

ALERE INC.  
Form 10-Q  
November 04, 2016  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2016**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**COMMISSION FILE NUMBER 001-16789**

**ALERE INC.**

**(Exact name of registrant as specified in its charter)**

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)  
**51 SAWYER ROAD, SUITE 200**  
**WALTHAM, MASSACHUSETTS 02453**  
(Address of principal executive offices)(Zip code)  
(781) 647-3900  
(Registrant's telephone number, including area code)

**04-3565120**  
(I.R.S. Employer  
Identification No.)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares outstanding of the registrant's common stock, par value of \$0.001 per share, as of October 31, 2016 was 87,001,035.



**Table of Contents****ALERE INC.****REPORT ON FORM 10-Q****For the Quarterly Period Ended September 30, 2016**

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. A number of important factors could cause actual results of Alere Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and other risk factors identified herein or from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review these forward-looking statements and these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.*

*Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to we, us and our refer to Alere Inc. and its subsidiaries.*

**TABLE OF CONTENTS**

	<b>PAGE</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Financial Statements (unaudited)</u>	3
a) <u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2016 and 2015</u>	3
b) <u>Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2016 and 2015</u>	4
c) <u>Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	5
d) <u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015</u>	6
e) <u>Notes to Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	43
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	58
Item 4. <u>Controls and Procedures</u>	58
<b><u>PART II. OTHER INFORMATION</u></b>	<b>59</b>
Item 1. <u>Legal Proceedings</u>	59
Item 1A. <u>Risk Factors</u>	62
Item 3. <u>Default Upon Senior Securities</u>	62
Item 6. <u>Exhibits</u>	62
<b><u>SIGNATURE</u></b>	<b>63</b>



Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****ALERE INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

(unaudited)

(in thousands, except per share amounts)

	<b>Three Months Ended September 30,</b>		<b>Three Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net product sales	\$ 456,096	\$ 472,128	\$ 1,399,613	\$ 1,447,515
Services revenue	123,778	128,341	364,296	378,825
Net product sales and services revenue	579,874	600,469	1,763,909	1,826,340
License and royalty revenue	2,480	3,299	7,742	13,691
<b>Net revenue</b>	<b>582,354</b>	<b>603,768</b>	<b>1,771,651</b>	<b>1,840,031</b>
Cost of net product sales	238,946	245,814	726,805	743,808
Cost of services revenue	76,639	79,851	228,033	232,277
Cost of net product sales and services revenue	315,585	325,665	954,838	976,085
Cost of license and royalty revenue	641	1,137	2,567	4,431
<b>Cost of net revenue</b>	<b>316,226</b>	<b>326,802</b>	<b>957,405</b>	<b>980,516</b>
<b>Gross profit</b>	<b>266,128</b>	<b>276,966</b>	<b>814,246</b>	<b>859,515</b>
Operating expenses:				
Research and development	31,430	36,011	86,938	91,225
Sales and marketing	101,979	106,493	304,308	323,596
General and administrative	129,287	101,306	372,597	255,170
Impairment and (gain) loss on dispositions, net		2,074	(3,810)	42,408
<b>Operating income</b>	<b>3,432</b>	<b>31,082</b>	<b>54,213</b>	<b>147,116</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(44,130)	(52,333)	(128,565)	(158,258)
Other income (expense), net	(14,312)	3,658	(29,773)	4,486
<b>Loss from continuing operations before benefit for income taxes</b>	<b>(55,010)</b>	<b>(17,593)</b>	<b>(104,125)</b>	<b>(6,656)</b>
Benefit for income taxes	(50,888)	(10,212)	(47,979)	(2,376)

<b>Loss from continuing operations before equity earnings of unconsolidated entities, net of tax</b>	(4,122)	(7,381)	(56,146)	(4,280)
Equity earnings of unconsolidated entities, net of tax	26,149	5,000	33,305	10,320
Income (loss) from continuing operations	22,027	(2,381)	(22,841)	6,040
Income from discontinued operations, net of tax				216,777
<b>Net income (loss)</b>	22,027	(2,381)	(22,841)	222,817
Less: Net income (loss) attributable to non-controlling interests	207	(61)	453	386
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	21,820	(2,320)	(23,294)	222,431
Preferred stock dividends	(5,366)	(5,369)	(15,983)	(15,927)
<b>Net income (loss) available to common stockholders</b>	\$ 16,454	\$ (7,689)	\$ (39,277)	\$ 206,504
<b>Basic net income (loss) per common share:</b>				
Income (loss) from continuing operations	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ (0.13)
Income from discontinued operations				2.56
Net income (loss) per common share	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ 2.43
<b>Diluted net income (loss) per common share:</b>				
Income (loss) from continuing operations	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ (0.13)
Income from discontinuing operations				2.56
Net income (loss) per common share	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ 2.43
<b>Weighted-average shares basic</b>	86,753	85,895	86,708	85,141
<b>Weighted-average shares diluted</b>	87,885	85,895	86,708	85,141

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

Table of Contents**ALERE INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

(unaudited)

(in thousands)

	<b>Three Months Ended September 30, 2016</b>		<b>Three Months Ended September 30, 2015</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net income (loss)	\$ 22,027	\$ (2,381)	\$ (22,841)	\$ 222,817
Other comprehensive income (loss), before tax:				
Changes in cumulative translation adjustment	8,727	(88,812)	(13,215)	(122,428)
Minimum pension liability adjustment	221	419	907	(1,337)
Other comprehensive income (loss), before tax	8,948	(88,393)	(12,308)	(123,765)
Other comprehensive income (loss), net of tax	8,948	(88,393)	(12,308)	(123,765)
<b>Comprehensive income (loss)</b>	<b>30,975</b>	<b>(90,774)</b>	<b>(35,149)</b>	<b>99,052</b>
Less: Comprehensive income (loss) attributable to non-controlling interests	207	(61)	453	386
<b>Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries</b>	<b>\$ 30,768</b>	<b>\$ (90,713)</b>	<b>\$ (35,602)</b>	<b>\$ 98,666</b>

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



**Table of Contents**

**ALERE INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

(unaudited)

(in thousands, except par value)

	September 30, 2016	December 31, 2015
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 566,213	\$ 502,200
Restricted cash	4,999	5,694
Marketable securities	75	164
Accounts receivable, net of allowances of \$102,500 and \$89,701 at September 30, 2016 and December 31, 2015, respectively	427,241	445,833
Inventories, net	348,845	347,001
Prepaid expenses and other current assets	163,833	152,233
Assets held for sale – current		4,165
<b>Total current assets</b>	<b>1,511,206</b>	<b>1,457,290</b>
Property, plant and equipment, net	446,313	446,039
Goodwill	2,805,682	2,836,915
Other intangible assets with indefinite lives	27,991	28,110
Finite-lived intangible assets, net	864,785	997,281
Restricted cash	42,438	43,228
Other non-current assets	16,219	18,078
Investments in unconsolidated entities	80,885	65,333
Deferred tax assets	56,638	13,993
Non-current income tax receivable	3,517	3,517
Assets held for sale – non-current		13,337
<b>Total assets</b>	<b>\$ 5,855,674</b>	<b>\$ 5,923,121</b>
<b>LIABILITIES AND EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Short-term debt and current portion of long-term debt	\$ 41,424	\$ 199,992
Current portion of capital lease obligations	3,713	3,962
Accounts payable	211,476	195,752
Accrued expenses and other current liabilities	449,897	324,465
Liabilities related to assets held for sale – current		363
<b>Total current liabilities</b>	<b>706,510</b>	<b>724,534</b>
<b>LONG-TERM LIABILITIES:</b>		
Long-term debt, net of current portion	2,905,067	2,831,166

Edgar Filing: ALERE INC. - Form 10-Q

Capital lease obligations, net of current portion	8,033	7,181
Deferred tax liabilities	52,513	147,618
Other long-term liabilities	133,182	154,193
<b>Total long-term liabilities</b>	<b>3,098,795</b>	<b>3,140,158</b>

**Commitments and contingencies**

**STOCKHOLDERS EQUITY:**

Series B preferred stock, \$0.001 par value (liquidation preference: \$709,701 at September 30, 2016 and \$709,763 at December 31, 2015); Authorized: 2,300 shares; Issued: 2,065 shares at September 30, 2016 and December 31, 2015; Outstanding: 1,774 shares at September 30, 2016 and December 31, 2015	606,406	606,468
Common stock, \$0.001 par value; authorized: 200,000 shares; Issued: 94,613 shares at September 30, 2016 and 94,043 shares at December 31, 2015; Outstanding: 86,934 shares at September 30, 2016 and 86,364 shares at December 31, 2015	95	94
Additional paid-in capital	3,465,898	3,438,732
Accumulated deficit	(1,489,661)	(1,466,381)
Treasury stock, at cost, 7,679 shares at September 30, 2016 and December 31, 2015	(184,971)	(184,971)
Accumulated other comprehensive loss	(352,085)	(339,777)
<b>Total stockholders equity</b>	<b>2,045,682</b>	<b>2,054,165</b>
Non-controlling interests	4,687	4,264
<b>Total equity</b>	<b>2,050,369</b>	<b>2,058,429</b>
<b>Total liabilities and equity</b>	<b>\$ 5,855,674</b>	<b>\$ 5,923,121</b>

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

**Table of Contents****ALERE INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash Flows from Operating Activities:</b>		
Net income (loss)	\$ (22,841)	\$ 222,817
Income from discontinued operations, net of tax		216,777
Income (loss) from continuing operations	(22,841)	6,040
Adjustments to reconcile income (loss) from continuing operations to net cash provided by operating activities:		
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	9,305	10,627
Depreciation and amortization	214,187	233,651
Non-cash stock-based compensation expense	31,115	19,596
Impairment of inventory	915	201
Impairment of long-lived assets	634	378
Loss on disposition of fixed assets	5,492	3,273
Equity earnings of unconsolidated entities, net of tax	(33,305)	(10,320)
Deferred income taxes	(25,242)	(43,472)
(Gain) loss related to impairment and net loss on dispositions	(3,810)	42,323
Loss on extinguishment of debt		3,480
Other non-cash items	7,668	(4,785)
Non-cash change in fair value of contingent purchase price consideration	(16,290)	(51,911)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	22,051	(3,161)
Inventories, net	(31,660)	(58,152)
Prepaid expenses and other current assets	(22,630)	(14,953)
Accounts payable	18,493	(16,000)
Accrued expenses and other current liabilities	110,683	34,972
Other non-current liabilities	(117,479)	(8,540)
Cash paid for contingent purchase price consideration	(324)	(6,315)
Net cash provided by continuing operations	146,962	136,932
Net cash provided by discontinued operations		318
<b>Net cash provided by operating activities</b>	<b>146,962</b>	<b>137,250</b>
<b>Cash Flows from Investing Activities:</b>		
(Increase) Decrease in restricted cash	199	(438,765)

Edgar Filing: ALERE INC. - Form 10-Q

Purchases of property, plant and equipment	(49,995)	(67,947)
Proceeds from sale of property, plant and equipment	1,150	1,486
Cash received from dispositions, net of cash divested	21,470	586,625
Cash paid for business acquisitions, net of cash acquired	(5,958)	(60,135)
Cash received from sales of marketable securities	88	99
Cash received from equity method investments	3,357	14,297
Cash paid for equity investments	(184)	
Proceeds from sale of equity investments	40,751	
Decrease in other assets	460	881
Net cash provided by continuing operations	11,338	36,541
Net cash used in discontinued operations		(209)
<b>Net cash provided by investing activities</b>	<b>11,338</b>	<b>36,332</b>
<b>Cash Flows from Financing Activities:</b>		
Cash paid for financing costs	(29,186)	(16,053)
Cash paid for contingent purchase price consideration	(575)	(14,079)
Cash paid for dividends	(15,969)	(15,970)
Proceeds from issuance of common stock, net of issuance costs	13,923	76,457
Proceeds from issuance of long-term debt	462	2,162,022
Payments on short-term debt	(1,722)	(25,584)
Payments on long-term debt	(187,817)	(2,129,165)
Net proceeds (payments) under revolving credit facilities	124,876	(126,603)
Excess tax benefits on exercised stock options		6,102
Principal payments on capital lease obligations	(3,103)	(4,339)
Net cash used in continuing operations	(99,111)	(87,212)
Net cash used in discontinued operations		(76)
<b>Net cash used in financing activities</b>	<b>(99,111)</b>	<b>(87,288)</b>
Foreign exchange effect on cash and cash equivalents	4,824	(8,674)
Net increase in cash and cash equivalents	64,013	77,620
Cash and cash equivalents, beginning of period continuing operations	502,200	378,461
<b>Cash and cash equivalents, beginning of period discontinued operations</b>		<b>23,300</b>
<b>Cash and cash equivalents, end of period</b>	<b>566,213</b>	<b>479,381</b>
<b>Less: Cash and cash equivalents of discontinued operations, end of period</b>		
<b>Cash and cash equivalents of continuing operations, end of period</b>	<b>\$ 566,213</b>	<b>\$ 479,381</b>

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

**Table of Contents**

**ALERE INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**(1) Basis of Presentation of Financial Information**

The accompanying consolidated financial statements of Alere Inc. are unaudited. In the opinion of management, the unaudited consolidated financial statements contain all adjustments considered normal and recurring and necessary for their fair statement. Interim results are not necessarily indicative of results to be expected for the year. These interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, comprehensive income and cash flows. Our audited consolidated financial statements for the year ended December 31, 2015 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on August 8, 2016. These unaudited consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2015.

Certain amounts presented may not recalculate directly, due to rounding.

**(2) Revision of Previously Reported Consolidated Financial Statements**

In connection with the preparation of our consolidated financial statements for the fiscal year ended December 31, 2015, we determined that, in fiscal years 2013 and 2014, each of the interim periods of 2014 and the first three quarters of fiscal year 2015, we had incorrectly reported the timing of recognition of certain revenue transactions for such periods. As a result, we revised our consolidated financial statements as of December 31, 2014 and for the fiscal years ended December 31, 2014 and 2013, each of the interim periods in 2014 and the first three quarters of fiscal year 2015.

Specifically, the errors in the application of U.S. GAAP rules regarding the timing of revenue recognition primarily related to: (i) transactions, principally in Africa, in which we recognized revenue when the product shipped to the distributor, but we contractually retained title in the products until the distributor paid for the products in full or the distributor was not obligated to pay us until the products were sold through to the end-user; (ii) bill and hold transactions, principally in China, which did not meet the criteria for revenue recognition under U.S. GAAP; and (iii) other transactions, in which we recognized revenue prior to full satisfaction of all contractual criteria for title and risk of loss passing to the customer.

These errors required adjustments to the period in which certain revenues were recognized so that such revenues were recognized in the period in which: physical delivery occurred as defined by the contractual relationship; title and risk of loss had transferred to the buyer; or the buyer had the contractual obligation to pay the amounts invoiced, as required by U.S. GAAP revenue recognition rules and our accounting policy relating to revenue recognition. The impact of these adjustments was an increase in revenue of \$1.7 million and \$0.7 million for the three and nine months ended September 30, 2015, respectively.

Additionally, we have reflected other out-of-period adjustments in the periods in which such adjustments originated. These adjustments were identified during the financial closing process in connection with the fiscal years ended December 31, 2014 and 2013 and the first three quarters of fiscal year 2015 but were not reflected in our prior filings because they were deemed immaterial. The financial statements included in this Quarterly Report on Form 10-Q have been adjusted to include the adjustments in the period in which these items originated. These out-of-period adjustments are treated as corrections to our prior period financial results. For the three months ended September 30, 2015 these adjustments include a \$1.1 million decrease in other income and expense, net due to the measurement of a royalty obligation and a \$9.2 million decrease in the income tax benefit related to tax return to provision adjustments and the release of income tax reserves on uncertain tax positions. For the nine months ended September 30, 2015 these adjustments include a \$1.2 million increase in operating expenses related to a bonus accrual, a \$3.3 million decrease in other income and expense, net due to the measurement of a royalty obligation, and an \$8.6 million decrease in the income tax benefit related to tax return to provision adjustments and the release of income tax reserves on uncertain tax positions. Although management has determined that the errors, as well as the revenue recognition issues noted in the preceding paragraphs, individually and in the aggregate, were not material to prior periods, the financial statements for the three and nine months ended September 30, 2015, included herein, have been revised to correct for the impact of these items. Unless otherwise indicated, the consolidated financial information as of and for the three and nine months ended September 30, 2015 presented in this Quarterly Report on Form 10-Q reflects these revisions.

**Table of Contents**

The following schedules reconcile the amounts as previously reported in the applicable financial statement to the corresponding revised amounts:

**Three Months Ended September 30, 2015****Revised Consolidated Statement of Operations (in thousands, except per share data)**

	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net product sales	\$ 470,404	\$ 1,724	\$ 472,128
Net product sales and services revenue	\$ 598,745	\$ 1,724	\$ 600,469
Net revenue	\$ 602,044	\$ 1,724	\$ 603,768
Cost of net product sales	\$ 246,055	\$ (241)	\$ 245,814
Cost of service revenue	\$ 79,803	\$ 48	\$ 79,851
Cost of net product sales and services revenue	\$ 325,858	\$ (193)	\$ 325,665
Cost of net revenue	\$ 326,995	\$ (193)	\$ 326,802
Gross profit	\$ 275,049	\$ 1,917	\$ 276,966
Operating income	\$ 29,165	\$ 1,917	\$ 31,082
Other income (expense), net	\$ 4,745	\$ (1,087)	\$ 3,658
Loss from continuing operations before provision for income taxes	\$ (18,423)	\$ 830	\$ (17,593)
Benefit for income taxes	\$ 18,924	\$ (8,712)	\$ 10,212
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	\$ 501	\$ (7,882)	\$ (7,381)
Income (loss) from continuing operations	\$ 5,501	\$ (7,882)	\$ (2,381)
Net income (loss)	\$ 5,501	\$ (7,882)	\$ (2,381)
Net income (loss) attributable to Alere Inc. and Subsidiaries	\$ 5,562	\$ (7,882)	\$ (2,320)
Net income (loss) available to common stockholders	\$ 193	\$ (7,882)	\$ (7,689)
Basic and diluted loss per common share:			
Income from continuing operations	\$	\$ (0.10)	\$ (0.10)
Basic and diluted net loss per common share:			
Net loss per common share	\$	\$ (0.10)	\$ (0.10)

**Nine Months Ended September 30, 2015****Revised Consolidated Statement of Operations (in thousands, except per share data)**

	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net product sales	\$ 1,446,837	\$ 678	\$ 1,447,515
Net product sales and services revenue	\$ 1,825,662	\$ 678	\$ 1,826,340
Net revenue	\$ 1,839,353	\$ 678	\$ 1,840,031
Cost of net product sales	\$ 743,177	\$ 631	\$ 743,808
Cost of service revenue	\$ 232,137	\$ 140	\$ 232,277

Edgar Filing: ALERE INC. - Form 10-Q

Cost of net product sales and services revenue	\$	975,314	\$	771	\$	976,085
Cost of net revenue	\$	979,745	\$	771	\$	980,516
Gross profit	\$	859,608	\$	(93)	\$	859,515
Sales and marketing	\$	322,756	\$	840	\$	323,596
General and administrative	\$	254,810	\$	360	\$	255,170
Operating income	\$	148,409	\$	(1,293)	\$	147,116
Other income (expense), net	\$	7,735	\$	(3,249)	\$	4,486
Loss from continuing operations before benefit for income taxes	\$	(2,114)	\$	(4,542)	\$	(6,656)
Benefit for income taxes	\$	10,009	\$	(7,633)	\$	2,376
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	\$	7,895	\$	(12,175)	\$	(4,280)
Income from continuing operations	\$	18,215	\$	(12,175)	\$	6,040
Net income	\$	234,992	\$	(12,175)	\$	222,817
Net income attributable to Alere Inc. and Subsidiaries	\$	234,606	\$	(12,175)	\$	222,431
Net income available to common stockholders	\$	218,679	\$	(12,175)	\$	206,504
Basic and diluted income per common share: Income from continuing operations	\$	2.57	\$	(0.14)	\$	2.43
Basic and diluted net income per common share: Net income per common share	\$	2.57	\$	(0.14)	\$	2.43



**Table of Contents****Three Months Ended September 30, 2015**

<b>Revised Consolidated Statement of Comprehensive Loss (in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income (loss)	\$ 5,501	\$ (7,882)	\$ (2,381)
Comprehensive loss	\$ (82,892)	\$ (7,882)	\$ (90,774)
Comprehensive loss attributable to Alere Inc. and Subsidiaries	\$ (82,831)	\$ (7,882)	\$ (90,713)

**Nine Months Ended September 30, 2015**

<b>Revised Consolidated Statement of Comprehensive Income (in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income	\$ 234,992	\$ (12,175)	\$ 222,817
Comprehensive income	\$ 111,227	\$ (12,175)	\$ 99,052
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 110,841	\$ (12,175)	\$ 98,666

**Nine Months Ended September 30, 2015**

<b>Revised Consolidated Statement of Cash Flows (in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income	\$ 234,992	\$ (12,175)	\$ 222,817
Income from continuing operations	\$ 18,215	\$ (12,175)	\$ 6,040
Depreciation and amortization	\$ 233,511	\$ 140	\$ 233,651
Deferred income taxes	\$ (46,740)	\$ 3,268	\$ (43,472)
Accounts receivable, net	\$ (11,269)	\$ 8,108	\$ (3,161)
Inventories, net	\$ (58,781)	\$ 629	\$ (58,152)
Accrued expenses and other current liabilities	\$ 35,192	\$ (220)	\$ 34,972
Other non-current liabilities	\$ (8,790)	\$ 250	\$ (8,540)

We have also reflected these corrections as applicable in our consolidated financial statements and our consolidating financial statements presented in Note 22 *Guarantor Financial Information*.

**(3) Merger Agreement***Merger Agreement with Abbott Laboratories*

On January 30, 2016, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Abbott Laboratories, or Abbott. The Merger Agreement provides for the merger of a newly formed, wholly owned subsidiary of Abbott with and into Alere, or the merger, with Alere surviving the merger as a wholly owned subsidiary of Abbott, or the surviving corporation. Under the terms of the Merger Agreement, holders of shares of our common stock will receive \$56.00 in cash, without interest, in exchange for each share of common stock. Each share of our Series B Convertible Perpetual Preferred Stock, par value \$0.001 per share, or Series B Preferred Stock, issued and outstanding immediately prior to the effective time of the merger will remain issued and outstanding immediately following the consummation of the merger as one share of Series B Convertible Preferred Stock, par value \$0.001 per share, of the surviving corporation. The Merger Agreement was approved by our board of directors, and, on October 21, 2016, the

holders of a majority of the outstanding shares of our common stock approved the adoption of the Merger Agreement. Completion of the merger is subject to remaining customary closing conditions, including (1) there being no judgment or law enjoining or otherwise prohibiting the consummation of the merger and (2) the expiration of the waiting period applicable to the merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, and receipt of other required antitrust approvals. Under the terms of the Merger Agreement, Abbott has agreed to make certain divestitures if necessary to obtain the consent of the antitrust authorities to the transaction contemplated by the Merger Agreement, subject to certain exceptions set forth in the Merger Agreement. The obligation of each of the parties to consummate the merger is also conditioned on the other party's representations and warranties being true and correct (subject to certain materiality exceptions) and the other party having performed in all material respects its obligations under the Merger Agreement. The Merger Agreement contains certain termination rights and provides that, upon termination of the Merger Agreement under certain circumstances, Alere would be required to pay Abbott a termination fee equal to \$177.0 million.

On May 2, 2016, Abbott and Alere received a request for additional information, or a second request, from the United States Federal Trade Commission, or the FTC, relating to Abbott's potential acquisition of Alere. The second request was issued under the HSR Act. In addition, Abbott has agreed voluntarily to provide the FTC at least 60 days advance notice before certifying substantial compliance with the second request and to extend the waiting period imposed by the HSR Act to not less than 60 days after Abbott and Alere have certified substantial compliance with the second request, unless the period is further extended voluntarily by the

## **Table of Contents**

parties or terminated sooner by the FTC.

Between April and October 2016, Abbott received six separate requests for additional information from the European Commission. The parties are working to provide the European Commission with information in response to these requests and continue to work cooperatively with the European Commission in connection with this review. Once the completed notification has been formally submitted to the European Commission, the European Commission has 25 business days from the day following the date of such notification, which period may be extended to 35 business days after the date of notification under certain circumstances, in which to consider whether the merger raises serious doubts as to its compatibility with the common market (as prescribed by European Union regulations). By the end of that period, the European Commission must issue a decision either clearing the merger, which may be conditional upon satisfaction of commitments, or open an in-depth Phase II investigation. A Phase II investigation may last a maximum of an additional 125 business days.

On June 23, 2016, Abbott and Alere received a request for additional information, or a supplemental information request, from the Canadian Competition Bureau, or the Bureau, relating to Abbott's potential acquisition of Alere. The supplemental information request was issued under the Competition Act of Canada, or the Competition Act. The effect of the supplemental information request is to extend the waiting period imposed by the Competition Act until 30 days after Abbott and Alere have each complied with the supplemental information request, unless the period is extended voluntarily by the parties or terminated sooner by the Bureau.

On October 20, 2016, the Ministry of Commerce of the People's Republic of China determined that it will not prohibit the acquisition of Alere by Abbott.

On August 25, 2016, we filed a complaint against Abbott in Delaware Chancery Court, which seeks to compel Abbott to fulfill its obligations under the terms of the Merger Agreement to take all actions necessary to promptly obtain all required antitrust approvals for the merger. The complaint alleges, among other things, that Abbott is purposefully failing to comply with its obligations set forth in the Merger Agreement related to obtaining antitrust approvals. Specifically, the complaint alleges that Abbott: (i) purposefully failed to supply information requested by the FTC as promptly as reasonably practicable after such requests were made, as expressly required by the Merger Agreement; (ii) purposefully failed to supply information requested and make antitrust filings pursuant to antitrust laws in various foreign jurisdictions as promptly as reasonably practicable after such requests were made; (iii) purposefully failed to promptly take any and all steps necessary to avoid or eliminate impediments to obtaining antitrust clearance in the United States and in various foreign jurisdictions; (iv) purposefully failed to keep Alere informed in all material respects and on a reasonably timely basis of material communications with respect to the merger with antitrust authorities in the United States and in various foreign jurisdictions; and (v) purposefully failed to cooperate and consult with Alere, as well as give due consideration to Alere's views with respect to antitrust matters. We asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by the Merger Agreement. On August 30, 2016, Abbott filed its response in opposition to the motion to expedite the proceedings in this matter. On September 2, 2016, the Delaware Chancery Court granted our motion to expedite the proceedings. On September 29, 2016, the Delaware Chancery Court entered an order that, among other things, adopted a detailed schedule setting forth actions required to be taken by specified dates in order to obtain all antitrust clearances required by the Merger Agreement. By order of the court, the schedule is confidential. The court order also (i) requires Abbott to provide us with advance notice of, and the right to participate (in a manner not inconsistent with the terms of the Merger Agreement) in, all future discussions with antitrust regulators worldwide; (ii) appoints a Special Master to confidentially mediate any disputes regarding compliance with the order or the parties obligations under the Merger Agreement; (iii) lifts the stay of the case and permits discovery to commence immediately, including with respect to potential breaches of the Merger Agreement by Abbott; and (iv) sets a preliminary injunction hearing date on our claims for January 27, 2017, if necessary.

On November 3, 2016, Abbott filed a complaint against Alere in the Delaware Chancery Court. Abbott asserts a single claim against Alere for breach of contract stemming from Alere's refusal to provide Abbott with certain categories of documents under the Merger Agreement. The complaint makes no claim for damages and seeks to compel Alere to produce certain categories of documents and information which Abbott contends Alere is obligated to produce under the terms of the Merger Agreement. Alere believes it has fulfilled its contractual obligations under the merger agreement.

#### (4) Discontinued Operations

On January 9, 2015, we completed the sale of our health management business to OptumHealth Care Solutions for a purchase price of \$599.9 million. We used the net cash proceeds of the sale to repay \$575.0 million in aggregate principal amount of outstanding indebtedness under our prior credit facility.

The following summarized financial information related to the health management business has been segregated from continuing operations and reported as discontinued operations in our consolidated statements of operations for the nine months ended September 30, 2015. The results are as follows (in thousands):

	<b>Nine Months Ended September 30, 2015</b>
Net revenue	\$ 7,373
Cost of net revenue	(4,413)
Sales and marketing	(996)
General and administrative	(5,001)
Interest expense	(9)
Other income (expense), net	160
Gain on disposal	366,191
Income from discontinued operations before provision for income taxes	363,305
Provision for income taxes	146,528
Income from discontinued operations, net of tax	\$ 216,777

#### (5) Cash and Cash Equivalents

We consider all highly-liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At September 30, 2016, our cash equivalents consisted of money market funds.

**Table of Contents****(6) Inventories**

Inventories are stated at the lower of cost (first in, first out) or market and are comprised of the following (in thousands):

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Raw materials	\$ 123,558	\$ 130,171
Work-in-process	72,562	69,178
Finished goods	152,725	147,652
	\$ 348,845	\$ 347,001

**(7) Stock-based Compensation**

We recorded stock-based compensation expense in our consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015, as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Cost of net revenue	\$ 456	\$ 326	\$ 1,536	\$ 866
Research and development	494	287	1,374	893
Sales and marketing	2,475	1,260	7,035	3,605
General and administrative	7,084	5,444	21,170	14,232
	\$ 10,509	\$ 7,317	\$ 31,115	\$ 19,596

**(8) Net Income (Loss) per Common Share**

The following table sets forth the computation of basic and diluted net income (loss) per common share for the periods presented (in thousands, except per share data):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Basic and diluted net income (loss) per common share:</b>				
<b><u>Numerator:</u></b>				
Income (loss) from continuing operations	\$ 22,027	\$ (2,381)	\$ (22,841)	\$ 6,040
Preferred stock dividends	(5,366)	(5,369)	(15,983)	(15,927)
	16,661	(7,750)	(38,824)	(9,887)

Income (loss) from continuing operations attributable to common shares				
Less: Net income (loss) attributable to non-controlling interest	207	(61)	453	386
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	16,454	(7,689)	(39,277)	(10,273)
Income from discontinued operations				216,777
Net income (loss) available to common stockholders	\$ 16,454	\$ (7,689)	\$ (39,277)	\$ 206,504

**Denominator:**

Weighted-average common shares outstanding basic	86,753	85,895	86,708	85,141
Weighted-average common shares outstanding diluted	87,885	85,895	86,708	85,141

Basic net income (loss) per common share:				
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ (0.13)
Income from discontinued operations				2.56
Basic net income (loss) per common share	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ 2.43
Diluted net income (loss) per common share:				
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ (0.13)
Income from discontinuing operations				2.56
Diluted net income (loss) per common share	\$ 0.19	\$ (0.10)	\$ (0.45)	\$ 2.43

**Table of Contents**

The following potential dilutive securities were not included in the calculation of diluted net income (loss) per common share for our continuing operations because the inclusion thereof would be antidilutive (in thousands):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
<b>Denominator:</b>				
Options to purchase shares of common stock and RSUs	5,884	7,062	7,016	7,062
Warrants				4
Conversion shares related to 3% convertible senior subordinated notes		3,411	1,693	3,411
Conversion shares related to subordinated convertible promissory notes		27		27
Conversion shares related to Series B convertible preferred stock	10,239	10,239	10,239	10,239
Total number of antidilutive potentially issuable shares of common stock excluded from diluted common shares outstanding	16,123	20,739	18,948	20,743

**(9) Stockholders Equity and Non-controlling Interests***(a) Preferred Stock*

For each of the three and nine months ended September 30, 2016 and 2015, Series B preferred stock dividends amounted to \$5.3 million and \$15.9 million, respectively, which reduced earnings available to common stockholders for purposes of calculating net income (loss) per common share for each of the respective periods. As of September 30, 2016, \$5.3 million of Series B preferred stock dividends was accrued. As of October 15, 2016, payments have been made covering all dividend periods through September 30, 2016.

The Series B preferred stock dividends for the three and nine months ended September 30, 2016 and 2015 were paid in cash in the subsequent quarters.

*(b) Changes in Stockholders Equity and Non-controlling Interests*

A summary of the changes in stockholders equity and non-controlling interests comprising total equity for the nine months ended September 30, 2016 is provided below (in thousands):

	Nine Months Ended September 30, 2016		
	Total Stockholders Equity	Non-controlling Interests	Total Equity
Equity, beginning of period	\$ 2,054,165	\$ 4,264	\$ 2,058,429

Edgar Filing: ALERE INC. - Form 10-Q

Issuance of common stock under employee compensation plans	14,110		14,110
Surrender of common stock to settle taxes on restricted stock units	(2,137)		(2,137)
Preferred stock dividends	(15,969)		(15,969)
Stock-based compensation expense	31,115		31,115
Other adjustments		(30)	(30)
Net income	(23,294)	453	(22,841)
Total other comprehensive loss	(12,308)		(12,308)
Equity, end of period	\$ 2,045,682	\$ 4,687	\$ 2,050,369



**Table of Contents****(10) Business Combinations**

Our business acquisitions have historically been made at prices above the fair value of the assets acquired and liabilities assumed, resulting in goodwill, based on our expectations of synergies and other benefits of combining the businesses. These synergies and benefits include elimination of redundant facilities, functions and staffing; use of our existing commercial infrastructure to expand sales of the products of the acquired businesses; and use of the commercial infrastructure of the acquired businesses to expand product sales in a cost-efficient manner.

Net assets acquired are recorded at their estimated fair value and are subject to adjustment upon finalization of the fair value analysis. The estimated useful lives of the individual categories of intangible assets were based on the nature of the applicable intangible asset and the expected future cash flows to be derived from the intangible asset.

Amortization of intangible assets with finite lives is recognized over the shorter of the respective lives of the agreement or the period of time the intangible assets are expected to contribute to future cash flows. We amortize our finite-lived intangible assets based on patterns on which the respective economic benefits are expected to be realized.

*(a) Acquisition in 2016***EDTS**

On February 11, 2016, we acquired all of the outstanding shares of European Drug Testing Services EDTS AB, or EDTS, located in Lidingo, Sweden, a provider of services related to on-site drug testing. The aggregate purchase price was approximately \$6.5 million and was paid in cash. The operating results of EDTS are included in our professional diagnostics reporting unit and business segment.

Our consolidated statements of operations for the three and nine months ended September 30, 2016 included revenue totaling approximately \$1.2 million and \$3.8 million, respectively, related to this business. Goodwill has been recognized in the acquisition and amounted to approximately \$2.1 million, which is deductible for tax purposes.

A summary of the fair values of the net assets acquired from EDTS is as follows (in thousands):

	<b>Fair Value</b>
Current assets	\$ 1,371
Property, plant and equipment	115
Goodwill	2,060
Intangible assets	4,220
<b>Total assets acquired</b>	<b>\$ 7,766</b>
Current liabilities	\$ 368
Non-current liabilities	928
<b>Total liabilities assumed</b>	<b>\$ 1,296</b>
<b>Net assets acquired</b>	<b>\$ 6,470</b>
Cash paid	\$ 6,470

The following table provides information regarding the intangible assets acquired in connection with the EDTS acquisition and their respective fair values and weighted-average useful lives (dollars in thousands):

	<b>Fair Value</b>	<b>Weighted- average Useful Life</b>
Core technology and patents	\$ 540	10.0 years
Trademarks and trade names	310	20.0 years
Customer relationships	2,800	14.0 years
Non-compete agreements	570	3.0 years
<b>Total intangible assets</b>	<b>\$ 4,220</b>	

**Table of Contents***(b) Acquisitions in 2015*

## US Diagnostics

On July 10, 2015, we acquired substantially all of the assets of US Diagnostics, Inc., or USD, located in Huntsville, Alabama, a provider of instant on-site drug testing products designed for quick and accurate drug test results. The aggregate purchase price was approximately \$60.1 million and was paid in cash. The operating results of USD are included in our professional diagnostics reporting unit and business segment.

Our consolidated statements of operations for each of the three and nine months ended September 30, 2016 included revenue totaling approximately \$5.7 million and \$16.8 million, respectively, related to this business. Our consolidated statements of operations for each of the three and nine months ended September 30, 2015 included revenue totaling approximately \$5.0 million related to this business. Goodwill has been recognized in the acquisition and amounted to approximately \$29.4 million, which is deductible for tax purposes.

A summary of the fair values of the net assets acquired from USD is as follows (in thousands):

	<b>Total</b>
Current assets	\$ 4,652
Property, plant and equipment	182
Goodwill	29,422
Intangible assets	27,200
<b>Total assets acquired</b>	<b>\$ 61,456</b>
Current liabilities	\$ 1,321
<b>Total liabilities assumed</b>	<b>\$ 1,321</b>
Net assets acquired	\$ 60,135
<b>Cash paid</b>	<b>\$ 60,135</b>

The following are the intangible assets acquired in connection with the USD acquisition and their respective fair values and weighted-average useful lives (dollars in thousands):

	<b>Total</b>	<b>Weighted-average Useful Life</b>
Trademarks	\$ 1,600	3.0 - 13.0 years
Customer relationships	24,900	13.0 years
Non-compete agreements	700	2.0 years
<b>Total intangible assets</b>	<b>\$ 27,200</b>	



**Table of Contents****(11) Restructuring Plans**

The following table sets forth aggregate restructuring charges recorded in our consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015 (in thousands):

Statement of Operations Caption	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of net revenue	\$ 1,531	\$ 522	\$ 3,901	\$ 2,921
Research and development	587	18	3,541	667
Sales and marketing	511	619	1,420	2,572
General and administrative	8,661	1,105	18,876	5,227
Total operating expenses	11,290	2,264	27,738	11,387
Interest expense, including amortization of original issue discounts and deferred financing costs	2	6	9	19
Total restructuring charges	\$ 11,292	\$ 2,270	\$ 27,747	\$ 11,406

**(a) Restructuring Plans**

During 2016, management developed world-wide cost reduction plans to reduce costs and improve operational efficiencies within our professional diagnostics and corporate and other business segments, primarily impacting our manufacturing and supply chain, and research and development groups, as well as closing certain business locations in Europe and the United States. The following table summarizes the restructuring activities related to the 2016 restructuring plans, in addition to our earlier restructuring plans as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, for the three and nine months ended September 30, 2016 and 2015 and since inception of these restructuring plans (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Inception
	2016	2015	2016	2015	
<b><u>Professional Diagnostics</u></b>					
Severance-related costs	\$ 1,765	\$ 1,322	\$ 8,039	\$ 5,385	\$ 46,026
Facility and transition costs	426	132	1,620	4,139	13,288
Other exit costs	2	6	9	19	831
Cash charges	2,193	1,460	9,668	9,543	60,145
Fixed asset and inventory impairments	545	124	964	579	16,917
Other non-cash charges	(2)		208		2,190
Total professional diagnostics charges	\$ 2,736	\$ 1,584	\$ 10,840	\$ 10,122	\$ 79,252

**Corporate and Other**

Severance-related costs	\$ 69	\$ 686	\$ 65	\$ 1,297	\$ 4,342
Facility and transition costs	8,487		16,842	(13)	28,164
Total corporate and other charges	\$ 8,556	\$ 686	\$ 16,907	\$ 1,284	\$ 32,506
Total restructuring charges	\$ 11,292	\$ 2,270	\$ 27,747	\$ 11,406	\$ 111,758

We anticipate incurring approximately \$2.7 million and \$6.0 million in additional costs under our 2016 restructuring plans related to our professional diagnostics and corporate and other business segments, respectively, primarily related to integration and operational initiatives and site closures. We may develop additional restructuring plans over the remainder of 2016. In addition, we anticipate incurring approximately \$3.1 million in additional costs, related to our professional diagnostics business segment, under earlier restructuring plans as in effect at September 30, 2016, primarily related to the closure of our manufacturing facility in Israel.

*(b) Restructuring Reserves*

The following table summarizes our restructuring reserves related to the plans described above, of which \$9.9 million is included in accrued expenses and other current liabilities and \$0.6 million is included in other long-term liabilities on our accompanying consolidated balance sheets (in thousands):

	Severance- related Costs	Facility and Transition Costs	Other Exit Costs	Total
Balance, December 31, 2015	\$ 1,633	\$ 1,966	\$ 180	\$ 3,779
Cash charges	8,104	18,462	9	26,575
Payments	(5,821)	(14,018)	(111)	(19,950)
Currency adjustments	10	42		52
Balance, September 30, 2016	\$ 3,926	\$ 6,452	\$ 78	\$ 10,456

**Table of Contents****(12) Long-term Debt**

We had the following long-term debt balances outstanding (in thousands):

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
A term loans <sup>(1)(2)</sup>	\$ 551,266	\$ 575,746
B term loans <sup>(1)(2)</sup>	954,608	965,740
Revolving loans <sup>(1)</sup>	125,000	
7.25% Senior notes <sup>(2)</sup>	441,498	446,320
6.5% Senior subordinated notes <sup>(2)</sup>	414,391	419,209
6.375% Senior subordinated notes <sup>(2)</sup>	412,363	418,133
3% Convertible senior subordinated notes <sup>(3)</sup>		149,839
Other lines of credit		136
Other	47,365	56,035
	2,946,491	3,031,158
Less: Short-term debt and current portion of long-term debt <sup>(3)</sup>	(41,424)	(199,992)
Long-term debt	\$ 2,905,067	\$ 2,831,166

(1) Incurred under our secured credit facility entered into on June 18, 2015.

(2) As discussed more fully below in this Note 12, (i) on March 31, 2016 we were in default under the credit agreement governing our secured credit facility, or the Credit Agreement, and the respective indentures governing our 7.25% senior notes, our 6.5% senior subordinated notes, our 6.375% senior subordinated notes and our 3% convertible senior subordinated notes as a result of our failure to timely furnish to the holders of such debt our annual financial statements for the year ended December 31, 2015 and (ii) we subsequently entered into an amendment to the Credit Agreement and solicited consents from the requisite holders of our senior notes and senior subordinated notes (other than holders of our 3% convertible senior subordinated notes) to waive certain defaults and extend the deadline dates for the filing and delivery, as applicable, of our Annual Report on Form 10-K for the year ended December 31, 2015, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and certain related deliverables in order to avoid events of default under the Credit Agreement and the indentures governing our notes. As discussed more fully below in this Note 12, in August 2016 we entered into a further amendment to the Credit Agreement with respect to our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 to, among other things, extend the deadline date for such filing. In addition, because we had not filed our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 at or prior to the time set forth in the indentures governing our outstanding notes, we were also in default thereunder. However, with the filing of such Quarterly Report on Form 10-Q on September 6, 2016 cured this default prior to the expiration of the applicable cure periods under the indentures governing our notes. As of September 30, 2016, we were in compliance with all of our obligations and covenants under the Credit Agreement and the indentures governing our outstanding notes.

(3) The principal amount of the 3% convertible senior subordinated notes is included in the short-term debt and current portion of long-term debt on our consolidated balance sheets as of December 31, 2015, as these notes

matured (and were fully paid and discharged) in May 2016.

In connection with our significant long-term debt issuances, we recorded interest expense, including amortization and write-offs

of deferred financing costs and original issue discounts, in our accompanying consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Secured credit facility <sup>(1)</sup>	\$ 19,072	\$ 18,161	\$ 53,949	\$ 20,763
Prior credit facility <sup>(2) (3)</sup>				49,437
7.25% Senior notes	9,372	8,524	26,800	25,573
6.5% Senior subordinated notes	7,618	7,274	22,254	21,741
6.375% Senior subordinated notes <sup>(4)</sup>	7,242	7,002	21,357	7,544
8.625% Senior subordinated notes <sup>(4)</sup>		9,273		27,820
3% Convertible senior subordinated convertible notes		1,246	1,847	3,738
Other	826	853	2,358	1,642
	\$ 44,130	\$ 52,333	\$ 128,565	\$ 158,258

<sup>(1)</sup> Includes A term loans, B term loans, and revolving line of credit loans.



---

**Table of Contents**

- (2) Includes the following loans under our prior credit facility: A term loans, including the Delayed-Draw term loans; B term loans, including the term loans previously referred to as Incremental B-1 term loans and Incremental B-2 term loans and later converted into and consolidated into the B term loans; and revolving line of credit loans.
- (3) Includes a \$3.5 million loss on extinguishment of debt associated with our prior credit facility.
- (4) For the three and nine months ended September 30, 2015, the amounts include \$0.4 million and \$1.1 million, respectively, related to the amortization of fees paid for certain debt modifications.

*April and August 2016 Amendments to Secured Credit Facility*

On April 22, 2016, we and the requisite lenders under the Credit Agreement entered into an amendment to the Credit Agreement pursuant to which the requisite lenders agreed to (i) waive certain Defaults and Events of Defaults (each as defined in the Credit Agreement) that may have occurred, are occurring or will occur, resulting from, among other things, (x) our failure to deliver to the Administrative Agents (as defined in the Credit Agreement) the financial statements and certain related deliverables for the year ended December 31, 2015 by the applicable deadline under the Credit Agreement, (y) any restatement of certain financial statements as a result of our incorrect application of revenue recognition principles for the years ended December 31, 2013, 2014 and 2015, or (z) any breach of any representation or affirmative covenant as a result of certain deliverables being incorrect when delivered, which breach is discovered as part of the audit of our financial statements for the year ended December 31, 2015, to the extent that such breach is due to our incorrect application of revenue recognition principles for the years ended December 31, 2013, 2014 and 2015, and (ii) extend the deadlines for delivery of the financial statements for the year ended December 31, 2015, the financial statements for the quarter ended March 31, 2016 and certain related deliverables. Under the terms of this amendment, we were required to deliver our unaudited financial statements for the three months ended March 31, 2016 and certain related deliverables on or before August 18, 2016. We made the required deliveries before that date. In connection with this amendment, we paid, among other fees and expenses, to each consenting lender aggregate consent fees of 0.250% of the sum of (i) the aggregate principal amount of such lender's Term Loans (as defined in the Credit Agreement) outstanding on the effective date of the amendment and (ii) such lender's Revolving Credit Commitment (as defined in the Credit Agreement) outstanding on the effective date of the amendment, or approximately \$4.5 million in the aggregate for all consenting lenders. The amendment was deemed to be a debt modification, and therefore the payments were capitalized and will be amortized to interest expense over the remaining term of the debt. The amendment also increased the applicable interest rate margins for all loans outstanding under our secured credit facility by 0.25% per annum for the period from July 1, 2016 to the date of delivery of such financial reports and related deliverables under our secured credit facility.

On August 18, 2016, we and the requisite lenders under the Credit Agreement entered into a further amendment to the Credit Agreement pursuant to which the requisite lenders agreed to (i) waive certain Defaults and Events of Defaults (each as defined in the Credit Agreement) that may have occurred, are occurring or will occur, resulting from, among other things, our failure to deliver to the Administrative Agents (as defined in the Credit Agreement) (x) the financial statements and certain related deliverables for the three months ended March 31, 2016, which we refer to as the Q1 Financial Reports, by the applicable deadline under the Credit Agreement or (y) the financial statements and certain related deliverables for the three months ended June 30, 2016, which we refer to as the Q2 Financial Reports, by the applicable deadline under the Credit Agreement, and (ii) extend the deadline for delivery of the Q1 Financial Reports to August 25, 2016 and the deadline for the delivery of the Q2 Financial Reports to September 13, 2016. In connection with this amendment, we paid, among other fees and expenses, to each consenting lender aggregate consent fees of 0.125% of the sum of (i) the aggregate principal amount of such lender's Term Loans outstanding on the effective date of the amendment and (ii) such lender's Revolving Credit Commitment outstanding on the effective date of the amendment, or approximately \$2.2 million in the aggregate for all consenting lenders. The amendment was deemed to be a debt modification, and therefore the payments were capitalized and will be amortized to interest expense over the remaining term of the debt.

*May 2016 Waivers with respect to Senior Notes and Senior Subordinated Notes*

On April 29, 2016, we commenced consent solicitations relating to our 6.5% senior subordinated notes, our 6.375% senior subordinated notes and our 7.25% senior notes, which we refer to collectively as the Notes. The consent solicitations were made to holders of record of the Notes as of April 28, 2016, and such solicitations were completed on May 9, 2016. Pursuant to the consent solicitations, the requisite holders of each series of Notes agreed to extend the deadline for delivery of certain financial information and to waive, through and until 5:00 p.m., New York City time, on August 31, 2016, any default or event of default that occurred, is continuing or may occur under the indentures under which the Notes were issued (and its consequences) in connection with any failure to timely file with the SEC or to timely furnish to the relevant trustees pursuant to the indentures, our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and our subsequent Quarterly Reports on Form 10-Q, or the Failures to File. In connection with the Failures to File, we paid, in May and July 2016, to each holder of Notes who validly delivered a consent aggregate cash payments equal to \$15.00 for each \$1,000 aggregate principal amount of such holder's Notes, or an aggregate of \$19.2 million. The waivers were deemed to be a debt modification, and therefore the payments were capitalized and will be amortized to interest expense over the remaining term of the debt.

**Table of Contents***Maturity of our 3.0% convertible senior subordinated notes*

Our 3% convertible senior subordinated notes matured and were repaid in full on May 15, 2016. Based on the price of our common stock on the date of maturity, we paid all outstanding principal and accrued interest owing under such notes in cash. The aggregate amount paid to the noteholders at maturity was approximately \$152.0 million, consisting of \$125.0 million in cash drawn under our revolving credit facility plus \$27.0 million of cash available on such date.

**(13) Fair Value Measurements**

We apply fair value measurement accounting to value our financial assets and liabilities. Fair value measurement accounting provides a framework for measuring fair value under U.S. GAAP and requires expanded disclosures regarding fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

Described below are the three levels of inputs that may be used to measure fair value:

*Level 1* Quoted prices in active markets for identical assets or liabilities.

*Level 2* Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*Level 3* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

Description	September 30, 2016	Significant Other		
		Quoted Prices in Active Markets (Level 1)	Observable Input (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Marketable securities	\$ 75	\$ 75	\$	\$
Total assets	\$ 75	\$ 75	\$	\$
Liabilities:				
Contingent consideration obligations <sup>(1)</sup>	\$ 40,500	\$	\$	\$ 40,500
Total liabilities	\$ 40,500	\$	\$	\$ 40,500

Description	December 31, 2015	Quoted Prices in	Significant	Unobservable Inputs
		Active Markets (Level 1)	Other Observable Input (Level 2)	
Assets:				
Marketable securities	\$ 164	\$ 164	\$	\$
Total assets	\$ 164	\$ 164	\$	\$
Liabilities:				
Contingent consideration obligations <sup>(1)</sup>	\$ 57,744	\$	\$	\$ 57,744
Total liabilities	\$ 57,744	\$	\$	\$ 57,744

- <sup>(1)</sup> We determine the fair value of the contingent consideration obligations based on a probability-weighted approach derived from earn-out criteria estimates and a probability assessment with respect to the likelihood of achieving the various earn-out criteria. The measurement is based upon significant inputs not observable in the market. Significant increases or decreases in any of these inputs could result in a significantly higher or lower fair value measurement. Changes in the fair value of these contingent consideration obligations are recorded as income or expense within operating income in our consolidated statements of operations. See Note 17(a) for additional information on the valuation of our contingent consideration obligations.

**Table of Contents**

Changes in the fair value of our Level 3 contingent consideration obligations during the nine months ended September 30, 2016

were as follows (in thousands):

Fair value of contingent consideration obligations, December 31, 2015	\$ 57,744
Payments	(955)
Fair value adjustments	(16,290)
Foreign currency adjustments	1
Fair value of contingent consideration obligations, September 30, 2016	\$ 40,500

At September 30, 2016 and December 31, 2015, the carrying amounts of cash and cash equivalents, restricted cash, receivables, accounts payable and other current liabilities approximated their estimated fair values.

The carrying amount and estimated fair value of our long-term debt (including the current portion) were both \$2.9 billion at September 30, 2016. The carrying amount and estimated fair value of our long-term debt (including the current portion) were \$3.1 billion and \$3.0 billion, respectively, at December 31, 2015. The estimated fair value of our long-term debt was determined using market sources that were derived from available market information (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future.

**(14) Financial Information by Segment**

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision-making group is composed of the chief executive officer and certain members of senior management. We currently have three reportable operating segments: (i) professional diagnostics, (ii) consumer diagnostics and (iii) corporate and other. Our operating results include license and royalty revenue which are allocated to professional diagnostics and consumer diagnostics on the basis of the original license or royalty agreement. We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands):

	Professional Diagnostics	Consumer Diagnostics	Corporate and Other	Total
<b>Three Months Ended September 30, 2016:</b>				
Net revenue	\$ 563,007	\$ 19,347	\$	\$ 582,354
Operating income (loss)	\$ 84,341	\$ 718	\$ (81,627)	\$ 3,432
Depreciation and amortization	\$ 68,263	\$ 1,263	\$ 2,256	\$ 71,782
Restructuring charge	\$ 2,733	\$	\$ 8,557	\$ 11,290

Edgar Filing: ALERE INC. - Form 10-Q

Stock-based compensation	\$	\$	\$ 10,509	\$ 10,509
<b>Three Months Ended September 30, 2015:</b>				
Net revenue	\$	585,021	\$ 18,747	\$ 603,768
Operating income (loss)	\$	56,520	\$ 1,038	\$ (26,476)
Impairment and loss on dispositions, net	\$	1,923	\$	\$ 151
Depreciation and amortization	\$	83,865	\$ 717	\$ 1,966
Restructuring charge	\$	1,578	\$	\$ 686
Stock-based compensation	\$		\$ 7,317	\$ 7,317
<b>Nine Months Ended September 30, 2016:</b>				
Net revenue	\$	1,715,068	\$ 56,583	\$ 1,771,651
Operating income (loss)	\$	252,557	\$ 1,281	\$ (199,625)
(Gain) loss on dispositions, net	\$	4,967	\$ (8,777)	\$ (3,810)
Depreciation and amortization	\$	203,488	\$ 4,138	\$ 6,561
Restructuring charge	\$	10,830	\$	\$ 16,908
Stock-based compensation	\$		\$ 31,115	\$ 31,115
<b>Nine Months Ended September 30, 2015:</b>				
Net revenue	\$	1,774,671	\$ 65,360	\$ 1,840,031
Operating income (loss)	\$	299,303	\$ 4,321	\$ (156,508)
Impairment and (gain) loss on dispositions, net	\$	(38,643)	\$	\$ 81,051
Depreciation and amortization	\$	226,523	\$ 2,153	\$ 4,975
Restructuring charge	\$	10,103	\$	\$ 1,284
Stock-based compensation	\$		\$ 19,596	\$ 19,596
<b>Assets:</b>				
As of September 30, 2016	\$	5,410,679	\$ 192,885	\$ 252,110
As of December 31, 2015	\$	5,619,901	\$ 172,551	\$ 130,669

**Table of Contents**

The following tables summarize our net revenue from the professional diagnostics reporting segments by groups of similar products and services for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Cardiometabolic	\$ 188,731	\$ 208,979	\$ 587,289	\$ 621,588
Infectious disease	183,375	164,822	556,777	523,059
Toxicology	155,871	162,571	460,849	468,822
Other	32,550	45,350	102,411	147,511
<b>Total professional diagnostics net product sales and services revenue</b>	<b>560,527</b>	<b>581,722</b>	<b>1,707,326</b>	<b>1,760,980</b>
<b>License and royalty revenue</b>	<b>2,480</b>	<b>3,299</b>	<b>7,742</b>	<b>13,691</b>
<b>Total professional diagnostics net revenue</b>	<b>\$ 563,007</b>	<b>\$ 585,021</b>	<b>\$ 1,715,068</b>	<b>\$ 1,774,671</b>

**(15) Related Party Transactions***(a) SPD Joint Venture*

In May 2007, we completed the formation of SPD Swiss Precision Diagnostics GmbH, or SPD, our 50/50 joint venture with Procter & Gamble, or P&G, for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiometabolic, diabetes and oral care fields. Upon completion of the arrangement to form the joint venture, we ceased to consolidate the operating results of our consumer diagnostic products business related to the joint venture and instead account for our 50% interest in the results of the joint venture under the equity method of accounting.

We had a net payable to SPD of \$7.1 million as of September 30, 2016 and \$1.2 million as of December 31, 2015. The \$7.1 million net payable balance as of September 30, 2016 is net of a receivable of approximately \$1.3 million for costs incurred in connection with our 2008 SPD-related restructuring plans. The \$1.2 million net payable balance as of December 31, 2015 is net of a receivable of approximately \$1.5 million for costs incurred in connection with our 2008 SPD-related restructuring plans. We have also recorded a long-term receivable totaling approximately \$6.5 million and \$8.9 million as of September 30, 2016 and December 31, 2015, respectively, related to the 2008 SPD-related restructuring plans. Additionally, customer receivables associated with revenue earned after the formation of the joint venture have been classified as other receivables within prepaid and other current assets on our consolidated balance sheets in the amounts of \$9.3 million and \$7.8 million as of September 30, 2016 and December 31, 2015, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables. Sales to the joint venture under our manufacturing agreement totaled \$21.5 million and \$61.0 million during the three and nine months ended September 30, 2016, respectively, and \$17.3 million and \$58.5 million during the three and nine months ended September 30, 2015, respectively. Additionally, services revenue generated pursuant to the long-term services agreement with the joint venture totaled \$0.3 million and \$0.8 million during the three and nine months ended September 30, 2016, respectively, and \$0.2 million and \$0.8 million during the three and nine months ended September 30, 2015, respectively. Sales under our manufacturing agreement and long-term services agreement are included in net product sales and services revenue, respectively, in our accompanying consolidated statements of operations.

Under the terms of our product supply agreement, SPD purchases products from our manufacturing facilities in China. SPD in turn sells a portion of those tests back to us for final assembly and packaging. Once packaged, a portion of the tests are sold to P&G for distribution to third-party customers in North America. We defer our profit on products sold to SPD until the products are sold through to the customer. As a result of these related transactions, we have recorded \$11.8 million and \$9.9 million of trade receivables which are included in accounts receivable on our consolidated balance sheets as of September 30, 2016 and December 31, 2015, respectively, and \$40.2 million and \$24.9 million of trade accounts payable which are included in accounts payable on our consolidated balance sheets as of September 30, 2016 and December 31, 2015, respectively.



**Table of Contents**

The following table summarizes our related party balances with SPD within our consolidated balance sheets (in thousands):

<b>Balance Sheet Caption</b>	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Accounts receivable, net of allowances	\$ 11,827	\$ 9,873
Prepaid expenses and other current assets	\$ 9,343	\$ 6,602
Other non-current assets	\$ 6,504	\$ 8,895
Accounts payable	\$ 40,152	\$ 24,887

As previously disclosed, SPD is currently involved in civil litigation brought by a competitor in the United States with respect to the advertising of one of SPD's products in the United States. During 2015, SPD appealed the district court's injunction with respect to sales and advertising of such product, and the court's determination that SPD violated certain laws with respect to the advertising of such product. On September 9, 2016, the panel of the appellate court affirmed the district court's decision and, on September 23, 2016, SPD filed a petition for a rehearing en banc (meaning before the full appellate court). In the meantime, the injunction remains stayed. In addition, a class action lawsuit was decided involving SPD and P&G in the United States District Court for the Central District of California, alleging violations of certain laws in connection with the sales and advertising of one of SPD's products which claims are based on similar grounds as those at issue in the litigation described above in this paragraph. On August 19, 2016, the class action lawsuit was dismissed with prejudice. The plaintiffs have appealed the district court's decision. There may be additional lawsuits against SPD or us relating to this matter in the future. The ultimate resolution of these matters is not known at this time, nor is the potential impact they or future litigation may have on SPD or us, including whether any such resolution or any damages imposed by a court would have a material adverse impact on SPD and, ultimately, by virtue of our 50% interest in SPD, on our financial position or results of operations.

*(b) Entrustment Loan Arrangement with SPD Shanghai*

Our subsidiary Alere (Shanghai) Diagnostics Co., Ltd., or Alere Shanghai, and SPD's subsidiary SPD Trading (Shanghai) Co., Ltd., or SPD Shanghai, entered into an entrustment loan arrangement for a maximum of CNY 23 million (approximately \$3.4 million at September 30, 2016), in order to finance the latter's short-term working capital needs, with the Royal Bank of Scotland (China) Co., Ltd. Shanghai Branch, or RBS. The agreement governs the setting up of an Entrustment Loan Account with RBS, into which Alere Shanghai deposits certain monies. This restricted cash account provides a guarantee to RBS of amounts borrowed from RBS by SPD Shanghai. The Alere Shanghai RBS account is recorded as restricted cash on our balance sheet and amounted to \$3.4 million at September 30, 2016.

*(c) TechLab*

On September 16, 2016, we sold our 49% interest in TechLab Inc., a company that provides diagnostic testing products used by physicians and other health care customers to diagnose, treat, and monitor intestinal diseases and other medical conditions. Prior to this sale, we accounted for this interest in TechLab as an equity method investment. Alere served as a distributor of TechLab products prior to the September 16, 2016 sale and will remain the principal global distributor of TechLab products pursuant to the terms of a distribution agreement with TechLab. We had trade payables owed to Techlab of \$1.6 million and \$3.2 million as of September 30, 2016 and December 31, 2015, respectively. We made product purchases from Techlab of \$4.6 million and \$4.5 million during the three months ended September 30, 2016 and 2015, respectively, and \$13.7 million and \$13.0 million during the nine months ended September 30, 2016 and 2015.

As a result of the September 16, 2016 sale of our interest in TechLab, we recorded a gain in equity earnings of unconsolidated entities, net of tax, of \$18.7 million.

#### **(16) Other Arrangements**

In September 2014, we entered into a contract with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority, or BARDA, to develop diagnostic countermeasures for pandemic influenza. Under the terms of the contract, BARDA has agreed to provide up to \$12.9 million to us to support the development of a rapid, molecular, low-cost influenza diagnostic device with PCR-like performance at the point of care. The project is designed to help support future preparedness and medical response to an influenza pandemic. Funding from BARDA is subject to successful completion of various interim feasibility and development milestones as defined in the agreement. For the three months ended September 30, 2016 and 2015, we had incurred \$1.4 million and \$0.8 million, respectively, of qualified expenditures under the contract, for which we had received cash reimbursement from BARDA in the amount of \$1.0 million and \$0.6 million, respectively, and \$0.4 million and \$0.6 million were recorded as receivables as of September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016 and 2015, we had incurred \$3.1 million and \$2.2 million, respectively, of qualified expenditures under the contract, for which we had received cash reimbursement from BARDA in the amount of \$2.7 million and \$1.6 million, respectively. Reimbursements of qualified expenditures under this contract are recorded as a reduction of our related qualified research and development expenditures.

In February 2013, we entered into an agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation, whereby we were awarded a grant by the Gates Foundation in the amount of \$21.6 million to support the development and commercialization

**Table of Contents**

of validated, low-cost, nucleic-acid assays and cartridges for clinical tuberculosis detection and drug-resistance testing, and adaptation of an analyzer platform capable of operation in rudimentary laboratories in low-resource settings. In connection with this agreement, we also entered into a loan agreement with the Gates Foundation, or the Gates Loan Agreement, which provided for the making of subordinated term loans by the Gates Foundation to us from time to time, subject to the achievement of certain milestones, in an aggregate principal amount of up to \$20.6 million. In April 2016, we and the Gates Foundation agreed to mutually terminate this grant and loan agreement and, therefore, there will be no additional grants and no advances will be available under the loan agreement. Prior to its termination, we did not borrow any amounts under the Gates Loan Agreement. As of September 30, 2016, we had received approximately \$19.7 million in grant-related funding from the Gates Foundation (all of which was received prior to the April 2016 mutual termination). Grant funds were recorded upon receipt as restricted cash and deferred grant funding, with the deferred grant funding classified within accrued expenses and other current liabilities on our accompanying consolidated balance sheet. As qualified expenditures were incurred under the terms of the grant, we used the deferred funding to recognize a reduction of our related qualified research and development expenditures. For the three months ended September 30, 2015, we incurred approximately \$0.3 million of qualified expenditures, and for the nine months ended September 30, 2015 we incurred approximately \$3.9 million of qualified expenditures, for which we reduced our deferred grant funding balance and recorded an offset to our research and development expenses. There were no amounts remaining as restricted cash or deferred grant funding under the February 2013 grant agreement as of September 30, 2016.

In addition to the February 2013 grant discussed above, we have also been awarded several smaller grants by the Gates Foundation in the aggregate amount of approximately \$2.9 million to support the elimination of malaria. We incurred qualifying expenses totaling approximately \$0.7 million and \$0.2 million for the three months ended September 30, 2016 and 2015, respectively. We incurred qualifying expenses totaling approximately \$1.0 million and \$3.9 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, \$0.8 million under these grants was recorded as restricted cash and \$0.7 million as deferred grant funding on our consolidated balance sheet.

**(17) Commitments and Contingencies***(a) Acquisition-related Contingent Consideration Obligations*

We have contractual contingent purchase price consideration obligations related to certain of our acquisitions. We determine the acquisition date fair value of the contingent consideration obligations based on a probability-weighted approach derived from the overall likelihood of achieving certain performance targets, including product development milestones or financial metrics. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement, as defined in fair value measurement accounting. The resultant probability-weighted earn-out payments are discounted using a discount rate based upon the weighted-average cost of capital. At each reporting date, we revalue the contingent consideration obligations to the reporting date fair values and record increases and decreases in the fair values as income or expense in our consolidated statements of operations.

Increases or decreases in the fair values of the contingent consideration obligations may result from, among other things, changes in discount periods and rates, changes in the timing and amount of earn-out criteria and changes in probability assumptions with respect to the likelihood of achieving the various earn-out criteria. From time to time, we have entered into amendments to modify the provisions governing the contingent consideration obligations, and such amendments have resulted in changes to the fair value of these obligations. We may in the future enter into additional amendments that may also result in changes to such fair values.

The following table summarizes our contractual contingent purchase price consideration obligations related to certain of our acquisitions (in thousands):

Acquisition	Acquisition Date	Acquisition Date Fair Value	Maximum Remaining Earn-out Potential as of September 30, 2016	Remaining Earn-out Period as of September 30, 2016	Estimated Fair Value as of September 30, 2016	Estimated Payments Fair Value as of December 31, 2015	Estimated Payments Made During 2016
TwistDx, Inc. <sup>(1)</sup>	March 11, 2010	\$ 35,600	\$ 102,870	2016 - 2025 <sup>(3)</sup>	\$ 33,100	\$ 47,800	\$ 377
Epocal <sup>(2)</sup>	February 1, 2013	\$ 75,000	\$ 42,825	2016 - 2018	2,900	4,700	
Other	Various	\$ 30,373	\$ (4)	2016	4,500	5,244	578
					\$ 40,500	\$ 57,744	\$ 955

- <sup>(1)</sup> The terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain revenue and product development targets through 2025.

## **Table of Contents**

- (2) The terms of the acquisition agreement require us to pay earn-outs and management incentive payments upon successfully meeting certain product development and United States Food and Drug Administration regulatory approval milestones from the date of acquisition through December 31, 2018.
- (3) The maximum earn-out period ends on the fifteenth anniversary of the acquisition date.
- (4) The maximum remaining earn-out potential for the other acquisitions is not determinable due to the nature of one of the earn-outs, which is tied to an unlimited revenue metric.

### *(b) Legal Proceedings*

#### *Abbott Laboratories*

On August 25, 2016, Alere Inc. filed suit against Abbott Laboratories in the Delaware Chancery Court, and filed an accompanying motion to expedite the proceedings. The complaint alleges, among other things, that Abbott is purposefully failing to comply with its obligations set forth in the Merger Agreement related to obtaining antitrust approvals. Specifically, the complaint alleges that Abbott: (i) purposefully failed to supply information requested by the FTC as promptly as reasonably practicable after such requests were made, as expressly required by the Merger Agreement; (ii) purposefully failed to supply information requested and make antitrust filings pursuant to antitrust laws in various foreign jurisdictions as promptly as reasonably practicable after such requests were made; (iii) purposefully failed to promptly take any and all steps necessary to avoid or eliminate impediments to obtaining antitrust clearance in the United States and in various foreign jurisdictions; (iv) purposefully failed to keep Alere informed in all material respects and on a reasonably timely basis of material communications with respect to the merger with antitrust authorities in the United States and in various foreign jurisdictions; and (v) purposefully failed to cooperate and consult with Alere, as well as give due consideration to Alere's views with respect to antitrust matters. We asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by the Merger Agreement. On August 30, 2016, Abbott filed its response in opposition to the motion to expedite the proceedings in this matter. On September 2, 2016, the Delaware Chancery Court granted our motion to expedite the proceedings. On September 29, 2016, the Delaware Chancery Court entered an order that, among other things, adopted a detailed schedule setting forth actions required to be taken by specified dates in order to obtain all antitrust clearances required by the Merger Agreement. By order of the court, the schedule is confidential. The court order also (i) requires Abbott to provide us with advance notice of, and the right to participate (in a manner not inconsistent with the terms of the Merger Agreement) in, all future discussions with antitrust regulators worldwide; (ii) appoints a Special Master to confidentially mediate any disputes regarding compliance with the order or the parties' obligations under the Merger Agreement; (iii) lifts the stay of the case and permits discovery to commence immediately, including with respect to potential breaches of the Merger Agreement by Abbott; and (iv) sets a preliminary injunction hearing date on our claims for January 27, 2017, if necessary.

On November 3, 2016, Abbott filed a complaint against Alere in the Delaware Chancery Court. Abbott asserts a single claim against Alere for breach of contract stemming from Alere's refusal to provide Abbott with certain categories of documents under the Merger Agreement. The complaint makes no claim for damages and seeks to compel Alere to produce certain categories of documents and information which Abbott contends Alere is obligated to produce under the terms of the Merger Agreement. Alere believes it has fulfilled its contractual obligations under the merger agreement.

#### *U.S. Securities and Exchange Commission Subpoenas*

On August 28, 2015, we received a subpoena from the SEC which indicated that it is conducting a formal investigation of Alere. The SEC's subpoena relates to, among other things, (i) our previously filed restatement and revision to our financial statements, including the accounting for deferred taxes for discontinued operations, as well as our tax strategies and policies and (ii) our sales practices and dealings with third parties (including distributors and

foreign government officials) in Africa relating to sales to government entities. On January 14, 2016, we received a second subpoena from the SEC in connection with this formal investigation seeking, among other things, additional information related to sales of products and services to end-users in Africa, as well as revenue recognition relating to sales of products and services to end-users in Africa. We have also received, from time to time, requests in connection with the investigation to voluntarily produce additional information to the SEC, including information pertaining to certain other countries in Asia and Latin America, as well as additional information on revenue recognition matters and revisions to our financial statements referenced in our Annual Report on Form 10-K for the year ended December 31, 2015.

We are cooperating with the SEC and have provided documents in response to the subpoenas and voluntary requests. We are unable to predict when this matter will be resolved or what further action, if any, the SEC may take in connection with it.

#### *Department of Justice Grand Jury Subpoena*

On March 11, 2016, we received a grand jury subpoena from the United States Department of Justice requiring the production of documents relating to, among other things, sales, sales practices and dealings with third parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act.

We are cooperating with the Department of Justice and have provided information in response to the subpoena. We are unable to predict when this matter will be resolved or what further action, if any, the Department of Justice may take in connection with it.

#### *Securities Class Actions*

On April 21, 2016, a class action lawsuit captioned *Godinez v. Alere Inc.*, was filed against us in the United States District Court for the District of Massachusetts. On May 4, 2016, a second class action lawsuit captioned *Breton v. Alere Inc.*, was filed against us in

**Table of Contents**

the United States District Court for the District of Massachusetts. Both of these class actions purport to assert claims against us and certain current and former officers for alleged violations of Section 10(b) and Section 20(a) of the Exchange Act and Rule 10b-5 under the Exchange Act. Each plaintiff seeks to represent a proposed class of all persons who purchased or otherwise acquired our common stock during the period May 9, 2013 through April 20, 2016. Each complaint seeks damages allegedly caused by alleged materially misleading statements and/or material omissions by us and the officers regarding our business, prospects and operations, each plaintiff claims, which allegedly operated to inflate artificially the price paid for our common stock during the class period. Each complaint seeks unspecified compensatory damages, attorneys' fees and costs. On July 11, 2016, the court entered an order consolidating the two actions and appointing lead plaintiffs and lead counsel. A consolidated amended complaint filed on September 23, 2016 alleges certain additional misleading statements and omissions and changes the proposed class period to May 18, 2015 through July 27, 2016. Oral argument on defendants' motion to dismiss is set for April 2017. We are filing our motion to dismiss the amended complaint on November 8, 2016 and the court has scheduled oral argument on that motion for April 5, 2017.

We are unable at this time to determine the outcome of this class action lawsuit or our potential liability, if any.

*Matters Relating to our San Diego Facility*

On October 9, 2012, we received a warning letter from the FDA referencing inspectional observations set forth in a Form FDA 483 received in June 2012. The observations were the result of an inspection of our San Diego facility conducted earlier during 2012 relating to our Alere Triage products, which resulted in two recalls of certain Alere Triage products and revised release specifications for our Alere Triage meter-based products. In September 2014, as follow up to a further inspection of our San Diego facility, the FDA notified us that this inspection was classified voluntary action indicated, meaning that the objectionable conditions or practices found in the inspection did not meet the threshold of significance requiring regulatory action, but that formal close-out of the October 2012 warning letter could not occur until after a future inspection.

In May 2012, we also received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG, seeking documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the government and are responding to the investigation, which is ongoing. We have been engaged in discussions with the government about this matter, including a resolution of potential related False Claims Act and common law liability exposure for the products under review. As a result of these discussions, management has accrued \$20.7 million for this matter in the nine months ended September 30, 2016. We would need to obtain certain approvals before we could agree to any proposed resolution. There can be no assurance that future discussions with the government to resolve these matters will be successful, that the approvals we need will be obtained or that any potential settlement will be agreed to or finalized. We may be required to engage in litigation of this matter, which may be time consuming and costly. Based on the ongoing uncertainties and potentially wide range of outcomes associated with any potential resolution, the ultimate amount of potential loss may materially exceed the accrual we have established.

We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with them.

*INRatio Class Actions*

On May 26, 2016, a class action complaint, captioned *Dina Andren, et al. v. Alere Inc., et al.*, was filed against us in the United States District Court for the Southern District of California, and the plaintiffs filed an amended class action complaint on October 3, 2016. In addition, on July 22, 2016, a class action complaint captioned *J.E. J.D., and all*

*others similarly situated v. Alere Inc., Alere San Diego, Inc. and Alere Home Monitoring, Inc.*, was filed against us in the United States District Court for the District of Massachusetts, and the plaintiffs filed an amended class action complaint on October 10, 2016. These class actions, as amended, purport to assert claims against us under several legal theories, including fraud, breach of warranty, breach of contract, unjust enrichment and violation of applicable unfair competition/business practice statutes in connection with the manufacturing, marketing and sale of our INRatio products. The seven named plaintiffs in the *Dina Andren* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for INRatio products during the period January 1, 2009 to the present in the United States, or alternatively, California, Colorado, Florida, Georgia, Maryland, New York, and/or Pennsylvania. The two named plaintiffs in the *J.E., J.D., and all others similarly situated* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for INRatio products during the period April 1, 2008 to present. Both class action complaints seek restitution and damages allegedly resulting from inaccurate PT/INR readings and from the purchase of devices and/or test strips that claimants say they would not have purchased had they known of the alleged propensity of these devices to yield inaccurate PT/INR results. Among other things, plaintiffs in these class action lawsuits seek a refund of money spent on INRatio products. Each complaint also seeks unspecified compensatory damages, injunctive relief, attorneys' fees and costs.

We are unable, at this time, to predict the outcome of these class action lawsuits.



*Claims in the Ordinary Course and Other Matters*

We are also party to certain other legal proceedings and other governmental investigations, or are requested to provide information in connection with such proceedings or investigations. For example, in December 2014, we and our subsidiary, Avee Laboratories Inc., or Avee, received subpoenas from the United States Attorney for the District of New Jersey seeking marketing materials and other documents relating primarily to billing and marketing practices related to toxicology testing. In addition, we received a U.S. Department of Justice criminal subpoena addressed to Alere Toxicology Services, Inc. on July 1, 2016 which seeks records related to Medicare, Medicaid and Tricare billings dating back to 2010 for specific patient samples tested at our Austin, Texas pain management laboratory and payments made to physicians. We are cooperating with these investigations and are providing

**Table of Contents**

documents in response to both subpoenas. We and our subsidiary, Arriva Medical, LLC, are also in the process of responding to Civil Investigative Demands, or CIDs, from the United States Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid. The most recent of the CIDs was received in July 2016. The CIDs request patient and insurance billing and medical records, records related to interactions with third parties, and correspondence related to the same, dating back to January 2010. We are cooperating with the investigation and are providing documents responsive to the CIDs. We cannot predict what effect, if any, these investigations, or any resulting claims, could have on Alere or its subsidiaries.

We have received, from time to time, additional subpoenas and requests for information from the United States Department of Justice, other federal government agencies and state attorneys general, and we have, in each of these cases, cooperated with the applicable governmental entity in responding to the applicable subpoena or request for information. For example, in May 2016, we received a subpoena from the U.S. Attorney for the District of New Jersey, which seeks various documents related to the accuracy, reliability and performance of the INRatio System, including documents relating to prior interactions with the FDA and others regarding the system.

Our diabetes, toxicology and patient self-testing businesses are subject to audit and claims for reimbursement brought in the ordinary course by private third-party payers, including health insurers, Zone Program Integrity Contractors, or ZPICs, and Medicare Administrative Contractors, or MACs, to monitor compliance with coverage and reimbursement rules and guidelines. These types of audits and claims can include, but are not limited to, claims relating to proper documentation and support or claims relating to the medical necessity of certain testing and can lead to assertions or determinations that certain claims should not have been, or will no longer be, paid by the private third-party payer or by Medicare or Medicaid. In such cases, the payer or program may seek to recoup or offset amounts they assert have been paid in error.

Our businesses may also be subject at any time to other commercial disputes, product liability claims, personal injury claims, including claims arising from or relating to product recalls, negligence claims, third-party subpoenas or various other lawsuits arising in the ordinary course of business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. For example, several individuals have filed suits against us alleging personal injury claims in connection with the use of our INRatio products (which are in addition to the class action suits described above).

Such lawsuits or claims generally seek damages or reimbursement, sometimes in substantial amounts. There are possible unfavorable outcomes related to litigation or governmental investigations that could adversely impact our business, results of operations, financial condition, and cash flows.

**(18) Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that we adopt on or before the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position, results of operations, comprehensive income or cash flows upon adoption. Please also see Note 3, *Summary of Significant Accounting Policies*, to our consolidated financial statements included within our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

***Recently Issued Standards***

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, or ASU 2016-15. ASU 2016-15 provides cash flow statement classification

guidance for: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2016-15 on our consolidated financial statements.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12. ASU 2016-12: (1) clarifies the objective of the collectability criterion for applying Accounting Standards Codification, or ASC, paragraph 606-10-25-7; (2) permits an entity to exclude amounts collected from customers for all sales (and other similar) taxes from the transaction price; (3) specifies that the measurement date for non-cash consideration is contract inception; (4) provides a practical expedient that permits an entity to reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented when identifying the satisfied and unsatisfied performance obligations, determining the transaction price, and allocating the transaction price to the satisfied and unsatisfied performance obligations; (5) clarifies that a completed contract for purposes of transition is a contract for which all (or substantially all) of the revenue was recognized under legacy GAAP before the date of initial

---

**Table of Contents**

application, and (6) clarifies that an entity that retrospectively applies the guidance in Topic 606 to each prior reporting period is not required to disclose the effect of the accounting change for the period of adoption. ASU 2016-12 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the impact of the adoption of ASU 2016-15 on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, or ASU 2016-10. ASU 2016-10 adds further guidance on identifying performance obligations and also to improve the operability and understandability of the licensing implementation guidance. ASU 2016-10 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2016-10 on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 simplifies several aspects of the accounting for share-based payment award transactions including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We do not expect the adoption of ASU 2016-09 to have a significant impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-07, *Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting*, or ASU 2016-07. ASU 2016-07 eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect during all previous periods that the investment had been held. ASU 2016-07 requires that the equity method investor add the cost of acquiring the additional interest in the investee to the current basis of the investor's previously held interest and adopt the equity method of accounting as of the date the investment becomes qualified for equity method accounting. Therefore, upon qualifying for the equity method of accounting, no retroactive adjustment of the investment is required. ASU 2016-07 also requires that an entity that has an available-for-sale equity security that becomes qualified for the equity method of accounting recognize through earnings the unrealized holding gain or loss in accumulated other comprehensive income at the date the investment becomes qualified for use of the equity method. ASU 2016-07 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and should be applied prospectively with early adoption permitted. We do not expect the adoption of ASU 2016-07 to have a significant impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. ASU 2016-02 requires lessees to recognize for all leases (with the exception of short-term leases) at the commencement date, a lease liability which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and should be applied with a modified retrospective transition approach, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2016-02 on our consolidated financial statements.

We believe that there were no other accounting standards recently issued that had or are expected to have a material impact on our consolidated financial statements.

### ***Recently Adopted Standards***

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*, or ASU 2015-16. ASU 2015-16 requires that an acquirer recognize adjustments to estimated amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date with earlier application permitted for financial statements that have not been issued. Effective January 1, 2016, we adopted ASU 2015-16. The adoption did not have a significant impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, or ASU 2015-03. ASU 2015-03 is intended to simplify the presentation of debt issuance costs. It requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015, and for interim periods within those fiscal years. Early adoption is permitted. In August 2015, the FASB issued ASU No. 2015-15, *Interest Imputation of Interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements (Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting)*, or ASU 2015-15. ASU 2015-15 adds the authoritative guidance on presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements to ASU 2015-03. Effective December 31, 2015, we adopted ASU 2015-03 and ASU 2015-15, and accordingly we have reclassified \$34.1 million of debt issuance costs from other non-current assets to long-term debt, net of current portion on our balance sheet as of December 31, 2015.

**Table of Contents**

In June 2014, the FASB issued ASU No. 2014-12, *Compensation – Stock Compensation (Topic 718) – Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*, or ASU 2014-12. ASU 2014-12 requires that a performance target which affects vesting and which could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for fiscal years beginning after December 15, 2015, and for interim periods within those fiscal years. Effective January 1, 2016, we adopted ASU 2014-12. The adoption did not have a significant impact on our consolidated financial statements.

**(19) Equity Investments**

We account for the results from our equity investments under the equity method of accounting in accordance with ASC 323, *Investments – Equity Method and Joint Ventures*, based on the percentage of our ownership interest in the business. Our equity investments primarily include the following:

**(a) SPD**

We recorded earnings of \$6.7 million and \$12.9 million during the three and nine months ended September 30, 2016, respectively, and earnings of \$5.3 million and \$9.5 million during the three and nine months ended September 30, 2015, respectively, in equity earnings of unconsolidated entities, net of tax, in our consolidated statements of operations, which represented our 50% share of SPD's net income for the respective periods and elimination of intercompany profit in inventory related to sales from Alere to SPD which is reflected in SPD's net income. During the nine months ended September 30, 2015, we received \$12.1 million in cash from SPD as a return of capital.

**(b) TechLab**

We recorded earnings of \$19.5 million and \$20.5 million during the three and nine months ended September 30, 2016, respectively, and losses of \$0.3 million and earnings of \$1.0 million during the three and nine months ended September 30, 2015, respectively, in equity earnings of unconsolidated entities, net of tax, in our consolidated statements of operations, which represented our minority share of TechLab's net income for the respective periods. During the nine months ended September 30, 2015, we received \$2.2 million in cash from TechLab as a return of capital. On September 16, 2016, we completed the sale of our 49% interest in the TechLab business and, in connection with such sale, we recorded a gain in equity earnings of unconsolidated entities, net of tax, of \$18.7 million.

Summarized financial information for SPD and TechLab on a combined basis is as follows (in thousands):

<b>Combined Condensed Results of Operations:</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net revenue	\$ 56,622	\$ 56,303	\$ 165,133	\$ 157,319
Gross profit	\$ 44,979	\$ 43,538	\$ 117,832	\$ 111,368
Net income after taxes	\$ 14,927	\$ 15,735	\$ 29,396	\$ 26,831

**Combined Condensed Balance Sheet:**

**September 30, 2016 December 31, 2015**

Edgar Filing: ALERE INC. - Form 10-Q

Current assets	\$	109,911	\$	71,542
Non-current assets		29,674		30,802
Total assets	\$	139,585	\$	102,344
Current liabilities	\$	52,045	\$	37,609
Non-current liabilities		5,255		5,157
Total liabilities	\$	57,300	\$	42,766

**(20) Impairment and (Gain) Loss on Dispositions, Net**

In January 2016, we completed the sale of our Alere E-Santé business, which was a component of our professional diagnostics reporting unit and business segment. We received cash consideration of approximately \$8.1 million, net of a final working capital

---

**Table of Contents**

adjustment totaling approximately \$0.2 million, and we are eligible to receive up to \$1.5 million of contingent cash consideration. As a result of this transaction, we recorded a \$3.8 million gain in the three months ended March 31, 2016 on the disposition of the Alere E-Santé business.

In July 2015, we sold certain assets of our Inverness Medical Innovations Australia Pty Ltd business, which was part of our professional diagnostics reporting unit and business segment, for AUD 0.2 million (approximately \$0.1 million as of the date of disposition) in cash proceeds and, as a result of this transaction, we recorded a loss of \$1.2 million during the three and nine months ended September 30, 2015.

We recorded additional charges of approximately \$0.9 million in connection with certain other business closures or divestitures during the three and nine months ended September 30, 2015.

In May 2015, we sold our Alere Analytics business, which was part of our professional diagnostics reporting unit and business segment. Under the terms of the sale we received nominal consideration and agreed to contribute working capital of \$2.7 million to Alere Analytics, of which \$2.4 million was contributed in cash immediately prior to the closing of the sale and the remaining \$0.3 million of which was deposited in escrow pending the performance by the buyers under certain contracts. As a result of this transaction we recorded a loss of \$4.7 million during the second quarter of 2015. During the three months ended March 31, 2015, before identifying a buyer for Alere Analytics, our management decided to close the business, and in connection with this decision we recorded an impairment charge of \$26.7 million during the period, including the write-off of \$26.2 million of acquisition-related intangible assets and \$0.5 million of fixed assets.

In March 2015, we sold certain assets of our AdnaGen GmbH business, which was part of our professional diagnostics reporting unit and business segment, for approximately \$4.6 million in cash proceeds and, as a result of this transaction, we recorded a loss of \$0.3 million during the three months ended March 31, 2015.

In March 2015, we sold our Gesellschaft fur Patientenhilfe DGP GmbH subsidiary, which was part of our professional diagnostics reporting unit and business segment, for 7.6 million (approximately \$8.2 million at March 31, 2015) and, as a result of this transaction, we recorded a loss on disposition of \$7.5 million during the three months ended March 31, 2015.

In December 2014, our management decided to close our Alere Connect, LLC subsidiary, which is part of our professional diagnostics reporting unit and business segment. During the nine months ended September 30, 2015, in connection with this decision, we recorded impairment charges of \$1.1 million, consisting primarily of severance costs, inventory write-offs and other closure-related expenses.

The financial results for the above businesses are immaterial to our consolidated financial results.

**(21) Income Taxes**

We determine our estimated annual effective tax rate at the end of each interim period based on forecasted full-year pre-tax income (loss) by jurisdiction and permanent items. Our effective tax rate by quarter may vary based on actual quarter to date income and the forecasted mix of jurisdictional income (loss), as well as discrete items.

A reconciliation between the U.S. federal statutory rate and our effective tax rate is summarized as follows:



Edgar Filing: ALERE INC. - Form 10-Q

	For the Three Months Ended September 30		For the nine Months Ended September 30	
	2016	2015	2016	2015
Statutory rate	35%	35%	35%	35%
State income taxes, net of federal benefit	5%	-4%	5%	12%
Rate differential on foreign earnings and impact of foreign inclusion	20%	-6%	19%	21%
Change in estimated annual effective tax rate	46%	33%		
Change in valuation allowance	-11%	-22%	-11%	-77%
Stock-based compensation	-4%	5%	-3%	22%
Uncertain tax positions	-9%	14%	-8%	9%
Sale of business		2%		-102%
Other	6%	22%	4%	46%
Contingent consideration	5%	-21%	5%	69%
Effective tax rate	93%	58%	46%	35%

**Table of Contents**

For the three months and nine months ended September 30, 2016, compared to the same periods in 2015, our effective tax rate increase is primarily attributed to change in overall profitability, jurisdictional mix of income and losses and non-recurring discrete impacts in 2015. The change in overall profitability is primarily attributable to increased expenses related to the pending transaction with Abbott, legal and consulting fees related to certain government investigations and other charges associated with our various restructuring plans.

**(22) Guarantor Financial Information**

Our 7.25% senior notes due 2018, our 6.5% senior subordinated notes due 2020 and our 6.375% senior subordinated notes due 2023 are guaranteed, and before their redemption on October 1, 2015, our 8.625% senior subordinated notes due 2018 were guaranteed, by certain of our consolidated 100% owned subsidiaries, or the Guarantor Subsidiaries. The guarantees are full and unconditional and joint and several. The following supplemental financial information sets forth, on a consolidating basis, balance sheets as of September 30, 2016 and December 31, 2015, the related statements of operations and statements of comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015, and statements of cash flows for the nine months ended September 30, 2016 and 2015, respectively, for Alere Inc., the Guarantor Subsidiaries and our other subsidiaries, or the Non-Guarantor Subsidiaries. The supplemental financial information reflects the investments of Alere Inc. and the Guarantor Subsidiaries in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

We have extensive transactions and relationships between various members of the consolidated group. These transactions and relationships include intercompany pricing agreements, intellectual property royalty agreements and general and administrative and research and development cost sharing agreements. Because of these relationships, it is possible that the terms of these transactions are not the same as those that would result from transactions among wholly unrelated parties.

Effective December 31, 2015, we adopted ASU 2015-03 and ASU 2015-15, and accordingly we have reclassified \$34.1 million of debt issuance costs from other non-current assets to long-term debt, net of current portion on our balance sheet as of December 31, 2015, as described in Note 18 *Recent Accounting Pronouncements*.

As discussed in Note 2 *Revision to Previously Reported Financial Statements*, in connection with the preparation of our consolidated financial statements for 2015, we determined that, in 2013 and 2014, each of the interim periods in 2014, and the first three quarters of 2015, we had incorrectly recorded the revenue for such periods. In addition, we corrected several out-of-period adjustments. As a result, we revised our consolidated financial information for the years ended December 31, 2014 and 2013, each of the interim periods in 2014 and the first three quarters of 2015. The revisions to the consolidating statements of cash flows in this Note 22 did not impact previously reported net cash flows from operating activities, investing activities, or financing activities and as a result, there was no net impact to net change in cash and cash equivalents for the previously reported periods reflected in this Note 22. Additionally, we have revised the consolidating balance sheet as of December 31, 2015 to correct the classification of certain immaterial income tax related balance sheet items.

The following schedules reconcile the amounts as previously reported in our consolidating financial statements to the corresponding revised amounts:

**Three Months Ended  
September 30, 2015**

**Revised Consolidating Statement of Operations- Guarantor Subsidiaries**

<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 347,014	\$ 1,024	\$ 348,038
Cost of net revenue	\$ 206,803	\$ 253	\$ 207,056
Income from continuing operations before benefit for income taxes	\$ 37,740	\$ (317)	\$ 37,423
Benefit for income taxes	\$ 33,431	\$ (4,785)	\$ 28,646
Income from continuing operations	\$ 71,171	\$ (5,102)	\$ 66,069

**Three Months Ended  
September 30, 2015**

**Revised Consolidating Statement of Operations- Non-Guarantor Subsidiaries**

<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 327,031	\$ 700	\$ 327,731
Cost of net revenue	\$ 188,137	\$ (447)	\$ 187,690
Income from continuing operations before benefit for income taxes	\$ 25,489	\$ 1,147	\$ 26,636
Benefit for income taxes	\$ 63,534	\$ (3,929)	\$ 59,605
Income from continuing operations	\$ 94,371	\$ (2,782)	\$ 91,589

**Table of Contents****Nine Months Ended September 30,  
2015****Revised Consolidating Statement of Operations- Guarantor Subsidiaries**

<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 1,006,296	\$ (2,157)	\$ 1,004,139
Cost of net revenue	\$ 594,072	\$ (629)	\$ 593,443
Income from continuing operations before benefit for income taxes	\$ 97,789	\$ (4,778)	\$ 93,011
Benefit for income taxes	\$ 20,334	\$ (3,269)	\$ 17,065
Income from continuing operations	\$ 118,123	\$ (8,047)	\$ 110,076

**Nine Months Ended September 30,  
2015****Revised Consolidating Statement of Operations- Non-Guarantor Subsidiaries**

<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 1,037,808	\$ 2,835	\$ 1,040,643
Cost of net revenue	\$ 586,462	\$ 1,399	\$ 587,861
Income from continuing operations before benefit for income taxes	\$ 213,783	\$ 236	\$ 214,019
Benefit for income taxes	\$ 31,051	\$ (4,366)	\$ 26,685
Income from continuing operations	\$ 254,174	\$ (4,130)	\$ 250,044

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Three Months Ended September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$	\$ 220,694	\$ 309,896	\$ (74,494)	\$ 456,096
Services revenue		112,045	11,733		123,778
Net product sales and services revenue		332,739	321,629	(74,494)	579,874
License and royalty revenue		3,940	1,617	(3,077)	2,480
<b>Net revenue</b>		<b>336,679</b>	<b>323,246</b>	<b>(77,571)</b>	<b>582,354</b>
Cost of net product sales	130	125,740	176,740	(63,664)	238,946
Cost of services revenue	723	77,875	7,325	(9,284)	76,639
Cost of net product sales and services revenue	853	203,615	184,065	(72,948)	315,585
Cost of license and royalty revenue		5	3,711	(3,075)	641
<b>Cost of net revenue</b>	<b>853</b>	<b>203,620</b>	<b>187,776</b>	<b>(76,023)</b>	<b>316,226</b>
<b>Gross profit (loss)</b>	<b>(853)</b>	<b>133,059</b>	<b>135,470</b>	<b>(1,548)</b>	<b>266,128</b>
Operating expenses:					
Research and development	3,228	20,338	7,864		31,430
Sales and marketing	1,867	52,928	47,184		101,979
General and administrative	75,261	18,319	36,196	(489)	129,287
<b>Operating income (loss)</b>	<b>(81,209)</b>	<b>41,474</b>	<b>44,226</b>	<b>(1,059)</b>	<b>3,432</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(43,291)	(713)	(2,831)	2,705	(44,130)
Other income (expense), net	(11,058)	1,574	(2,124)	(2,704)	(14,312)
<b>Income (loss) before provision (benefit) for income taxes</b>	<b>(135,558)</b>	<b>42,335</b>	<b>39,271</b>	<b>(1,058)</b>	<b>(55,010)</b>
Provision (benefit) for income taxes	(227,263)	75,980	100,395		(50,888)
<b>Income (loss) before equity in earnings of subsidiaries and unconsolidated entities, net of tax</b>	<b>91,705</b>	<b>(33,645)</b>	<b>(61,124)</b>	<b>(1,058)</b>	<b>(4,122)</b>
Equity in earnings of subsidiaries, net of tax	(88,559)			88,559	

Edgar Filing: ALERE INC. - Form 10-Q

Equity earnings of unconsolidated entities, net of tax	18,881		6,677	591	26,149
<b>Net income (loss)</b>	22,027	(33,645)	(54,447)	88,092	22,027
Less: Net income attributable to non-controlling interests			207		207
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	22,027	(33,645)	(54,654)	88,092	21,820
Preferred stock dividends	(5,366)				(5,366)
<b>Net income (loss) available to common stockholders</b>	\$ 16,661	\$ (33,645)	\$ (54,654)	\$ 88,092	\$ 16,454

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Three Months Ended September 30, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$	\$ 228,963	\$ 310,571	\$ (67,406)	\$ 472,128
Services revenue		115,829	12,512		128,341
Net product sales and services revenue		344,792	323,083	(67,406)	600,469
License and royalty revenue		3,246	4,648	(4,595)	3,299
<b>Net revenue</b>		<b>348,038</b>	<b>327,731</b>	<b>(72,001)</b>	<b>603,768</b>
Cost of net product sales	2,091	125,106	175,341	(56,724)	245,814
Cost of services revenue	74	81,549	6,999	(8,771)	79,851
Cost of net product sales and services revenue	2,165	206,655	182,340	(65,495)	325,665
Cost of license and royalty revenue	(19)	401	5,350	(4,595)	1,137
<b>Cost of net revenue</b>	<b>2,146</b>	<b>207,056</b>	<b>187,690</b>	<b>(70,090)</b>	<b>326,802</b>
<b>Gross profit (loss)</b>	<b>(2,146)</b>	<b>140,982</b>	<b>140,041</b>	<b>(1,911)</b>	<b>276,966</b>
Operating expenses:					
Research and development	5,670	15,015	15,326		36,011
Sales and marketing	1,335	53,862	51,296		106,493
General and administrative	22,960	34,817	43,529		101,306
Impairment and (gain) loss on dispositions, net	150	85	1,839		2,074
<b>Operating income (loss)</b>	<b>(32,261)</b>	<b>37,203</b>	<b>28,051</b>	<b>(1,911)</b>	<b>31,082</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(51,705)	(2,613)	(4,999)	6,984	(52,333)
Other income (expense), net	4,225	2,833	3,584	(6,984)	3,658
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	<b>(79,741)</b>	<b>37,423</b>	<b>26,636</b>	<b>(1,911)</b>	<b>(17,593)</b>
Provision (benefit) for income taxes	78,040	(28,646)	(59,605)	(1)	(10,212)
<b>Income (loss) from continuing operations before equity in earnings</b>	<b>(157,781)</b>	<b>66,069</b>	<b>86,241</b>	<b>(1,910)</b>	<b>(7,381)</b>

**(losses) of subsidiaries and****unconsolidated entities, net of tax**

Equity in earnings of subsidiaries, net of tax	155,764			(155,764)	
Equity earnings (losses) of unconsolidated entities, net of tax	(364)		5,348	16	5,000
<b>Net income (loss)</b>	<b>(2,381)</b>	<b>66,069</b>	<b>91,589</b>	<b>(157,658)</b>	<b>(2,381)</b>
Less: Net loss attributable to non-controlling interests			(61)		(61)
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	<b>(2,381)</b>	<b>66,069</b>	<b>91,650</b>	<b>(157,658)</b>	<b>(2,320)</b>
Preferred stock dividends	(5,369)				(5,369)
<b>Net income (loss) available to common stockholders</b>	<b>\$ (7,750)</b>	<b>\$ 66,069</b>	<b>\$ 91,650</b>	<b>\$ (157,658)</b>	<b>\$ (7,689)</b>



Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Nine Months Ended September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$	\$ 668,028	\$ 942,273	\$ (210,688)	\$ 1,399,613
Services revenue		329,227	35,069		364,296
Net product sales and services revenue		997,255	977,342	(210,688)	1,763,909
License and royalty revenue		10,308	6,183	(8,749)	7,742
<b>Net revenue</b>		<b>1,007,563</b>	<b>983,525</b>	<b>(219,437)</b>	<b>1,771,651</b>
Cost of net product sales	464	377,293	531,200	(182,152)	726,805
Cost of services revenue	827	229,573	23,125	(25,492)	228,033
Cost of net product sales and services revenue	1,291	606,866	554,325	(207,644)	954,838
Cost of license and royalty revenue		15	11,300	(8,748)	2,567
<b>Cost of net revenue</b>	<b>1,291</b>	<b>606,881</b>	<b>565,625</b>	<b>(216,392)</b>	<b>957,405</b>
<b>Gross profit (loss)</b>	<b>(1,291)</b>	<b>400,682</b>	<b>417,900</b>	<b>(3,045)</b>	<b>814,246</b>
Operating expenses:					
Research and development	10,359	50,991	25,588		86,938
Sales and marketing	4,771	160,548	138,989		304,308
General and administrative	177,616	81,965	113,505	(489)	372,597
Impairment and (gain) loss on dispositions, net			(3,810)		(3,810)
<b>Operating income (loss)</b>	<b>(194,037)</b>	<b>107,178</b>	<b>143,628</b>	<b>(2,556)</b>	<b>54,213</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(126,235)	(5,588)	(8,673)	11,931	(128,565)
Other income (expense), net	(17,214)	8,179	(8,807)	(11,931)	(29,773)
<b>Income (loss) before provision (benefit) for income taxes</b>	<b>(337,486)</b>	<b>109,769</b>	<b>126,148</b>	<b>(2,556)</b>	<b>(104,125)</b>
Provision (benefit) for income taxes	(207,552)	69,471	90,102		(47,979)
<b>Income (loss) before equity in earnings of subsidiaries and unconsolidated entities, net of tax</b>	<b>(129,934)</b>	<b>40,298</b>	<b>36,046</b>	<b>(2,556)</b>	<b>(56,146)</b>

Edgar Filing: ALERE INC. - Form 10-Q

Equity in earnings of subsidiaries, net of tax	86,943			(86,943)	
Equity earnings of unconsolidated entities, net of tax	20,150		12,815	340	33,305
<b>Net income (loss)</b>	(22,841)	40,298	48,861	(89,159)	(22,841)
Less: Net income attributable to non-controlling interests			453		453
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	(22,841)	40,298	48,408	(89,159)	(23,294)
Preferred stock dividends	(15,983)				(15,983)
<b>Net income (loss) available to common stockholders</b>	\$ (38,824)	\$ 40,298	\$ 48,408	\$ (89,159)	\$ (39,277)

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Nine Months Ended September 30, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$	\$ 655,594	\$ 985,966	\$ (194,045)	\$ 1,447,515
Services revenue		338,869	39,956		378,825
Net product sales and services revenue		994,463	1,025,922	(194,045)	1,826,340
License and royalty revenue		9,676	14,721	(10,706)	13,691
<b>Net revenue</b>		<b>1,004,139</b>	<b>1,040,643</b>	<b>(204,751)</b>	<b>1,840,031</b>
Cost of net product sales	2,924	358,354	551,340	(168,810)	743,808
Cost of services revenue	204	233,470	22,963	(24,360)	232,277
Cost of net product sales and services revenue	3,128	591,824	574,303	(193,170)	976,085
Cost of license and royalty revenue	(40)	1,619	13,558	(10,706)	4,431
<b>Cost of net revenue</b>	<b>3,088</b>	<b>593,443</b>	<b>587,861</b>	<b>(203,876)</b>	<b>980,516</b>
<b>Gross profit (loss)</b>	<b>(3,088)</b>	<b>410,696</b>	<b>452,782</b>	<b>(875)</b>	<b>859,515</b>
Operating expenses:					
Research and development	11,213	43,927	36,085		91,225
Sales and marketing	4,165	159,190	160,241		323,596
General and administrative	67,873	123,875	63,422		255,170
Impairment and (gain) loss on dispositions, net	81,051	(8,719)	(29,924)		42,408
<b>Operating income (loss)</b>	<b>(167,390)</b>	<b>92,423</b>	<b>222,958</b>	<b>(875)</b>	<b>147,116</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(156,889)	(8,958)	(13,744)	21,333	(158,258)
Other income (expense), net	11,468	9,546	4,805	(21,333)	4,486
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	<b>(312,811)</b>	<b>93,011</b>	<b>214,019</b>	<b>(875)</b>	<b>(6,656)</b>
Provision (benefit) for income taxes	41,067	(17,065)	(26,685)	307	(2,376)
<b>Income (loss) from continuing operations before equity in earnings</b>	<b>(353,878)</b>	<b>110,076</b>	<b>240,704</b>	<b>(1,182)</b>	<b>(4,280)</b>

**of subsidiaries and unconsolidated entities, net of tax**

Equity in earnings of subsidiaries, net of tax	357,024			(357,024)	
Equity earnings of unconsolidated entities, net of tax	982		9,340	(2)	10,320
Income from continuing operations	4,128	110,076	250,044	(358,208)	6,040
Income (loss) from discontinued operations, net of tax	218,689	(1,912)			216,777
<b>Net income</b>	<b>222,817</b>	<b>108,164</b>	<b>250,044</b>	<b>(358,208)</b>	<b>222,817</b>
Less: Net income attributable to non-controlling interests			386		386
<b>Net income attributable to Alere Inc. and Subsidiaries</b>	<b>222,817</b>	<b>108,164</b>	<b>249,658</b>	<b>(358,208)</b>	<b>222,431</b>
Preferred stock dividends	(15,927)				(15,927)
<b>Net income available to common stockholders</b>	<b>\$ 206,890</b>	<b>\$ 108,164</b>	<b>\$ 249,658</b>	<b>\$ (358,208)</b>	<b>\$ 206,504</b>

**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Three Months Ended September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income (loss)	\$ 22,027	\$ (33,645)	\$ (54,447)	\$ 88,092	\$ 22,027
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	2,433	(272)	6,577	(11)	8,727
Minimum pension liability adjustment			221		221
Other comprehensive income (loss), before tax	2,433	(272)	6,798	(11)	8,948
Other comprehensive income (loss)	2,433	(272)	6,798	(11)	8,948
Comprehensive income (loss)	24,460	(33,917)	(47,649)	88,081	30,975
Less: Comprehensive income attributable to non-controlling interests			207		207
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ 24,460	\$ (33,917)	\$ (47,856)	\$ 88,081	\$ 30,768

**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Three Months Ended September 30, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income (loss)	\$ (2,381)	\$ 66,069	\$ 91,589	\$ (157,658)	\$ (2,381)
Other comprehensive loss, before tax:					
Changes in cumulative translation adjustment	(748)	(570)	(87,314)	(180)	(88,812)
Minimum pension liability adjustment			419		419
Other comprehensive loss, before tax	(748)	(570)	(86,895)	(180)	(88,393)
Other comprehensive loss, net of tax	(748)	(570)	(86,895)	(180)	(88,393)
Comprehensive income (loss)	(3,129)	65,499	4,694	(157,838)	(90,774)
Less: Comprehensive loss attributable to non-controlling interests			(61)		(61)
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (3,129)	\$ 65,499	\$ 4,755	\$ (157,838)	\$ (90,713)

**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Nine Months Ended September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income (loss)	\$ (22,841)	\$ 40,298	\$ 48,861	\$ (89,159)	\$ (22,841)
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	2,824	(1,100)	(14,936)	(3)	(13,215)
Minimum pension liability adjustment			907		907
Other comprehensive income (loss), before tax	2,824	(1,100)	(14,029)	(3)	(12,308)
Other comprehensive income (loss)	2,824	(1,100)	(14,029)	(3)	(12,308)
Comprehensive income (loss)	(20,017)	39,198	34,832	(89,162)	(35,149)
Less: Comprehensive income attributable to non-controlling interests			453		453
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (20,017)	\$ 39,198	\$ 34,379	\$ (89,162)	\$ (35,602)

**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Nine Months Ended September 30, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income	\$ 222,817	\$ 108,164	\$ 250,044	\$ (358,208)	\$ 222,817
Other comprehensive loss, before tax:					
Changes in cumulative translation adjustment	(1,208)	(453)	(120,587)	(180)	(122,428)
Minimum pension liability adjustment			(1,337)		(1,337)
Other comprehensive loss, before tax	(1,208)	(453)	(121,924)	(180)	(123,765)
Other comprehensive loss, net of tax	(1,208)	(453)	(121,924)	(180)	(123,765)
Comprehensive income	221,609	107,711	128,120	(358,388)	99,052
Less: Comprehensive income attributable to non-controlling interests			386		386
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 221,609	\$ 107,711	\$ 127,734	\$ (358,388)	\$ 98,666



Table of Contents**CONSOLIDATING BALANCE SHEET****September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>ASSETS</b>					
<b>Current assets:</b>					
Cash and cash equivalents	\$ 201,982	\$ 545	\$ 363,686	\$	\$ 566,213
Restricted cash	757		4,242		4,999
Marketable securities		75			75
Accounts receivable, net of allowances		190,077	237,164		427,241
Inventories, net		178,382	194,560	(24,097)	348,845
Prepaid expenses and other current assets	10,499	35,605	111,243	6,486	163,833
Intercompany receivables	1,052,091	904,512	213,963	(2,170,566)	
<b>Total current assets</b>	<b>1,265,329</b>	<b>1,309,196</b>	<b>1,124,858</b>	<b>(2,188,177)</b>	<b>1,511,206</b>
Property, plant and equipment, net	27,797	231,197	190,075	(2,756)	446,313
Goodwill		1,822,771	982,911		2,805,682
Other intangible assets with indefinite lives		7,511	20,539	(59)	27,991
Finite-lived intangible assets, net	2,618	537,041	328,326	(3,200)	864,785
Restricted cash			42,438		42,438
Other non-current assets	559	2,058	14,335	(733)	16,219
Investments in subsidiaries	3,378,517	158,194	57,650	(3,594,361)	
Investments in unconsolidated entities	684	14,765	50,747	14,689	80,885
Deferred tax assets	212,822		58,758	(214,942)	56,638
Non-current income tax receivable	3,517				3,517
Intercompany notes receivables	1,765,528	710,007	602	(2,476,137)	
<b>Total assets</b>	<b>\$ 6,657,371</b>	<b>\$ 4,792,740</b>	<b>\$ 2,871,239</b>	<b>\$ (8,465,676)</b>	<b>\$ 5,855,674</b>
<b>LIABILITIES AND EQUITY</b>					
<b>Current liabilities:</b>					
Short-term debt and current portion of long-term debt	\$ 40,073	\$	\$ 1,351	\$	\$ 41,424
Current portion of capital lease obligations		1,764	1,949		3,713
Accounts payable	41,465	77,717	92,294		211,476
Accrued expenses and other current liabilities	115,152	139,909	192,714	2,122	449,897

Edgar Filing: ALERE INC. - Form 10-Q

Intercompany payables	1,052,028	777,234	341,304	(2,170,566)	
<b>Total current liabilities</b>	<b>1,248,718</b>	<b>996,624</b>	<b>629,612</b>	<b>(2,168,444)</b>	<b>706,510</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	2,859,054		46,013		2,905,067
Capital lease obligations, net of current portion		2,322	5,711		8,033
Deferred tax liabilities		218,898	46,355	(212,740)	52,513
Other long-term liabilities	16,821	42,279	74,815	(733)	133,182
Intercompany notes payables	487,096	1,163,898	825,143	(2,476,137)	
<b>Total long-term liabilities</b>	<b>3,362,971</b>	<b>1,427,397</b>	<b>998,037</b>	<b>(2,689,610)</b>	<b>3,098,795</b>
<b>Total stockholders' equity</b>	<b>2,045,682</b>	<b>2,368,719</b>	<b>1,238,903</b>	<b>(3,607,622)</b>	<b>2,045,682</b>
Non-controlling interests			4,687		4,687
<b>Total equity</b>	<b>2,045,682</b>	<b>2,368,719</b>	<b>1,243,590</b>	<b>(3,607,622)</b>	<b>2,050,369</b>
<b>Total liabilities and equity</b>	<b>\$ 6,657,371</b>	<b>\$ 4,792,740</b>	<b>\$ 2,871,239</b>	<b>\$ (8,465,676)</b>	<b>\$ 5,855,674</b>

**Table of Contents****CONSOLIDATING BALANCE SHEET****December 31, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>ASSETS</b>					
<b>Current assets:</b>					
Cash and cash equivalents	\$ 139,153	\$ 21,150	\$ 341,897	\$	\$ 502,200
Restricted cash	1,250		4,444		5,694
Marketable securities		164			164
Accounts receivable, net of allowances		192,591	253,242		445,833
Inventories, net		173,383	194,192	(20,574)	347,001
Prepaid expenses and other current assets	7,576	27,095	110,961	6,601	152,233
Assets held for sale – current			4,165		4,165
Intercompany receivables	1,237,474	812,957	50,691	(2,101,122)	
<b>Total current assets</b>	<b>1,385,453</b>	<b>1,227,340</b>	<b>959,592</b>	<b>(2,115,095)</b>	<b>1,457,290</b>
Property, plant and equipment, net	31,384	228,065	188,084	(1,494)	446,039
Goodwill		1,823,919	1,012,996		2,836,915
Other intangible assets with indefinite lives		7,638	20,531	(59)	28,110
Finite-lived intangible assets, net	2,951	627,269	370,261	(3,200)	997,281
Restricted cash			43,228		43,228
Other non-current assets	804	2,340	15,380	(446)	18,078
Investments in subsidiaries	3,294,857	158,195	57,650	(3,510,702)	
Investments in unconsolidated entities	502	14,764	37,947	12,120	65,333
Deferred tax assets	91,220		51,329	(128,556)	13,993
Non-current income tax receivable	3,517				3,517
Assets held for sale – non-current	13,337				13,337
Intercompany notes receivables	1,905,188	672,032	6,900	(2,584,120)	
<b>Total assets</b>	<b>\$ 6,729,213</b>	<b>\$ 4,761,562</b>	<b>\$ 2,763,898</b>	<b>\$ (8,331,552)</b>	<b>\$ 5,923,121</b>
<b>LIABILITIES AND EQUITY</b>					
<b>Current liabilities:</b>					
Short-term debt and current portion of long-term debt	\$ 197,084	\$	\$ 2,908	\$	\$ 199,992
Current portion of capital lease obligations		2,018	1,944		3,962

Edgar Filing: ALERE INC. - Form 10-Q

Accounts payable	15,981	76,890	102,881		195,752
Accrued expenses and other current liabilities	62,287	126,346	133,594	2,238	324,465
Liabilities related to assets held for sale - current			363		363
Intercompany payables	1,122,042	773,839	205,241	(2,101,122)	
<b>Total current liabilities</b>	<b>1,397,394</b>	<b>979,093</b>	<b>446,931</b>	<b>(2,098,884)</b>	<b>724,534</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	2,784,913		46,253		2,831,166
Capital lease obligations, net of current portion		840	6,341		7,181
Deferred tax liabilities		219,224	54,749	(126,355)	147,618
Other long-term liabilities	14,962	59,309	80,369	(447)	154,193
Intercompany notes payables	477,779	1,181,168	925,173	(2,584,120)	
<b>Total long-term liabilities</b>	<b>3,277,654</b>	<b>1,460,541</b>	<b>1,112,885</b>	<b>(2,710,922)</b>	<b>3,140,158</b>
<b>Total stockholders' equity</b>	<b>2,054,165</b>	<b>2,321,928</b>	<b>1,199,818</b>	<b>(3,521,746)</b>	<b>2,054,165</b>
Non-controlling interests			4,264		4,264
<b>Total equity</b>	<b>2,054,165</b>	<b>2,321,928</b>	<b>1,204,082</b>	<b>(3,521,746)</b>	<b>2,058,429</b>
<b>Total liabilities and equity</b>	<b>\$ 6,729,213</b>	<b>\$ 4,761,562</b>	<b>\$ 2,763,898</b>	<b>\$ (8,331,552)</b>	<b>\$ 5,923,121</b>

Table of Contents**CONSOLIDATING STATEMENT OF CASH FLOWS****For the Nine Months Ended September 30, 2016**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows from Operating Activities:</b>					
Net income (loss)	\$ (22,841)	\$ 40,298	\$ 48,861	\$ (89,159)	\$ (22,841)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(86,943)			86,943	
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	9,186	9	110		9,305
Depreciation and amortization	6,829	133,532	72,848	978	214,187
Non-cash stock-based compensation expense	16,347	7,595	7,173		31,115
Impairment of inventory			915		915
Impairment of long-lived assets		548	86		634
Loss on sale of fixed assets	75	4,530	887		5,492
Equity earnings of unconsolidated entities, net of tax	(20,150)		(12,815)	(340)	(33,305)
Deferred income taxes	(6,392)	(300)	(18,550)		(25,242)
Gain on dispositions			(3,810)		(3,810)
Other non-cash items	815	(1,824)	8,684	(7)	7,668
Non-cash change in fair value of contingent purchase price consideration	(1,800)	(14,323)	(167)		(16,290)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		2,502	19,549		22,051
Inventories, net		(34,902)	1,666	1,576	(31,660)
Prepaid expenses and other current assets	547	(8,417)	(14,876)	116	(22,630)
Accounts payable	25,483	2,517	(9,507)		18,493
Accrued expenses and other current liabilities	41,025	15,149	60,896	(6,387)	110,683
Other non-current liabilities	(112,172)	(2,170)	(3,137)		(117,479)
Cash paid for contingent consideration	(321)		(3)		(324)
Intercompany payable (receivable)	269,507	(143,767)	(132,020)	6,280	
<b>Net cash provided by operating activities</b>	<b>119,195</b>	<b>977</b>	<b>26,790</b>		<b>146,962</b>

**Cash Flows from Investing Activities:**

(Increase) decrease in restricted cash	493		(294)		199
Purchases of property, plant and equipment	(3,783)	(20,325)	(27,529)	1,642	(49,995)
Proceeds from sale of property, plant and equipment	92	367	2,333	(1,642)	1,150
Cash received from (used in) dispositions, net of cash divested	(1,337)		22,807		21,470
Cash paid for business acquisitions, net of cash acquired			(5,958)		(5,958)
Cash received from sales of marketable securities.		88			88
Cash received from equity method investments	3,357				3,357
Cash paid for investments	(184)				(184)
Proceeds from sale of equity investments.	38,157		2,594		40,751
(Increase) decrease in other assets	(50)	(104)	614		460
<b>Net cash provided by (used in) investing activities</b>	<b>36,745</b>	<b>(19,974)</b>	<b>(5,433)</b>		<b>11,338</b>

**Cash Flows from Financing Activities:**

Cash paid for financing costs	(29,186)				(29,186)
Cash paid for contingent purchase price consideration			(575)		(575)
Cash paid for dividends	(15,969)				(15,969)
Proceeds from issuance of common stock, net of issuance costs	13,923				13,923
Proceeds from issuance of long-term debt			462		462
Payments on long-term debt			(1,722)		(1,722)
Payments on long-term debt	(186,879)		(938)		(187,817)
Net proceeds (payments) under revolving credit facilities	125,000		(124)		124,876
Principal payments on capital lease obligations		(1,782)	(1,321)		(3,103)
<b>Net cash used in financing activities</b>	<b>(93,111)</b>	<b>(1,782)</b>	<b>(4,218)</b>		<b>(99,111)</b>
Foreign exchange effect on cash and cash equivalents		174	4,650		4,824
Net increase (decrease) in cash and cash equivalents	62,829	(20,605)	21,789		64,013
Cash and cash equivalents, beginning of period	139,153	21,150	341,897		502,200
<b>Cash and cash equivalents, end of period</b>	<b>\$ 201,982</b>	<b>\$ 545</b>	<b>\$ 363,686</b>	<b>\$</b>	<b>\$ 566,213</b>



**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS****For the Nine Months Ended September 30, 2015**

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows from Operating Activities:</b>					
Net income	\$ 222,817	\$ 108,164	\$ 250,044	\$ (358,208)	\$ 222,817
Income (loss) from discontinued operations, net of tax	218,689	(1,912)			216,777
Income from continuing operations	4,128	110,076	250,044	(358,208)	6,040
Adjustments to reconcile net income from continuing operations to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	(357,024)			357,024	
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	10,542	19	66		10,627
Depreciation and amortization	7,891	128,363	97,390	7	233,651
Non-cash stock-based compensation expense	10,600	4,251	4,745		19,596
Impairment of inventory		133	68		201
Impairment of long-lived assets		64	314		378
Loss on disposition of fixed assets		2,768	505		3,273
Equity earnings of unconsolidated entities, net of tax	(982)		(9,340)	2	(10,320)
Deferred income taxes	(8,687)	(27,430)	(7,794)	439	(43,472)
Loss related to impairment and net (gain) loss on dispositions	81,051	(8,804)	(29,924)		42,323
Loss on extinguishment of debt	3,480				3,480
Other non-cash items	(376)	(1,054)	(3,358)	3	(4,785)
Non-cash change in fair value of contingent purchase price consideration	(33,667)	16,616	(34,860)		(51,911)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		(9,213)	6,052		(3,161)
Inventories, net		(31,708)	(26,651)	207	(58,152)
Prepaid expenses and other current assets	3,098	(28,016)	4,917	5,048	(14,953)



Edgar Filing: ALERE INC. - Form 10-Q

Accounts payable	(7,435)	777	(9,342)		(16,000)
Accrued expenses and other current liabilities	(1,455)	72,936	(27,203)	(9,306)	34,972
Other non-current liabilities	(16,114)	740	5,389	1,445	(8,540)
Cash paid for contingent purchase price consideration	(6,302)		(13)		(6,315)
Intercompany payable (receivable)	447,475	(282,519)	(167,580)	2,624	
Net cash provided by (used in) continuing operations	136,223	(52,001)	53,425	(715)	136,932
Net cash provided by discontinued operations		318			318
<b>Net cash provided by (used in) operating activities</b>	<b>136,223</b>	<b>(51,683)</b>	<b>53,425</b>	<b>(715)</b>	<b>137,250</b>
<b>Cash Flows from Investing Activities:</b>					
Increase in restricted cash	(421,157)		(17,608)		(438,765)
Purchases of property, plant and equipment	(7,514)	(25,915)	(36,093)	1,575	(67,947)
Proceeds from sale of property, plant and equipment		846	1,554	(914)	1,486
Cash received from (used in) disposition, net of cash divested	593,066	(8,722)	2,281		586,625
Cash paid for business acquisitions, net of cash acquired	(60,135)				(60,135)
Cash received from (paid for) sales of marketable securities		103	(4)		99
Cash received from equity method investments	2,205		12,092		14,297
(Increase) decrease in other assets	368	497	(219)	235	881
Net cash provided by (used in) continuing operations	106,833	(33,191)	(37,997)	896	36,541
Net cash used in discontinued operations		(209)			(209)
<b>Net cash provided by (used in) investing activities</b>	<b>106,833</b>	<b>(33,400)</b>	<b>(37,997)</b>	<b>896</b>	<b>36,332</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(15,836)		(217)		(16,053)
Cash paid for contingent purchase price consideration	(13,640)		(439)		(14,079)
Cash paid for dividends	(15,970)				(15,970)
Proceeds from issuance of common stock, net of issuance costs	76,457				76,457
Proceeds from issuance of long-term debt	2,119,125		42,897		2,162,022

Edgar Filing: ALERE INC. - Form 10-Q

Payments on short-term debt			(25,584)		(25,584)
Payments on long-term debt	(2,128,625)		(540)		(2,129,165)
Net proceeds (payments) under revolving credit facilities	(127,000)		397		(126,603)
Excess tax benefits on exercised stock options	3,264	2,531	307		6,102
Principal payments on capital lease obligations		(1,876)	(2,463)		(4,339)
Net cash provided by (used in) continuing operations	(102,225)	655	14,358		(87,212)
Net cash used in discontinued operations		(76)			(76)
<b>Net cash provided by (used in) financing activities</b>	(102,225)	579	14,358		(87,288)
Foreign exchange effect on cash and cash equivalents	16	(301)	(8,208)	(181)	(8,674)
Net increase (decrease) in cash and cash equivalents	140,847	(84,805)	21,578		77,620
Cash and cash equivalents, beginning of period continuing operations	2,149	69,154	307,158		378,461
Cash and cash equivalents, beginning of period discontinued operations		23,300			23,300
<b>Cash and cash equivalents, end of period</b>	\$ 142,996	\$ 7,649	\$ 328,736	\$	\$ 479,381

**Table of Contents****(23) Subsequent Events***Arriva LLC Billing Number*

On October 12, 2016, our subsidiary, Arriva Medical, LLC, or Arriva, which is our durable medical equipment, or DME, supply business that specializes in the furnishing of diabetic testing supplies via mail order, received a notice, dated October 5, 2016, that its Medicare enrollment will be revoked by CMS, based on CMS' assertion that, over a five year period, Arriva had allegedly submitted claims for 211 deceased patients (even if the products were appropriately ordered in advance of the patient's death). The CMS letter only identifies 47 of the 211 claims. Our initial appeal of this determination was denied by CMS on November 2, 2016 and, therefore, Arriva's Medicare enrollment will be revoked effective November 4, 2016, pending the outcome of further appeals. We have conducted an initial investigation into the issue and do not believe that Arriva received or retained improper reimbursement for the DME items furnished. We are continuing to work through the appeals process, with the goal that Arriva's enrollment status will be reactivated retroactively to November 4, 2016. Unless and until the enrollment status is reactivated, Arriva will be ineligible for reimbursement for any products or services furnished on or after November 4, 2016. If the enrollment is reactivated retroactive to November 4, 2016, we would be able to bill and be reimbursed for all covered products or services furnished. The Company's results of operation for the nine months ended September 30, 2016 included approximately \$88 million in revenue attributable to Arriva.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Forward-looking Statements**

*This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. Forward-looking statements include, without limitation, statements regarding the expected closing of, and the Company's confidence with respect to the closing of, the transactions contemplated by the Merger Agreement with Abbott Laboratories, the benefits of our improved products, the impact of the revocation or reinstatement of Arriva's Medicare billing number, our plans to voluntarily withdraw the INRatio and INRatio2 PT/INR Monitoring Systems from the market, future competition in our markets, the implementation, timing and effectiveness of efforts to remediate our material weaknesses, the outcome of certain tax examinations, the timing of decisions and the outcome of certain legal proceedings and governmental investigations to which we and other parties are or may be subject, the sources of funds to pay the principal and interest on our indebtedness and certain expenses, intention to retain earnings to support our growth strategy, future trends with respect to license and royalty revenues, future trends with respect to amortization expense, the source of funds and the expected ability to fund short and long-term working capital needs, the anticipated use of proceeds from divestitures, future plans with respect to the repatriation of cash held by foreign entities, future litigation and investigations being brought against us and the impact of such litigation and investigations, the expected impact of recently announced and adopted accounting standards and other accounting standards on our financial statements, anticipated increases or decreases to certain tax benefits, anticipated future net operating loss tax carryforwards, expected future expenses in connection with the voluntary withdrawal of INRatio products from the market and the expected timing of the completion of such withdrawal, anticipated expenses and costs in connection with certain restructuring plans, future charges in connection with a withdrawal of a product from the market, potential new product and technology achievements and the potential for selective divestitures of non-core assets. Actual results or developments could*

*differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2015 and other risk factors identified herein including in Part II, Item 1A or from time to time in our periodic filings with the SEC. We do not undertake any obligation to update any forward-looking statements unless required by law. This report and, in particular, the following discussion and analysis of our financial condition and results of operations, should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.*

---

**Table of Contents**

**Overview**

We deliver reliable and actionable health information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Our high-performance diagnostics for infectious disease, cardiometabolic disease and toxicology are designed to meet the growing global demand for accurate, easy-to-use and cost-effective near-patient tests. Our goal is to make our products accessible to more people around the world, even those located in remote and resource-limited areas, by making them affordable and usable in any setting. By making critical clinical diagnostic information available to doctors and patients in an actionable timeframe, our products help streamline healthcare delivery and improve patient outcomes.

**Recent Developments**

*Merger Agreement with Abbott Laboratories*

On January 30, 2016, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Abbott Laboratories, or Abbott. The Merger Agreement provides for the merger of a newly formed, wholly owned subsidiary of Abbott with and into Alere, or the merger, with Alere surviving the merger as a wholly owned subsidiary of Abbott, or the surviving corporation. Under the terms of the Merger Agreement, holders of shares of our common stock will receive \$56.00 in cash, without interest, in exchange for each share of common stock. Each share of our Series B Convertible Perpetual Preferred Stock, par value \$0.001 per share, or Series B Preferred Stock, issued and outstanding immediately prior to the effective time of the merger will remain issued and outstanding immediately following the consummation of the merger as one share of Series B Convertible Preferred Stock, par value \$0.001 per share, of the surviving corporation. The Merger Agreement was approved by our board of directors and, on October 21, 2016, the holders of a majority of the outstanding shares of our common stock approved the adoption of the Merger Agreement. Completion of the merger is subject to remaining customary closing conditions, including (1) there being no judgment or law enjoining or otherwise prohibiting the consummation of the merger and (2) the expiration of the waiting period applicable to the merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, and receipt of other required antitrust approvals. Under the terms of the Merger Agreement, Abbott has agreed to make certain divestitures if necessary to obtain the consent of the antitrust authorities to the transaction contemplated by the Merger Agreement, subject to certain exceptions set forth in the Merger Agreement. The obligation of each of the parties to consummate the merger is also conditioned on the other party's representations and warranties being true and correct (subject to certain materiality exceptions) and the other party having performed in all material respects its obligations under the Merger Agreement. The Merger Agreement contains certain termination rights and provides that, upon termination of the Merger Agreement under certain circumstances, Alere would be required to pay Abbott a termination fee equal to \$177.0 million. We are confident that the transaction will be completed in accordance with the terms set forth in the Merger Agreement.

On May 2, 2016, Abbott and Alere received a request for additional information, or a second request, from the United States Federal Trade Commission, or the FTC, relating to Abbott's potential acquisition of Alere. The second request was issued under the HSR Act. In addition, Abbott has agreed voluntarily to provide the FTC at least 60 days advance notice before certifying substantial compliance with the second request and to extend the waiting period imposed by the HSR Act to not less than 60 days after Abbott and Alere have certified substantial compliance with the second request, unless the period is further extended voluntarily by the parties or terminated sooner by the FTC.

Between April and October 2016, Abbott received six separate requests for additional information from the European Commission. The parties are working to provide the European Commission with information in response to these requests and continue to work cooperatively with the European Commission in connection with this review. Once the completed notification has been formally submitted to the European Commission, the European Commission has

25 business days from the day following the date of such notification, which period may be extended to 35 business days after the date of notification under certain circumstances, in which to consider whether the merger raises serious doubts as to its compatibility with the common market (as prescribed by European Union regulations). By the end of that period, the European Commission must issue a decision either clearing the merger, which may be conditional upon satisfaction of commitments, or open an in-depth Phase II investigation. A Phase II investigation may last a maximum of an additional 125 business days.

On June 23, 2016, Abbott and Alere received a request for additional information, or a supplemental information request, from the Canadian Competition Bureau, or the Bureau, relating to Abbott's potential acquisition of Alere. The supplemental information request was issued under the Competition Act of Canada, or the Competition Act. The effect of the supplemental information request is to extend the waiting period imposed by the Competition Act until 30 days after Abbott and Alere have each complied with the supplemental information request, unless the period is extended voluntarily by the parties or terminated sooner by the Bureau.

On October 20, 2016, the Ministry of Commerce of the People's Republic of China determined that it will not prohibit the acquisition of Alere by Abbott.

In addition, after entering into the Merger Agreement, Abbott informed us that it had serious concerns about, among other things, the accuracy of various representations, warranties and covenants made by us in the Merger Agreement. Abbott indicated that these concerns relate to the delay in filing our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 as well as governmental investigations previously announced by us. Abbott has since requested information from us about these and other matters, citing contractual rights to receive information under the Merger Agreement. In the initial meeting in which Abbott expressed its concerns to us, as part of a discussion about potential paths forward, Abbott requested that we agree to terminate the Merger Agreement in return for a payment by Abbott to us in the range of between \$30 and \$50 million in respect of our transaction expenses. Our Board of Directors promptly rejected that request. In these discussions, Abbott affirmed its commitment to abide by its obligations under the Merger Agreement.

On August 25, 2016, we filed a complaint against Abbott in Delaware Chancery Court, which seeks to compel Abbott to fulfill its obligations under the terms of the Merger Agreement to take all actions necessary to promptly obtain all required antitrust approvals for the merger. The complaint alleges, among other things, that Abbott is purposefully failing to comply with its obligations set forth in the Merger Agreement related to obtaining antitrust approvals. Specifically, the complaint alleges that Abbott: (i) purposefully failed to supply information requested by the FTC as promptly as reasonably practicable after such requests were made, as expressly required by the Merger Agreement; (ii) purposefully failed to supply information requested and make antitrust filings pursuant to antitrust laws in various foreign jurisdictions as promptly as reasonably practicable after such requests were

**Table of Contents**

made; (iii) purposefully failed to promptly take any and all steps necessary to avoid or eliminate impediments to obtaining antitrust clearance in the United States and in various foreign jurisdictions; (iv) purposefully failed to keep Alere informed in all material respects and on a reasonably timely basis of material communications with respect to the merger with antitrust authorities in the United States and in various foreign jurisdictions; and (v) purposefully failed to cooperate and consult with Alere, as well as give due consideration to Alere's views with respect to antitrust matters. We asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by the Merger Agreement. On August 30, 2016, Abbott filed its response in opposition to the motion to expedite the proceedings in this matter. On September 2, 2016, the Delaware Chancery Court granted our motion to expedite the proceedings. On September 29, 2016, the Delaware Chancery Court entered an order that, among other things, adopted a detailed schedule setting forth actions required to be taken by specified dates in order to obtain all antitrust clearances required by the Merger Agreement. By order of the court, the schedule is confidential. The court order also (i) requires Abbott to provide us with advance notice of, and the right to participate (in a manner not inconsistent with the terms of the Merger Agreement) in, all future discussions with antitrust regulators worldwide; (ii) appoints a Special Master to confidentially mediate any disputes regarding compliance with the order or the parties' obligations under the Merger Agreement; (iii) lifts the stay of the case and permits discovery to commence immediately, including with respect to potential breaches of the Merger Agreement by Abbott; and (iv) sets a preliminary injunction hearing date on our claims for January 27, 2017, if necessary.

On November 3, 2016, Abbott filed a complaint against Alere in the Delaware Chancery Court. Abbott asserts a single claim against Alere for breach of contract stemming from Alere's refusal to provide Abbott with certain categories of documents under the Merger Agreement. The complaint makes no claim for damages and seeks to compel Alere to produce certain categories of documents and information which Abbott contends Alere is obligated to produce under the terms of the Merger Agreement. Alere believes it has fulfilled its contractual obligations under the merger agreement.

*Sale of Minority Interest in TechLab*

On September 16, 2016, we sold our 49% interest in TechLab Inc., a company that provides diagnostic testing products used by physicians and other health care customers to diagnose, treat, and monitor intestinal diseases and other medical conditions. In connection with this sale, we recorded a gain in equity earnings of unconsolidated entities, net of tax, of \$18.7 million. We accounted for this interest in TechLab as an equity method investment.

Prior to our sale we served as a distributor of TechLab products and we will remain the principal global distributor of TechLab products pursuant to the terms of a distribution agreement with TechLab.

*INRatio and INRatio®2 PT/INR Monitoring System Voluntary Withdrawal*

In July 2016 we announced that we would be initiating a voluntary withdrawal of the Alere INRatio and INRatio2 PT/INR Monitoring System. We are currently implementing the product withdrawal and product discontinuation which we expect will be completed in early 2017.

In December 2014, we initiated a voluntary correction to inform users of the Alere INRatio and INRatio2 PT/INR Monitoring Systems that patients with certain medical conditions should not be tested with the systems. We proactively reported these device concerns to the FDA and began conducting a thorough investigation into these events.

Over the course of the past two years, Alere invested in the research and development of software enhancements intended to address the potential, in certain cases, of the system to deliver a result that differs from that of another

measurement method.

We submitted the software enhancements to the FDA at the end of 2015. The FDA notified us that it believes that our studies do not adequately demonstrate the effectiveness of the software modification and advised us to submit a proposed plan to voluntarily remove the INRatio® device from the market.

In light of this input from the FDA and our business considerations, in July 2016 we determined to voluntarily remove the INRatio systems from the market.

Due to the fact that the circumstances giving rise to the voluntary withdrawal in the United States and related action outside the U.S. existed as of December 31, 2015, certain charges incurred in connection with the withdrawal were recorded in the fourth quarter of 2015. Specifically, we recorded a charge of approximately \$38.0 million in the year ended December 31, 2015, related to impairment of inventory and production equipment and estimated costs of removing our INRatio and INRatio2 from the market. As of September 30, 2016, \$15.4 million of the estimated costs of removing INRatio and INRatio 2 from the market were included in accrued expenses. Additionally, our decision to withdraw the INRatio and INRatio2 PT/INR Monitoring Systems impacted the useful life assumptions of certain tangible and intangible assets. As a result of this change in estimate, we recorded approximately \$4.1 million and \$12.3 million of accelerated amortization of intangible assets and approximately \$0.6 million and \$2.1 million of accelerated depreciation of tangible assets in the three and nine months ended September 30, 2016, respectively. Finally, during the remainder of fiscal year 2016 we expect to incur approximately \$4.1 million of accelerated amortization, approximately \$0.6 million of accelerated depreciation, and \$1.9 million of other one-time cash expenditures.

Alere Home Monitoring, our patient self-testing anticoagulation business, will continue to distribute other PT/INR coagulation monitors following the withdrawal of the INRatio and INRatio2 PT/INR Monitoring Systems from the market.



**Table of Contents***Amendment to our Credit Agreement*

On August 18, 2016, we and the requisite lenders under the Credit Agreement entered into an amendment to our Credit Agreement pursuant to which the requisite lenders agreed to (i) waive certain Defaults and Events of Defaults (each as defined in the Credit Agreement) that may have occurred, are occurring or will occur, resulting from, among other things, our failure to deliver to the Administrative Agents (as defined in the Credit Agreement) (x) the financial statements and certain related deliverables for the three months ended March 31, 2016, which we refer to as the Q1 Financial Reports, by the applicable deadline under the Credit Agreement or (y) the financial statements and certain related deliverables for the three months ended June 30, 2016, which we refer to as the Q2 Financial Reports, by the applicable deadline under the Credit Agreement, and (ii) extend the deadline for delivery of the Q1 Financial Reports to August 25, 2016 and the deadline for the delivery of the Q2 Financial Reports to September 13, 2016. We delivered the Q1 Financial Reports and the Q2 Financial Reports prior to the deadlines set forth in this amendment to the Credit Agreement. In connection with this amendment, we paid, among other fees and expenses, to each consenting lender aggregate consent fees of 0.125% of the sum of (i) the aggregate principal amount of such lender's Term Loans outstanding on the effective date of the amendment and (ii) such lender's Revolving Credit Commitment outstanding on the effective date of the amendment, or approximately \$2.2 million in the aggregate for all consenting lenders.

*Arriva LLC Billing Number*

Certain aspects of our business that seek reimbursement from federal healthcare programs, including Medicare and Medicaid, require that we are successfully enrolled in such programs and maintain certain standards necessary for continued enrollment. From time to time, the enrollment status of one or more of our businesses can be threatened or revoked by government agencies, such as the Center for Medicare and Medicaid Services, or CMS. Unless overturned by appeal, the revocation of the enrollment of one of our businesses would prevent us from being able to bill or be reimbursed by the federal health care program in question for any otherwise covered items or services furnished by that business to beneficiaries of the health care program. On October 12, 2016, our subsidiary, Arriva Medical, LLC, or Arriva, which is our durable medical equipment, or DME, supply business that specializes in the furnishing of diabetic testing supplies via mail order, received a notice, dated October 5, 2016, that its Medicare enrollment will be revoked by CMS, based on CMS' assertion that, over a five year period, Arriva had allegedly submitted claims for 211 deceased patients (even if the products were appropriately ordered in advance of the patient's death). The CMS letter only identifies 47 of the 211 claims. The 211 claims constitute less than 0.003% of the approximately 5.7 million claims submitted by Arriva during the five year period in question. Our initial appeal of this determination was denied by CMS on November 2, 2016 and, therefore, Arriva's Medicare enrollment will be revoked effective November 4, 2016, pending the outcome of further appeals. We have conducted an initial investigation into the issue and do not believe that Arriva received or retained improper reimbursement for the DME items furnished. We are continuing to work through the appeals process, with the goal that Arriva's enrollment status will be reactivated retroactively to November 4, 2016. Unless and until the enrollment status is reactivated, Arriva will be ineligible for reimbursement for any products or services furnished on or after November 4, 2016. If the enrollment is reactivated retroactive to November 4, 2016, we would be able to bill and be reimbursed for all covered products or services furnished. There can be no guarantee that Arriva's Medicare enrollment will be reinstated, that it will be reinstated retroactively, or that we will be reimbursed by Medicare for any diabetes testing supplies supplied to customers on or after November 4, 2016. Further, if our appeal is not successful, Arriva will be barred from re-applying for enrollment in the Medicare program for at least three years. The Medicare revocation would also prevent Arriva from being able to be reimbursed for any Medicaid covered products or services. If we are not successful in getting Arriva's Medicare enrollment reinstated, our cardiometabolic business may be adversely affected. Our results of operations for the nine-month period ended September 30, 2016, included approximately \$88 million in revenue attributable to Arriva.

**Financial Highlights**

Net revenue decreased by \$21.4 million, or 4%, to \$582.4 million for the three months ended September 30, 2016 from \$603.8 million for the three months ended September 30, 2015. Net revenue decreased by \$68.4 million, or 4%, to \$1.78 billion for the nine months ended September 30, 2016 from \$1.84 billion for the nine months ended September 30, 2015.

Gross profit decreased by \$10.8 million, or 4%, to \$266.1 million for the three months ended September 30, 2016 from \$277.0 million for the three months ended September 30, 2015. Gross profit decreased by \$45.3 million, or 5%, to \$814.2 million for the nine months ended September 30, 2016 from \$859.5 million for the nine months ended September 30, 2015.

For the three months ended September 30, 2016, we generated net income available to common stockholders of \$16.5 million, or \$0.19 per basic and diluted common share, compared to a net loss available to common stockholders of \$7.7 million, or \$0.10 per basic and diluted common share, for the three months ended September 30, 2015. The net income generated in the three months ended September 30, 2016 was largely attributable to a gain, net of tax, of \$18.8 million on the sale of our interest in TechLab. For the nine months ended September 30, 2016, we generated a net loss available to common stockholders of \$39.3 million, or \$0.45 per basic and diluted common share, compared to net income available to common stockholders of \$206.5 million, or \$2.43 per basic and diluted common share, for the nine months ended September 30, 2015. The net income generated in the nine months ended September 30, 2015 was largely attributable to a \$363.3 million pre-tax gain (\$216.8 million, net of tax) on the sale of our health management business.

For the three months ended September 30, 2016, income from continuing operations available to common stockholders was \$16.5 million, or \$0.19 per basic and diluted common share, compared to a loss from continuing operations available to common stockholders of \$7.7 million, or \$0.10 per basic and diluted common share, for the three months ended September 30, 2015. For the nine months ended September 30, 2016, loss from continuing operations available to common stockholders was \$39.3 million, or \$0.45 per basic and diluted common share, compared to a loss from continuing operations available to common stockholders of \$10.3 million, or \$0.13 per basic and diluted common share, for the nine months ended September 30, 2015.

## **Results of Operations**

The following discussion relates primarily to our results of operations from our continuing operations, as reflected in our accompanying consolidated statements of operations.

In connection with the preparation of our consolidated financial statements for 2015, we determined that, in 2013 and 2014, each of the interim periods in 2014, and the first three quarters of fiscal 2015, we had incorrectly reported the revenue for such periods. In addition, we made several out-of-period adjustments related to the first, second and third quarters of 2015. As a result, we have revised our consolidated financial information for the three and nine months ended September 30, 2015, and the financial information presented below in this Item 2 reflects these revisions. For more information on these revisions, see Note 2 to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Further, of the revenue that we deferred in connection with the revision of our financial statements through September 30, 2015, approximately \$9.0 million remained deferred at December 31, 2015 and none remained deferred at September 30, 2016.

Where discussed, results excluding the impact of foreign currency translation are calculated on the basis of local currency results, using foreign currency exchange rates applicable to the earlier comparative period. We believe

presenting information using the same foreign currency exchange rates helps investors isolate the impact of changes in those rates from other factors.

**Table of Contents**

**Net Product Sales and Services Revenue, Total and by Business Segment.** Total net product sales and services revenue decreased by \$20.6 million, or 3%, to \$579.9 million for the three months ended September 30, 2016, from \$600.5 million for the three months ended September 30, 2015. Net product sales and services revenue decreased during the three months ended September 30, 2016 when compared to the same period in the prior year primarily as a result of a \$15.0 million reduction in revenue due to the disposition of our BBI business in November 2015, a \$12.1 million decrease in revenue from our mail order diabetic supplies business, and a \$4.5 million unfavorable impact of foreign currency exchange rates. These revenue declines were partially offset by sales increases during the three months ended September 30, 2016 of \$10.5 million of malaria-related products.

Total net product sales and services revenue decreased by \$62.4 million, or 3%, to \$1.76 billion for the nine months ended September 30, 2016, from \$1.83 billion for the nine months ended September 30, 2015. Net product sales and services revenue decreased during the nine months ended September 30, 2016 when compared to the same period in the prior year primarily as a result of a \$45.7 million reduction in revenue attributable to the disposition of our BBI business in November 2015, a \$32.7 million unfavorable impact of foreign currency exchange rates, and a \$22.4 million decrease in revenues from our mail order diabetic supplies business. The revenue declines were partially offset by sales increases of \$15.5 million attributable to our acquisition of US Diagnostics and European Drug Testing Services EDTS AB, or EDTS, \$14.2 million of HIV-related products, and \$10.3 million by Alere Home Monitoring, our patient self-testing anticoagulation business.

Net product sales and services revenue by business segment for the three and nine months ended September 30, 2016 and 2015 are as follows (in thousands):

	Three Months Ended September 30,%			Nine Months Ended September 30, %		
	2016	2015	Change	2016	2015	Change
Professional diagnostics	\$ 560,527	\$ 581,722	(4)%	\$ 1,707,326	\$ 1,760,980	(3)%
Consumer diagnostics	19,347	18,747	3%	56,583	65,360	(13)%
Net product sales and services revenue	\$ 579,874	\$ 600,469	(3)%	\$ 1,763,909	\$ 1,826,340	(3)%

*Professional Diagnostics*

The following table summarizes our net product sales and services revenue from our professional diagnostics business segment by groups of similar products and services for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,%			Nine Months Ended September 30, %		
	2016	2015	Change	2016	2015	Change
Cardiometabolic	\$ 188,731	\$ 208,979	(10)%	\$ 587,289	\$ 621,588	(6)%
Infectious disease	183,375	164,822	11%	556,777	523,059	6%
Toxicology	155,871	162,571	(4)%	460,849	468,822	(2)%
Other	32,550	45,350	(28)%	102,411	147,511	31%
	\$ 560,527	\$ 581,722	(4)%	\$ 1,707,326	\$ 1,760,980	(3)%

Professional diagnostics net  
product sales and services  
revenue

Net product sales and services revenue from our professional diagnostics business segment decreased by \$21.2 million, or 4%, to \$560.5 million for the three months ended September 30, 2016, from \$581.7 million for the three months ended September 30, 2015 driven primarily by a \$12.8 million reduction in revenue due to the disposition of our BBI business and a \$12.1 million decrease in revenue from our mail order diabetic supplies business.

Net product sales and services revenue from our professional diagnostics business segment decreased by \$53.7 million, or 3%, to \$1.71 billion for the nine months ended September 30, 2016, from \$1.76 billion for the nine months ended September 30, 2015 primarily as a result of decreased revenues of \$39.5 million due to our disposition of BBI, a \$29.5 million unfavorable impact of foreign currency exchange rates, and \$22.4 million in our mail order diabetic supplies business. The revenue declines were partially offset by sales increases of \$14.2 million of HIV related products, \$11.7 million attributable to our acquisition of US Diagnostics, and \$10.3 million by Alere Home Monitoring, our patient self-testing anticoagulation business.

Net product sales and services revenue from our professional diagnostics business segment in the U.S. decreased by \$29.8 million, or 9%, to \$306.9 million for the three months ended September 30, 2016 from \$336.7 million for the three months ended September 30, 2015. The decrease in revenues in the U.S. during the three months ended September 30, 2016 when compared to the same period in the prior year in the U.S. was primarily driven by a \$17.0 million decline in sales of cardiometabolic products and services, principally as a result of decreased sales in our mail order diabetic supplies business, a \$6.1 million decline in toxicology sales, mainly due to decreased revenue from our eScreen and pain management businesses, and a \$4.1 million decline due to the disposition of our BBI business. eScreen provides automated and efficient workplace drug testing to our customers.

**Table of Contents**

Net product sales and services revenue from our professional diagnostics business segment in the U.S. decreased by \$37.8 million, or 3.9%, to \$940.1 million for the nine months ended September 30, 2016 from \$978.0 million for the nine months ended September 30, 2015. The decrease during the nine months ended September 30, 2016 when compared to the same period in the prior year was primarily driven by revenue declines of \$24.7 million in our US toxicology pain management and eScreen businesses, and \$22.4 million in our mail order diabetic supplies business. U.S. revenues also declined by \$12.9 million due to the disposition of our BBI business. These revenue declines were partially offset by \$10.8 million in revenues attributable to our acquisition of US Diagnostics and increased revenues of \$10.3 million due to our Alere Home Monitoring business.

In international markets, net product sales and services revenue from our professional diagnostics business segment increased \$8.6 million, or 4%, to \$253.6 million during the three months ended September 30, 2016, from \$245.0 million in the comparable period in 2015. The higher sales in international markets during the three months ended September 30, 2016 when compared to the same period in the prior year were driven by a \$13.4 million, or 32%, increase in revenues attributable to the Africa region predominately due to malaria and HIV products and a \$2.2 million increase in revenues attributable to the Latin America region predominately due to HIV products. This increase in international revenues was partially offset by an \$8.3 million decrease in European sales, primarily due to both the disposition of the BBI business in November 2015 and the impact of foreign currency exchange rates, and the balance of the offset was largely attributable to the impact of foreign currency exchange rates outside Europe.

Net product sales and services revenue from our professional diagnostics business segment in international markets decreased \$15.8 million, or 2%, to \$767.2 million during the nine months ended September 30, 2016, from \$783.0 million in the comparable period in 2015. The lower sales in international markets were driven primarily by a \$29.8 million, or 9%, decrease in revenues attributable to Europe, primarily due to both the disposition of the BBI business in November 2015 and the impact of foreign currency exchange rates. International sales decreases for our professional diagnostics business segment were partially offset by an increase in sales in Africa, mainly due to HIV products.

Within our professional diagnostics business segment, our cardiometabolic net product sales and services revenue decreased by \$20.2 million, or 10%, to \$188.7 million for the three months ended September 30, 2016, from \$209.0 million in the same period in 2015, primarily as a result of a decline in sales by Arriva, our mail order diabetic supplies business, and the remainder was largely attributed to decreases in sales of BNP and cholesterol products. Infectious disease net product sales and services revenue increased by \$18.6 million, or 11%, to \$183.4 million for the three months ended September 30, 2016, from \$164.8 million for the three months ended September 30, 2015. The increase in infectious disease revenue in the three months ended September 30, 2016 was primarily due to a \$17.1 million increase in sales of malaria and HIV products. Toxicology net product sales and services revenue decreased by \$6.7 million, or 4.1%, to \$155.9 million for the three months ended September 30, 2016, from \$162.6 million for the comparable period in 2015, primarily as a result of decreased sales in our eScreen and pain management businesses. These decreases in toxicology revenue were partially offset by increased revenues due to our acquisitions of EDTS and US Diagnostics. Other revenue decreased by \$12.8 million, or 28%, to \$32.6 million during the three months ended September 30, 2016, compared to \$45.3 million during the comparable period in 2015, primarily due to the disposition of our BBI business.

Within our professional diagnostics business segment, our cardiometabolic net product sales and services revenue decreased by \$34.3 million, or 5.5%, to \$587.3 million for the nine months ended September 30, 2016, from \$621.6 million in the same period in 2015, primarily as a result of a decline in sales by Arriva, our mail order diabetic supply business, and reduced revenues from sales of our Triage and cholesterol products, partially offset by increased sales by Alere Home Monitoring, our patient anticoagulation monitoring business. Infectious disease net product sales and services revenue increased by \$33.7 million, or 6.4%, to \$556.8 million for the nine months ended September 30,

2016, from \$523.1 million for the nine months ended September 30, 2015. The increase in infectious disease revenue in the nine months ended September 30, 2016 was primarily attributable to increased revenue of \$14.7 million from sales of our Alere i product, as well as increased HIV-related product sales. Toxicology net product sales and services revenue decreased by \$8.0 million, or 1.7%, to \$460.8 million for the nine months ended September 30, 2016, from \$468.8 million for the comparable period in 2015, primarily as a result of decreased sales in our eScreen and pain management businesses. These decreases were partially offset by increased revenues due to our acquisitions of EDTS and US Diagnostics. Other revenue decreased by \$45.1 million, or 30.6%, to \$102.4 million during the nine months ended September 30, 2016, compared to \$147.5 million during the comparable period in 2015, primarily due to the disposition of our BBI business.

#### *Consumer Diagnostics*

Net product sales and services revenue from our consumer diagnostics business segment increased by \$0.6 million, or 3%, to \$19.3 million for the three months ended September 30, 2016, from \$18.7 million for the three months ended September 30, 2015. The increase in sales is mostly attributable to increased revenue under our long-term manufacturing service agreement with SPD, partially offset by the disposition of our BBI business, which also sold products that were part of our consumer diagnostics segment.

**Table of Contents**

Net product sales and services revenue from our consumer diagnostics business segment decreased by \$8.8 million, or 13%, to \$56.6 million for the nine months ended September 30, 2016, from \$65.4 million for the nine months ended September 30, 2015. The decrease primarily resulted from a \$6.2 million decrease in revenue attributable to the disposition of our BBI business in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015. The balance of the decrease in the nine months ended September 30, 2016 was the result of a decrease in sales to SPD under our long-term manufacturing service agreement.

**License and Royalty Revenue.** License and royalty revenue represents license and royalty fees from intellectual property license agreements with third parties. License and royalty revenue decreased by \$0.8 million, or 25%, to \$2.5 million for the three months ended September 30, 2016 from \$3.3 million for the three months ended September 30, 2015. The decrease in royalty revenue for the three months ended September 30, 2016, compared to the comparable period in 2015, is primarily a result of lower royalties earned under existing licensing agreements, as certain patents related to our lateral flow technology expired in 2015. Based on our license and royalty agreements in effect as of September 30, 2016, we expect this trend in comparatively lower license and royalty revenues to continue in 2016 as compared to 2015.

License and royalty revenue decreased by \$5.9 million, or 43%, to \$7.7 million for the nine months ended September 30, 2016 from \$13.7 million for the nine months ended September 30, 2015. The decrease in royalty revenue for the nine months ended September 30, 2016, compared to the comparable period in 2015, is primarily a result of lower royalties earned under existing licensing agreements, as certain patents related to our lateral flow technology expired in 2015.

**Gross Profit and Margin Percentage.** Gross profit decreased by \$10.9 million, or 4%, to \$266.1 million for the three months ended September 30, 2016 from \$277.0 million for the three months ended September 30, 2015. The decrease in gross profit during the three months ended September 30, 2016, compared to the same period in 2015, was largely attributable to a \$5.2 million decrease in gross profit as a result of our divested businesses, a \$1.7 million negative impact of foreign currency exchange rates and the balance of the decrease was primarily due to decreased profits in our mail order diabetic supplies business.

Gross profit decreased by \$45.3 million, or 5%, to \$814.2 million for the nine months ended September 30, 2016 from \$859.5 million for the nine months ended September 30, 2015. The decrease in gross profit during the nine months ended September 30, 2016, compared to the comparable period in 2015, was largely attributable to a \$21.1 million decrease in gross profit due to our divested businesses, a \$12.7 million negative impact of foreign currency exchange rates, as well as the impact from lower revenues discussed above and decreased manufacturing volumes.

Overall gross margin for each of the three and nine months ended September 30, 2016 was 46%, as compared to 46% and 47%, respectively, for the three and nine months ended September 30, 2015.

**Gross Profit from Net Product Sales and Services Revenue, Total and by Business Segment.** Gross profit from net product sales and services revenue decreased by \$10.5 million, or 4%, to \$264.3 million for the three months ended September 30, 2016 from \$274.8 million for the three months ended September 30, 2015. Gross profit from net product sales and services revenue decreased by \$41.2 million, or 5%, to \$809.1 million for the nine months ended September 30, 2016 from \$850.3 million for the nine months ended September 30, 2015. Gross profit from net product sales and services revenue by business segment for the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands):



	Three Months Ended September 30, %			Nine Months Ended September 30, %		
	2016	2015	Change	2016	2015	Change
Professional diagnostics	\$ 262,812	\$ 272,939	(4)%	\$ 805,464	\$ 843,749	(5)%
Consumer diagnostics	1,477	1,865	(21)%	3,607	6,506	(45)%
Gross profit from net product sales and services revenue	\$ 264,289	\$ 274,804	(4)%	\$ 809,071	\$ 850,255	(5)%

#### *Professional Diagnostics*

Gross profit from our professional diagnostics net product sales and services revenue decreased by \$10.1 million, or 4%, to \$262.8 million for the three months ended September 30, 2016 compared to \$272.9 million for the three months ended September 30, 2015. The lower gross profit for the three months ended September 30, 2016 as compared to the same period in the prior year principally reflects the \$5.3 million decrease in gross profit as a result of divested businesses, \$1.7 million decrease due to the negative impact of foreign currency exchange rates and the balance of the decrease was primarily due to decreased gross profit from our mail order diabetic supplies business.

**Table of Contents**

Gross profit from our professional diagnostics net product sales and services revenue decreased by \$38.3 million, or 5%, to \$805.5 million for the nine months ended September 30, 2016 compared to \$843.7 million for the nine months ended September 30, 2015. The lower gross profit for the nine months ended September 30, 2016 as compared to the same period in the prior year principally reflects the \$21.0 million impact from divested businesses and \$12.5 million due to the negative impact of foreign currency exchange rates as well as the impact from lower revenues discussed above and decreased manufacturing volumes. These decreases to gross profit were partially offset by a \$5.6 million increase in gross profit from our acquired businesses, principally US Diagnostics and EDTS.

As a percentage of our professional diagnostics net product sales and services revenue, gross margin for the three and nine months ended September 30, 2016 was 47%, compared to 47% and 48% for the three and nine months ended September 30, 2015, respectively. The lower gross margin in the nine months ended September 30, 2016 principally reflects the impact of lower revenues discussed above and decreased manufacturing volumes.

*Consumer Diagnostics*

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$0.4 million, or 21%, to \$1.5 million for the three months ended September 30, 2016 from \$1.9 million for the three months ended September 30, 2015.

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$2.9 million, or 45%, to \$3.6 million for the nine months ended September 30, 2016 from \$6.5 million for the nine months ended September 30, 2015. The decrease in gross profit in both the three and nine months ended September 30, 2016, as compared to the same periods in the prior year, were primarily driven by our transactions with SPD.

As a percentage of our consumer diagnostics net product sales and services revenue, gross margin for the three and nine months ended September 30, 2016 was 8% and 6%, respectively, compared to 10% for the three and nine months ended September 30, 2015.

**Research and Development Expense.** Research and development expense decreased by \$4.6 million, or 13%, to \$31.4 million in the three months ended September 30, 2016 from \$36.0 million in the three months ended September 30, 2015, primarily due to a \$7.4 million reduction in amortization expense and a \$0.6 million reduction in our restructuring-related expenses. Additionally, \$0.9 million of the decrease is attributable to increased grant funding from third parties as our research and development expense during the three months ended September 30, 2016 and 2015 is reported net of grant funding of \$2.0 million and \$1.1 million, respectively, arising from the research and development funding relationship with the Gates Foundation and our contract with BARDA. For additional information on the agreements with the Gates Foundation and BARDA, see Note 16 to the consolidated financial statements elsewhere in this Quarterly Report on Form 10-Q. These decreases were partially offset by a \$5.0 million increase in project spending related to a payment made in connection with achieving certain contractual milestones.

Research and development expense decreased by \$4.3 million, or 5%, to \$86.9 million in the nine months ended September 30, 2016 from \$91.2 million in the nine months ended September 30, 2015, primarily due to an \$8.0 million reduction in amortization expense, \$0.9 million from the favorable impact of foreign exchange rates and a \$2.8 million reduction in our restructuring-related expenses. These decreases were partially offset by a \$5.0 million increase in project spending related to a payment made in connection with achieving certain contractual milestones and a \$2.4 million decrease in grant funding from third parties as our research and development expense during the nine months ended September 30, 2016 and 2015 is reported net of grant funding of \$4.5 million and \$6.9 million, respectively, arising from the research and development funding relationship with the Gates Foundation and our contract with BARDA.

Research and development expense as a percentage of net revenue was 5% for the three and nine months ended September 30, 2016. Research and development expense as a percentage of net revenue was 6% and 5% for the three and nine months ended September 30, 2015, respectively.

**Sales and Marketing Expense.** Sales and marketing expense decreased by \$4.5 million, or 4%, to \$102.0 million for the three months ended September 30, 2016 from \$106.5 million for the three months ended September 30, 2015. This decrease was primarily attributable to a \$3.7 million reduction in amortization expense related to customer relationship intangible assets and a \$0.4 million favorable impact of foreign currency exchange rates.

Sales and marketing expense decreased by \$19.3 million, or 6%, to \$304.3 million for the nine months ended September 30, 2016 from \$323.6 million for the nine months ended September 30, 2015. This decrease was primarily attributable to an \$8.5 million reduction in amortization expense related to customer relationship intangible assets, a \$5.0 million reduction in sales and marketing expenses associated with businesses we divested after June 30, 2015, including our BBI business, a \$4.4 million favorable impact of foreign currency exchange rates, and a \$1.1 million decrease in restructuring expenses.

---

**Table of Contents**

Sales and marketing expense as a percentage of net revenue was 18% and 17% for the three and nine months ended September 30, 2016, respectively, compared to 18% for each of the three and nine months ended September 30, 2015.

**General and Administrative Expense.** General and administrative expense increased by \$28.0 million, or 28%, to \$129.3 million for the three months ended September 30, 2016 from \$101.3 million for the three months ended September 30, 2015. The increase was primarily attributable to \$17.3 million of expenses related to the pending transaction with Abbott, \$13.3 million in legal and consulting fees related to certain government investigations, an increase of \$7.6 million in charges associated with our various restructuring plans and the balance was largely attributable to employee related expenses. These expenses were partially offset by a decrease in our estimate of the fair value of an acquisition-related contingent earn-out obligation of \$15.5 million, decreased bad debt expense of \$3.2 million, \$2.7 million reduced expense due to the delay in the medical device excise tax, and a \$0.6 million favorable impact from foreign currency exchange rates.

General and administrative expense increased by \$117.4 million, or 46%, to \$372.6 million for the nine months ended September 30, 2016 from \$255.2 million for the nine months ended September 30, 2015. The increase was primarily attributable to \$38.2 million of expenses related to the pending transaction with Abbott, \$21.9 million in legal and consulting fees related to certain government investigations and \$13.6 million in charges associated with our various restructuring plans. Additionally, \$35.6 million of the increase relates to changes in our estimates of the fair value of an acquisition-related contingent earn-out obligations when compared to the comparable period in 2015. The remaining portion of the increase, or an aggregate of \$7.0 million, is attributable primarily to increased legal and consulting fees (other than in connection with our pending transaction with Abbott or government investigations) when compared to the comparable period in 2015.

General and administrative expense as a percentage of net revenue was 22% and 21% for the three and nine months ended September 30, 2016, respectively, compared to 17% and 14% for the three and nine months ended September 30, 2015.

**Impairment and (Gain) Loss on Dispositions, Net.** In January 2016, we completed the sale of our Alere E-Santé business, which was a component of our professional diagnostics reporting unit and business segment. We received cash consideration of approximately \$8.1 million, net of a final working capital adjustment totaling approximately \$0.2 million, and we are eligible to receive up to \$1.5 million of contingent cash consideration. As a result of this transaction, we recorded a \$3.8 million gain in the three months ended March 31, 2016 on the disposition of the Alere E-Santé business.

In July 2015, we sold certain assets of our Inverness Medical Innovations Australia Pty Ltd business, which was part of our professional diagnostics reporting unit and business segment, for AUD 0.2 million (approximately \$0.1 million as of the date of disposition) in cash proceeds and, as a result of this transaction, we recorded a loss of \$1.2 million during the three and nine months ended September 30, 2015. We recorded additional charges of approximately \$0.9 million in connection with certain other business closures or divestitures during the three and nine months ended September 30, 2015.

In May 2015, we sold our Alere Analytics business, which was part of our professional diagnostics reporting unit and business segment. Under the terms of the sale we received nominal consideration and agreed to contribute working capital of \$2.7 million to Alere Analytics, of which \$2.4 million was contributed in cash immediately prior to the closing of the sale and the remaining \$0.3 million of which was deposited in escrow pending the performance by the buyers under certain contracts. As a result of this transaction we recorded a loss of \$4.7 million during the second quarter of 2015. During the three months ended March 31, 2015, before identifying a buyer for Alere Analytics, our management decided to close the business, and in connection with this decision we recorded an impairment charge of

\$26.7 million during the period, including the write-off of \$26.2 million of acquisition-related intangible assets and \$0.5 million of fixed assets.

In March 2015, we sold certain assets of our AdnaGen GmbH business, which was part of our professional diagnostics reporting unit and business segment, for approximately \$4.6 million in cash proceeds and, as a result of this transaction, we recorded a loss of \$0.3 million during the three months ended March 31, 2015.

In March 2015, we sold our Gesellschaft fur Patientenhilfe DGP GmbH subsidiary, which was part of our professional diagnostics reporting unit and business segment, for 7.6 million (approximately \$8.2 million at March 31, 2015) and, as a result of this transaction, we recorded a loss on disposition of \$7.5 million during the three months ended March 31, 2015.

In December 2014, our management decided to close our Alere Connect, LLC subsidiary, which is part of our professional diagnostics reporting unit and business segment. During the nine months ended September 30, 2015, in connection with this decision, we recorded impairment charges of \$1.1 million, consisting primarily of severance costs, inventory write-offs and other closure-related expenses.

The financial results for the above businesses are immaterial to our consolidated financial results.

**Interest Expense.** Interest expense includes interest charges and the amortization of deferred financing costs and original issue discounts associated with certain debt issuances. Interest expense decreased by \$8.2 million, or 16%, to \$44.1 million for the three months ended September 30, 2016 from \$52.3 million for the three months ended September 30, 2015. The decrease is due to lower interest expense incurred as a result of our reduced outstanding debt balances during the three months ended September 30, 2016 when compared to same period in 2015.

**Table of Contents**

Interest expense decreased by \$29.7 million, or 19%, to \$128.6 million for the nine months ended September 30, 2016 from \$158.3 million for the nine months ended September 30, 2015. The decrease is due to lower interest expense incurred as a result of our reduced outstanding debt balances during the nine months ended September 30, 2016 when compared to same period in 2015. The decrease was also attributable to the \$10.2 million write-off of third-party costs associated with refinancing our credit facility, including underwriter's fees and other payments to external advisors, and a \$3.5 million loss on extinguishment of debt associated with our prior credit facility that we incurred in the nine months ended September 30, 2015.

**Other Income (Expense), Net.** Other income (expense), net includes interest income, realized and unrealized foreign exchange losses, and other income (expense), net. The components and the respective amounts of other income (expense), net are summarized as follows (in thousands)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
Interest income	\$ 776	\$ 2,335	\$ (1,559)	\$ 2,586	\$ 3,662	\$ (1,076)
Foreign exchange gains (losses), net	(7,430)	1,285	(8,715)	(15,337)	589	(15,926)
Other, net	(7,658)	38	(7,696)	(17,022)	235	(17,257)

Total other income (expense), net	\$ (14,312)	\$ 3,658	\$ (17,970)	\$ (29,773)	\$ 4,486	\$ (34,259)
-----------------------------------	-------------	----------	-------------	-------------	----------	-------------

Interest income is related principally to our cash deposits, including restricted cash.

Foreign exchange gains (losses), net during the three and nine months ended September 30, 2016 were primarily related to the impact of foreign currency translation on intercompany balances denominated in British Pound Sterling and Korean Won.

Other, net for the three and nine months ended September 30, 2016 primarily reflects accruals of \$10.5 million and \$20.7 million, respectively, in connection with an on-going governmental investigation that commenced in May 2012 when we received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG. For additional information on this matter, see Part II Item 1. Legal Proceedings *Matters Relating to our San Diego Facility* included elsewhere in this Quarterly Report on Form 10-Q.

**Benefits for Income Taxes.** Our benefit for income taxes increased by \$40.7 million to \$(50.9) million for the three months ended September 30, 2016, from \$(10.2) million for the three months ended September 30, 2015. The effective tax rate for the three months ended September 30, 2016 and 2015 was 93% and 58%, respectively. Our effective tax rate is primarily impacted by changes in the forecasted income (loss) across various jurisdictions as well as items that are accounted for discretely in the quarter. The increase in the benefits for income taxes from the three months ended September 30, 2015 to the three months ended September 30, 2016 is primarily attributed to change in overall profitability, jurisdictional mix of income and losses and non-recurring discrete impacts in 2015. Our benefit for income taxes increased by \$45.6 million to \$(48.0) million for nine months ended September 30, 2016 from \$(2.4) million for the nine months ended September 30, 2015. The effective tax rate for the nine months ended September 30, 2016 and 2015 was 46% and 35%, respectively. The increase in our benefits for income taxes for nine months ended September 30, 2016 compared to nine months ended September 30, 2015 is primarily attributed to change in overall profitability, jurisdictional mix of income and losses and non-recurring discrete impacts in 2015. The change in overall profitability is primarily attributable to increased expenses related to the pending transaction with Abbott,

legal and consulting fees related to certain government investigations and other charges associated with our various restructuring plans.

**Equity Earnings (Losses) of Unconsolidated Entities, Net of Tax.** Equity earnings (losses) of unconsolidated entities are reported net of tax and includes our share of earnings (losses) in entities that we account for under the equity method of accounting. Equity earnings of unconsolidated entities, net of tax for the three and nine months ended September 30, 2016 reflects the following: (i) our 50% interest in SPD in the amount of \$6.7 million and \$12.9 million, respectively, and (ii) our 49% interest in TechLab, Inc., or TechLab, in the amount of \$19.5 million and \$20.5 million, respectively. As noted above, on September 16, 2016, we sold our interest in TechLab. In connection with this sale, we recorded a gain in equity earnings of unconsolidated entities, net of tax, of

---

**Table of Contents**

\$18.7 million. Equity earnings (losses) of unconsolidated entities, net of tax for the three and nine months ended September 30, 2015 reflects the following: (i) our 50% interest in SPD in the amount of \$5.3 million and \$9.5 million, respectively, and (ii) our 49% interest in TechLab in the amount of \$(0.3) million and \$1.0 million, respectively.

**Income from Discontinued Operations, Net of Tax.** The results of our former health management business are included in income from discontinued operations, net of tax, for the nine months ended September 30, 2015, given our January 9, 2015 divestiture of this business. For the nine months ended September 30, 2015, the discontinued operations generated income, net of tax, of \$216.8 million. This income from discontinued operations was largely attributable to a \$366.2 million pre-tax gain (\$218.6 million, net of tax) on the sale of our health management business. See Note 4 of our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### **Liquidity and Capital Resources**

Based upon our current working capital position, current operating plans and expected business conditions, we expect to fund our short and long-term working capital needs primarily using existing cash and our operating cash flow. As of September 30, 2016, we had approximately \$2.9 billion of indebtedness outstanding. As our various debt instruments mature over the next several years, we may need or want to re-finance some or all this indebtedness with new debt, including potential borrowings under our revolving credit facility, in order to preserve our existing cash for other uses, including to continue to fund our operations. During the nine months ended September 30, 2016, we generated net cash proceeds of \$21.5 million from divestitures, net of cash divested, and used \$17.4 million of our cash to reduce our outstanding indebtedness under our credit facilities. Additionally, we received cash consideration in connection with our September 2016 sale of our minority stake in TechLab, which amount is reflected in our cash and cash equivalent of our balance sheet as of September 30, 2016. In May 2016, we paid approximately \$152.0 million in cash to satisfy the principal and interest due under our 3% convertible senior subordinated notes, which matured on May 15, 2016 (of which amount \$125.0 million was drawn under our revolving credit facility and \$27.0 million was paid using available cash). We may divest one or more of our businesses in accordance with the covenants under the Merger Agreement with Abbott and we expect that, if and when completed, we will use all or a portion of the net proceeds of such divestitures to fund our working capital, operations, research and development or to reduce our outstanding debt, among other purposes, in each case to the extent permitted under the Merger Agreement and in accordance with our secured credit facility and the indentures governing our notes. As of September 30, 2016, we had \$566.2 million of cash and cash equivalents, of which \$205.0 million was held by domestic subsidiaries and \$361.2 million was held by foreign entities. We do not currently plan to repatriate cash held by most of our foreign entities if there are adverse tax implications, including incremental U.S. tax liabilities and potential foreign withholding tax liabilities. If circumstances were to change, however, we may be required to repatriate all or a portion of the cash held by foreign entities, which could result in the payment of significant tax liabilities.

We may also utilize amounts available under our secured credit facility, as described below, or other new sources of financing to fund a portion of our capital expenditures, contractual contingent consideration obligations, other commitments, the refinancing of existing indebtedness and future acquisitions. New sources of financing may not be available on acceptable terms, or at all, and we may be required to obtain certain consents in connection with completing such financings, which we may not be able to obtain on acceptable terms or at all.

On June 18, 2015, we entered into a new secured credit facility, which initially provided for term loan facilities totaling \$1.7 billion (consisting of \$650 million of A term loans and \$1.05 billion of B term loans), all of which were drawn at closing, and, subject to our continued compliance with the secured credit facility, a \$250.0 million revolving credit facility (which includes a \$50.0 million sublimit for the issuance of letters of credit). As of September 30, 2016, \$125.0 million was drawn and outstanding under the revolving credit facility.



We used approximately \$1.68 billion of the proceeds of the term loans drawn at closing to repay in full all indebtedness outstanding under our prior credit facility, whereupon that facility was terminated, and to pay various fees and expenses associated with the transactions contemplated by the new secured credit facility.

In November 2015 we used \$115.0 million of the net cash proceeds from our sale of the BBI business (which represented all of the net proceeds from the closing of the sale prior to giving effect to the final working capital adjustment) to repay \$115.0 million in aggregate principal amount of outstanding A term loans and B term loans under the secured credit facility.

We must repay the A term loans in nineteen consecutive quarterly installments, which began on September 30, 2015 and continue through March 31, 2020, followed by a final installment on June 18, 2020; after giving effect to the prepayment of a portion of the A term loans in connection with our sale of the BBI business, the principal amount of each remaining installment through March 31, 2020 is approximately \$7,572,000, and the principal amount of the final installment is approximately \$461,882,000. We must repay the B term loans in twenty-seven consecutive quarterly installments, which began on September 30, 2015 and continue through March 31, 2022, followed by a final installment on June 18, 2022; after giving effect to the prepayment of a portion of the B term loans in connection with our sale of the BBI business, the principal amount of each remaining installment through March 31, 2022 is approximately \$2,446,000, and the principal amount of the final installment is approximately \$912,471,000. We may repay any borrowings under the revolving credit facility at any time (without any premium or penalty, other than customary LIBOR breakage costs, if applicable), but in no event later than June 18, 2020.

**Table of Contents**

As of September 30, 2016, we had \$2.9 billion in aggregate principal amount of outstanding indebtedness, including \$1.5 billion in aggregate principal amount outstanding under our secured credit facility, \$441.5 million in aggregate outstanding principal amount of our 7.25% senior notes due 2018, \$414.4 million in aggregate outstanding principal amount of our 6.5% senior subordinated notes due 2020 and \$412.4 million in aggregate outstanding principal amount of our 6.375% senior subordinated notes due 2023. As noted above, our 3% convertible senior subordinated notes matured on May 15, 2016, and we used \$125.0 million of cash drawn under our revolving credit facility plus \$27.0 million of available cash to pay the \$152.0 million of outstanding principal and accrued interest due under the notes. The terms and conditions of our outstanding debt instruments contain covenants that expressly restrict our ability to incur additional indebtedness and conduct other financings, subject to certain exceptions. In addition, the Merger Agreement with Abbott contains restrictions on our ability to incur additional indebtedness and conduct other financings, subject to certain exceptions.

On April 22, 2016, we and the requisite lenders under the Credit Agreement entered into an amendment to the Credit Agreement, or the April 2016 Amendment. Pursuant to the April 2016 Amendment, these lenders agreed to (i) waive certain Defaults and Events of Defaults (each as defined in the Credit Agreement) that may have occurred, are occurring or will occur, resulting from, among other things, (x) our failure to deliver to the Administrative Agents (as defined in the Credit Agreement) the financial statements and certain related deliverables for 2015 by the applicable deadline under the Credit Agreement, (y) any restatement of certain financial statements as a result of our incorrect application of revenue recognition principles for 2013, 2014 and 2015, or (z) any breach of any representation or affirmative covenant as a result of certain deliverables being incorrect when delivered, which breach is discovered as part of the audit of our financial statements for 2015, to the extent that such breach is due to our incorrect application of revenue recognition principles for 2013, 2014 and 2015, and (ii) extend the deadlines for delivery of the financial statements for 2015, the financial statements for the quarter ended March 31, 2016 and certain related deliverables. Under the terms of this amendment, we were required to deliver our unaudited financial statements for the three months ended March 31, 2016 and certain related deliverables on or before August 18, 2016. We made the required deliveries before such date. In connection with this amendment, we paid, among other fees and expenses, to each consenting lender aggregate consent fees of 0.250% of the sum of (i) the aggregate principal amount of such lender's Term Loans outstanding on the effective date of the amendment and (ii) such lender's Revolving Credit Commitment (each as defined in the Credit Agreement) outstanding on the effective date of the amendment, or approximately \$4.5 million in the aggregate for all consenting lenders. The amendment also increased the applicable interest rate margins for all loans outstanding under our secured credit facility by 0.25% per annum for the period from July 1, 2016 to the date of delivery of such financial reports and related deliverables under our secured credit facility.

In addition, on April 29, 2016, we commenced consent solicitations relating to our 6.5% senior subordinated notes, 6.375% senior subordinated notes and 7.25% senior notes, which we refer to collectively as the Notes. The consent solicitations were made to holders of record of the Notes as of April 28, 2016, and such solicitations were completed on May 9, 2016. Pursuant to the consent solicitations, the requisite holders of each series of Notes agreed to extend the deadline for delivery of certain financial information and to waive, through and until 5:00 p.m., New York City time, on August 31, 2016, any default or event of default that occurred, is continuing or may occur under the indentures under which the Notes were issued (and its consequences) in connection with any failure to timely file with the SEC, or to timely furnish to the relevant trustees pursuant to the indentures, our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and our subsequent Quarterly Reports on Form 10-Q, or the Failures to File. In connection with the Failures to File, we paid, in May and July 2016, to each holder of Notes who validly delivered a consent aggregate cash payments equal to \$15.00 for each \$1,000 aggregate principal amount of such holder's Notes, or an aggregate of \$19.2 million.

On August 18, 2016, we and the requisite lenders under the Credit Agreement entered into a further amendment to the Credit Agreement pursuant to which they agreed to (i) waive certain Defaults and Events of Defaults (each as defined

in the Credit Agreement) that may have occurred, are occurring or will occur, resulting from, among other things, our failure to deliver to the Administrative Agents (as defined in the Credit Agreement) (x) the financial statements and certain related deliverables for the three months ended March 31, 2016, which we refer to as the Q1 Financial Reports, by the applicable deadline under the Credit Agreement or (y) the financial statements and certain related deliverables for the three months ended June 30, 2016, which we refer to as the Q2 Financial Reports, by the applicable deadline under the Credit Agreement, and (ii) extend the deadline for delivery of the Q1 Financial Reports to August 25, 2016 and the deadline for the delivery of the Q2 Financial Reports to September 13, 2016. We delivered the Q1 Financial Reports and the Q2 Financial Reports prior to the deadlines set forth in this amendment to the Credit Agreement. In connection with this amendment, we paid, among other fees and expenses, to each consenting lender aggregate consent fees of 0.125% of the sum of (i) the aggregate principal amount of such lender's Term Loans outstanding on the effective date of the amendment and (ii) such lender's Revolving Credit Commitment (each as defined in the Credit Agreement) outstanding on the effective date of the amendment, or approximately \$2.2 million in the aggregate for all consenting lenders.

Our indebtedness outstanding at September 30, 2016 matures at various times between 2018 and 2023. We may not have sufficient cash resources at the time of maturity of our remaining indebtedness to pay the aggregate principal and accrued interest under such indebtedness. If the capital and credit markets experience volatility or the availability of funds is limited, we may be unable to re-finance this debt on commercially reasonable terms, including because of increased costs associated with issuing debt

**Table of Contents**

instruments, or at all. In addition, it is possible that our ability to access the capital and credit markets could be limited by the amount of our indebtedness or other factors at a time when we would like, or need, to do so, which could have an adverse impact on our ability to refinance maturing debt and/or react to changing economic and business conditions.

Our funding plans for our working capital needs and other commitments may be adversely impacted if our underlying assumed revenues and expenses are not realized. In particular, we could experience decreased product sales or lower average selling prices, unexpected costs associated with our potential divestitures, the transaction with Abbott, operational integration efforts, core research and development projects, cost-saving initiatives and existing or unforeseen lawsuits, regulatory actions, governmental investigations, or other claims against us, such as those we incurred in connection with our previously announced withdrawal of our INRatio and INRatio 2 products from the market. We may also choose to make significant investment to pursue legal remedies against potential infringers of our intellectual property rights. If we decide to engage in such activities, or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed or may be available only on terms which could have a negative impact on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then-existing stockholders may result. In connection with any such financing, we may be required to obtain consents from the requisite lenders under our secured credit facility and/or the requisite holders of our outstanding Notes or from Abbott pursuant to the Merger Agreement, and there is no guarantee we will be able to obtain those consents.

*Cash Flow Summary (in thousands)*

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
Net cash from operating activities:		
Continuing operations	\$ 146,962	\$ 136,932
Discontinued operations		318
Net cash provided by operating activities	146,962	137,250
Net cash from investing activities:		
Continuing operations	11,338	36,541
Discontinued operations		(209)
Net cash provided by investing activities	11,338	36,332
Net cash from financing activities:		
Continuing operations	(99,111)	(87,212)
Discontinued operations		(76)
Net cash used in financing activities	(99,111)	(87,288)
Foreign exchange effect on cash and cash equivalents	4,824	(8,674)

Edgar Filing: ALERE INC. - Form 10-Q

Net increase in cash and cash equivalents	64,013	77,620
Cash and cash equivalents, beginning of period continuing operations	502,200	378,461
Cash and cash equivalents, beginning of period discontinued operations		23,300
Cash and cash equivalents, end of period	566,213	479,381
Less: Cash and cash equivalents, end of period discontinued operations		
Cash and cash equivalents, end of period continued operations	\$ 566,213	\$ 479,381

*Summary of Changes in Cash Position*

As of September 30, 2016, we had cash and cash equivalents of \$566.2 million, a \$64.0 million increase from December 31, 2015. Our primary sources of cash during the nine months ended September 30, 2016 included \$147.0 million generated by our operating activities, \$124.9 million related to net borrowings under revolving credit facilities, \$40.8 million received from sales of equity investments, \$21.5 million received from dispositions, net of cash divested, \$13.9 million of cash received from common stock issuances under employee stock option and stock purchase plans, \$3.4 million from equity method investments, \$1.2 million in proceeds from the sale of property, plant and equipment, \$0.5 million from a decrease in other assets, \$0.5 million from issuance of long-term debt, and \$0.2 million related to a decrease in restricted cash. Our primary uses of cash during the nine months ended September 30, 2016 were \$187.8 million related to the repayment of long-term debt obligations, \$50.0 million of capital expenditures,

**Table of Contents**

\$29.2 million for financing costs, \$16.0 million for cash dividends paid on our Series B preferred stock, \$6.0 million paid for acquisitions, net of cash acquired, \$3.1 million for principal payments on our capital lease obligations, \$1.7 million related to payments on short-term debt, and \$0.6 million related to payments of acquisition-related contingent consideration obligations. Fluctuations in foreign currencies favorably impacted our cash balance by \$4.8 million during the nine months ended September 30, 2016.

As of September 30, 2015, we had cash and cash equivalents of continuing operations of \$479.4 million, a \$100.9 million increase from December 31, 2014. Our primary sources of cash for continuing operations during the nine months ended September 30, 2015 included \$2.2 billion from issuance of long-term debt, \$586.6 million received from dispositions, net of cash divested, \$136.9 million generated by our continuing operating activities, \$76.5 million of cash received from common stock issuances under employee stock option and stock purchase plans, \$14.3 million received from equity method investments, \$6.1 million in excess tax benefits on exercised stock options, \$1.5 million in proceeds from the sale of property, plant and equipment and \$0.9 million from a decrease in other assets. Our primary uses of cash for our continuing operations during the nine months ended September 30, 2015 were \$2.1 billion related to the repayment of long-term debt obligations, a \$438.8 million increase in restricted cash, including \$425.9 million placed in a trust account for repayment of our 8.625% notes, \$126.6 million related to net payments under revolving credit facilities, \$67.9 million of capital expenditures, \$60.1 million paid for an acquisition, net of cash acquired, \$25.6 million related to the repayment of short-term debt obligations, \$16.1 million for financing costs, \$16.0 million for cash dividends paid on our Series B preferred stock, \$14.1 million related to payments of acquisition-related contingent consideration obligations and \$4.3 million for principal payments on our capital lease obligations. Fluctuations in foreign currencies unfavorably impacted our cash balance by \$8.7 million during the nine months ended September 30, 2015.

*Cash Flows from Operating Activities*

Net cash provided by operations during the nine months ended September 30, 2016 was \$147.0 million, which resulted from \$190.7 million of non-cash items, offset by \$20.9 million of cash used to meet working capital needs during the period and our loss of \$22.8 million. The \$190.7 million of non-cash items included \$214.2 million related to depreciation and amortization, \$31.1 million related to non-cash stock-based compensation, \$9.3 million of non-cash interest expense related to the amortization of deferred financing costs and original issue discounts, \$7.7 million of other non-cash expenses, a \$5.5 million loss on the disposition of fixed assets, \$0.9 million related to inventory impairment and \$0.6 million related to fixed assets impairment, partially offset by \$33.3 million in equity earnings of unconsolidated entities, net of tax, a \$25.2 million decrease related to changes in our deferred income taxes, \$16.3 million non-cash change in fair value of contingent purchase price consideration, which resulted in part from amortization of intangible assets, and a \$3.8 million gain related to impairment and net loss on dispositions.

Net cash provided by continuing operations during the nine months ended September 30, 2015 was \$136.9 million, which resulted from income from continuing operations of \$6.0 million and \$203.0 million of non-cash items, offset by \$72.1 million of cash used to meet working capital needs during the period. The \$203.0 million of non-cash items included \$233.7 million related to depreciation and amortization, a \$42.3 million loss related to impairment and net loss on dispositions, which reflects both a \$27.7 million impairment charge associated with a closed business and a \$14.6 million net loss from business dispositions, \$19.6 million related to non-cash stock-based compensation, \$10.6 million of non-cash interest expense related to the amortization of deferred financing costs and original issue discounts, a \$3.5 million loss on the extinguishment of debt and a \$3.3 million loss on the disposition of fixed assets, partially offset by a \$51.9 million non-cash change in fair value of contingent purchase price consideration, a \$43.5 million decrease related to changes in our deferred income taxes, which resulted in part from amortization of intangible assets, \$10.3 million in equity earnings of unconsolidated entities, net of tax, and \$4.8 million related to

other non-cash items. In addition, \$0.3 million of net cash was provided by discontinued operations.

*Cash Flows from Investing Activities*

Net cash provided by our investing activities during the nine months ended September 30, 2016 was \$11.3 million, including \$40.8 million from the sale of equity investments, \$21.5 million of cash received from dispositions, net of cash divested, \$3.4 million of cash received from equity method investments, \$1.2 million of proceeds from the sale of property, plant and equipment, a \$0.5 million decrease in other assets and a \$0.2 million decrease in restricted cash, partially offset by \$50.0 million of capital expenditures, \$6.0 million paid for acquisitions and \$0.2 million paid for equity investments.

Our investing activities for continuing operations during the nine months ended September 30, 2015 provided \$36.5 million of cash, including, among other items, \$586.6 million of cash received from the disposition of our health management business and other divestitures, net of cash divested, \$14.3 million of cash received from equity method investments, \$1.5 million of proceeds from the sale of property, plant and equipment and a \$0.9 million decrease in other assets, partially offset by a \$438.8 million increase in restricted cash, including \$425.9 million placed in a trust account for repayment of long-term debt, \$67.9 million of capital expenditures and \$60.1 million paid for an acquisition. In addition, discontinued operations used \$0.2 million of net cash for investing activities.

**Table of Contents***Cash Flows from Financing Activities*

Net cash used in financing activities during the nine months ended September 30, 2016 was \$99.1 million. Financing activities during the nine months ended September 30, 2016 included, among other items, \$187.8 million for the payment of long-term debt obligations, \$29.2 million of financing costs, \$16.0 million for dividend payments related to our Series B preferred stock, \$3.1 million for payment of capital lease obligations, \$1.7 million for net payments for short-term debt, and \$0.6 million for payments of acquisition-related contingent consideration obligations. We received \$124.9 million of net proceeds from our revolving credit facilities, \$13.9 million of cash from common stock issuances under our employee stock option and stock purchase plans and \$0.5 million of proceeds from the issuance of long-term debt.

Net cash used in financing activities for continuing operations during the nine months ended September 30, 2015 was \$87.3 million. Financing activities during the nine months ended September 30, 2015 included, among other items, \$2.1 billion for the payment of long-term debt obligations, \$126.6 million for net payments for revolving credit facilities, \$25.6 million for the payment of short-term debt obligations, \$16.1 million for financing costs, \$16.0 million for dividend payments related to our Series B preferred stock, \$14.1 million for payments of acquisition-related contingent consideration obligations and \$4.3 million for payment of capital lease obligations. We received \$2.2 billion of proceeds from issuance of long-term debt, \$76.5 million of cash from common stock issuances under employee stock option and stock purchase plans and had a \$6.1 million excess tax benefit associated with exercised stock options. In addition, discontinued operations used less than \$0.1 million of net cash for financing activities.

As of September 30, 2016, we had an aggregate of \$11.7 million in outstanding capital lease obligations which are payable through 2022.

*Income Taxes*

As of September 30, 2016, our federal, state and foreign net operating loss carryforwards from prior years for income tax purposes were approximately \$30.6 million, \$876.5 million, and \$234.6 million, respectively. If not utilized, a portion of the federal, state and foreign net operating loss carryforwards will begin to expire in 2020, 2016 and 2017, respectively. Certain foreign net operating loss carryforwards can be carried forward indefinitely. As of September 30, 2016, our federal and foreign capital loss carryforwards for income tax purposes were approximately \$256.1 million and \$62.1 million, respectively. If not utilized, a portion of the federal capital loss carryforwards will begin to expire in 2016. The foreign capital loss carryforwards can be carried forward indefinitely. As of September 30, 2016, we had \$22.9 million of U.S. federal and state research and development credit carryforwards, \$4.4 million of U.S. federal Alternative Minimum Tax ( AMT ) credit carryforwards, \$79.2 million of U.S. foreign tax credit carryforwards and \$1.2 million of other foreign tax credit carryforwards. If not utilized, a portion of the research and development credit and foreign tax credit will begin to expire in 2026 and 2018, respectively.

We have recorded a valuation allowance against a portion of the deferred tax assets related to our U.S. foreign tax credits and certain other net operating losses, capital loss and credit carryforwards, as well as certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets.

**Off-Balance Sheet Arrangements**

We had no material off-balance sheet arrangements as of September 30, 2016.

**Contractual Obligations**



As of September 30, 2016, our contractual obligations have not changed significantly since December 31, 2015, as presented in

our Annual Report on Form 10-K for the year ended December 31, 2015.

### **Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements in accordance with generally accepted accounting principles requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On a quarterly basis, we evaluate our estimates, including those related to revenue recognition and related allowances, bad debt, inventory, valuation of long-lived assets, including intangible assets and goodwill, income taxes, including any valuation allowance for our net deferred tax assets, contingent consideration obligations, contingencies and litigation, and stock-based compensation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

There were no significant changes in our critical accounting policies or management estimates between December 31, 2015 and September 30, 2016. A comprehensive discussion of our critical accounting policies and management estimates is included in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2015.

---

**Table of Contents**

**Recent Accounting Pronouncements**

See Note 18 of the consolidated financial statements included in this Quarterly Report on Form 10-Q, regarding the impact of certain recent accounting pronouncements on our consolidated financial statements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended December 31, 2015. In the nine months ended September 30, 2016, there were no material changes to our market risks or our management of such risks.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), which are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate to allow timely decisions regarding required disclosure. Our management, with the participation of our CEO and CFO, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our CEO and CFO concluded that, as a result of the material weaknesses in internal control over financial reporting previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and described below, our disclosure controls and procedures were not effective as of September 30, 2016.

*Previously Reported Material Weaknesses*

As reported in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2015, our management concluded that our internal control over financial reporting was ineffective as of that date because material weaknesses existed in our internal control over financial reporting related to our accounting for income taxes and revenue recognition. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

**Material Weakness Related to Accounting for Income Taxes**

We did not maintain a sufficient complement of resources with adequate experience and expertise in accounting for income taxes, as a result of which our controls did not operate at a level of precision to identify errors in the calculation of tax balances resulting from dispositions and U.S. taxes on foreign earnings. The material weakness resulted in the previous restatements to our consolidated financial statements for the year ended December 31, 2014 and our interim financial information for the three and nine months ended September 30, 2014. This material weakness could result in a material misstatement of the consolidated financial statements that would not be prevented

or detected.

Material Weaknesses Related to Revenue Recognition

We did not maintain a sufficient complement of resources at our subsidiaries with appropriate knowledge, experience and training to ensure proper application of US GAAP in determining revenue recognition.

We also did not maintain effective controls over information and communications as it relates to revenue recognition at our subsidiaries. Specifically, we did not implement and reinforce an adequate process for internally communicating nonstandard terms and conditions between our subsidiaries' commercial operations and finance groups and between our subsidiaries' finance groups and our corporate accounting group. These material weaknesses contributed to the following material weaknesses.

We did not design effective controls over the review of terms of purchase orders and customer contracts, including amendments to contracts, to ensure proper application of US GAAP in determining revenue recognition.

We did not design effective controls to ensure that revenue would not be recognized until title and risk of loss had passed to our customers.

These material weaknesses resulted in a revision to our financial statements for the years ended December 31, 2013 and 2014 and each of the interim periods in 2014 and 2015. Although the adjustments resulting in the revision to our financial statements were not material, we concluded that these material weaknesses could result in a material misstatement of the consolidated financial statements that would not be prevented or detected.

---

**Table of Contents**

***Plan for Remediation of Material Weaknesses in Internal Control Over Financial Reporting***

With the oversight of senior management, including our Chief Executive Officer, our Chief Financial Officer and our Chief Accounting Officer, and the audit committee of our board of directors, we have implemented, and will continue to identify and implement, steps to remediate the material weaknesses described above. The specific actions taken and planned additional actions are described below.

**Material Weakness Related to Accounting for Income Taxes**

supplementing our accounting and tax professionals with additional personnel with the appropriate experience, certification, education, training and expertise in accounting for the income tax effects of dispositions and other complex transactions. Between May 1, 2015 and September 30, 2016, we hired a Corporate Controller and Chief Accounting Officer, Vice President, Global Tax, a Senior Director, International Tax, a Director, Global Tax Accounting, a Senior Manager, Global Tax Accounting, and a Senior Manager, Domestic Tax, all of whom have experience working on tax provisions of multinational companies;

enhancing our income tax controls to include specific activities to assess the accounting for deductible outside basis differences that could reverse as a result of transactions to dispose of components of the company. Between May 1, 2015 and September 30, 2016, Company tax department personnel have attended internal and external trainings related to income tax accounting; and

enhancing our controls over the income tax provision process to include specific controls over the determination of U.S. taxes on foreign earnings.

**Material Weakness Related to Revenue Recognition**

hiring additional Finance personnel to support our commercial subsidiaries who have experience working in global finance organizations and have expertise in revenue recognition and US GAAP. Specifically, in 2015 and 2016, we hired new finance directors in Latin America and Africa and plan to hire additional resources at some of our foreign subsidiaries;

reorganizing Finance and commercial operations to facilitate global communication to enhance compliance with the corporate revenue recognition policy and US GAAP;

enhancing the formal contract and purchase order review process at our commercial subsidiaries to ensure appropriate application of US GAAP, including approvals at appropriate levels;

creating and implementing formal global processes that require revenue recognition subject matter experts to review and approve any nonstandard arrangements, including significant transactions, significant

promotional programs, sales incentives or other deviations from standard order fulfillment processes;

formalizing periodic revenue recognition training for all finance, order fulfillment and customer-facing employees;

expanding the scope of internal audit testing of controls over the order-to-cash cycles at subsidiaries as well as, implementing more precise entity level controls related to revenue transactions to ensure strict adherence to Company policy and procedures

These ongoing actions are subject to ongoing review by our senior management, as well as oversight by the audit committee of our board of directors. Although we plan to complete this remediation process as quickly as possible, we cannot, at this time, estimate when such remediation may occur, and our initiatives may not prove successful in remediating these material weaknesses. Management may determine to enhance other existing controls and/or implement additional controls as the implementation progresses. It will take time to determine whether the additional controls we are implementing will be sufficient to accomplish their intended purpose; accordingly, these material weaknesses may continue for a period of time. While the audit committee of our board of directors and senior management are closely monitoring this implementation, until the remediation efforts discussed in this section, including any additional remediation efforts that our senior management identifies as necessary, are completed, tested and determined effective, we will not be able to conclude that these material weaknesses have been remediated.

#### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

#### ***Abbott Laboratories***

On August 25, 2016, Alere Inc. filed suit against Abbott Laboratories in the Delaware Chancery Court, and filed an accompanying motion to expedite the proceedings. The complaint alleges, among other things, that Abbott is purposefully failing to

**Table of Contents**

comply with its obligations set forth in the Merger Agreement related to obtaining antitrust approvals. Specifically, the complaint alleges that Abbott: (i) purposefully failed to supply information requested by the FTC as promptly as reasonably practicable after such requests were made, as expressly required by the Merger Agreement; (ii) purposefully failed to supply information requested and make antitrust filings pursuant to antitrust laws in various foreign jurisdictions as promptly as reasonably practicable after such requests were made; (iii) purposefully failed to promptly take any and all steps necessary to avoid or eliminate impediments to obtaining antitrust clearance in the United States and in various foreign jurisdictions; (iv) purposefully failed to keep Alere informed in all material respects and on a reasonably timely basis of material communications with respect to the merger with antitrust authorities in the United States and in various foreign jurisdictions; and (v) purposefully failed to cooperate and consult with Alere, as well as give due consideration to Alere's views with respect to antitrust matters. We asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by the Merger Agreement. On August 30, 2016, Abbott filed its response in opposition to the motion to expedite the proceedings in this matter. On September 2, 2016, the Delaware Chancery Court granted our motion to expedite the proceedings. On September 29, 2016, the Delaware Chancery Court entered an order that, among other things, adopted a detailed schedule setting forth actions required to be taken by specified dates in order to obtain all antitrust clearances required by the Merger Agreement. By order of the court, the schedule is confidential. The court order also (i) requires Abbott to provide us with advance notice of, and the right to participate (in a manner not inconsistent with the terms of the Merger Agreement) in, all future discussions with antitrust regulators worldwide; (ii) appoints a Special Master to confidentially mediate any disputes regarding compliance with the order or the parties obligations under the Merger Agreement; (iii) lifts the stay of the case and permits discovery to commence immediately, including with respect to potential breaches of the Merger Agreement by Abbott; and (iv) sets a preliminary injunction hearing date on our claims for January 27, 2017, if necessary.

On November 3, 2016, Abbott filed a complaint against Alere in the Delaware Chancery Court. Abbott asserts a single claim against Alere for breach of contract stemming from Alere's refusal to provide Abbott with certain categories of documents under the Merger Agreement. The complaint makes no claim for damages and seeks to compel Alere to produce certain categories of documents and information which Abbott contends Alere is obligated to produce under the terms of the Merger Agreement. Alere believes it has fulfilled its contractual obligations under the merger agreement.

*U.S. Securities and Exchange Commission Subpoenas*

On August 28, 2015, we received a subpoena from the SEC which indicated that it is conducting a formal investigation of Alere. The SEC's subpoena relates to, among other things, (i) our previously filed restatement and revision to our financial statements, including the accounting for deferred taxes for discontinued operations, as well as our tax strategies and policies and (ii) our sales practices and dealings with third parties (including distributors and foreign government officials) in Africa relating to sales to government entities. On January 14, 2016, we received a second subpoena from the SEC in connection with this formal investigation seeking, among other things, additional information related to sales of products and services to end-users in Africa, as well as revenue recognition relating to sales of products and services to end-users in Africa. We have also received, from time to time, requests in connection with the investigation to voluntarily produce additional information to the SEC, including information pertaining to certain other countries in Asia and Latin America, as well as additional information on revenue recognition matters and revisions to our financial statements referenced in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

We are cooperating with the SEC and have provided documents in response to the subpoenas and voluntary requests. We are unable to predict when this matter will be resolved or what further action, if any, the SEC may take in connection with it.

*Department of Justice Grand Jury Subpoena*

On March 11, 2016, we received a grand jury subpoena from the United States Department of Justice requiring the production of documents relating to, among other things, sales, sales practices and dealings with third parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act.

We are cooperating with the Department of Justice and have provided information in response to the subpoena. We are unable to predict when this matter will be resolved or what further action, if any, the Department of Justice may take in connection with it.

*Securities Class Actions*

On April 21, 2016, a class action lawsuit captioned *Godinez v. Alere Inc.*, was filed against us in the United States District Court for the District of Massachusetts. On May 4, 2016, a second class action lawsuit captioned *Breton v. Alere Inc.*, was filed against us in the United States District Court for the District of Massachusetts. Both of these class actions purport to assert claims against us and certain current and former officers for alleged violations of Section 10(b) and Section 20(a) of the Exchange Act and Rule 10b-5 under the Exchange Act. Each plaintiff seeks to represent a proposed class of all persons who purchased or otherwise acquired our common stock during the period May 9, 2013 through April 20, 2016. Each complaint seeks damages allegedly caused by alleged materially misleading statements and/or material omissions by us and the officers regarding our business, prospects and operations, each plaintiff claims, which allegedly operated to inflate artificially the price paid for our common stock during the class period. Each complaint seeks unspecified compensatory damages, attorneys' fees and costs. On July 11, 2016, the court entered an order consolidating the two actions and appointing lead plaintiffs and lead counsel. A consolidated amended complaint filed on September 23, 2016 alleges certain additional misleading statements and omissions and changes the proposed class period to May 28, 2015 through July 27, 2016. We are filing our motion to dismiss the amended complaint on November 8, 2016 and the court has scheduled oral argument on that motion for April 5, 2017.

We are unable at this time to determine the outcome of this class action lawsuit or our potential liability, if any.

*Matters Relating to our San Diego Facility*

On October 9, 2012, we received a warning letter from the FDA referencing inspectional observations set forth in a Form FDA 483 received in June 2012. The observations were the result of an inspection of our San Diego facility conducted earlier during 2012 relating to our Alere Triage products, which resulted in two recalls of certain Alere Triage products and revised release specifications



**Table of Contents**

for our Alere Triage meter-based products. In September 2014, as follow up to a further inspection of our San Diego facility, the FDA notified us that this inspection was classified voluntary action indicated, meaning that the objectionable conditions or practices found in the inspection did not meet the threshold of significance requiring regulatory action, but that formal close-out of the October 2012 warning letter could not occur until after a future inspection.

In May 2012, we also received a subpoena from the Office of Inspector General of the Department of Health and Human Services, or the OIG, seeking documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the government and are responding to the investigation, which is ongoing. We have been engaged in discussions with the government about this matter, including a resolution of potential related False Claims Act and common law liability exposure for the products under review. As a result of these discussions, management has accrued \$20.7 million for this matter in the nine months ended September 30, 2016. We would need to obtain certain approvals before we could agree to any proposed resolution. There can be no assurance that future discussions with the government to resolve these matters will be successful, that the approvals we need will be obtained or that any potential settlement will be agreed to or finalized. We may be required to engage in litigation of this matter, which may be time consuming and costly. Based on the ongoing uncertainties and potentially wide range of outcomes associated with any potential resolution, the ultimate amount of potential loss may materially exceed the accrual we have established.

We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with them.

*INRatio Class Actions*

On May 26, 2016, a class action complaint, captioned *Dina Andren, et al. v. Alere Inc., et al.*, was filed against us in the United States District Court for the Southern District of California, and the plaintiffs filed an amended class action complaint on October 3, 2016. In addition, on July 22, 2016, a class action complaint captioned *J.E, J.D., and all others similarly situated v. Alere Inc., Alere San Diego, Inc. and Alere Home Monitoring, Inc.*, was filed against us in the United States District Court for the District of Massachusetts, and the plaintiffs filed an amended class action complaint on October 10, 2016. These class actions, as amended, purport to assert claims against us under several legal theories, including fraud, breach of warranty, breach of contract, unjust enrichment and violation of applicable unfair competition/business practice statutes in connection with the manufacturing, marketing and sale of our INRatio products. The seven named plaintiffs in the *Dina Andren* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for INRatio products during the period January 1, 2009 to the present in the United States, or alternatively, California, Colorado, Florida, Georgia, Maryland, New York, and/or Pennsylvania. The two named plaintiffs in the *J.E, J.D., and all others similarly situated* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for INRatio products during the period April 1, 2008 to present. Both class action complaints seek restitution and damages allegedly resulting from inaccurate PT/INR readings and from the purchase of devices and/or test strips that claimants say they would not have purchased had they known of the alleged propensity of these devices to yield inaccurate PT/INR results. Among other things, plaintiffs in these class action lawsuits seek a refund of money spent on INRatio products. Each complaint also seeks unspecified compensatory damages, injunctive relief, attorneys' fees and costs.

We are unable, at this time, to predict the outcome of these class action lawsuits.

*Claims in the Ordinary Course and Other Matters*

We are also party to certain other legal proceedings and other governmental investigations, or are requested to provide information in connection with such proceedings or investigations. For example, in December 2014, we and our subsidiary, Avee Laboratories Inc., or Avee, received subpoenas from the United States Attorney for the District of New Jersey seeking marketing materials and other documents relating primarily to billing and marketing practices related to toxicology testing. In addition, we received a U.S. Department of Justice criminal subpoena addressed to Alere Toxicology Services, Inc. on July 1, 2016 which seeks records related to Medicare, Medicaid and Tricare billings dating back to 2010 for specific patient samples tested at our Austin, Texas pain management laboratory and payments made to physicians. We are cooperating with these investigations and are providing documents in response to both subpoenas. We and our subsidiary, Arriva Medical, LLC, are also in the process of responding to Civil Investigative Demands, or CIDs, from the United States Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid. The most recent of the CIDs was received in July 2016. The CIDs request patient and insurance billing and medical records, records related to interactions with third parties, and correspondence related to the same, dating back to January 2010. We are cooperating with the investigation and are providing documents responsive to the CIDs. We cannot predict what effect, if any, these investigations, or any resulting claims, could have on Alere or its subsidiaries.

We have received, from time to time, additional subpoenas and requests for information from the United States Department of Justice, other federal government agencies and state attorneys general, and we have, in each of these cases, cooperated with the applicable governmental entity in responding to the applicable subpoena or request for information. For example, in May 2016, we received a subpoena from the U.S. Attorney for the District of New Jersey, which seeks various documents related to the accuracy, reliability and performance of the INRatio System, including documents relating to prior interactions with the FDA and others regarding the system.

## **Table of Contents**

Our diabetes, toxicology and patient self-testing businesses are subject to audit and claims for reimbursement brought in the ordinary course by private third-party payers, including health insurers, Zone Program Integrity Contractors, or ZPICs, and Medicare Administrative Contractors, or MACs, to monitor compliance with coverage and reimbursement rules and guidelines. These types of audits and claims can include, but are not limited to, claims relating to proper documentation and support or claims relating to the medical necessity of certain testing and can lead to assertions or determinations that certain claims should not have been, or will no longer be, paid by the private third-party payer or by Medicare or Medicaid. In such cases, the payer or program may seek to recoup or offset amounts they assert have been paid in error.

Our businesses may also be subject at any time to other commercial disputes, product liability claims, personal injury claims, including claims arising from or relating to product recalls, negligence claims, third-party subpoenas or various other lawsuits arising in the ordinary course of business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. For example, several individuals have filed suits against us alleging personal injury claims in connection with the use of our INRatio products (which are in addition to the class action suits described above).

Such lawsuits or claims generally seek damages or reimbursement, sometimes in substantial amounts. There are possible unfavorable outcomes related to litigation or governmental investigations that could adversely impact our business, results of operations, financial condition, and cash flows.

### **ITEM 1A. RISK FACTORS**

Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the SEC on August 8, 2016. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, other than the fact that on October 21, 2016, the holders of a majority of the outstanding shares of our common stock approved the adoption of the Merger Agreement, but the merger remains subject to regulatory approvals and other customary closing conditions, and we are confident that the transaction will be completed in accordance with the terms set forth in the Merger Agreement.

### **ITEM 3. DEFAULT UPON SENIOR SECURITIES**

As previously disclosed, as of March 31, 2016, we were in default under the Credit Agreement and the respective indentures

governing our 7.25% senior notes, our 6.5% senior subordinated notes, our 6.375% senior subordinated notes and our 3% convertible

senior subordinated notes as a result of our failure to timely furnish to the holders of such debt our annual financial statements for the

fiscal year ended December 31, 2015. We subsequently entered into an amendment and obtained waivers with respect to such debt

instruments (other than with respect to our 3% convertible senior subordinated notes) with the requisite holders of such debt with

regard to such defaults and certain other defaults thereunder (including our subsequent failure to timely furnish to the holders of such

debt our quarterly financial statements for the three months ended March 31, 2016). For more information regarding this default and

these amendments and waivers, see Note 12 to the consolidated financial statements Long-term Debt included elsewhere in this

Quarterly Report on Form 10-Q.

## ITEM 6. EXHIBITS

### Exhibit No.

### Description

- |       |   |
|-------|---|
| 10.1  | Second Amendment, dated as of August 18, 2016, among Alere Inc., certain subsidiaries of the Alere Inc., the several lenders from time to time party thereto, Goldman Sachs Bank USA as B term loan administrative agent, Healthcare Financial Solutions, LLC, as pro rata administrative agent, to the secured Credit Agreement, dated as of June 18, 2015, among Alere Inc., the several lenders from time to time party thereto, the Administrative Agents and certain other agents and arrangers (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, event date August 18, 2016, filed with the SEC on August 18, 2016) |
| *31.1 | Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| *31.2 | Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| *32.1 | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  |
| *101  | Interactive Data Files regarding (a) our Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2016 and 2015, (b) our Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2016 and 2015, (c) our Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (d) our Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015 and (e) the Notes to such Consolidated Financial Statements.  |

\* Filed herewith

**Table of Contents**

**SIGNATURE**

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.

ALERE INC.

Date: November 4, 2016

By: /s/ Jonathan Wygant  
Jonathan Wygant  
*Chief Accounting Officer and Corporate Controller  
and an authorized officer*