,801	\$55,735
Due in 1-3 years	25,257	25,157	25,040	24,913
Total	\$119,228	\$118,982	\$80,841	\$80,648

Proceeds from sales of marketable securities (including principal paydowns), for the three months ended September 30, 2018 and 2017 were \$0 and \$3.0 million, respectively, and for the nine months ended September 30, 2018 and 2017 were \$3.0 million and \$9.5 million, respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no realized gains from sales of marketable securities for the three and nine months September 30, 2018 and 2017. No balances were reclassified out of accumulated other comprehensive income (loss) for the three and nine months September 30, 2018 and 2017.

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses as of September 30, 2018 and December 31, 2017 are temporary in nature because the change in market value

for those securities has resulted from fluctuating interest rates rather than a deterioration of the credit worthiness of the issuers. The Company does not intend to sell investments and it is more likely than not that we will not be required to sell investments before recovering the amortized cost.

NOTE 7. INVENTORY

Inventories consisted of the following at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	\$ 4,819	\$ 4,220
Work in process	1,144	377
Finished goods	3,443	3,466
Inventory	\$ 9,406	\$ 8,063

NOTE 8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Computer equipment	\$ 2,801	\$ 2,756
Technical equipment	3,820	3,348
Facilities	4,006	3,621
Instruments	4,821	1,400
Capital projects in progress	107	349
Total property and equipment	\$ 15,555	\$ 11,474
Accumulated depreciation	(8,143)	(6,584)
Property and equipment, net	\$ 7,412	\$ 4,890

Depreciation expense for the three months ended September 30, 2018 and 2017 was \$662,000 and \$550,000, respectively, and for the nine months ended September 30, 2018 and 2017 was \$1.7 million and \$1.6 million, respectively.

During the nine months ended September 30, 2018, \$1.9 million of systems in the field were reclassified out of inventory and into property and equipment, which included \$1.2 million of systems in the field as a component of inventory at June 30, 2018. These transfers were the result of a change in the Company's principal model for instrument acquisition from outright sales of systems to placing systems with customers and recovering that cost through the sale of test kits pursuant to reagent rental agreements. The reclassification from inventory to property and equipment did not have an effect on prior period net income, and the systems will be depreciated going forward.

NOTE 9. LICENSE AGREEMENTS AND GRANTS

National Institute of Health Grant

In February 2015, the National Institute of Health awarded Denver Health and the Company a five-year, \$5.0 million grant to develop a fast and reliable identification and categorical susceptibility test for carbapenem-resistant Enterobacteriaceae directly from whole blood. The cumulative amount awarded to date under these subawards is \$1.1 million. The amounts invoiced for the three months ended September 30, 2018 and 2017 were \$69,000 and \$180,000, respectively, and for the nine months ended September 30, 2018 and 2017 were \$167,000 and \$183,000, respectively.

Arizona Commerce Authority

In August 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 provided certain state and county sponsored incentives for the Company relocating its corporate headquarters to, and expanding

its business within, the State of Arizona (the “Project”). Pursuant to the Grant Agreement, the Authority provided a total grant in the amount of \$1.0 million (the “Grant”). The Grant was paid 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 \$4.5 million.

For purposes of the Grant Agreement, a “Qualified Job” was a job which was permanent, full-time, new to Arizona and for which the Company paid an average annual wage of at least \$63,000 and included health insurance benefits, for which the Company paid at least 65% of the premiums. The Grant Agreement also contained other customary provisions, including representations, warranties and covenants of both parties. As of December 31, 2017, the full amount was collected and recorded in current deferred revenue and income.

In January 2018, the full amount was recognized due to the economic development provisions of the grant being satisfied in full, and the “claw-back” provisions expiring. The \$1.0 million was recognized as an offset to expense. Further details are included in Note 10, Deferred Revenue, Income and Remaining Performance Obligations.

NOTE 10. DEFERRED REVENUE, INCOME AND REMAINING PERFORMANCE OBLIGATIONS

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 September 30, 2018 and December 31, 2017 follows (in thousands):

	September 30, 2018	December 31, 2017
Products and services not yet delivered	\$ 202	\$ 71
Arizona Commerce Authority grant	—	1,000
Deferred revenue and income	\$ 202	\$ 1,071

We recognized \$30,000 and \$65,000 of revenues that were included in the contract liabilities balances during the three and nine months ended September 30, 2018, respectively. No material amount of revenue recognized during the period was from performance obligations satisfied in prior periods.

Transaction Price Allocated to Remaining Performance Obligations

As of September 30, 2018, \$1.4 million of revenue is expected to be recognized from remaining performance obligations. This balance primarily relates to executed, service contracts that begin as warranty periods expire. These contracts typically provide for four-year terms and revenue is recognized on a straight-line basis over the contract term.

The Company elects not to disclose the value of unsatisfied performance obligations for (i) contracts with an expected length of one year or less and (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for services performed.

NOTE 11. CONVERTIBLE NOTES

On March 27, 2018, the Company issued \$150.0 million aggregate principal amount of 2.50% Senior Convertible Notes due 2023. In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional \$22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in \$21.5 million of additional proceeds, for total proceeds of \$171.5 million. The Notes are the Company's senior unsecured obligations and mature on March 15, 2023 (the "Maturity Date"), unless earlier repurchased or converted into shares of common stock under certain circumstances described below. The Notes are convertible into shares of the Company's common stock, can be repurchased for cash, or a combination thereof, at the Company's election, at an initial conversion rate of 32.3428 shares of common stock per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$30.92 per share of common stock, subject to adjustment. The Company will pay interest on the Notes semi-annually in arrears on March 15 and September 15 of each year.

The \$171.5 million of proceeds received from the issuance of the Notes were allocated between long-term debt (the "liability component") of \$116.6 million and contributed capital (the "equity component") of \$54.9 million. The fair value of the liability component was measured using rates determined for similar debt instruments without a conversion feature. The carrying amount of the equity component, representing the conversion option, was determined by deducting the fair value of the liability component from the aggregate face value of the Notes. The liability component will be accreted up to the face value of the Notes of \$171.5 million, which will result in additional non-cash interest expense being recognized through the Maturity Date. The equity component will not be remeasured as long as it continues to meet the conditions for equity classification.

The Company incurred approximately \$5.0 million of issuance costs related to the issuance of the Notes, of which \$3.4 million and \$1.6 million were recorded to long-term debt and contributed capital, respectively. The \$3.4 million of issuance costs recorded as long-term debt on the condensed consolidated balance sheet are being amortized over the five-year contractual term of the Notes using the effective interest method. The effective interest rate on the Notes, including accretion of the Notes to par and debt issuance cost amortization, is 11.52%.

The Notes include customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately. Holders have the option to convert the Notes in multiples of \$1,000 principal amount at any time prior to December 15, 2022, but only in the following circumstances:

- if the Company's stock price exceeds 130% of the conversion price for 20 of the last 30 trading days of any calendar quarter after June 30, 2018;
- during the 5 business day period after any 5 consecutive trading day period in which the Notes' trading price is less than 98% of the product of the common stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger or liquidation.

At any time on or after December 15, 2022, a holder may convert its Notes in multiples of \$1,000 principal amount. Holders of the Notes who convert their Notes in connection with a make-whole fundamental change (as defined in the Indenture pursuant to which the Notes were issued) are, under certain circumstances, entitled to an increase in the conversion rate. In addition, in the event of a fundamental change or event of default prior to the Maturity Date, holders will, subject to certain conditions, have the right, at their option, to require the Company to repurchase for cash all or part of the Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest up to, but excluding, the repurchase date.

As of September 30, 2018, the outstanding principal amount on the Notes was \$171.5 million, the unamortized debt discount was \$50.6 million, the unamortized debt issuance cost was \$3.1 million and the net carrying amount of the liability component was \$117.8 million, which was recorded as convertible notes within the condensed consolidated balance sheet. The Company recorded \$1.1 million and \$2.2 million for contractual coupon interest for the three and nine months ended September 30, 2018, respectively. The Company made its first cash interest expense payment in September 2018 for \$2.0 million. The Company also recorded \$131,000 and \$264,000 for amortization of debt issuance costs for the three and nine months ended September 30, 2018, respectively, and \$2.1 million and \$4.3 million for amortization of the debt discount for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, no Notes were convertible pursuant to their terms.

In connection with the debt issuance, the Company entered into a prepaid forward stock repurchase transaction (“Prepaid Forward”) with a financial institution (“Forward Counterparty”). Pursuant to the Prepaid Forward, the Company used approximately \$45.1 million of the net proceeds from its issuance of the Notes to fund the Prepaid Forward. The aggregate number of shares of the Company’s common stock underlying the Prepaid Forward was approximately 1,858,500. The expiration date for the Prepaid Forward is March 15, 2023, although it may be settled earlier in whole or in part. Upon settlement of the Prepaid Forward, at expiration or upon any early settlement, the Forward Counterparty will deliver to the Company the number of shares of common stock underlying the Prepaid Forward or the portion thereof being settled early. The shares purchased under the Prepaid Forward are treated as treasury stock and not outstanding for purposes of the calculation of basic and diluted earnings per share, but will remain outstanding for corporate law purposes, including for purposes of any future stockholders’ votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to the Company. The Company’s Prepaid Forward hedge transaction exposes the Company to credit risk to the extent that its counterparty may be unable to meet the terms of the transaction. The Company mitigates this risk by limiting its counterparty to a major financial institution.

NOTE 12. EARNINGS 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 at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Shares issuable upon the release of restricted stock awards	66	24
Shares issuable upon exercise of stock options	8,182	7,328
	8,248	7,352

NOTE 13. EMPLOYEE EQUITY-BASED COMPENSATION

The following table summarizes option activity under all plans during the nine-month period ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price per Share
Options Outstanding January 1, 2018	7,328,131	\$ 10.16
Granted	1,355,371	24.70
Forfeited	(131,226)	21.35
Exercised	(351,626)	10.55
Expired	(18,266)	24.24
Options Outstanding September 30, 2018	8,182,384	\$ 12.34

The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of options awarded during the periods shown below:

	Three Months Ended September 30,		
	2018	2017	
Expected term (in years)	5.53	6.46	
Volatility	58	% 74	%
Expected dividends	—	—	
Risk free interest rates	2.75	% 2.02	%
Weighted average fair value	\$ 11.48	\$ 15.74	

The following table shows summary information for outstanding options and options that are exercisable (vested) as of September 30, 2018:

	Options Outstanding	Options Exercisable
Number of options	8,182,384	5,751,558
Weighted average remaining contractual term (in years)	6.05	4.95
Weighted average exercise price	\$ 12.34	\$ 8.26
Weighted average fair value	\$ 8.57	\$ 5.83
Aggregate intrinsic value (in thousands)	\$ 91,273	\$ 85,694

The following table summarizes restricted stock unit and restricted stock award activity during the nine-month period ending September 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding January 1, 2018	24,150	\$ 26.45
Granted	50,000	20.80
Forfeited	—	—
Vested/released	(8,050)	26.45
Outstanding September 30, 2018	66,100	22.18

Equity-based compensation is summarized below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	\$68	\$ 22	\$172	\$ 44
Research and development	1,476	994	3,926	2,886

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Sales, general and administrative	1,921	2,504	8,378	8,040
Equity-based compensation expense	\$3,465	\$ 3,520	\$ 12,476	\$ 10,970

As of September 30, 2018 and 2017, \$380,000 and \$262,000 of equity-based compensation expense was included as a component of capitalized inventory, respectively. As of September 30, 2018 and 2017, \$170,000 and \$33,000 of equity-based compensation expense was included as a component of capitalized property and equipment, respectively.

As of September 30, 2018, unrecognized equity-based compensation expense related to unvested stock options and unvested restricted stock units was \$21.5 million and \$1.1 million, respectively. This is expected to be recognized over the years 2018 through 2023.

Included in the above-noted stock option grants and stock compensation expense are performance-based stock options which vest only upon the achievement of certain targets. These options were valued in the same manner as the time-based options. However, the Company only recognizes stock compensation expense to the extent that the targets are determined to be probable of being achieved, which triggers the vesting of the performance options. In August, 2018, the Company granted 225,000 performance based-options to certain employees. The Company recognized \$545,000 of stock compensation expense for the three and nine months ended September 30, 2018, for performance-based stock options.

NOTE 14. INCOME TAXES

For the three and nine months ended September 30, 2018, the Company recorded a provision for income taxes of approximately \$147,000 and \$432,000, respectively, which primarily relates to profitable foreign jurisdictions without any net operating loss carryforwards. The Company's tax expense for the three and nine months ended September 30, 2018 differs from the tax expense computed by applying the U.S. statutory tax rate to its year-to-date pre-tax loss of \$22.0 million and \$65.7 million, respectively, as no tax benefits were recorded for tax losses generated in the U.S. and other foreign jurisdictions. At September 30, 2018, the Company had deferred tax assets primarily related to U.S. federal and state tax loss carryforwards. The Company provided a full valuation allowance against its deferred tax assets as future realization of such assets is not more likely than not to occur.

We account for uncertain tax positions pursuant to the recognition and measurement criteria under ASC 740, Income Taxes. For the three and nine months ended September 30, 2018, we did not note any significant changes to our uncertain tax positions. We do not anticipate significant changes to uncertain tax position within the next 12 months.

Tax Cuts and Jobs Act

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act. The Tax Act reduced the corporate tax rate from the maximum federal statutory rate of 35% to 21%. The Tax Act states that the 21% corporate tax rate is effective for tax years beginning on or after January 1, 2018. The Company revalued its net deferred tax assets for U.S. federal purposes to 21% as of December 31, 2017, with a corresponding adjustment to the valuation allowance. Therefore, the reduction in the U.S. corporate tax rate had no impact on the Company's earnings.

In conjunction with the Tax Act, the SEC staff issued SAB 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company has recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Act. Any subsequent determinations and adjustments will be recorded during the remainder of the year ended December 31, 2018, as they are identified.

The Tax Act subjects a U.S. shareholder to tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for GILTI, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. Given the complexity of the GILTI provisions, we are still evaluating the effects of the GILTI

provisions and have not yet determined our accounting policy. At September 30, 2018, because we are still evaluating the GILTI provisions and our analysis of future taxable income subject to GILTI, we have included GILTI related to current-year operations only in our estimated annual effective tax rate, with a corresponding adjustment to the valuation allowance, and have not provided additional GILTI on deferred items.

At September 30, 2018, the Company has not completed its accounting for all of the tax effects of the Tax Act and has not made any adjustments to the provisional amounts recorded at December 31, 2017. The Company will continue to make and refine its calculations as additional analysis is completed. The Company's estimates may also be affected as additional guidance is issued with regards to the Tax Act. These changes are not expected to be material to the Company's financial statements since the effective tax rate impact will be offset by the corresponding adjustment in the valuation allowance.

NOTE 15. COMMITMENTS

Leases

The Company has entered into lease agreements, lease amendments, and lease extensions ("Lease Agreements") for office, laboratory and manufacturing space located in Tucson, Arizona and Europe, the last of which expires in 2022. Total rent expense, including common area charges was \$338,000 and \$303,000 for the three months ended September 30, 2018 and 2017, respectively, and for the nine months ended September 30, 2018 and 2017 was \$1.0 million and \$928,000, respectively. Future minimum lease payments under these agreements are as follows (in thousands):

Year ending December 31:

2018	\$284
2019	266
2020	145
2021	98
2022	22
Thereafter	—
	\$815

Clinical Trial & Study Agreements

The Company has entered into master agreements with clinical trial and study sites in which we typically pay a set amount for start-up costs and then pay for work performed. These agreements typically indemnify the clinical trial sites from any and all losses arising from third party claims as a result of the Company's negligence, willful misconduct or misrepresentation. The expense incurred as part of the clinical trial is included in research and development on the Company's condensed consolidated statements of operations and comprehensive loss.

Marketing Study Agreements

The Company has entered into marketing study agreements with research institutions and hospitals in which we typically pay a set amount for start-up costs and then pay for work performed. These agreements typically indemnify the sites from any and all losses arising from third party claims as a result of the Company's negligence, willful misconduct or misrepresentation.

NOTE 16. INDUSTRY, GEOGRAPHIC AND REVENUE DISAGGREGATION

The Company operates as one operating segment. Sales to customers outside the U.S. represented 14% and 39% for the three months ended September 30, 2018 and 2017, respectively, and 22% and 24% for the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018 and December 31, 2017, balances due from foreign customers, in U.S. dollars, were \$621,000 and \$1.0 million, respectively.

	Three Months Ended September 30, (in thousands)	Nine Months Ended September 30, (in thousands)	
	2018	2017	2018 2017
Primary Geographic Markets:			
Domestic	\$ 1,172	\$ 507	\$ 2,988 \$ 1,569
Foreign	183	321	860 489
Net sales	\$ 1,355	\$ 828	\$ 3,848 \$ 2,058

Line of Business:			
Accelerate Pheno™ revenue	\$ 1,325	\$ 803	\$ 3,760 \$ 1,983
Other revenue	30	25	88 75
Net sales	\$ 1,355	\$ 828	\$ 3,848 \$ 2,058

Products and Services:			
Products	\$ 1,331	\$ 820	\$ 3,798 \$ 2,044
Services	24	8	50 14
Net sales	\$ 1,355	\$ 828	\$ 3,848 \$ 2,058

Lease income included in net sales for the three months ended September 30, 2018 and 2017 was \$229,000 and \$8,000, respectively, and \$410,000 and \$21,000 for the nine months ended September 30, 2018 and 2017, respectively, which does not represent revenues recognized from contracts with customers.

The following presents long-lived assets (excluding intangible assets) by geographic territory (in thousands):

	September 30, 2018	December 31, 2017
Domestic	\$ 6,195	\$ 3,779
Foreign	1,217	1,111
Property and equipment, net	\$ 7,412	\$ 4,890

NOTE 17. RELATED PARTY TRANSACTIONS

As part of the transaction discussed in Note 11, Convertible Notes, an affiliate of one member of the Company's board of directors purchased an aggregate of \$30 million of the Notes. The affiliated entity is a Qualified Institutional Buyer which purchased and holds the Notes at September 30, 2018.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Introductory Note

Except as otherwise indicated by the context, references in this Quarterly Report on Form 10-Q (this "Form 10-Q") to the "Company," "Accelerate," "we," "us" or "our" are references to the combined business of Accelerate Diagnostics, Inc.

Forward-Looking Statements

This Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities

23

Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as “may,” “will,” “expect,” “anticipate,” “estimate,” or “continue,” or variations thereon or comparable terminology, include the plans and objectives of management for future operations, including plans and objectives relating to the products and future economic performance of the Company. In addition, all statements other than statements of historical facts that address activities, events, or developments the Company expects, believes, or anticipates will or may occur in the future, and other such matters, are forward-looking statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions that the Company will retain key management personnel, the Company will be successful in the commercialization of the Accelerate Pheno™ system, the Company will obtain sufficient capital to commercialize the Accelerate Pheno™ system and continue development of complementary products, the Company will be able to protect its intellectual property, the Company’s ability to respond to technological change, the Company will accurately anticipate market demand for the Company’s products and there will be no material adverse change in the Company’s operations or business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the results contemplated in forward-looking statements will be realized. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) summarizes the significant factors affecting our results of operations, liquidity, capital resources and contractual obligations. The following discussion and analysis should be read in conjunction with the Company’s unaudited condensed consolidated financial statements and related notes included elsewhere herein. Certain information contained in the discussion and analysis set forth below and elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. The Company’s future operating results may be affected by various trends and factors which are beyond the Company’s control. These include, among other factors, general public perception of issues and solutions, and other uncertain business conditions that may affect the Company’s business. The Company cautions the reader that a number of important factors discussed herein, and in other reports filed with the SEC including but not limited to the risks in the section entitled “Risk Factors” in its Annual Report on Form 10-K for the period ended December 31, 2017 and in this form 10-Q, could affect the Company’s actual results and cause actual results to differ materially from those discussed in forward-looking statements.

All amounts in the MD&A have been rounded to the nearest thousand unless otherwise indicated.

Overview

Accelerate Diagnostics, Inc. (“Accelerate”) is an in vitro diagnostics company dedicated to providing solutions that improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributing factor to the rise of resistance is the overuse and misuse of antibiotics, which is exacerbated by a lack of timely diagnostic results. The delay of identification and antibiotic susceptibility results is often due to the reliance by microbiology laboratories on traditional culture-based tests that often take two to three days to complete. Our technology platform is built to address

these challenges by delivering significantly faster and more accurate testing of infectious pathogens in various patient sample types.

Since 2004, we have focused our efforts on the research, development, and commercialization of an innovative rapid diagnostic platform, the Accelerate Pheno™ system. The Accelerate Pheno™ system utilizes genotypic technology to identify (ID) infectious pathogens and phenotypic technology to conduct antibiotic susceptibility testing, (AST) which determines whether live bacterial and fungal cells are resistant or susceptible to a particular antibiotic. The Accelerate PhenoTest™ BC Kit provides ID and AST results for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk. The Accelerate PhenoTest™ BC Kit is a highly

multiplexed panel targeting over 80% of the routine and significant pathogens causing blood stream infections and over 90% of the antibiotics useful in treating those pathogens.

On June 30, 2015, we declared our conformity to the European In Vitro Diagnostic Directive 98/79 EC and applied a CE Mark to the Accelerate Pheno™ system and the Accelerate PhenoTest™ BC Kit for in vitro diagnostic use. On February 23, 2017, the U.S. Food and Drug Administration (“FDA”) granted our de novo request to market our Accelerate Pheno™ system and Accelerate PhenoTest™ BC Kit.

In 2017, we began selling the Accelerate Pheno™ system in hospitals in the United States, Europe, and the Middle East. Consistent with the Company's business model, revenues were generated from the sale of the instrument and the sale of single use consumable test kits.

Changes in Results of Operations: Three and nine months ended September 30, 2018 compared to three and nine months ended September 30, 2017

	Three Months Ended September 30, (in thousands)					Nine Months Ended September 30, (in thousands)				
	2018	2017	\$	%		2018	2017	\$	%	
			Change	Change				Change	Change	
Net sales	\$1,355	\$828	\$ 527	64	%	\$3,848	\$2,058	\$1,790	87	%

For the three and nine months ended September 30, 2018, total revenues increased due to increased sales of Accelerate Pheno™ systems and Accelerate PhenoTest™ BC Kits.

	Three Months Ended September 30, (in thousands)					Nine Months Ended September 30, (in thousands)				
	2018	2017	\$	%		2018	2017	\$	%	
			Change	Change				Change	Change	
Cost of sales	\$680	\$191	\$ 489	256	%	\$1,889	\$352	\$ 1,537	437	%
Gross profit	\$675	\$637	\$ 38	6	%	\$1,959	\$1,706	\$ 253	15	%

For the three and nine months ended September 30, 2018, cost of sales and gross profit increased as a result of higher sales for the three and nine months ended September 30, 2018. Inventory without a cost basis was sold to customers for the three and nine months ended September 30, 2018 and 2017. Sales for the three and nine months ended September 30, 2018 included proportionately fewer sales of inventory expensed in a previous period; this decrease contributed to an increase in cost of sales. Pre-launch inventory previously not capitalized and expensed in a previous period for the three months ended September 30, 2018 and 2017, was \$164,000 and \$147,000, respectively, and \$408,000 and \$513,000 for the nine months ended September 30, 2018 and 2017, respectively.

Cost of sales included non-cash equity-based compensation of \$68,000 and \$22,000 for the three months ended September 30, 2018 and 2017, respectively, and \$172,000 and \$44,000 for the nine months ended September 30, 2018 and 2017, respectively.

Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
2018	2017	2018	2017

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

	\$	%		\$	%
	Change	Change		Change	Change
Research and development	\$7,891	\$6,351	\$1,540	24	%
	\$20,734	\$16,166	\$4,568	28	%

Research and development expenses for the three and nine months ended September 30, 2018 increased as compared to the three and nine months ended September 30, 2017. The increase was primarily the result of an increase in headcount, non-cash equity-based compensation, and increased purchases of laboratory and engineering

materials. During the three months ended September 30, 2018, the Company granted performance based options to certain employees which increased expenses.

Pre-launch inventory not capitalized in accordance with U.S. GAAP, which included instruments and consumables charged to research and development, were \$335,000 and \$225,000 for the three months ended September 30, 2018 and 2017, respectively, and \$360,000 and \$376,000 for the nine months ended September 30, 2018 and 2017, respectively.

Research and development expenses included non-cash equity-based compensation of \$1.5 million and \$1.0 million for the three months ended September 30, 2018 and 2017, respectively, and \$3.9 million and \$2.9 million for the nine months ended September 30, 2018 and 2017, respectively. For the nine months ended September 30, 2018 the Company granted immediately vested stock options as a part of its annual bonus program, as well as granting performance based options associated with R&D milestones to certain employees, which increased expenses.

	Three Months Ended September 30, (in thousands)				Nine Months Ended September 30, (in thousands)			
	2018	2017	\$ Change	% Change	2018	2017	\$ Change	% Change
Sales, general and administrative	\$12,153	\$11,601	\$ 552	5 %	\$41,835	\$33,589	\$8,246	25 %

Sales, general and administrative expenses for the three months ended September 30, 2018 increased as compared to the three months ended September 30, 2017. The increase was primarily the result of an increase in headcount and related expenses as we continued to ramp up our sales and marketing operations globally. Sales, general and administrative expenses for the nine months ended September 30, 2018 increased as compared to the nine months ended September 30, 2017. The increase was primarily the result of an increase in headcount, non-cash equity-based compensation and customer evaluations of instruments, as we continued to ramp up our sales and marketing operations globally.

Pre-launch inventory not capitalized in accordance with U.S. GAAP, which included instruments and consumables charged to sales, general and administrative expenses, were \$0 and \$10,000 for the three months ended September 30, 2018 and 2017, respectively, and \$0 and \$40,000 for the nine months ended September 30, 2018 and 2017, respectively.

Sales, general and administrative expenses included non-cash equity-based compensation of \$1.9 million and \$2.5 million for the three months ended September 30, 2018 and 2017, respectively, and \$8.4 million and \$8.0 million for the nine months ended September 30, 2018 and 2017, respectively. In March of 2018, the Company granted immediately vested stock options as a part of its annual bonus program, which increased expenses relative to the same periods in 2017.

	Three Months Ended September 30, (in thousands)				Nine Months Ended September 30, (in thousands)			
	2018	2017	\$ Change	% Change	2018	2017	\$ Change	% Change
Loss from operations	\$(19,369)	\$(17,315)	\$(2,054)	12 %	\$(60,610)	\$(48,049)	\$(12,561)	26 %

For the three and nine months ended September 30, 2018, our loss from operations increased. The increase was the result of our continued investments in research and development, sales and marketing, and increased employee

headcount, along with other factors.

Loss from operations included non-cash equity-based compensation of \$3.5 million for each of the three months ended September 30, 2018 and 2017, and \$12.5 million and \$11.0 million for the nine months ended September 30, 2018 and 2017, respectively. This loss and further losses are anticipated and was the result of our continued investments in sales and marketing, key research and development personnel, related costs associated with product development, and commercialization of the Company's products.

	Three Months Ended September 30, (in thousands)				Nine Months Ended September 30, (in thousands)			
	2018	2017	\$	%	2018	2017	\$	%
			Change	Change			Change	Change
Total other income (expense), net	\$(2,582)	\$285	\$(2,867)	(1,006)%	\$(5,093)	\$536	\$(5,629)	(1,050)%

Other expense for the three and nine months ended September 30, 2018 increased compared to the three and nine months ended September 30, 2017, primarily due to an increase in interest expense associated with our convertible notes, offset in part by interest income.

	Three Months Ended September 30, (in thousands)				Nine Months Ended September 30, (in thousands)			
	2018	2017	\$	%	2018	2017	\$	%
			Change	Change			Change	Change
Provision for income taxes	\$(147)	\$(45)	\$(102)	227 %	\$(432)	\$(220)	\$(212)	96 %

Due to net losses incurred, we have only recorded tax provisions related to tax liabilities generated by our foreign subsidiaries for international income taxes.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock and the issuance of our convertible notes. As of September 30, 2018, the Company had \$180.6 million in cash and cash equivalents and available-for-sale securities, an increase of \$71.4 million from \$109.2 million at December 31, 2017. The primary reason for the change in these assets was due to our convertible notes offering that occurred during the nine months ended September 30, 2018.

The Company is subject to lease agreements. The future minimum lease payments under these lease agreements is included in Item 1, Note 15, Commitments.

As of September 30, 2018, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

The following summarizes selected items in the Company's consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017:

Cash Flow Summary (in thousands)

	Nine Months Ended		
	September 30, 2018	September 30, 2017	Change
Net cash used in operating activities	\$(53,430)	\$(42,498)	\$(10,932)
Net cash used in investing activities	(38,980)	(30,907)	(8,073)
Net cash provided by financing activities	125,596	88,303	37,293

The net cash used in operating activities was \$53.4 million and \$42.5 million for the nine months ended September 30, 2018 and 2017, respectively. The change in net cash used in operating activities was primarily the result of the increased net loss for the nine months ended September 30, 2018 compared to the prior year period due to our continued investments in research and development, sales and marketing, increased employee headcount, along with other factors.

The net cash used in investing activities was \$39.0 million for the nine months ended September 30, 2018 and \$30.9 million for the nine months ended September 30, 2017. The net cash used is comprised of the purchases of available-for-sale securities, offset by maturities of available-for-sale securities for both periods.

The net cash provided by financing activities was \$125.6 million for the nine months ended September 30, 2018, and is primarily comprised of proceeds from our convertible note offering, partially offset by the prepayment of a forward stock repurchase. The net cash provided by financing activities was \$88.3 million for the nine months ended September 30, 2017, and was primarily comprised of the sale of common stock in a public offering.

Our primary use of capital has been for the commercialization and development of the Accelerate Pheno™ system. We believe our capital requirements will continue to be met with our existing cash balance and those provided under revenue, grants, exercises of stock options and/or additional issuance of equity or debt securities. However, if capital requirements vary materially from those currently planned, we may require additional capital sooner than expected. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us, if at all. Additional issuances of equity or convertible debt securities will result in dilution to our current common stockholders.

Convertible Notes

On March 27, 2018, the Company issued \$150.0 million aggregate principal amount of 2.50% Convertible Senior Notes ("Notes"). In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional \$22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in \$21.5 million of additional proceeds, for total proceeds of \$171.5 million. The Notes mature on March 15, 2023, unless earlier repurchased or converted into shares of common stock subject to certain conditions. The Notes are convertible into shares of the Company's common stock, can be repurchased for cash, or a combination thereof, at the Company's election, at an initial conversion rate of 32.3428 shares of common stock per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$30.92 per share of common stock, subject to adjustment. We will pay interest on the Notes semi-annually in arrears on March 15 and September 15 of each year with interest payments beginning on September 15, 2018. Proceeds received from the issuance of the Notes was allocated between long-term debt (the "liability component") and contributed capital (the "equity component"), within the condensed consolidated balance sheet. The fair value of the liability component was measured using rates determined for similar debt instruments without a conversion feature.

In connection with the offering, we entered into a prepaid forward stock repurchase transaction (the "Prepaid Forward") with a financial institution. Pursuant to the Prepaid Forward, we used approximately \$45.1 million of the proceeds from the offering of the Notes to pay the prepayment amount. The aggregate number of our common stock underlying the Prepaid Forward is approximately 1.9 million shares (based on the sale price of \$24.25). The expiration date for the Prepaid Forward is March 15, 2023, although it may be settled earlier in whole or in part. Upon settlement of the Prepaid Forward, at expiration or upon any early settlement, the Forward Counterparty will deliver to us the number of shares of common stock underlying the Prepaid Forward or the portion thereof being settled early. The shares purchased under the Prepaid Forward were treated as treasury stock on the condensed consolidated balance sheet (and not outstanding for purposes of the calculation of basic and diluted earnings per share), but remain outstanding for corporate law purposes, including for purposes of any future stockholders' votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to us. We intend to use the remaining net proceeds less issuance cost from the offering of approximately \$121.4 million for general corporate purposes.

Contractual Obligations

There have been no material changes in our reported contractual obligations, as described under “Contractual Obligations” in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2018.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our estimates on an ongoing basis, including those related to accounts receivable, inventories, property and equipment, intangible assets, accruals, warranty liabilities, tax valuation accounts and stock-based compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities is not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Additional critical accounting policies added to Item 1, Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation; Significant Accounting Policies, include the the adoption of ASC 606, Revenue from Contracts with Customers, and the Company's accounting policy relating to convertible notes during the nine months ended September 30, 2018.

Item 3. Quantitative and Qualitative Disclosures

Interest Rate Risk

Our investment portfolio is exposed to market risk from changes in interest rates. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would change the fair value of our interest sensitive financial instruments by approximately \$750,000 as of September 30, 2018 and \$555,000 as of December 31, 2017.

Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. Further information regarding our investments is included in Item 1, Note 6, Investments.

Foreign Currency Risk

We operate primarily in the United States and a majority of our cost, expense and capital purchasing activities for the nine months ended September 30, 2018 were transacted in United States dollars. As a corporation with international and domestic operations, we are exposed to changes in foreign exchange rates. Our international revenue is predominantly in Europe and the Middle East and is denominated in Euros and United States dollars. In our international operations, we pay payroll and other expenses in local currencies. Our exposures to foreign currency risks may change over time and could have a material adverse impact on our financial results.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's Principal Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of September 30, 2018, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period ended September 30, 2018 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are from time to time subject to various claims and legal actions in the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

Except as described below, there have been no material changes to the risk factors that were disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Risks related to our convertible senior notes

We have indebtedness in the form of convertible senior notes.

On March 27, 2018, the Company issued \$150.0 million aggregate principal amount of 2.50% Convertible Senior Notes due 2023. In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional \$22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in \$21.5 million of additional proceeds, for total proceeds of \$171.5 million. Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a purchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any. In addition, the indenture for the Notes provides that we are required to repay amounts due under the indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to maturity date for the Notes. There can be no assurance that we will be able to repay this indebtedness when due, or that we will be able to refinance this indebtedness on acceptable terms or at all. In addition, this indebtedness could, among other things:

- heighten our vulnerability to adverse general economic conditions and competitive pressures;

- require us to dedicate a larger portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;

- limit our flexibility in planning for, or reacting to, changes in our business and industry; and

- impair our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes.

Our failure to repurchase Notes at a time when the repurchase is required by the indenture (whether upon a fundamental change or otherwise under the indenture) or pay cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, repurchase the Notes or make cash payments upon conversions thereof.

The prepaid forward may affect the value of the Notes and our common stock and may result in unexpected market activity in the Notes and/or our common stock.

In connection with the issuance of the Notes, we entered into a prepaid forward with a forward counterparty. The prepaid forward is intended to facilitate privately negotiated derivative transactions by which investors in the Notes will be able to hedge their investment. In connection with establishing its initial hedge of the prepaid forward, the forward counterparty (or its affiliate) was to purchase shares of our common stock from, and/or enter into one or more derivative transactions with respect to our common stock, with purchasers of the Notes concurrently with or after the

offering of the Notes. The prepaid forward is intended to reduce the dilution to our stockholders from the issuance of our common stock (if any) upon conversion of the Notes and to allow certain investors to establish short positions that generally correspond to initial hedges of their investment in the Notes. Neither we nor the forward counterparty control how such investors may use such derivative transactions. In addition, such investors may enter into other transactions in connection with such derivative transactions, including the purchase or sale of our common stock, at any time. As a result, the existence of the prepaid forward, such derivative transactions, and any related market activity could cause more sales of our common stock over the term of the prepaid forward than there would have otherwise been had we not entered into the prepaid forward. Such sales could potentially impact the market price of our common stock and/or the Notes.

We are subject to counterparty risk with respect to the prepaid forward.

We will be subject to the risk that the forward counterparty might default under the prepaid forward. Our exposure to the credit risk of the forward counterparty will not be secured by any collateral. Global economic conditions have in the recent past resulted in, and may again result in, the actual or perceived failure or financial difficulties of many financial institutions. If the forward counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with the forward counterparty. Our exposure will depend on many factors, but, generally, an increase in our exposure will be correlated to an increase in the market price of our common stock. In addition, upon a default by the forward counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the forward counterparty to the prepaid forward.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description	Filing Information
<u>3.1</u>	<u>Certificate of Incorporation of Registrant</u>	Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A filed on November 13, 2012
<u>3.1.1</u>	<u>Certificate of Amendment to Certificate of Incorporation of Registrant</u>	Incorporated by reference to Exhibit A to the Registrant's Definitive Information Statement on Schedule 14C filed on July 12, 2013
<u>3.1.2</u>	<u>Certificate of Amendment to Certificate of Incorporation of Registrant</u>	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 15, 2016
<u>3.2</u>	<u>Bylaws of Registrant</u>	Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012, filed on October 26, 2012
<u>3.2.1</u>	<u>Amendment No. 1 to the By-laws of Registrant</u>	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on November 16, 2017
<u>10.9.5*</u>	<u>Third Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan</u>	Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 10, 2017
<u>10.9.6*</u>	<u>Fourth Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan</u>	Filed herewith
<u>10.9.7*</u>	<u>UK Sub-Plan under the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan</u>	Filed herewith
<u>31.1</u>	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed herewith
<u>31.2</u>	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed herewith
<u>32</u>	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	Furnished herewith
101**	XBRL Instance Document	
101**	XBRL Taxonomy Extension Schema Document	
101**	XBRL Taxonomy Calculation Linkbase Document	
101**	XBRL Taxonomy Extension Definition Linkbase Document	
101**	XBRL Taxonomy Label Linkbase Document	
101**	XBRL Taxonomy Presentation Linkbase Document	

* Management contract or compensatory plan or arrangement.

** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these

interactive data files are deemed not filed and otherwise are not subject to liability.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCELERATE DIAGNOSTICS, INC.

November 6, 2018 /s/ Lawrence Mehren

Lawrence Mehren
President and Chief Executive Officer
(Principal Executive Officer)

November 6, 2018 /s/ Steve Reichling

Steve Reichling
Chief Financial Officer
(Principal Financial and Accounting Officer)