

ALERE INC.  
Form 10-Q  
September 06, 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 June 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 August 30, 2016 was 86,740,318.



**Table of Contents****ALERE INC.****REPORT ON FORM 10-Q****For the Quarterly Period Ended June 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 Six Months Ended June 30, 2016 and 2015</u>	3
b) <u>Consolidated Statements of Comprehensive Income (Loss) for the Three and Six Months Ended June 30, 2016 and 2015</u>	4
c) <u>Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015</u>	5
d) <u>Consolidated Statements of Cash Flows for the Six Months Ended June 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>	41
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	55
Item 4. <u>Controls and Procedures</u>	55
<b><u>PART II. OTHER INFORMATION</u></b>	<b>57</b>
Item 1. <u>Legal Proceedings</u>	57
Item 1A. <u>Risk Factors</u>	59
Item 3. <u>Default Upon Senior Securities</u>	59
Item 6. <u>Exhibits</u>	59
<b><u>SIGNATURE</u></b>	<b>61</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 June 30, Six Months Ended June 30,</b>			
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net product sales	\$ 483,746	\$ 491,049	\$ 943,517	\$ 975,387
Services revenue	124,809	126,628	240,518	250,484
Net product sales and services revenue	608,555	617,677	1,184,035	1,225,871
License and royalty revenue	2,533	5,694	5,262	10,392
<b>Net revenue</b>	<b>611,088</b>	<b>623,371</b>	<b>1,189,297</b>	<b>1,236,263</b>
Cost of net product sales	250,398	257,893	487,859	497,994
Cost of services revenue	78,294	76,800	151,394	152,426
Cost of net product sales and services revenue	328,692	334,693	639,253	650,420
Cost of license and royalty revenue	535	1,344	1,926	3,294
<b>Cost of net revenue</b>	<b>329,227</b>	<b>336,037</b>	<b>641,179</b>	<b>653,714</b>
<b>Gross profit</b>	<b>281,861</b>	<b>287,334</b>	<b>548,118</b>	<b>582,549</b>
Operating expenses:				
Research and development	28,446	27,198	55,508	55,214
Sales and marketing	102,516	108,024	202,329	217,103
General and administrative	128,354	61,173	243,310	153,864
Impairment and (gain) loss on dispositions, net		5,542	(3,810)	40,334
<b>Operating income</b>	<b>22,545</b>	<b>85,397</b>	<b>50,781</b>	<b>116,034</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(42,329)	(59,494)	(84,435)	(105,925)
Other income (expense), net	(14,112)	3,195	(15,461)	828
<b>Income (loss) from continuing operations before provision for income taxes</b>	<b>(33,896)</b>	<b>29,098</b>	<b>(49,115)</b>	<b>10,937</b>
Provision (benefit) for income taxes	3,117	15,689	2,909	7,836

<b>Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax</b>	(37,013)	13,409	(52,024)	3,101
Equity earnings of unconsolidated entities, net of tax	2,122	1,361	7,156	5,320
Income (loss) from continuing operations	(34,891)	14,770	(44,868)	8,421
Income from discontinued operations, net of tax				216,777
<b>Net income (loss)</b>	(34,891)	14,770	(44,868)	225,198
Less: Net income attributable to non-controlling interests	143	359	246	447
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	(35,034)	14,411	(45,114)	224,751
Preferred stock dividends	(5,308)	(5,308)	(10,617)	(10,558)
<b>Net income (loss) available to common stockholders</b>	\$ (40,342)	\$ 9,103	\$ (55,731)	\$ 214,193
<b>Basic net income (loss) per common share:</b>				
Income (loss) from continuing operations	\$ (0.46)	\$ 0.11	\$ (0.64)	\$ (0.03)
Income from discontinued operations				2.56
Net income (loss) per common share	\$ (0.46)	\$ 0.11	\$ (0.64)	\$ 2.53
<b>Diluted net income (loss) per common share:</b>				
Income (loss) from continuing operations	\$ (0.46)	\$ 0.11	\$ (0.64)	\$ (0.03)
Income from discontinued operations				2.56
Net income (loss) per common share	\$ (0.46)	\$ 0.11	\$ (0.64)	\$ 2.53
<b>Weighted-average shares basic</b>	86,737	85,173	86,692	84,758
<b>Weighted-average shares diluted</b>	86,737	86,635	86,692	84,758

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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net income (loss)	\$ (34,891)	\$ 14,770	\$ (44,868)	\$ 225,198
Other comprehensive income (loss), before tax:				
Changes in cumulative translation adjustment	(44,135)	46,726	(21,942)	(33,616)
Minimum pension liability adjustment	531	(374)	686	(1,756)
Other comprehensive income (loss), before tax	(43,604)	46,352	(21,256)	(35,372)
Other comprehensive income (loss)	(43,604)	46,352	(21,256)	(35,372)
<b>Comprehensive income (loss)</b>	<b>(78,495)</b>	<b>61,122</b>	<b>(66,124)</b>	<b>189,826</b>
Less: Comprehensive income attributable to non-controlling interests	143	359	246	447
<b>Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries</b>	<b>\$ (78,638)</b>	<b>\$ 60,763</b>	<b>\$ (66,370)</b>	<b>\$ 189,379</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)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 506,164	\$ 502,200
Restricted cash	5,662	5,694
Marketable securities	74	164
Accounts receivable, net of allowances of \$92,983 and \$89,701 at June 30, 2016 and December 31, 2015, respectively	427,222	445,833
Inventories, net	333,846	347,001
Prepaid expenses and other current assets	162,339	152,233
Assets held for sale - current		4,165
<b>Total current assets</b>	<b>1,435,307</b>	<b>1,457,290</b>
Property, plant and equipment, net	438,787	446,039
Goodwill	2,811,545	2,836,915
Other intangible assets with indefinite lives	28,279	28,110
Finite-lived intangible assets, net	909,208	997,281
Restricted cash	42,589	43,228
Other non-current assets	16,290	18,078
Investments in unconsolidated entities	74,511	65,333
Deferred tax assets	18,638	13,993
Non-current income tax receivable	3,517	3,517
Assets held for sale - non-current	12,223	13,337
<b>Total assets</b>	<b>\$ 5,790,894</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	\$ 43,681	\$ 199,992
Current portion of capital lease obligations	3,500	3,962
Accounts payable	194,235	195,752
Accrued expenses and other current liabilities	320,526	324,465
Liabilities related to assets held for sale - current		363
<b>Total current liabilities</b>	<b>561,942</b>	<b>724,534</b>
<b>Long-term liabilities:</b>		
Long-term debt, net of current portion	2,920,789	2,831,166



Edgar Filing: ALERE INC. - Form 10-Q

Capital lease obligations, net of current portion	6,972	7,181
Deferred tax liabilities	140,864	147,618
Other long-term liabilities	148,165	154,193
<b>Total long-term liabilities</b>	<b>3,216,790</b>	<b>3,140,158</b>
<b>Commitments and contingencies</b>		
<b>Stockholders equity:</b>		
Series B preferred stock, \$0.001 par value (liquidation preference: \$709,701 at June 30, 2016 and \$709,763 at December 31, 2015); Authorized: 2,300 shares; Issued: 2,065 shares at June 30, 2016 and December 31, 2015; Outstanding: 1,774 shares at June 30, 2016 and December 31, 2015	606,406	606,468
Common stock, \$0.001 par value; Authorized: 200,000 shares; Issued: 94,419 shares at June 30, 2016 and 94,043 shares at December 31, 2015; Outstanding: 86,740 shares at June 30, 2016 and 86,364 shares at December 31, 2015	94	94
Additional paid-in capital	3,458,639	3,438,732
Accumulated deficit	(1,511,481)	(1,466,381)
Treasury stock, at cost, 7,679 shares at June 30, 2016 and December 31, 2015	(184,971)	(184,971)
Accumulated other comprehensive loss	(361,033)	(339,777)
<b>Total stockholders equity</b>	<b>2,007,654</b>	<b>2,054,165</b>
Non-controlling interests	4,508	4,264
<b>Total equity</b>	<b>2,012,162</b>	<b>2,058,429</b>
<b>Total liabilities and equity</b>	<b>\$ 5,790,894</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>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash Flows from Operating Activities:</b>		
Net income (loss)	\$ (44,868)	\$ 225,198
Income from discontinued operations, net of tax		216,777
Income (loss) from continuing operations	(44,868)	8,421
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	5,261	7,784
Depreciation and amortization	142,405	147,103
Non-cash stock-based compensation expense	20,607	12,279
Impairment of inventory	870	68
Impairment of long-lived assets	633	387
Loss on disposition of fixed assets	4,235	3,318
Equity earnings of unconsolidated entities, net of tax	(7,156)	(5,320)
Gain on sales of marketable securities		(8)
Deferred income taxes	(13,210)	(42,171)
(Gain) loss related to impairment and net loss on dispositions	(3,810)	40,334
(Gain) loss on extinguishment of debt		3,480
Other non-cash items	9,720	(2,332)
Non-cash change in fair value of contingent purchase price consideration	(1,780)	(52,867)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	20,023	(18,016)
Inventories, net	(5,820)	(45,219)
Prepaid expenses and other current assets	(24,881)	(27,077)
Accounts payable	(1)	(23,251)
Accrued expenses and other current liabilities	(1,676)	23,052
Other non-current liabilities	(6,106)	8,536
Cash paid for contingent purchase price consideration	(324)	(3,781)
Net cash provided by continuing operations	94,122	34,720
Net cash provided by discontinued operations		318
<b>Net cash provided by operating activities</b>	<b>94,122</b>	<b>35,038</b>

**Cash Flows from Investing Activities:**

Edgar Filing: ALERE INC. - Form 10-Q

Increase in restricted cash	(449)	(424,025)
Purchases of property, plant and equipment	(32,318)	(47,284)
Proceeds from sale of property, plant and equipment	892	1,120
Cash received from dispositions, net of cash divested	21,470	586,625
Cash paid for business acquisitions, net of cash acquired	(5,958)	
Cash received from equity method investments	2,383	14,297
Cash received from sales of marketable securities	90	93
Cash paid for investments	(184)	
Decrease in other assets	495	1,750
Net cash provided by (used in) continuing operations	(13,579)	132,576
Net cash used in discontinued operations		(209)
<b>Net cash provided by (used in) investing activities</b>	<b>(13,579)</b>	<b>132,367</b>
<b>Cash Flows from Financing Activities:</b>		
Cash paid for financing costs	(19,564)	(15,731)
Cash paid for contingent purchase price consideration	(485)	(6,373)
Proceeds from issuance of common stock, net of issuance costs	11,124	56,332
Proceeds from issuance of long-term debt	381	2,121,851
Payments on short-term debt	(791)	(584)
Payments on long-term debt	(177,637)	(2,118,264)
Net (payments) proceeds under revolving credit facilities	126,213	(126,320)
Cash paid for dividends	(10,646)	(10,646)
Principal payments on capital lease obligations	(2,210)	(2,910)
Net cash used in continuing operations	(73,615)	(102,645)
Net cash used in discontinued operations		(76)
<b>Net cash used in financing activities</b>	<b>(73,615)</b>	<b>(102,721)</b>
Foreign exchange effect on cash and cash equivalents	(2,964)	(1,574)
Net increase in cash and cash equivalents	3,964	63,110
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>506,164</b>	<b>464,871</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>\$ 506,164</b>	<b>\$ 464,871</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 a decrease in revenue of \$5.8 million and \$1.0 million for the three and six months ended June 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 June 30, 2015 these adjustments include a \$1.2 million increase in operating expenses related to a bonus accrual, a \$1.1 million increase in other income and expense, net due to the measurement of a royalty obligation and the income tax impact of these adjustments. For the six months ended June 30, 2015 these adjustments include a \$1.2 million increase in operating expenses related to a bonus accrual, a \$2.2 million increase in other income and expense, net due to the measurement of a royalty obligation and the income tax impact of these adjustments. 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 six months ended June 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 six months ended June 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 June 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	\$ 496,834	\$ (5,785)	\$ 491,049
Net product sales and services revenue	\$ 623,462	\$ (5,785)	\$ 617,677
Net revenue	\$ 629,156	\$ (5,785)	\$ 623,371
Cost of net product sales	\$ 258,485	\$ (592)	\$ 257,893
Cost of service revenue	\$ 76,753	\$ 47	\$ 76,800
Cost of net product sales and services revenue	\$ 335,238	\$ (545)	\$ 334,693
Cost of net revenue	\$ 336,582	\$ (545)	\$ 336,037
Gross profit	\$ 292,574	\$ (5,240)	\$ 287,334
Sales and marketing	\$ 107,184	\$ 840	\$ 108,024
General and administrative	\$ 60,813	\$ 360	\$ 61,173
Operating income	\$ 91,837	\$ (6,440)	\$ 85,397
Other income (loss), net	\$ 4,260	\$ (1,065)	\$ 3,195
Income from continuing operations before provision for income taxes	\$ 36,603	\$ (7,505)	\$ 29,098
Provision for income taxes	\$ 17,701	\$ (2,012)	\$ 15,689
Income from continuing operations before equity earnings of unconsolidated entities, net of tax	\$ 18,902	\$ (5,493)	\$ 13,409
Income from continuing operations	\$ 20,263	\$ (5,493)	\$ 14,770
Net income	\$ 20,263	\$ (5,493)	\$ 14,770
Net income attributable to Alere Inc. and Subsidiaries	\$ 19,904	\$ (5,493)	\$ 14,411
Net income available to common stockholders	\$ 14,596	\$ (5,493)	\$ 9,103
Basic and diluted income per common share: Income from continuing operations	\$ 0.17	\$ (0.06)	\$ 0.11
Basic and diluted net income per common share: Net income per common share	\$ 0.17	\$ (0.06)	\$ 0.11

**Six Months Ended June 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	\$ 976,433	\$ (1,046)	\$ 975,387
Net product sales and services revenue	\$ 1,226,917	\$ (1,046)	\$ 1,225,871
Net revenue	\$ 1,237,309	\$ (1,046)	\$ 1,236,263
Cost of net product sales	\$ 497,122	\$ 872	\$ 497,994
Cost of service revenue	\$ 152,334	\$ 92	\$ 152,426
Cost of net product sales and services revenue	\$ 649,456	\$ 964	\$ 650,420
Cost of net revenue	\$ 652,750	\$ 964	\$ 653,714
Gross profit	\$ 584,559	\$ (2,010)	\$ 582,549
Sales and marketing	\$ 216,263	\$ 840	\$ 217,103

Edgar Filing: ALERE INC. - Form 10-Q

General and administrative	\$ 153,504	\$ 360	\$ 153,864
Operating income	\$ 119,244	\$ (3,210)	\$ 116,034
Other income (loss), net	\$ 2,990	\$ (2,162)	\$ 828
Income from continuing operations before benefit for income taxes	\$ 16,309	\$ (5,372)	\$ 10,937
Provision for income taxes	\$ 8,915	\$ (1,079)	\$ 7,836
Income from continuing operations before equity earnings of unconsolidated entities, net of tax	\$ 7,394	\$ (4,293)	\$ 3,101
Income from continuing operations	\$ 12,714	\$ (4,293)	\$ 8,421
Net income	\$ 229,491	\$ (4,293)	\$ 225,198
Net income attributable to Alere Inc. and Subsidiaries	\$ 229,044	\$ (4,293)	\$ 224,751
Net income available to common stockholders	\$ 218,486	\$ (4,293)	\$ 214,193
Basic and diluted income (loss) per common share: Income (loss) from continuing operations	\$ 0.02	\$ (0.05)	\$ (0.03)
Basic and diluted net income per common share: Net income per common share	\$ 2.54	\$ (0.01)	\$ 2.53

**Table of Contents****Three Months Ended June 30, 2015****Revised Consolidated Statement of Comprehensive**

<b>Loss (in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income	\$ 20,263	\$ (5,493)	\$ 14,770
Comprehensive income	\$ 66,615	\$ (5,493)	\$ 61,122
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 66,256	\$ (5,493)	\$ 60,763

**Six Months Ended June 30, 2015****Revised Consolidated Statement of Comprehensive**

<b>Loss (in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income	\$ 229,491	\$ (4,293)	\$ 225,198
Comprehensive income	\$ 194,119	\$ (4,293)	\$ 189,826
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 193,672	\$ (4,293)	\$ 189,379

**Six Months Ended June 30, 2015****Revised Consolidated Statement of Cash Flows**

<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Adjustment</b>	<b>As Revised</b>
Net income	\$ 229,491	\$ (4,293)	\$ 225,198
Income from continuing operations	\$ 12,714	\$ (4,293)	\$ 8,421
Depreciation and amortization	\$ 147,011	\$ 92	\$ 147,103
Deferred income taxes	\$ (40,655)	\$ (1,516)	\$ (42,171)
Accounts receivable, net	\$ (27,464)	\$ 9,448	\$ (18,016)
Inventories, net	\$ (46,093)	\$ 874	\$ (45,219)
Accrued expenses and other current liabilities	\$ 27,657	\$ (4,605)	\$ 23,052
Other non-current liabilities	\$ 6,025	\$ 2,511	\$ 8,536
Net cash provided by continuing operations	\$ 32,209	\$ 2,511	\$ 34,720
Net cash provided by operating activities	\$ 32,527	\$ 2,511	\$ 35,038
Excess tax benefits on exercised stock options	\$ 2,511	\$ (2,511)	\$
Net cash used in continuing operations	\$ (100,134)	\$ (2,511)	\$ (102,645)
Net cash used in financing activities	\$ (100,210)	\$ (2,511)	\$ (102,721)

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. Completion of the merger is



subject to customary closing conditions, including (1) the adoption of the Merger Agreement by the affirmative vote of the holders of at least a majority of all outstanding shares of our common stock, (2) there being no judgment or law enjoining or otherwise prohibiting the consummation of the merger and (3) 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. 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. 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. 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.

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 have asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by 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 three and six months ended June 30, 2015. The results are as follows (in thousands):

	<b>Three and Six Months Ended June 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 June 30, 2016, our cash equivalents consisted of money market funds.

**(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>June 30, 2016</b>	<b>December 31, 2015</b>
Raw materials	\$ 121,904	\$ 130,171
Work-in-process	74,206	69,178
Finished goods	137,736	147,652
	\$ 333,846	\$ 347,001

**Table of Contents****(7) Stock-based Compensation**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of net revenue	\$ 601	\$ 287	\$ 1,080	\$ 540
Research and development	481	282	879	606
Sales and marketing	2,636	1,251	4,561	2,345
General and administrative	7,286	5,310	14,086	8,788
	\$ 11,004	\$ 7,130	\$ 20,607	\$ 12,279

**(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 amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Basic and diluted net income (loss) per common share:</b>				
<b>Numerator:</b>				
Income (loss) from continuing operations	\$ (34,891)	\$ 14,770	\$ (44,868)	\$ 8,421
Preferred stock dividends	(5,308)	(5,308)	(10,617)	(10,558)
Income (loss) from continuing operations attributable to common shares	(40,199)	9,462	(55,485)	(2,137)
Less: Net income attributable to non-controlling interest	143	359	246	447
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	(40,342)	9,103	(55,731)	(2,584)
Income from discontinued operations				216,777
Net income (loss) available to common stockholders	\$ (40,342)	\$ 9,103	\$ (55,731)	\$ 214,193
<b>Denominator:</b>				
Weighted-average common shares outstanding basic	86,737	85,173	86,692	84,758
	86,737	86,635	86,692	84,758

Weighted-average common shares outstanding  
diluted

<b>Basic net income (loss) per common share:</b>					
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	\$	(0.46)	\$	0.11	\$ (0.64) \$ (0.03)
Income from discontinued operations					2.56
Basic net income (loss) per common share	\$	(0.46)	\$	0.11	\$ (0.64) \$ 2.53
<b>Diluted net income (loss) per common share:</b>					
Income (loss) from continuing operations attributable to Alere Inc. and Subsidiaries	\$	(0.46)	\$	0.11	\$ (0.64) \$ (0.03)
Income from discontinued operations					2.56
Diluted net income (loss) per common share	\$	(0.46)	\$	0.11	\$ (0.64) \$ 2.53

**Table of Contents**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Denominator:</b>				
Options to purchase shares of common stock	7,329	7,627	7,329	7,627
Warrants				4
Conversion shares related to 3% convertible senior subordinated notes	1,687	3,411	2,549	3,411
Conversion shares related to subordinated convertible promissory notes		27		27
Conversion shares related to Series B convertible preferred stock	10,238	10,239	10,238	10,239
Total number of antidilutive potentially issuable shares of common stock excluded from diluted common shares outstanding	19,254	21,304	20,116	21,308

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

For the three and six months ended June 30, 2016, Series B preferred stock dividends amounted to \$5.3 million and \$10.6 million, respectively, and for the three and six months ended June 30, 2015, Series B preferred stock dividends amounted to \$5.3 million and \$10.6 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 June 30, 2016, \$5.3 million of Series B preferred stock dividends was accrued. As of July 15, 2016, payments have been made covering all dividend periods through June 30, 2016.

The Series B preferred stock dividends for the three and six months ended June 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 six months ended June 30, 2016 is provided below (in thousands):

	Six Months Ended June 30, 2016		
	Total Stockholders Equity	Non- controlling Interests	Total Equity
Equity, beginning of period	\$ 2,054,165	\$ 4,264	\$ 2,058,429
	11,308		11,308

Issuance of common stock under employee compensation plans			
Net issuance of common stock to settle taxes on restricted stock units	(1,410)		(1,410)
Preferred stock dividends	(10,646)		(10,646)
Stock-based compensation expense	20,607		20,607
Other adjustments		(2)	(2)
Net income (loss)	(45,114)	246	(44,868)
Total other comprehensive loss	(21,256)		(21,256)
Equity, end of period	\$ 2,007,654	\$ 4,508	\$ 2,012,162

### (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.

**Table of Contents**

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.

*Acquisition in 2016***EDTS**

On February 11, 2016, we acquired the 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 six months ended June 30, 2016 included revenue totaling approximately \$1.7 million and \$2.6 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 preliminary 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	2,065
Intangible assets	4,220
<b>Total assets acquired</b>	<b>\$ 7,771</b>
Current liabilities	\$ 1,301
<b>Total liabilities assumed</b>	<b>\$ 1,301</b>
Net assets acquired	\$ 6,470
<b>Cash paid</b>	<b>\$ 6,470</b>

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

<b>Fair Value</b>	<b>Weighted- average Useful Life</b>
-------------------	--



Edgar Filing: ALERE INC. - Form 10-Q

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
Total intangible assets	\$ 4,220	

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

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

Statement of Operations Caption	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of net revenue	\$ 1,103	\$ 896	\$ 2,370	\$ 2,399
Research and development	1,034	156	2,954	649
Sales and marketing	259	570	909	1,953
General and administrative	6,389	3,231	10,215	4,122
<b>Total operating expenses</b>	<b>8,785</b>	<b>4,853</b>	<b>16,448</b>	<b>9,123</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	2	6	7	13
<b>Total restructuring charges</b>	<b>\$ 8,787</b>	<b>\$ 4,859</b>	<b>\$ 16,455</b>	<b>\$ 9,136</b>

*(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 six months ended June 30, 2016 and 2015 and since inception of these restructuring plans (in thousands):

Professional Diagnostics	Three Months Ended June 30,		Six Months Ended June 30,		Since Inception
	2016	2015	2016	2015	
Severance-related costs	\$ 3,183	\$ 1,264	\$ 6,274	\$ 4,064	\$ 44,261
Facility and transition costs	213	2,581	1,194	4,007	12,862
Other exit costs	2	6	7	13	829
Cash charges	3,398	3,851	7,475	8,084	57,952
Fixed asset and inventory impairments	21	445	419	454	16,372
Other non-cash charges	(3)		210		2,192
<b>Total professional diagnostics charges</b>	<b>\$ 3,416</b>	<b>\$ 4,296</b>	<b>\$ 8,104</b>	<b>\$ 8,538</b>	<b>\$ 76,516</b>
<b>Corporate and Other</b>					
Severance-related costs	\$ (19)	\$ 569	\$ (4)	\$ 611	\$ 4,273

Facility and transition costs	5,390	(6)	8,355	(13)	19,677
Total corporate and other charges	\$ 5,371	\$ 563	\$ 8,351	\$ 598	\$ 23,950
Total restructuring charges	\$ 8,787	\$ 4,859	\$ 16,455	\$ 9,136	\$ 100,466

We anticipate incurring approximately \$4.4 million and \$8.0 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 \$3.7 million in additional costs under earlier restructuring plans as in effect at June 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 \$9.5 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	6,270	9,549	7	15,826
Payments	(3,814)	(5,645)	(73)	(9,532)
Currency adjustments	(18)	11		(7)
Balance, June 30, 2016	\$ 4,071	\$ 5,881	\$ 114	\$ 10,066

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

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

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
A term loans <sup>(1)(2)</sup>	\$ 559,317	\$ 575,746
B term loans <sup>(1)(2)</sup>	958,337	965,740
Revolving loans <sup>(1)</sup>	125,000	
7.25% Senior notes <sup>(2)</sup>	442,533	446,320
6.5% Senior subordinated notes <sup>(2)</sup>	415,679	419,209
6.375% Senior subordinated notes <sup>(2)</sup>	414,033	418,133
3% Convertible senior subordinated notes <sup>(3)</sup>		149,839
Other lines of credit	1,335	136
Other	48,236	56,035
	2,964,470	3,031,158
Less: Short-term debt and current portion of long-term debt	(43,681)	(199,992)
Long-term debt	\$ 2,920,789	\$ 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, 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. On June 30, 2016, we were not in default under the Credit Agreement or 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 this Quarterly Report on Form 10-Q. At September 1, 2016, we were in default under the indentures governing our outstanding notes with respect to our failure to timely file this Quarterly Report on Form 10-Q and, by filing this Quarterly Report on Form 10-Q prior to the expiration of the applicable cure periods under the notes, we have cured this default.

(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.

**Table of Contents**

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

six months ended June 30, 2016 and 2015 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Secured credit facility <sup>(1)</sup>	\$ 17,834	\$ 12,851	\$ 34,877	\$ 12,851
Prior credit facility <sup>(2) (3)</sup>		19,726		39,188
7.25% Senior notes	8,904	8,525	17,428	17,049
6.5% Senior subordinated notes	7,405	7,234	14,636	14,467
6.375% Senior subordinated notes	7,112	542	14,115	542
8.625% Senior subordinated notes		9,274		18,547
3% Convertible senior subordinated convertible notes	603	1,246	1,847	2,492
Other	471	96	1,532	789
	\$ 42,329	\$ 59,494	\$ 84,435	\$ 105,925

(1) Includes A term loans, B term loans, and revolving line of credit loans.

(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. For the three and six months ended June 30, 2015, the amounts include \$0.3 million and \$0.7 million, respectively, related to the amortization of fees paid for certain debt modifications.

(3) Includes a \$3.5 million loss on extinguishment of debt associated with our prior credit facility.

*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.

---

**Table of Contents***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.

*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 June 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	Significant Quoted Prices in Other Observable Inputs			
	June 30, 2016	Active Markets (Level 1)	Observable Inputs (Level 2)	Observable Inputs (Level 3)
<b>Assets:</b>				
Marketable securities	\$ 74	\$ 74	\$	\$
<b>Total assets</b>	<b>\$ 74</b>	<b>\$ 74</b>	<b>\$</b>	<b>\$</b>
<b>Liabilities:</b>				
Contingent consideration obligations <sup>(1)</sup>	\$ 55,100	\$	\$	\$ 55,100
<b>Total liabilities</b>	<b>\$ 55,100</b>	<b>\$</b>	<b>\$</b>	<b>\$ 55,100</b>



**Table of Contents**

Description	Quoted Prices in Significant			
	December 31, 2015	Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Assets:</b>				
Marketable securities	\$ 164	\$ 164	\$	\$
<b>Total assets</b>	<b>\$ 164</b>	<b>\$ 164</b>	<b>\$</b>	<b>\$</b>
<b>Liabilities:</b>				
Contingent consideration obligations <sup>(1)</sup>	\$ 57,744	\$	\$	\$ 57,744
<b>Total liabilities</b>	<b>\$ 57,744</b>	<b>\$</b>	<b>\$</b>	<b>\$ 57,744</b>

- (1) 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.

Changes in the fair value of our Level 3 contingent consideration obligations during the six months ended June 30, 2016 were as follows (in thousands):

Fair value of contingent consideration obligations, December 31, 2015	\$ 57,744
Payments	(865)
Fair value adjustments	(1,780)
Foreign currency adjustments	1
<b>Fair value of contingent consideration obligations, June 30, 2016</b>	<b>\$ 55,100</b>

At June 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 \$3.0 billion at June 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 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 six months ended June 30, 2016 and 2015 is as follows (in thousands):

	<b>Professional Diagnostics</b>	<b>Consumer Diagnostics</b>	<b>Corporate and Other</b>	<b>Total</b>
<b>Three Months Ended June 30, 2016:</b>				
Net revenue	\$ 591,294	\$ 19,794	\$	\$ 611,088
Operating income (loss)	\$ 85,535	\$ 396	\$ (63,386)	\$ 22,545
Depreciation and amortization	\$ 66,393	\$ 1,374	\$ 2,134	\$ 69,901
Restructuring charge	\$ 3,414	\$	\$ 5,371	\$ 8,785
Stock-based compensation	\$	\$	\$ 11,004	\$ 11,004

**Table of Contents**

	Professional Diagnostics	Consumer Diagnostics	Corporate and Other	Total
<b>Three Months Ended June 30, 2015:</b>				
Net revenue	\$ 598,726	\$ 24,645	\$	\$ 623,371
Operating income (loss)	\$ 153,241	\$ 1,079	\$ (68,923)	\$ 85,397
Impairment and (gain) loss on dispositions, net	\$ (38,836)	\$	\$ 44,378	\$ 5,542
Depreciation and amortization	\$ 70,189	\$ 725	\$ 1,775	\$ 72,689
Restructuring charge	\$ 4,290	\$	\$ 563	\$ 4,853
Stock-based compensation	\$	\$	\$ 7,130	\$ 7,130
<b>Six Months Ended June 30, 2016:</b>				
Net revenue	\$ 1,152,061	\$ 37,236	\$	\$ 1,189,297
Operating income (loss)	\$ 168,215	\$ 563	\$ (117,997)	\$ 50,781
Impairment and (gain) loss on dispositions, net	\$ (3,810)	\$	\$	\$ (3,810)
Depreciation and amortization	\$ 135,225	\$ 2,873	\$ 4,307	\$ 142,405
Restructuring charge	\$ 8,097	\$	\$ 8,351	\$ 16,448
Stock-based compensation	\$	\$	\$ 20,607	\$ 20,607
<b>Six Months Ended June 30, 2015:</b>				
Net revenue	\$ 1,189,651	\$ 46,612	\$	\$ 1,236,263
Operating income (loss)	\$ 242,784	\$ 3,283	\$ (130,033)	\$ 116,034
Impairment and (gain) loss on dispositions, net	\$ (40,568)	\$	\$ 80,902	\$ 40,334
Depreciation and amortization	\$ 142,658	\$ 1,436	\$ 3,009	\$ 147,103
Restructuring charge	\$ 8,525	\$	\$ 598	\$ 9,123
Stock-based compensation	\$	\$	\$ 12,279	\$ 12,279
<b>Assets:</b>				
As of June 30, 2016	\$ 5,572,046	\$ 179,445	\$ 39,403	\$ 5,790,894
As of December 31, 2015	\$ 5,619,901	\$ 172,551	\$ 130,669	\$ 5,923,121

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cardiometabolic	\$ 203,982	\$ 211,672	\$ 398,559	\$ 412,608
Infectious disease	190,168	172,834	373,402	358,236
Toxicology	158,199	157,495	304,982	306,251
Other	36,412	51,031	69,856	102,164
<b>Total professional diagnostics net product sales and services revenue</b>	588,761	593,032	1,146,799	1,179,259
<b>License and royalty revenue</b>	2,533	5,694	5,262	10,392
<b>Total professional diagnostics net revenue</b>	\$ 591,294	\$ 598,726	\$ 1,152,061	\$ 1,189,651

**(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 \$3.7 million as of June 30, 2016 and \$1.2 million as of December 31, 2015. The \$3.7 million net payable balance as of June 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 \$6.7 million and \$8.9 million as of June 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

**Table of Contents**

amounts of \$8.8 million and \$7.8 million as of June 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 \$21.8 million and \$39.5 million during the three and six months ended June 30, 2016, respectively, and \$21.7 million and \$41.2 million during the three and six months ended June 30, 2015, respectively. Additionally, services revenue generated pursuant to the long-term services agreement with the joint venture totaled \$0.3 million and \$0.5 million during the three and six months ended June 31, 2016, respectively, and \$0.3 million and \$0.6 million during the three and six months ended June 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 \$11.7 million and \$9.9 million of trade receivables which are included in accounts receivable on our consolidated balance sheets as of June 30, 2016 and December 31, 2015, respectively, and \$31.6 million and \$24.9 million of trade accounts payable which are included in accounts payable on our consolidated balance sheets as of June 30, 2016 and December 31, 2015, respectively.

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

<b>Balance Sheet Caption</b>	<b>June 30, 2016</b>	<b>December 31, 2015</b>
Accounts receivable, net of allowances	\$ 11,670	\$ 9,873
Prepaid expenses and other current assets	\$ 8,768	\$ 6,602
Other non-current assets	\$ 6,699	\$ 8,895
Accounts payable	\$ 31,584	\$ 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, which was based on a finding that SPD violated certain laws with respect to the advertising of such product. The appellate court has issued a stay of the injunction, pending the outcome of the appeal. In addition, a class action lawsuit has been initiated against 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 may appeal the decision prior to September 19, 2016. 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 \$3.5 million at June 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 \$3.5 million at June 30, 2016.

*(c) TechLab*

We have an equity method investment in TechLab, Inc., or TechLab, 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. We own approximately 49% of Techlab. We have also entered into an exclusive distributor agreement with Techlab. This agreement grants us the global distribution rights to Techlab's products with certain exceptions. We had trade payables owed to Techlab of \$1.5 million and \$3.2 million as of June 30, 2016 and December 31, 2015, respectively. We made product purchases from Techlab of \$4.5 million and \$4.1 million during the three months ended June 30, 2016 and 2015, respectively, and \$9.2 million and \$8.5 million during the six months ended June 30, 2016 and 2015.

---

**Table of Contents****(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 3.5 year 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 June 30, 2016 and 2015, we had incurred \$1.0 million and \$0.9 million, respectively, of qualified expenditures under the contract, for which we had received cash reimbursement from BARDA in the amount of \$0.0 million and \$0.5 million, respectively, and \$1.0 million and \$0.4 million was recorded as a receivable as of June 30, 2016 and 2015, 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 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 June 30, 2016, we had received approximately \$19.7 million in grant-related funding from the Gates Foundation. 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 June 30, 2015, we incurred approximately \$1.8 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 June 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 \$0.3 million and \$0.1 million for the three months ended June 30, 2016 and 2015, respectively. We incurred qualifying expenses totaling approximately \$0.5 million and \$0.3 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, \$1.4 million under these grants was recorded as restricted cash and \$1.3 million as deferred grant funding on our accompanying 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 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.



**Table of Contents**

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

Acquisition	Acquisition Date	Acquisition Fair Value	Maximum Remaining Earn-out Potential as of June 30, 2016	Remaining Earn-out Period as of June 30, 2016	Estimated Fair Value as of June 30, 2016	Estimated Fair Value as of December 31, 2015	Payments Made During 2016
TwistDx, Inc. <sup>(1)</sup>	March 11, 2010	\$ 35,600	\$ 102,870	2016-2025 <sup>(3)</sup>	\$ 46,600	\$ 47,800	\$ 377
Epocal <sup>(2)</sup>	February 1, 2013	\$ 75,000	\$ 45,500	2016-2018	3,900	4,700	
Other	Various	\$ 30,373	\$ <sup>(4)</sup>	2016	4,600	5,244	488
					\$ 55,100	\$ 57,744	\$ 865

(1) The terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue and product development targets through 2025.

(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 have 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.

*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.

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, and on July 19, 2016, the court ordered a schedule for the filing of a consolidated amended complaint and for the motion to dismiss briefing.

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

---

**Table of Contents***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 \$10.2 million for this matter in the three months ended June 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 lawsuit captioned *Dina Andren and Sidney Bludman v. Alere Inc., et al.*, was filed against us in the United States District Court for the Southern District of California. In addition, on July 22, 2016, a class action lawsuit 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. These class actions purport to assert claims against us under several legal theories, including fraud, breach of warranty, unjust enrichment and violation of applicable unfair competition/business practice statutes in connection with the manufacturing, marketing and sale of our INRatio products. The plaintiffs in the *Dina Andren and Sidney Bludman* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for the INRatio system during the period January 1, 2009 to May 26, 2016 in the United States, or alternatively, California, Maryland and/or New York. The 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 the INRatio system 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 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. The *Andren* action also appears to seek damages for personal injury.

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, the most recent of which was received in July 2016, 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 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

---

**Table of Contents**

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 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 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 do not expect the adoption of ASU 2016-12 to have a significant impact 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.

---

**Table of Contents**

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 \$49.6 million and \$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 June 30, 2016 and December 31, 2015, respectively.

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. Early adoption is permitted. Effective March 31, 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 \$1.6 million and \$6.2 million during the three and six months ended June 30, 2016, respectively, and earnings of \$0.6 million and \$4.2 million during the three and six months ended June 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 three and six months ended June 30, 2015, we received \$12.1 million in cash from SPD as a return of capital.



**Table of Contents***(b) TechLab*

We recorded earnings of \$0.6 million and \$1.0 million during the three and six months ended June 30, 2016, respectively, and earnings of \$0.4 million and \$0.8 million during the three and six months ended June 30, 2015, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our minority share of TechLab's net income for the respective periods. During the three and six months ended June 30, 2015, we received \$2.2 million in cash from TechLab as a return of capital.

As of June 30, 2016, we continued to meet the held for sale criteria with respect to our 49% investment in TechLab. We intend to use all or a portion of the proceeds from any sale of this investment to fund our working capital, operations, research and development or repay a portion of our outstanding indebtedness. Accordingly, we have classified our investment in TechLab in assets held for sale—non-current in our consolidated balance sheet as of June 30, 2016.

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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net revenue	\$ 55,077	\$ 53,159	\$ 108,511	\$ 101,016
Gross profit	\$ 36,634	\$ 34,559	\$ 72,853	\$ 67,830
Net income after taxes	\$ 4,328	\$ 3,039	\$ 14,469	\$ 11,096

<b>Combined Condensed Balance Sheet:</b>	<b>June 30, 2016</b>	<b>December 31, 2015</b>
Current assets	\$ 91,942	\$ 71,542
Non-current assets	31,826	30,802
<b>Total assets</b>	<b>\$ 123,768</b>	<b>\$ 102,344</b>
Current liabilities	\$ 47,764	\$ 37,609
Non-current liabilities	5,845	5,157
<b>Total liabilities</b>	<b>\$ 53,609</b>	<b>\$ 42,766</b>

**(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 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 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 six months ended June 30, 2015, in connection with this decision, we recorded impairment charges of \$1.0 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.

**Table of Contents****(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:

	For the Three Months Ended		For the Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Statutory rate	35%	35%	35%	35%
State income taxes, net of federal benefit	(5)%	(4)%	(4)%	(5)%
Rate differential on foreign earnings	(61)%	(19)%	(58)%	(27)%
Change in valuation allowance	(4)%	(3)%	(6)%	10%
Stock-based compensation	11%	5%	11%	(9)%
Uncertain tax positions	12%	7%	9%	15%
Disposition of BBI	0%	27%	0%	65%
Other	3%	6%	7%	(12)%
<b>Effective tax rate</b>	<b>(9)%</b>	<b>54%</b>	<b>(6)%</b>	<b>72%</b>

For the three months and six months ended June 30, 2016, compared to the same periods in 2015, our effective tax rate decrease is primarily attributed to a more favorable jurisdictional mix of income and losses in the current year and non-recurring discrete tax impacts in 2015.

**(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 June 30, 2016 and December 31, 2015, the related statements of operations and statements of comprehensive income (loss) for the three and six months ended June 30, 2016 and 2015, and statements of cash flows for the six months ended June 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 \$49.6 million and \$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 June 30, 2016 and December 31, 2015, respectively, 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.

**Table of Contents**

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

<b>Three Months Ended June 30, 2015</b>			
<b>Revised Consolidating Statement of Operations- Guarantor Subsidiaries</b>			
<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 330,820	\$ (1,011)	\$ 329,809
Cost of net revenue	\$ 199,233	\$ 14	\$ 199,247
Income from continuing operations before benefit for income taxes	\$ 55,133	\$ (2,090)	\$ 53,043
Provision for income taxes	\$ 11,277	\$ (447)	\$ 10,830
Income from continuing operations	\$ 43,856	\$ (1,643)	\$ 42,213

<b>Three Months Ended June 30, 2015</b>			
<b>Revised Consolidating Statement of Operations- Non-Guarantor Subsidiaries</b>			
<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 367,418	\$ (4,774)	\$ 362,644
Cost of net revenue	\$ 205,840	\$ (559)	\$ 205,281
Income from continuing operations before benefit for income taxes	\$ 111,130	\$ (5,415)	\$ 105,715
Provision for income taxes	\$ 22,768	\$ (1,565)	\$ 21,203
Income from continuing operations	\$ 88,786	\$ (3,850)	\$ 84,936

<b>Six Months Ended June 30, 2015</b>			
<b>Revised Consolidating Statement of Operations- Guarantor Subsidiaries</b>			
<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 659,282	\$ (3,181)	\$ 656,101
Cost of net revenue	\$ 387,269	\$ (882)	\$ 386,387
Income from continuing operations before benefit for income taxes	\$ 60,049	\$ (4,461)	\$ 55,588
Provision for income taxes	\$ 13,097	\$ (1,516)	\$ 11,581
Income from continuing operations	\$ 46,952	\$ (2,945)	\$ 44,007

<b>Six Months Ended June 30, 2015</b>			
<b>Revised Consolidating Statement of Operations- Non-Guarantor Subsidiaries</b>			
<b>(in thousands)</b>	<b>As Previously Reported</b>	<b>Revision Adjustment</b>	<b>As Revised</b>
Net revenue	\$ 710,777	\$ 2,135	\$ 712,912
Cost of net revenue	\$ 398,325	\$ 1,846	\$ 400,171
Income from continuing operations before benefit for income taxes	\$ 188,294	\$ (911)	\$ 187,383
Provision for income taxes	\$ 32,483	\$ 437	\$ 32,920
Income from continuing operations	\$ 159,803	\$ (1,348)	\$ 158,455



Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Three Months Ended June 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	\$	\$ 222,954	\$ 335,540	\$ (74,748)	\$ 483,746
Services revenue		112,698	12,111		124,809
<b>Net product sales and services revenue</b>		<b>335,652</b>	<b>347,651</b>	<b>(74,748)</b>	<b>608,555</b>
License and royalty revenue		3,448	2,008	(2,923)	2,533
<b>Net revenue</b>		<b>339,100</b>	<b>349,659</b>	<b>(77,671)</b>	<b>611,088</b>
Cost of net product sales	220	126,795	188,478	(65,095)	250,398
Cost of services revenue	104	79,203	7,760	(8,773)	78,294
Cost of net product sales and services revenue	324	205,998	196,238	(73,868)	328,692
Cost of license and royalty revenue		(7)	3,466	(2,924)	535
<b>Cost of net revenue</b>	<b>324</b>	<b>205,991</b>	<b>199,704</b>	<b>(76,792)</b>	<b>329,227</b>
<b>Gross profit (loss)</b>	<b>(324)</b>	<b>133,109</b>	<b>149,955</b>	<b>(879)</b>	<b>281,861</b>
Operating expenses:					
Research and development	2,997	16,194	9,255		28,446
Sales and marketing	1,568	53,155	47,793		102,516
General and administrative	57,740	30,460	40,154		128,354
Impairment and (gain) loss on dispositions, net					
<b>Operating income (loss)</b>	<b>(62,629)</b>	<b>33,300</b>	<b>52,753</b>	<b>(879)</b>	<b>22,545</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(41,857)	(2,223)	(2,775)	4,526	(42,329)
Other income (expense), net	(8,144)	4,103	(5,544)	(4,527)	(14,112)
<b>Income (loss) before provision (benefit) for income taxes</b>	<b>(112,630)</b>	<b>35,180</b>	<b>44,434</b>	<b>(880)</b>	<b>(33,896)</b>
Provision (benefit) for income taxes	19,765	(6,759)	(9,889)		3,117
<b>Income (loss) before equity in earnings of subsidiaries and unconsolidated entities, net of tax</b>	<b>(132,395)</b>	<b>41,939</b>	<b>54,323</b>	<b>(880)</b>	<b>(37,013)</b>

Edgar Filing: ALERE INC. - Form 10-Q

Equity in earnings of subsidiaries, net of tax	96,916			(96,916)	
Equity earnings of unconsolidated entities, net of tax	588		1,557	(23)	2,122
<b>Net income (loss)</b>	<b>(34,891)</b>	<b>41,939</b>	<b>55,880</b>	<b>(97,819)</b>	<b>(34,891)</b>
Less: Net income attributable to non-controlling interests			143		143
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	<b>(34,891)</b>	<b>41,939</b>	<b>55,737</b>	<b>(97,819)</b>	<b>(35,034)</b>
Preferred stock dividends	(5,308)				(5,308)
<b>Net income (loss) available to common stockholders</b>	<b>\$ (40,199)</b>	<b>\$ 41,939</b>	<b>\$ 55,737</b>	<b>\$ (97,819)</b>	<b>\$ (40,342)</b>



Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Three Months Ended June 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	\$	\$ 211,593	\$ 345,289	\$ (65,833)	\$ 491,049
Services revenue		114,983	11,645		126,628
<b>Net product sales and services revenue</b>		<b>326,576</b>	<b>356,934</b>	<b>(65,833)</b>	<b>617,677</b>
License and royalty revenue		3,233	5,710	(3,249)	5,694
<b>Net revenue</b>		<b>329,809</b>	<b>362,644</b>	<b>(69,082)</b>	<b>623,371</b>
Cost of net product sales	417	120,953	193,593	(57,070)	257,893
Cost of services revenue	80	77,884	7,524	(8,688)	76,800
Cost of net product sales and services revenue	497	198,837	201,117	(65,758)	334,693
Cost of license and royalty revenue	19	410	4,164	(3,249)	1,344
<b>Cost of net revenue</b>	<b>516</b>	<b>199,247</b>	<b>205,281</b>	<b>(69,007)</b>	<b>336,037</b>
<b>Gross profit (loss)</b>	<b>(516)</b>	<b>130,562</b>	<b>157,363</b>	<b>(75)</b>	<b>287,334</b>
Operating expenses:					
Research and development	3,241	13,993	9,964		27,198
Sales and marketing	1,570	52,101	54,353		108,024
General and administrative	24,390	51,288	(14,505)		61,173
Impairment and (gain) loss on dispositions, net	44,378	(39,412)	576		5,542
<b>Operating income (loss)</b>	<b>(74,095)</b>	<b>52,592</b>	<b>106,975</b>	<b>(75)</b>	<b>85,397</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(59,086)	(3,060)	(4,702)	7,354	(59,494)
Other income (expense), net	3,596	3,511	3,442	(7,354)	3,195
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	<b>(129,585)</b>	<b>53,043</b>	<b>105,715</b>	<b>(75)</b>	<b>29,098</b>
Provision (benefit) for income taxes	(16,306)	10,830	21,203	(38)	15,689
<b>Income (loss) from continuing operations before equity in earnings</b>	<b>(113,279)</b>	<b>42,213</b>	<b>84,512</b>	<b>(37)</b>	<b>13,409</b>

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

Equity in earnings of subsidiaries, net of tax	127,127			(127,127)	
Equity earnings of unconsolidated entities, net of tax	922		424	15	1,361
<b>Net income</b>	<b>14,770</b>	<b>42,213</b>	<b>84,936</b>	<b>(127,149)</b>	<b>14,770</b>
Less: Net income attributable to non-controlling interests			359		359
<b>Net income attributable to Alere Inc. and Subsidiaries</b>	<b>14,770</b>	<b>42,213</b>	<b>84,577</b>	<b>(127,149)</b>	<b>14,411</b>
Preferred stock dividends	(5,308)				(5,308)
<b>Net income available to common stockholders</b>	<b>\$ 9,462</b>	<b>\$ 42,213</b>	<b>\$ 84,577</b>	<b>\$ (127,149)</b>	<b>\$ 9,103</b>

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Six Months Ended June 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	\$	\$ 447,334	\$ 632,377	\$ (136,194)	\$ 943,517
Services revenue		217,182	23,336		240,518
<b>Net product sales and services revenue</b>		<b>664,516</b>	<b>655,713</b>	<b>(136,194)</b>	<b>1,184,035</b>
License and royalty revenue		6,368	4,566	(5,672)	5,262
<b>Net revenue</b>		<b>670,884</b>	<b>660,279</b>	<b>(141,866)</b>	<b>1,189,297</b>
Cost of net product sales	334	251,553	354,460	(118,488)	487,859
Cost of services revenue	104	151,698	15,800	(16,208)	151,394
Cost of net product sales and services revenue	438	403,251	370,260	(134,696)	639,253
Cost of license and royalty revenue		10	7,589	(5,673)	1,926
<b>Cost of net revenue</b>	<b>438</b>	<b>403,261</b>	<b>377,849</b>	<b>(140,369)</b>	<b>641,179</b>
<b>Gross profit (loss)</b>	<b>(438)</b>	<b>267,623</b>	<b>282,430</b>	<b>(1,497)</b>	<b>548,118</b>
Operating expenses:					
Research and development	7,131	30,653	17,724		55,508
Sales and marketing	2,904	107,620	91,805		202,329
General and administrative	102,355	63,646	77,309		243,310
Impairment and (gain) loss on dispositions, net			(3,810)		(3,810)
<b>Operating income (loss)</b>	<b>(112,828)</b>	<b>65,704</b>	<b>99,402</b>	<b>(1,497)</b>	<b>50,781</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(82,944)	(4,875)	(5,842)	9,226	(84,435)
Other income (expense), net	(6,156)	6,605	(6,683)	(9,227)	(15,461)
<b>Income (loss) before provision (benefit) for income taxes</b>	<b>(201,928)</b>	<b>67,434</b>	<b>86,877</b>	<b>(1,498)</b>	<b>(49,115)</b>
Provision (benefit) for income taxes	19,711	(6,509)	(10,293)		2,909
<b>Income (loss) before equity in earnings of subsidiaries and unconsolidated entities, net of tax</b>	<b>(221,639)</b>	<b>73,943</b>	<b>97,170</b>	<b>(1,498)</b>	<b>(52,024)</b>

Edgar Filing: ALERE INC. - Form 10-Q

Equity in earnings of subsidiaries, net of tax	175,502			(175,502)	
Equity earnings of unconsolidated entities, net of tax	1,269		6,138	(251)	7,156
<b>Net income (loss)</b>	(44,868)	73,943	103,308	(177,251)	(44,868)
Less: Net income attributable to non-controlling interests			246		246
<b>Net income (loss) attributable to Alere Inc. and Subsidiaries</b>	(44,868)	73,943	103,062	(177,251)	(45,114)
Preferred stock dividends	(10,617)				(10,617)
<b>Net income (loss) available to common stockholders</b>	\$ (55,485)	\$ 73,943	\$ 103,062	\$ (177,251)	\$ (55,731)

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Six Months Ended June 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	\$	\$ 426,631	\$ 675,395	\$ (126,639)	\$ 975,387
Services revenue		223,040	27,444		250,484
<b>Net product sales and services revenue</b>		<b>649,671</b>	<b>702,839</b>	<b>(126,639)</b>	<b>1,225,871</b>
License and royalty revenue		6,430	10,073	(6,111)	10,392
<b>Net revenue</b>		<b>656,101</b>	<b>712,912</b>	<b>(132,750)</b>	<b>1,236,263</b>
Cost of net product sales	833	233,248	375,999	(112,086)	497,994
Cost of services revenue	130	151,921	15,964	(15,589)	152,426
Cost of net product sales and services revenue	963	385,169	391,963	(127,675)	650,420
Cost of license and royalty revenue	(21)	1,218	8,208	(6,111)	3,294
<b>Cost of net revenue</b>	<b>942</b>	<b>386,387</b>	<b>400,171</b>	<b>(133,786)</b>	<b>653,714</b>
<b>Gross profit (loss)</b>	<b>(942)</b>	<b>269,714</b>	<b>312,741</b>	<b>1,036</b>	<b>582,549</b>
Operating expenses:					
Research and development	5,543	28,912	20,759		55,214
Sales and marketing	2,830	105,328	108,945		217,103
General and administrative	44,913	89,058	19,893		153,864
Impairment and (gain) loss on dispositions, net	80,901	(8,804)	(31,763)		40,334
<b>Operating income (loss)</b>	<b>(135,129)</b>	<b>55,220</b>	<b>194,907</b>	<b>1,036</b>	<b>116,034</b>
Interest expense, including amortization of original issue discounts and deferred financing costs	(105,184)	(6,345)	(8,745)	14,349	(105,925)
Other income (expense), net	7,243	6,713	1,221	(14,349)	828
<b>Income (loss) from continuing operations before provision (benefit) for income taxes</b>	<b>(233,070)</b>	<b>55,588</b>	<b>187,383</b>	<b>1,036</b>	<b>10,937</b>
Provision (benefit) for income taxes	(36,973)	11,581	32,920	308	7,836
<b>Income (loss) from continuing operations before equity in earnings</b>	<b>(196,097)</b>	<b>44,007</b>	<b>154,463</b>	<b>728</b>	<b>3,101</b>

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

Equity in earnings of subsidiaries, net of tax	201,260			(201,260)	
Equity earnings of unconsolidated entities, net of tax	1,346		3,992	(18)	5,320
Income from continuing operations	6,509	44,007	158,455	(200,550)	8,421
Income (loss) from discontinued operations, net of tax	218,689	(1,912)			216,777
<b>Net income</b>	<b>225,198</b>	<b>42,095</b>	<b>158,455</b>	<b>(200,550)</b>	<b>225,198</b>
Less: Net income attributable to non-controlling interests			447		447
<b>Net income attributable to Alere Inc. and Subsidiaries</b>	<b>225,198</b>	<b>42,095</b>	<b>158,008</b>	<b>(200,550)</b>	<b>224,751</b>
Preferred stock dividends	(10,558)				(10,558)
<b>Net income available to common stockholders</b>	<b>\$ 214,640</b>	<b>\$ 42,095</b>	<b>\$ 158,008</b>	<b>\$ (200,550)</b>	<b>\$ 214,193</b>

**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Three Months Ended June 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)	\$ (34,891)	\$ 41,939	\$ 55,880	\$ (97,819)	\$ (34,891)
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	276	(699)	(43,720)	8	(44,135)
Minimum pension liability adjustment			531		531
Other comprehensive income (loss), before tax	276	(699)	(43,189)	8	(43,604)
Other comprehensive income (loss)	276	(699)	(43,189)	8	(43,604)
Comprehensive income (loss)	(34,615)	41,240	12,691	(97,811)	(78,495)
Less: Comprehensive income attributable to non-controlling interests			143		143
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (34,615)	\$ 41,240	\$ 12,548	\$ (97,811)	\$ (78,638)

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

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income	\$ 14,770	\$ 42,213	\$ 84,936	\$ (127,149)	\$ 14,770
Other comprehensive income, before tax:					
Changes in cumulative translation adjustment	197	689	45,840		46,726
Minimum pension liability adjustment			(374)		(374)
Other comprehensive income, before tax	197	689	45,466		46,352
Other comprehensive income	197	689	45,466		46,352
Comprehensive income	14,967	42,902	130,402	(127,149)	61,122
Less: Comprehensive income attributable to non-controlling interests			359		359
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 14,967	\$ 42,902	\$ 130,043	\$ (127,149)	\$ 60,763



**Table of Contents****CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Six Months Ended June 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)	\$ (44,868)	\$ 73,943	\$ 103,308	\$ (177,251)	\$ (44,868)
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	391	(828)	(21,513)	8	(21,942)
Minimum pension liability adjustment			686		686
Other comprehensive income (loss), before tax	391	(828)	(20,827)	8	(21,256)
Other comprehensive income (loss)	391	(828)	(20,827)	8	(21,256)
Comprehensive income (loss)	(44,477)	73,115	82,481	(177,243)	(66,124)
Less: Comprehensive income attributable to non-controlling interests			246		246
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (44,477)	\$ 73,115	\$ 82,235	\$ (177,243)	\$ (66,370)

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

(in thousands)

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non- Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net income	\$ 225,198	\$ 42,095	\$ 158,455	\$ (200,550)	\$ 225,198
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	(460)	117	(33,273)		(33,616)
Minimum pension liability adjustment			(1,756)		(1,756)
Other comprehensive income (loss), before tax	(460)	117	(35,029)		(35,372)
Other comprehensive income (loss)	(460)	117	(35,029)		(35,372)
Comprehensive income	224,738	42,212	123,426	(200,550)	189,826
Less: Comprehensive income attributable to non-controlling interests			447		447
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 224,738	\$ 42,212	\$ 122,979	\$ (200,550)	\$ 189,379

Table of Contents**CONSOLIDATING BALANCE SHEET****June 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	\$ 49,465	\$ 6,881	\$ 449,818	\$	\$ 506,164
Restricted cash	1,415		4,247		5,662
Marketable securities		74			74
Accounts receivable, net of allowances		190,438	236,784		427,222
Inventories, net		168,413	188,448	(23,015)	333,846
Deferred tax assets	(455)	6,513	(6,058)		
Prepaid expenses and other current assets	12,194	33,489	110,122	6,534	162,339
Intercompany receivables	360,548	827,927	158,858	(1,347,333)	
<b>Total current assets</b>	<b>423,167</b>	<b>1,233,735</b>	<b>1,142,219</b>	<b>(1,363,814)</b>	<b>1,435,307</b>
Property, plant and equipment, net	29,742	224,796	187,337	(3,088)	438,787
Goodwill		1,823,018	988,527		2,811,545
Other intangible assets with indefinite lives		7,538	20,800	(59)	28,279
Finite-lived intangible assets, net	2,745	566,973	342,690	(3,200)	909,208
Restricted cash			42,589		42,589
Other non-current assets	570	2,052	14,317	(649)	16,290
Investments in subsidiaries	3,455,642	158,195	57,650	(3,671,487)	
Investments in unconsolidated entities	687	14,765	44,654	14,405	74,511
Deferred tax assets	(66,034)	24,785	62,006	(2,119)	18,638
Non-current income tax receivable	3,517				3,517
Assets held for sale non-current	12,223				12,223
Intercompany notes receivables	1,887,589	708,708	2,901	(2,599,198)	
<b>Total assets</b>	<b>\$ 5,749,848</b>	<b>\$ 4,764,565</b>	<b>\$ 2,905,690</b>	<b>\$ (7,629,209)</b>	<b>\$ 5,790,894</b>
<b>LIABILITIES AND EQUITY</b>					
<b>Current liabilities:</b>					
Short-term debt and current portion of long-term debt	\$ 40,073	\$	\$ 3,608	\$	\$ 43,681
Current portion of capital lease obligations		1,654	1,846		3,500

Edgar Filing: ALERE INC. - Form 10-Q

Accounts payable	23,789	77,283	93,163		194,235
Accrued expenses and other current liabilities	(514,898)	635,590	197,663	2,171	320,526
Intercompany payables	965,315	178,406	203,621	(1,347,342)	
<b>Total current liabilities</b>	<b>514,279</b>	<b>892,933</b>	<b>499,901</b>	<b>(1,345,171)</b>	<b>561,942</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	2,874,825		45,964		2,920,789
Capital lease obligations, net of current portion		1,466	5,506		6,972
Deferred tax liabilities	(158,407)	250,292	48,897	82	140,864
Other long-term liabilities	14,741	56,618	77,455	(649)	148,165
Intercompany notes payables	496,756	1,162,748	939,694	(2,599,198)	
<b>Total long-term liabilities</b>	<b>3,227,915</b>	<b>1,471,124</b>	<b>1,117,516</b>	<b>(2,599,765)</b>	<b>3,216,790</b>
<b>Total stockholders equity</b>	<b>2,007,654</b>	<b>2,400,508</b>	<b>1,283,765</b>	<b>(3,684,273)</b>	<b>2,007,654</b>
Non-controlling interests			4,508		4,508
<b>Total equity</b>	<b>2,007,654</b>	<b>2,400,508</b>	<b>1,288,273</b>	<b>(3,684,273)</b>	<b>2,012,162</b>
<b>Total liabilities and equity</b>	<b>\$ 5,749,848</b>	<b>\$ 4,764,565</b>	<b>\$ 2,905,690</b>	<b>\$ (7,629,209)</b>	<b>\$ 5,790,894</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
Deferred tax assets	(52,410)	31,285	23,244	(2,119)	
Prepaid expenses and other current assets	7,575	27,095	110,961	6,602	152,233
Assets held for sale - current			4,165		4,165
Intercompany receivables	620,838	812,957	50,691	(1,484,486)	
<b>Total current assets</b>	<b>716,406</b>	<b>1,258,625</b>	<b>982,836</b>	<b>(1,500,577)</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	(14,078)	(14)	28,085		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>\$ 5,954,868</b>	<b>\$ 4,792,833</b>	<b>\$ 2,763,898</b>	<b>\$ (7,588,478)</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
		2,018	1,944		3,962

Edgar Filing: ALERE INC. - Form 10-Q

<b>Current portion of capital lease obligations</b>					
Accounts payable	15,981	76,890	102,881		195,752
Accrued expenses and other current liabilities	(554,350)	650,632	225,944	2,239	324,465
Liabilities related to assets held for sale current			363		363
Intercompany payables	1,122,042	249,553	112,891	(1,484,486)	
<b>Total current liabilities</b>	<b>780,757</b>	<b>979,093</b>	<b>446,931</b>	<b>(1,482,247)</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	(157,708)	250,495	54,749	82	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>3,119,946</b>	<b>1,491,812</b>	<b>1,112,885</b>	<b>(2,584,485)</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>\$ 5,954,868</b>	<b>\$ 4,792,833</b>	<b>\$ 2,763,898</b>	<b>\$ (7,588,478)</b>	<b>\$ 5,923,121</b>

**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS****For the Six Months Ended June 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)	\$ (44,868)	\$ 73,943	\$ 103,308	\$ (177,251)	\$ (44,868)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	(175,502)			175,502	
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	5,175	7	79		5,261
Depreciation and amortization	4,484	88,973	48,109	839	142,405
Non-cash stock-based compensation expense	10,541	5,462	4,604		20,607
Impairment of inventory			870		870
Impairment of long-lived assets		548	85		633
Loss on disposition of fixed assets	1	3,522	712		4,235
Equity earnings of unconsolidated entities, net of tax	(1,269)		(6,138)	251	(7,156)
Deferred income taxes		(200)	(13,010)		(13,210)
(Gain) loss related to impairment and net (gain) loss on dispositions			(3,810)		(3,810)
Other non-cash items	(66)	459	9,323	4	9,720
Non-cash change in fair value of contingent purchase price consideration	(800)	(823)	(157)		(1,780)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		2,141	17,882		20,023
Inventories, net		(11,723)	5,243	660	(5,820)
Prepaid expenses and other current assets	(4,283)	(7,408)	(13,258)	68	(24,881)
Accounts payable	7,807	396	(8,204)		(1)
Accrued expenses and other current liabilities	40,481	(13,721)	(28,367)	(69)	(1,676)
Other non-current liabilities	(1,054)	(1,561)	(3,491)		(6,106)
Cash paid for contingent consideration	(321)		(3)		(324)
Intercompany payable (receivable)	145,358	(141,518)	(3,836)	(4)	

<b>Net cash provided by (used in) operating activities</b>	(14,316)	(1,503)	109,941	94,122	
<b>Cash Flows from Investing Activities:</b>					
Increase in restricted cash	(165)		(284)	(449)	
Purchases of property, plant and equipment	(2,680)	(11,750)	(18,972)	1,084	(32,318)
Proceeds from sale of property, plant and equipment	92	45	1,839	(1,084)	892
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 equity method investments	2,383				2,383
Cash received from sales of marketable securities.		90			90
Cash paid for investments	(184)				(184)
(Increase) decrease in other assets	(50)	13	532		495
<b>Net cash used in investing activities</b>	(1,941)	(11,602)	(36)		(13,579)
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(19,564)				(19,564)
Cash paid for contingent purchase price consideration			(485)		(485)
Proceeds from issuance of common stock, net of issuance costs	11,124				11,124
Proceeds from issuance of long-term debt			381		381
Payments on short-term debt			(791)		(791)
Payments on long-term debt	(176,861)		(776)		(177,637)
Net proceeds under revolving credit facilities	125,000		1,213		126,213
Cash paid for dividends	(10,646)				(10,646)
Principal payments on capital lease obligations		(1,324)	(886)		(2,210)
<b>Net cash used in financing activities</b>	(70,947)	(1,324)	(1,344)		(73,615)
Foreign exchange effect on cash and cash equivalents	(2,484)	160	(640)		(2,964)
<b>Net increase (decrease) in cash and cash equivalents</b>	(89,688)	(14,269)	107,921		3,964
Cash and cash equivalents, beginning of period	139,153	21,150	341,897		502,200



<b>Cash and cash equivalents, end of period</b>	\$ 49,465	\$ 6,881	\$ 449,818	\$ 506,164
---	-----------	----------	------------	------------

**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS****For the Six Months Ended June 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	\$ 225,198	\$ 42,095	\$ 158,455	\$ (200,550)	\$ 225,198
Income (loss) from discontinued operations, net of tax	218,689	(1,912)			216,777
Income from continuing operations	6,509	44,007	158,455	(200,550)	8,421
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	(201,260)			201,260	
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	7,728	13	43		7,784
Depreciation and amortization	3,840	82,576	60,652	35	147,103
Non-cash stock-based compensation expense	6,458	2,633	3,188		12,279
Impairment of inventory		133	(65)		68
Impairment of long-lived assets		64	323		387
Loss on disposition of fixed assets		2,764	554		3,318
Equity earnings of unconsolidated entities, net of tax	(1,346)		(3,992)	18	(5,320)
Gain on sales of marketable securities		(8)			(8)
Deferred income taxes	(8,686)	(32,097)	(1,826)	438	(42,171)
(Gain) loss related to impairment and net (gain) loss on dispositions	80,901	(8,804)	(31,763)		40,334
Loss on extinguishment of debt	3,480				3,480
Other non-cash items	(159)	(1,497)	(676)		(2,332)
Non-cash change in fair value of contingent purchase price consideration	(30,895)	15,748	(37,720)		(52,867)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		(2,599)	(15,417)		(18,016)

Edgar Filing: ALERE INC. - Form 10-Q

Inventories, net	(27,824)	(15,984)	(1,411)	(45,219)
Prepaid expenses and other current assets	(3,052)	(19,127)	810	(27,077)
Accounts payable	(7,499)	(11,331)	(4,421)	(23,251)
Accrued expenses and other current liabilities	(8,944)	61,472	(33,374)	23,052
Other non-current liabilities	2,226	6,171	(1,476)	8,536
Cash paid for contingent purchase price consideration	(3,768)		(13)	(3,781)
Intercompany payable (receivable)	127,569	(101,515)	(26,054)	
Net cash provided by (used in) continuing operations	(26,898)	10,779	51,244	34,720
Net cash provided by discontinued operations		318		318
<b>Net cash provided by (used in) operating activities</b>	<b>(26,898)</b>	<b>11,097</b>	<b>51,244</b>	<b>35,038</b>
<b>Cash Flows from Investing Activities:</b>				
Increase in restricted cash	(422,169)		(1,856)	(424,025)
Purchases of property, plant and equipment	(5,147)	(19,386)	(23,907)	(47,284)
Proceeds from sale of property, plant and equipment		738	1,199	1,120
Cash received from (used in) disposition, net of cash divested	593,217	(8,723)	2,131	586,625
Cash received from equity method investments	2,205		12,092	14,297
Cash received from sales of marketable securities		93		93
Decrease in other assets	348	409	927	1,750
Net cash provided by (used in) continuing operations	168,454	(26,869)	(9,414)	132,576
Net cash used in discontinued operations		(209)		(209)
<b>Net cash provided by (used in) investing activities</b>	<b>168,454</b>	<b>(27,078)</b>	<b>(9,414)</b>	<b>132,367</b>
<b>Cash Flows from Financing Activities:</b>				
Cash paid for financing costs	(15,731)			(15,731)
Cash paid for contingent purchase price consideration	(5,503)		(870)	(6,373)
Proceeds from issuance of common stock, net of issuance costs	56,332			56,332
Proceeds from issuance of long-term debt	2,119,125		2,726	2,121,851

Edgar Filing: ALERE INC. - Form 10-Q

Payments on short-term debt			(584)	(584)
Payments on long-term debt	(2,117,875)		(389)	(2,118,264)
Net payments under revolving credit facilities	(127,000)		680	(126,320)
Cash paid for dividends	(10,646)			(10,646)
Principal payments on capital lease obligations		(1,263)	(1,647)	(2,910)
Net cash used in continuing operations	(101,298)	(1,263)	(84)	(102,645)
Net cash used in discontinued operations		(76)		(76)
<b>Net cash used in financing activities</b>	(101,298)	(1,339)	(84)	(102,721)
Foreign exchange effect on cash and cash equivalents		(129)	(1,445)	(1,574)
Net increase (decrease) in cash and cash equivalents	40,258	(17,449)	40,301	63,110
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 of continuing operations, end of period</b>	\$ 42,407	\$ 75,005	\$ 347,459	\$ 464,871

---

**Table of Contents**

**(23) Subsequent Events**

*Amendment to Credit Facility*

As further described in Note 12 above, in August 2016 we entered into an amendment to our Credit Agreement.

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

In July 2016 we announced that we will be initiating a voluntary withdrawal of the Alere INRatio and INRatio2 PT/INR Monitoring System. We are currently working with the FDA on implementing the product withdrawal and eventual product discontinuation.

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 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 June 30, 2016, \$16.0 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 \$8.2 million of accelerated amortization of intangible assets and approximately \$0.8 million and \$1.5 million of accelerated depreciation of tangible assets in the three and six months ended June 30, 2016, respectively. Finally, during the remainder of fiscal year 2016 we expect to incur approximately \$8.2 million of accelerated amortization, approximately \$1.6 million of accelerated depreciation, and \$2.0 million of other one-time cash expenditures.

**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, our plans to voluntarily withdraw the INRatio and INRatio2 PT/INR Monitoring Systems from the market, future competition in our markets, the implementation 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 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 being brought against us and the impact of such litigation, 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, expected future expenses in connection with the voluntary withdrawal of INRatio products from the market, 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*

---

## **Table of Contents**

*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 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.*

## **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. Completion of the merger is subject to customary closing conditions, including (1) the adoption of the Merger Agreement by the affirmative vote of the holders of at least a majority of all outstanding shares of our common stock, (2) there being no judgment or law enjoining or otherwise prohibiting the consummation of the merger and (3) 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. 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. 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. 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.

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.



---

**Table of Contents**

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 have asked the Delaware Chancery Court to require Abbott to specifically perform its obligations with respect to these matters, as required by the Merger Agreement.

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

In July 2016 we announced that we will be initiating a voluntary withdrawal of the Alere INRatio and INRatio<sup>2</sup> PT/INR Monitoring System. We are currently working with the FDA on implementing the product withdrawal and eventual product discontinuation.

In December 2014, we initiated a voluntary correction to inform users of the Alere INRatio and INRatio<sup>2</sup> 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<sup>®</sup> 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 million in the year ended December 31, 2015, related to impairment of inventory and production equipment and estimated costs of removing our INRatio and INRatio<sup>2</sup> from the market. As of June 30, 2016, \$16.0 million of the estimated costs of removing INRatio and INRatio<sup>2</sup> from the market were included in accrued expenses. Additionally, our decision to withdraw the INRatio and INRatio<sup>2</sup> 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 \$8.2 million of accelerated amortization of intangible assets and approximately \$0.8 million and \$1.5 million of accelerated depreciation of tangible assets in the three and six months ended June 30, 2016, respectively. Finally, during the

remainder of fiscal year 2016 we expect to incur approximately \$8.2 million of accelerated amortization, approximately \$1.6 million of accelerated depreciation, and \$2.0 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.

#### *Amendments to our Credit Agreement*

On April 22, 2016, we and the requisite lenders under the Credit Agreement entered into an 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, (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 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,

---

**Table of Contents**

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.

*Consent Solicitation to Note Holders*

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.

**Financial Highlights**

Net revenue decreased by \$12.3 million, or 2%, to \$611.1 million for the three months ended June 30, 2016 from \$623.4 million for the three months ended June 30, 2015. Net revenue decreased by \$47.0 million, or 4%, to \$1.19 billion for the six months ended June 30, 2016 from \$1.24 billion for the six months ended June 30, 2015.

Gross profit decreased by \$5.5 million, or 2%, to \$281.9 million for the three months ended June 30, 2016 from \$287.3 million for the three months ended June 30, 2015. Gross profit decreased by \$34.4 million, or 6%, to \$548.1 million for the six months ended June 30, 2016 from \$582.5 million for the six months ended June 30, 2015.

For the three months ended June 30, 2016, we generated net loss available to common stockholders of \$40.3 million, or \$0.46 per basic and diluted common share, compared to net income available to common stockholders of \$9.1 million, or \$0.11 per basic and diluted common share, for the three months ended June 30, 2015. For the six months ended June 30, 2016, we generated a net loss available to common stockholders of \$55.7 million, or \$0.64 per basic and diluted common share, compared to net income available to common stockholders of \$214.2 million, or \$2.53 per basic and diluted common share, for the six months ended June 30, 2015. The net income generated in the six months ended June 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 June 30, 2016, loss from continuing operations available to common stockholders was \$40.3 million, or \$0.46 per basic and diluted common share, compared to an income from continuing operations available to common stockholders of \$9.1 million, or \$0.11 per basic and diluted common share, for the three months ended June 30, 2015. For the six months ended June 30, 2016, the loss from continuing operations available to common stockholders was \$55.7 million, or \$0.64 per basic and diluted common share, compared to a loss from continuing operations available to common stockholders of \$2.6 million, or \$0.03 per basic and diluted common share, for the six months ended June 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 and second quarters of 2015. As a result, we have revised our consolidated financial information for the three and six months ended June 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 and \$1.0 million remained deferred at December 31, 2015 and June 30, 2016, respectively. 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 \$9.1 million, or 1%, to \$608.6 million for the three months ended June 30, 2016, from \$617.7 million for the three months ended June 30, 2015. Net product sales and services revenue decreased during the three months ended June 30, 2016 when compared to the same period in the prior year primarily as a result of a \$16.4 million reduction in revenue due to the disposition of our BBI business in November 2015, a \$10.5 million decrease in revenue from our mail order diabetic supplies business, and a \$10.1 million unfavorable impact of foreign currency exchange rates. These revenue declines were partially offset by sales increases during the three months ended June 30, 2016 of \$17.3 million in our infectious disease business and \$4.2 million increase in revenues from Alere Home Monitoring, our patient self-testing anticoagulation business. The revenue decline was also partially offset by revenues of \$5.5 million attributable to our acquisition of US Diagnostics in July 2015.

Total net product sales and services revenue decreased by \$41.8 million, or 3%, to \$1.18 billion for the six months ended June 30, 2016, from \$1.23 billion for the six months ended June 30, 2015. Net product sales and services revenue decreased during the six months ended June 30, 2016 when compared to the same period in the prior year primarily as a result of a \$30.7 million reduction in revenue attributable to the disposition of our BBI business in November 2015, a \$26.2 million unfavorable impact of foreign currency exchange rates, a \$10.7 million reduction in toxicology pain management sales, and a \$10.3 million decrease revenues from in our mail order diabetic supplies business. The revenue declines were partially offset by sales increases of \$15.2 million from our infectious disease business and a \$7.4 million increase from sales by Alere Home Monitoring, our patient self-testing anticoagulation business. The revenue decline was also partially offset by revenues of \$11.1 million attributable to our acquisition of US Diagnostics in July 2015.

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

	Three Months Ended June 30, %			Six Months Ended June 30, %		
	2016	2015	Change	2016	2015	Change
Professional diagnostics	\$ 588,761	\$ 593,032	(1)%	\$ 1,146,799	\$ 1,179,259	(3)%
Consumer diagnostics	19,794	24,645	(20)%	37,236	46,612	(20)%
Net product sales and services revenue	\$ 608,555	\$ 617,677	(1)%	\$ 1,184,035	\$ 1,225,871	(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 six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30, %			Six Months Ended June 30, %		
	2016	2015	Change	2016	2015	Change
Cardiometabolic	\$ 203,982	\$ 211,672	(4)%	\$ 398,559	\$ 412,608	(3)%
Infectious disease	190,168	172,834	10%	373,402	358,236	4%

Edgar Filing: ALERE INC. - Form 10-Q

Toxicology	158,199	157,495	%	304,982	306,251	%
Other	36,412	51,031	(29)%	69,856	102,164	(32)%

Professional diagnostics net product sales and services revenue	\$ 588,761	\$ 593,032	(1)%	\$ 1,146,799	\$ 1,179,259	(3)%
---	------------	------------	------	--------------	--------------	------

Net product sales and services revenue from our professional diagnostics business segment decreased by \$4.3 million, or 1%, to \$588.8 million for the three months ended June 30, 2016, from \$593.0 million for the three months ended June 30, 2015 driven primarily by the negative impact of foreign currency exchange rates and divested businesses. This negative impact was offset in part by the growth of sales in international markets.

Net product sales and services revenue from our professional diagnostics business segment decreased by \$32.5 million, or 3%, to \$1.15 billion for the six months ended June 30, 2016, from \$1.18 billion for the six months ended June 30, 2015 primarily as a result of decreased revenues in international markets, lower pain management sales, and lower revenue in our mail order diabetic supplies business, partially offset by increased revenues due to our acquisition of US Diagnostics.

Net product sales and services revenue from our professional diagnostics business segment in the U.S. decreased by \$7.0 million, or 2%, to \$315.3 million for the three months ended June 30, 2016 from \$322.3 million for the three months ended June 30, 2015. The decrease during the three months ended June 30, 2016 when compared to the same period in the prior year is primarily driven by a \$10.5 million decline in our mail order diabetic supplies revenue, and a \$4.7 million decline due to the disposition of our BBI business. The revenue declines were partially offset by \$5.2 million of revenue due to our acquisition of US Diagnostics and increased revenues of \$4.2 million from our Alere Home Monitoring business.

---

**Table of Contents**

Net product sales and services revenue from our professional diagnostics business segment in the U.S. decreased by \$8.0 million, or 1%, to \$633.2 million for the six months ended June 30, 2016 from \$641.2 million for the six months ended June 30, 2015. The decrease during the six months ended June 30, 2016 when compared to the same period in the prior year was primarily driven by revenue declines of \$10.7 million in our US toxicology pain management business and \$10.3 million in our mail order diabetic supplies business. U.S. revenues also declined by \$8.9 million due to the disposition of our BBI business. These revenue declines were partially offset by \$10.6 million in revenues attributable to our acquisition of US Diagnostics and increased revenues of \$7.4 million due to our Alere Home Monitoring business.

In international markets, net product sales and services revenue from our professional diagnostics business segment increased \$2.7 million, or 1%, to \$273.5 million during the three months ended June 30, 2016, from \$270.8 million in the comparable period in 2015. The higher sales in international markets during the three months ended June 30, 2016 when compared to the same period in the prior year were driven by a \$7.4 million, or 9%, increase in revenues attributable to the Asia Pacific region predominately due to infectious disease products. This increase in international revenues was partially offset by a \$5.6 million decrease in European sales, primarily due to the disposition of the BBI business in November 2015 and the impact of foreign currency exchange rates, as well as the impact of foreign currency exchange rates in other regions in which we operate.

Net product sales and services revenue from our professional diagnostics business segment in international markets decreased \$24.4 million, or 5%, to \$513.6 million during the six months ended June 30, 2016, from \$538.0 million in the comparable period in 2015. The lower sales in international markets were driven primarily by a \$21.5 million, or 10%, decrease in revenues attributable to Europe, primarily due to the disposition of the BBI business in November 2015 and the impact of foreign currency exchange rates.

Within our professional diagnostics business segment, our cardiometabolic net product sales and services revenue decreased by \$7.7 million, or 4%, to \$204.0 million for the three months ended June 30, 2016, from \$211.7 million in the same period in 2015, primarily as a result of a decline in sales by Arriva, our mail order diabetic supplies business, partially offset by increased sales by Alere Home Monitoring, our patient self-testing anticoagulation business. Infectious disease net product sales and services revenue increased by \$17.3 million, or 10%, to \$190.2 million for the three months ended June 30, 2016, from \$172.8 million for the three months ended June 30, 2015. The increase in infectious disease revenue in the three months ended June 30, 2016 was primarily due to a \$4.2 million increase in sales of Alere i, as well as increased sales of HIV and flu-related products in the second quarter of 2016 as compared to the second quarter of 2015. Toxicology net product sales and services revenue increased by \$0.7 million, or less than 1%, to \$158.2 million for the three months ended June 30, 2016, from \$157.5 million for the comparable period in 2015, primarily as a result of \$5.3 million of revenues due to the acquisition of US Diagnostics in July 2015, largely offset by lower pain management revenues. Other revenue decreased by \$14.6 million, or 29%, to \$36.4 million during the three months ended June 30, 2016, compared to \$51.0 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 \$14.0 million, or 3%, to \$398.6 million for the six months ended June 30, 2016, from \$412.6 million in the same period in 2015, primarily as a result of a decline in sales by Arriva and reduced revenues from sales of our Triage and cholesterol products, partially offset by increased sales by Alere Home Monitoring. Infectious disease net product sales and services revenue increased by \$15.2 million, or 4%, to \$373.4 million for the six months ended June 30, 2016, from \$358.2 million for the six months ended June 30, 2015. The increase in infectious disease revenue in the six months ended June 30, 2016 was primarily attributable to increased revenue of \$14.9 million from sales of our Alere i product, as well as increased HIV-related product sales, partially offset by the impact of foreign currency exchange rates. Toxicology net product sales and services revenue decreased by \$1.3 million, or less than 1%, to

\$305.0 million for the six months ended June 30, 2016, from \$306.3 million for the comparable period in 2015, primarily as a result of lower pain management revenues and the impact of foreign currency exchange rates in first half of 2016, partially offset by an increase of \$11.1 million due to the acquisition of US Diagnostics. Other revenue decreased by \$32.3 million, or 32%, to \$69.9 million during the six months ended June 30, 2016, compared to \$102.2 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 decreased by \$4.9 million, or 20%, to \$19.8 million for the three months ended June 30, 2016, from \$24.6 million for the three months ended June 30, 2015. Net product sales and services revenue from our consumer diagnostics business segment decreased by \$9.4 million, or 20%, to \$37.2 million for the six months ended June 30, 2016, from \$46.6 million for the six months ended June 30, 2015. The decrease resulted from a \$2.4 million and \$4.0 million decrease in revenue attributable to the disposition of our BBI business for the three month and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015. The balance of the decrease in both the three and six months ended June 30, 2016 was the result of a decrease in sales to SPD under our long-term manufacturing service agreement.



**Table of Contents**

**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 \$3.2 million, or 56%, to \$2.5 million for the three months ended June 30, 2016 from \$5.7 million for the three months ended June 30, 2015. The decrease in royalty revenue for the three months ended June 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 June 30, 2016, we expect this trend in lower license and royalty revenues to continue in 2016 as compared to 2015.

License and royalty revenue decreased by \$5.1 million, or 49%, to \$5.3 million for the six months ended June 30, 2016 from \$10.4 million for the six months ended June 30, 2015. The decrease in royalty revenue for the six months ended June 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 \$5.5 million, or 2%, to \$281.9 million for the three months ended June 30, 2016 from \$287.3 million for the three months ended June 30, 2015. The decrease in gross profit during the three months ended June 30, 2016, compared to the same period in 2015, was largely attributed to a \$9.3 million decrease in gross profit as a result of our divested businesses and a \$4.7 million negative impact of foreign currency exchange rates, offset partially by the \$2.7 million increase from our acquired businesses, as well as the improved gross profit of our Alere Home Monitoring business and growth in sales in the Asia Pacific region, largely due to our infectious disease business, as discussed above.

Gross profit decreased by \$34.4 million, or 6%, to \$548.1 million for the six months ended June 30, 2016 from \$582.5 million for the six months ended June 30, 2015. The decrease in gross profit during the six months ended June 30, 2016, compared to the comparable period in 2015, was largely attributed to \$15.9 million decrease in gross profit due to our divested businesses, a \$11.0 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 six months ended June 30, 2016 was 46%, as compared to 46% and 47%, respectively, for the three and six months ended June 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 \$3.1 million, or 1%, to \$279.9 million for the three months ended June 30, 2016 from \$283.0 million for the three months ended June 30, 2015. Gross profit from net product sales and services revenue decreased by \$30.7 million, or 5%, to \$544.8 million for the six months ended June 30, 2016 from \$575.5 million for the six months ended June 30, 2015. Gross profit from net product sales and services revenue by business segment for the three and six months ended June 30, 2016 and 2015 is as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	% Change	2016	2015	% Change
Professional diagnostics	\$ 278,684	\$ 281,501	(1)%	\$ 542,652	\$ 570,810	(5)%
Consumer diagnostics	1,178	1,483	(21)%	2,130	4,641	(54)%
Gross profit from net product sales and services revenue	\$ 279,862	\$ 282,984	(1)%	\$ 544,782	\$ 575,451	(5)%

*Professional Diagnostics*

Gross profit from our professional diagnostics net product sales and services revenue decreased by \$2.8 million, or 1%, to \$278.7 million for the three months ended June 30, 2016 compared to \$281.5 million for the three months ended June 30, 2015. The lower gross profit for the three months ended June 30, 2016 as compared to the same period in the prior year principally reflects the \$9.4 million decreases in gross profit as a result of divested businesses and \$4.6 million due to the negative impact of foreign currency exchange rates, partially offset by a \$2.7 million increase in gross profit from acquired businesses, as well as improved gross profit from our Alere Home Monitoring business and growth in sales in the Asia Pacific region, largely due to our infectious disease business, as discussed above.

Gross profit from our professional diagnostics net product sales and services revenue decreased by \$28.2 million, or 5%, to \$542.7 million for the six months ended June 30, 2016 compared to \$570.8 million for the six months ended June 30, 2015. The lower gross profit for the six months ended June 30, 2016 as compared to the same period in the prior year principally reflects the \$16.1 million impact from divested businesses and \$10.9 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 \$5.0 million increase in gross profit from our acquired businesses.

---

**Table of Contents**

As a percentage of our professional diagnostics net product sales and services revenue, gross margin for the three and six months ended June 30, 2016 was 47%, compared to 47% and 49% for the three and six months ended June 30, 2015, respectively. The lower gross margin in the six months ended June 30, 2016 principally reflects the impact of decreased manufacturing volumes and the revenue mix as discussed above.

*Consumer Diagnostics*

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$0.3 million, or 21%, to \$1.2 million for the three months ended June 30, 2016 from \$1.5 million for the three months ended June 30, 2015.

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$2.5 million, or 54%, to \$2.1 million for the six months ended June 30, 2016 from \$4.6 million for the six months ended June 30, 2015. The decrease in gross profit was primarily driven by decreased sales to SPD, as described above.

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

**Research and Development Expense.** Research and development expense increased by \$1.2 million, or 5%, to \$28.4 million in the three months ended June 30, 2016 from \$27.2 million in the three months ended June 30, 2015, primarily due to restructuring expenses. Research and development expense during the three months ended June 30, 2016 and 2015 is reported net of grant funding of \$0.3 million and \$1.5 million, respectively, arising from the research and development funding relationship with the Bill and Melinda Gates Foundation, or the Gates Foundation, and \$1.0 million and \$0.9 million of funding, respectively, related to our contract with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority, or BARDA, that we entered into in September 2014. For additional information on the agreements with BARDA and the Gates Foundation, including the April 2016 agreement to mutually terminate the February 2013 grant and the February 2013 loan agreement with the Gates Foundation, see Note 16 to the consolidated financial statements elsewhere in this Quarterly Report on Form 10-Q.

Research and development expense increased by \$0.3 million, or 1%, to \$55.5 million in the six months ended June 30, 2016 from \$55.2 million in the six months ended June 30, 2015, primarily from restructuring expenses and partially offset by the favorable impact of foreign exchange rates. Research and development expense during the six months ended June 30, 2016 and 2015 is reported net of grant funding of \$0.5 million and \$3.6 million, respectively, arising from the research and development funding relationship with the Gates Foundation, and \$1.7 million and \$1.4 million, respectively, of funding related to our contract with BARDA.

Research and development expense as a percentage of net revenue was 5% and 4% for the three and six months ended June 30, 2016 and 2015, respectively.

**Sales and Marketing Expense.** Sales and marketing expense decreased by \$5.5 million, or 5%, to \$102.5 million for the three months ended June 30, 2016 from \$108.0 million for the three months ended June 30, 2015. This decrease was primarily attributable to a \$2.2 million reduction in sales and marketing expenses associated with businesses we divested after March 31, 2015, a \$1.7 million reduction in amortization expense related to customer relationship intangible assets (as the underlying economic benefit of the intangibles is declining) and a \$1.2 million favorable impact of foreign currency exchange rates.

Sales and marketing expense decreased by \$14.8 million, or 7%, to \$202.3 million for the six months ended June 30, 2016 from \$217.1 million for the six months ended June 30, 2015. This decrease was primarily attributable to a \$5.0 million reduction in sales and marketing expenses associated with businesses we divested after March 31, 2015, a \$4.0 million favorable impact of foreign currency exchange rates, a \$3.0 million reduction in amortization expense related to customer relationship intangible assets and a \$1.0 million decrease in restructuring expenses.

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

**General and Administrative Expense.** General and administrative expense increase by \$67.2 million, or 110%, to \$128.4 million for the three months ended June 30, 2016 from \$61.2 million for the three months ended June 30, 2015. The increase was primarily attributable to the fact that, in the three months ended June 30, 2015, we benefited from a \$41.1 million gain resulting from a decrease in our estimate of the fair value of an acquisition-related contingent earn-out obligation. In the three months ended June 30, 2016, we also incurred \$10.5 million of expenses related to the pending transaction with Abbott. The remaining portion of the increase, or an aggregate of \$15.6 million, is primarily attributable to \$11.5 million increase in various employee related expenses, \$5.0 million in legal and consulting fees related to certain government investigations and \$3.6 million in charges associated with our various restructuring plans to reduce expenses. These expenses were partially offset by decreased expenses as a result of divestitures and disposal fees of businesses, foreign currency exchange rates and the reduced expense due to the delay in the medical device excise tax, in each case when compared to the comparable period in 2015.

---

**Table of Contents**

General and administrative expense increased by \$89.4 million, or 58%, to \$243.3 million for the six months ended June 30, 2016 from \$153.9 million for the six months ended June 30, 2015. The increase was primarily attributable to the fact that, in the six months ended June 30, 2015, we benefited from a \$52.9 million gain resulting from decreases in our estimate of the fair value of an acquisition-related contingent earn-out obligation. In the six months ended June 30, 2016, we also incurred \$20.9 million of expenses related to the pending transaction with Abbott. The remaining portion of the increase, or an aggregate of \$15.6 million, is attributable to \$9.4 million in legal and consulting fees related to certain government investigations, \$6.6 million in charges associated with our various restructuring plans to reduce expenses. We also incurred a \$17.4 million increase in various employee related expenses which were completely offset by decreased expenses as a result of divestitures and disposal fees of businesses, favorable foreign currency exchange rates and the reduced expense due to delay in the medical device excise tax, in each case when compared to the comparable period in 2015.

General and administrative expense as a percentage of net revenue was 21% and 20% for the three and six months ended June 30, 2016, respectively, compared to 10% and 12% for the three and six months ended June 30, 2015. This increase was largely due to the gain from an acquisition-related contingent earn-out obligation in the three months ended June 30, 2015 for which there was no corresponding gain in the three months ended June 30, 2016.

**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 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 that quarter, 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 six months ended June 30, 2015, in connection with this decision, we recorded impairment charges of \$1.0 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 \$17.2 million, or 29%, to \$42.3 million for the three months ended June 30, 2016 from \$59.5 million for the three months ended June 30, 2015. The decrease was driven by \$10.2 million of third-party costs, including underwriter's fees and other payments to external advisors, that we incurred in the three months ended June 30, 2015 associated with the credit facility that we put in place in that quarter. The decrease was also due to lower interest expense incurred as a result of our reduced outstanding debt balances during the second quarter of 2016.

Interest expense decreased by \$21.5 million, or 20%, to \$84.4 million for the six months ended June 30, 2016 from \$105.9 million for the six months ended June 30, 2015. The decrease is due to lower interest expense incurred as a result of our reduced outstanding debt balances during the six months ended June 30, 2016. The decrease was also driven by \$10.2 million of third-party costs that we incurred in the second quarter of 2015, as noted above.

**Table of Contents**

**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 June 30,			Six Months Ended June 30,		
	2016	2015	Change	2016	2015	Change
Interest income	\$ 645	\$ 728	\$ (83)	\$ 1,810	\$ 1,327	\$ 483
Foreign exchange gains (losses), net	(5,705)	2,906	(8,611)	(7,907)	(696)	(7,211)
Other, net	(9,052)	(439)	(8,613)	(9,364)	197	(9,561)
Total other income (expense), net	\$ (14,112)	\$ 3,195	\$ (17,307)	\$ (15,461)	\$ 828	\$ (16,289)

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

Foreign exchange gains (losses), net during the three and six months ended June 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 six months ended June 30, 2016 primarily reflects a \$10.2 million accrual 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.

**Provision for Income Taxes.** Our provision for income taxes decreased by \$12.6 million to \$3.1 million for the three months ended June 30, 2016, from \$15.7 million for the three months ended June 30, 2015. The effective tax rate for the three months ended June 30, 2016 and 2015 was (9)% and 54%, 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 decrease in the provision for income taxes from the three months ended June 30, 2015 to the three months ended June 30, 2016 is primarily attributed to favorable jurisdictional mix of income and losses in the current year and non-recurring discrete tax impacts in 2015.

Our provision for income taxes decreased by \$5.0 million to \$2.9 million for six months ended June 30, 2016 from \$7.9 million for the six months ended June 30, 2015. The effective tax rate for the six months ended June 30, 2016 and 2015 was (6)% and 72%, respectively. The decrease in our provision for income taxes for six months ended June 30, 2016 compared to six months ended June 30, 2015 is primarily attributed to favorable jurisdictional mix of income and losses in the current year and non-recurring discrete tax impacts in 2015.

**Equity Earnings of Unconsolidated Entities, Net of Tax.** Equity earnings of unconsolidated entities are reported net of tax and include our share of earnings in entities that we account for under the equity method of accounting. Equity earnings of unconsolidated entities, net of tax for the three and six months ended June 30, 2016 reflects the following: (i) our 50% interest in SPD in the amount of \$1.6 million and \$6.2 million, respectively, and (ii) our 49% interest in TechLab, Inc., or TechLab, in the amount of \$0.6 million and \$1.0 million, respectively. Equity earnings of unconsolidated entities, net of tax for the three and six months ended June 30, 2015 reflects the following: (i) our 50% interest in SPD in the amount of \$0.6 million and \$4.2 million, respectively, (ii) our 49% interest in TechLab in the amount of \$0.4 million and \$0.8 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 six months ended June 30, 2015, given our January 9, 2015 divestiture of this business. For the six months ended June 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 June 30, 2016, we had approximately \$3.0 billion of indebtedness outstanding. As our various debt instruments mature over the next several years, we may



---

**Table of Contents**

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 six months ended June 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. 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 June 30, 2016, we had \$506.2 million of cash and cash equivalents, of which \$60.2 million was held by domestic subsidiaries and \$446.0 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 June 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.

As of June 30, 2016, we had \$3.0 billion in aggregate principal amount of outstanding indebtedness, including \$1.5 billion in aggregate principal amount outstanding under our secured credit facility, \$442.5 million in aggregate outstanding principal amount of our 7.25% senior notes due 2018, \$415.7 million in aggregate outstanding principal amount of our 6.5% senior subordinated notes due 2020 and \$414.0 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

---

**Table of Contents**

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. 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 June 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 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, 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 recently 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.

**Table of Contents***Cash Flow Summary (in thousands)*

	<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Net cash provided by operating activities:</b>		
Continuing operations	\$ 94,122	\$ 34,720
Discontinued operations		318
Net cash provided by operating activities	94,122	35,038
<b>Net cash provided by (used in) investing activities:</b>		
Continuing operations	(13,579)	132,576
Discontinued operations		(209)
Net cash provided by (used in) investing activities	(13,579)	132,367
<b>Net cash used in financing activities:</b>		
Continuing operations	(73,615)	(102,645)
Discontinued operations		(76)
Net cash used in financing activities	(73,615)	(102,721)
Foreign exchange effect on cash and cash equivalents	(2,964)	(1,574)
Net increase in cash and cash equivalents	3,964	63,110
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	506,164	464,871
Less: Cash and cash equivalents, end of period discontinued operations, end of period		
Cash and cash equivalents of continuing operations, end of period	\$ 506,164	\$ 464,871

*Summary of Changes in Cash Position*

As of June 30, 2016, we had cash and cash equivalents of \$506.2 million, a \$4.0 million increase from December 31, 2015. Our primary sources of cash during the six months ended June 30, 2016 included \$126.2 million related to net borrowings under revolving credit facilities, \$94.1 million generated by our operating activities, \$21.5 million received from dispositions, net of cash divested, \$11.1 million of cash received from common stock issuances under employee stock option and stock purchase plans, \$2.4 million received from equity method investments, \$0.9 million in proceeds from the sale of property and equipment, \$0.5 million from a decrease in other assets and \$0.4 million from issuance of long-term debt. Our primary uses of cash during the six months ended June 30, 2016 were

\$177.6 million related to the repayment of long-term debt obligations, \$32.3million of capital expenditures, \$19.6 million for financing costs, \$10.6 million for cash dividends paid on our Series B preferred stock, \$6.0 million paid for acquisitions, \$2.2 million for principal payments on our capital lease obligations, \$0.8 million related to payments on short-term debt, \$0.5 million related to payments of acquisition-related contingent consideration obligations and a \$0.4 million related to an increase in restricted cash. Fluctuations in foreign currencies unfavorably impacted our cash balance by \$3.0 million during the six months ended June 30, 2016.

As of June 30, 2015, we had cash and cash equivalents of continuing operations of \$464.9 million, an \$86.4 million increase from December 31, 2014. Our primary sources of cash for continuing operations during the six months ended June 30, 2015 included \$2.1 billion from issuance of long-term debt, \$586.6 million received from dispositions, net of cash divested, \$56.3 million of cash received from common stock issuances under employee stock option and stock purchase plans, \$34.7 million generated by our continuing operating activities, \$14.3 million received from equity method investments, \$1.8 million from a decrease in other assets, and \$1.1 million in proceeds from the sale of property and equipment. Our primary uses of cash for our continuing operations during the six months ended June 30, 2015 were \$2.1 billion related to the repayment of long-term debt obligations, a \$424.0 million increase in restricted cash placed in a trust account for repayment of our 8.625% notes, \$126.3 million related to net payments under revolving credit facilities, \$47.3 million of capital expenditures, \$15.7 million for financing costs, \$10.6 million for cash dividends paid on our Series B preferred stock, \$6.4 million related to payments of acquisition-related contingent consideration obligations and \$2.9 million for principal payments on our capital lease obligations. Fluctuations in foreign currencies unfavorably impacted our cash balance by \$1.6 million during the six months ended June 30, 2015.

---

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

Net cash provided by operations during the six months ended June 30, 2016 was \$94.1 million, which resulted from our loss of \$44.9 million and \$18.8 million of cash used to meet working capital needs during the period, offset by \$157.8 million of non-cash items. The \$157.8 million of non-cash items included \$142.4 million related to depreciation and amortization, \$20.6 million related to non-cash stock-based compensation, \$9.7 million of other non-cash expenses, \$5.3 million of non-cash interest expense related to the amortization of deferred financing costs and original issue discounts, a \$4.2 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 a \$13.2 million decrease related to changes in our deferred income taxes, \$7.2 million in equity earnings of unconsolidated entities, net of tax, a \$3.8 million gain related to impairment and net loss on dispositions and a \$1.8 million non-cash change in fair value of contingent purchase price consideration, which resulted in part from amortization of intangible assets.

Net cash provided by continuing operations during the six months ended June 30, 2015 was \$34.7 million, which resulted from income from continuing operations of \$8.4 million and \$112.1 million of non-cash items, offset by \$85.8 million of cash used to meet working capital needs during the period. The \$112.1 million of non-cash items included \$147.1 million related to depreciation and amortization, a \$40.3 million loss related to impairment and a net loss on dispositions, which reflects both a \$27.7 million impairment charge associated with a closed business and a \$12.6 million net loss from business dispositions, \$12.3 million related to non-cash stock-based compensation, \$7.8 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 \$52.9 million non-cash change in fair value of contingent purchase price consideration, a \$42.2 million decrease related to changes in our deferred income taxes, which resulted in part from amortization of intangible assets, \$5.3 million in equity earnings of unconsolidated entities, net of tax, and \$2.3 million related to other non-cash items. In addition, \$0.3 million of net cash was provided by discontinued operations for operating activities.

*Cash Flows from Investing Activities*

Net cash used in our investing activities during the six months ended June 30, 2016 was \$13.6 million, including \$32.3 million of capital expenditures, \$6.0 million paid for acquisitions and \$0.4 million increase in restricted cash, partially offset by \$21.5 million of cash received from dispositions, net of cash divested, \$2.4 million of cash received from equity method investments, \$0.9 million of proceeds from the sale of property, plant and equipment and a \$0.5 million decrease in other assets.

Our investing activities for continuing operations during the six months ended June 30, 2015 provided \$132.6 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, a \$1.8 million decrease in other assets and \$1.1 million of proceeds from the sale of property, plant and equipment, partially offset by a \$424.0 million increase in restricted cash, including \$425.9 million placed in a trust account for repayment of long-term debt, and \$47.3 million of capital expenditures. In addition, discontinued operations used \$0.2 million of net cash for investing activities.

*Cash Flows from Financing Activities*

Net cash used in financing activities during the six months ended June 30, 2016 was \$73.6 million. Financing activities during the six months ended June 30, 2016 included, among other items, \$177.6 million for the payment of long-term debt obligations, \$19.6 million of financing costs, \$10.6 million for dividend payments related to our Series

B preferred stock, \$2.2 million for payment of capital lease obligations, \$0.8 million for net payments for short-term debt, and \$0.5 million for payments of acquisition-related contingent consideration obligations. We received \$126.2 million of net proceeds from our revolving credit facilities, \$11.1 million of cash from common stock issuances under our employee stock option and stock purchase plans and \$0.4 million of proceeds from issuance of long-term debt.

Net cash used in financing activities for continuing operations during the six months ended June 30, 2015 was \$102.6 million. Financing activities during the six months ended June 30, 2015 included, among other items, \$2.1 billion for the payment of long-term debt obligations, \$126.3 million for net payments for revolving credit facilities, \$15.7 million for financing costs, \$10.6 million for dividend payments related to our Series B preferred stock, \$6.4 million for payments of acquisition-related contingent consideration obligations and \$2.9 million for payment of capital lease obligations. We received \$2.1 billion of proceeds from issuance of long-term debt and \$56.3 million of cash from common stock issuances under employee stock option and stock purchase plans. In addition, discontinued operations used less than \$0.1 million of net cash for financing activities.

As of June 30, 2016, we had an aggregate of \$10.5 million in outstanding capital lease obligations which are payable through 2020.



*Income Taxes*

As of June 30, 2016, our federal, state and foreign net operating loss carryforwards 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, 2017 and 2017, respectively. Certain foreign net operating loss carryforwards can be carried forward indefinitely. As of June 30, 2016, our federal and foreign capital loss carryforwards for income tax purposes were

## **Table of Contents**

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 June 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 June 30, 2016.

## **Contractual Obligations**

As of June 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 June 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.

## **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 six months ended June 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 June 30, 2016.

## **Table of Contents**

### *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.

### ***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 June 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 June 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;

## **Table of Contents**

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 June 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 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 have 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.

#### *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.

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, and on July 19, 2016, the court ordered a schedule for the filing of a consolidated amended complaint and for the motion to dismiss briefing.

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 \$10.2 million for this matter in the three months ended June 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 lawsuit captioned *Dina Andren and Sidney Bludman v. Alere Inc., et al.*, was filed against us in the United States District Court for the Southern District of California. In addition, on July 22, 2016, a class action lawsuit 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. These class actions purport to assert claims against us under several legal theories, including fraud, breach of warranty, unjust enrichment and violation of applicable unfair competition/business practice statutes in connection



with the manufacturing, marketing and sale of our INRatio products. The plaintiffs in the *Dina Andren and Sidney Bludman* class action seek to represent a proposed class of all persons who purchased, rented or otherwise paid for the INRatio system during the period January 1, 2009 to May 26, 2016 in the United States, or alternatively, California, Maryland and/or New York. The 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 the INRatio system 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 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. The *Andren* action also appears to seek damages for personal injury.

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, the most recent of which was received in July 2016, 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 CIDs

## **Table of Contents**

request patient and insurance billing and medical records, records related to interactions with third parties, and correspondence relating 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.

### **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.

### **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

<b>Exhibit No.</b>	<b>Description</b>
------------------------	--------------------

10.1	First Amendment, dated as of April 22, 2016, among the Company, certain subsidiaries of the Company, 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 the Company, 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 the Company's Current Report on Form 8-K, event date April 22, 2016, as filed with the SEC on April 28, 2016).
------	--

---

**Table of Contents**

**Exhibit**

<b>No.</b>	<b>Description</b>
*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 Six Months Ended June 30, 2016 and 2015, (b) our Consolidated Statements of Comprehensive Income (Loss) for the Three and Six Months Ended June 30, 2016 and 2015, (c) our Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (d) our Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2016 and 2015 and (e) the Notes to such Consolidated Financial Statements.

\* Filed herewith  
 Management contract or compensatory plan or arrangement, of amendment thereto

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: September 2, 2016

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