

ALERE INC.
Form 10-Q
November 08, 2012
[Table of Contents](#)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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.

Edgar Filing: ALERE INC. - Form 10-Q

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

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

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)

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 November 5, 2012 was 80,858,705.

Table of Contents

ALERE INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended September 30, 2012

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, as amended, for the fiscal year ended December 31, 2011 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 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

	PAGE
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3
a) <u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011</u>	3
b) <u>Consolidated Statements of Comprehensive Income for the Three and Nine Months Ended September 30, 2012 and 2011</u>	4
c) <u>Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011</u>	5
d) <u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011</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>	40
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	52
Item 4. <u>Controls and Procedures</u>	54
<u>PART II. OTHER INFORMATION</u>	54
Item 1. <u>Legal Proceedings</u>	54
Item 1A. <u>Risk Factors</u>	54
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	55
Item 6. <u>Exhibits</u>	55
<u>SIGNATURE</u>	56

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)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net product sales	\$ 459,813	\$ 418,254	\$ 1,399,025	\$ 1,224,302
Services revenue	226,415	162,266	652,704	493,393
Net product sales and services revenue	686,228	580,520	2,051,729	1,717,695
License and royalty revenue	5,188	5,249	11,333	17,723
Net revenue	691,416	585,769	2,063,062	1,735,418
Cost of net product sales	223,612	193,899	671,664	573,919
Cost of services revenue	120,131	84,177	331,550	251,388
Cost of net product sales and services revenue	343,743	278,076	1,003,214	825,307
Cost of license and royalty revenue	1,898	1,731	5,394	5,214
Cost of net revenue	345,641	279,807	1,008,608	830,521
Gross profit	345,775	305,962	1,054,454	904,897
Operating expenses:				
Research and development	40,562	34,772	120,009	112,662
Sales and marketing	160,644	134,376	478,544	407,973
General and administrative	105,837	91,895	347,757	292,284
Total operating expenses	307,043	261,043	946,310	812,919
Operating income	38,732	44,919	108,144	91,978
Interest expense, including amortization of original issue discounts and deferred financing costs	(54,861)	(47,327)	(161,119)	(154,194)
Other income (expense), net	(1,072)	(8,250)	14,570	(5,477)
Gain on sale of joint venture		288,896		288,896
Income (loss) before provision (benefit) for income taxes	(17,201)	278,238	(38,405)	221,203
Provision (benefit) for income taxes	(10,677)	42,652	(12,621)	(4,414)
Income (loss) before equity earnings of unconsolidated entities, net of tax	(6,524)	235,586	(25,784)	225,617
Equity earnings of unconsolidated entities, net of tax	3,007	4,118	10,417	4,922
Net income (loss)	(3,517)	239,704	(15,367)	230,539

Edgar Filing: ALERE INC. - Form 10-Q

Less: Net income attributable to non-controlling interests	286	138	137	160
Net income (loss) attributable to Alere Inc. and Subsidiaries	(3,803)	239,566	(15,504)	230,379
Preferred stock dividends	(5,352)	(5,358)	(15,940)	(16,682)
Preferred stock repurchase				23,936
Net income (loss) available to common stockholders	\$ (9,155)	\$ 234,208	\$ (31,444)	\$ 237,633
Basic net income (loss) per common share	\$ (0.11)	\$ 2.84	\$ (0.39)	\$ 2.81
Diluted net income (loss) per common share	\$ (0.11)	\$ 2.48	\$ (0.39)	\$ 2.56
Weighted average shares basic	80,792	82,486	80,492	84,508
Weighted average shares diluted	80,792	97,090	80,492	100,058

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

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

(unaudited)

(in thousands)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net income (loss)	\$ (3,517)	\$ 239,704	\$ (15,367)	\$ 230,539
Other comprehensive income (loss), before tax:				
Changes in cumulative translation adjustment	39,695	(56,737)	38,857	(18,116)
Unrealized gains (losses) on available for sale securities	141	(625)	931	(944)
Unrealized gains (losses) on hedging instruments	10	(87)	465	11,901
Minimum pension liability adjustment	(98)	246	(218)	326
Other comprehensive income (loss), before tax	39,748	(57,203)	40,035	(6,833)
Income tax provision (benefit) related to items of other comprehensive income (loss)	360	(179)	360	4,433
Other comprehensive income (loss), net of tax	39,388	(57,024)	39,675	(11,266)
Comprehensive income	35,871	182,680	24,308	219,273
Less: Comprehensive income attributable to non-controlling interests	286	138	137	160
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 35,585	\$ 182,542	\$ 24,171	\$ 219,113

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

Table of Contents

ALERE INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except par value)

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 302,254	\$ 299,173
Restricted cash	3,216	8,987
Marketable securities	897	1,086
Accounts receivable, net of allowances of \$34,764 and \$24,577 at September 30, 2012 and December 31, 2011, respectively	508,591	475,824
Inventories, net	332,512	320,269
Deferred tax assets	10,193	42,975
Receivable from joint venture, net	4,017	2,503
Prepaid expenses and other current assets	139,039	142,910
Total current assets	1,300,719	1,293,727
Property, plant and equipment, net	516,814	491,205
Goodwill	3,032,089	2,821,271
Other intangible assets with indefinite lives	57,481	69,546
Finite-lived intangible assets, net	1,885,236	1,785,925
Deferred financing costs, net, and other non-current assets	97,031	97,786
Receivable from joint venture, net of current portion	14,533	15,455
Investments in unconsolidated entities	94,021	85,138
Marketable securities	3,181	2,254
Deferred tax assets	11,576	10,394
Total assets	\$ 7,012,681	\$ 6,672,701
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 52,486	\$ 61,092
Current portion of capital lease obligations	6,374	6,083
Short-term debt		6,240
Accounts payable	163,168	155,464
Accrued expenses and other current liabilities	425,554	395,573
Total current liabilities	647,582	624,452
Long-term liabilities:		
Long-term debt, net of current portion	3,527,579	3,267,451
Capital lease obligations, net of current portion	13,711	12,629
Deferred tax liabilities	413,808	380,700
Other long-term liabilities	178,406	153,398
Total long-term liabilities	4,133,504	3,814,178
Commitments and contingencies (Note 15)		
Redeemable non-controlling interest		2,497
Stockholders equity:		
	606,468	606,468

Edgar Filing: ALERE INC. - Form 10-Q

Series B preferred stock, \$0.001 par value (liquidation preference: \$709,763 at September 30, 2012 and December 31, 2011); Authorized: 2,300 shares; Issued: 2,065 shares at September 30, 2012 and December 31, 2011; Outstanding: 1,774 shares at September 30, 2012 and December 31, 2011		
Common stock, \$0.001 par value; Authorized: 200,000 shares; Issued: 88,533 shares at September 30, 2012 and 87,647 shares at December 31, 2011; Outstanding: 80,854 shares at September 30, 2012 and 79,968 shares at December 31, 2011	89	88
Additional paid-in capital	3,300,595	3,324,710
Accumulated deficit	(1,502,295)	(1,486,791)
Treasury stock, at cost, 7,679 shares at September 30, 2012 and December 31, 2011	(184,971)	(184,971)
Accumulated other comprehensive income (loss)	9,405	(30,270)
Total stockholders equity	2,229,291	2,229,234
Non-controlling interests	2,304	2,340
Total equity	2,231,595	2,231,574
Total liabilities and equity	\$ 7,012,681	\$ 6,672,701

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)

	Nine Months Ended September 30,	
	2012	2011
Cash Flows from Operating Activities:		
Net income (loss)	\$ (15,367)	\$ 230,539
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	16,087	32,726
Depreciation and amortization	322,371	287,033
Non-cash charges for sale of inventories revalued at the date of acquisition	4,681	
Non-cash stock-based compensation expense	11,868	16,275
Impairment of inventory	295	445
Impairment of long-lived assets	274	1,674
Impairment of intangible assets		2,938
Gain on sale of joint venture business		(288,896)
(Gain) loss on sale of property, plant and equipment	(4,194)	1,096
Gain on sales of marketable securities		(376)
Equity earnings of unconsolidated entities, net of tax	(10,417)	(4,922)
Deferred income taxes	(43,619)	(30,999)
Other non-cash items	5,736	(8,115)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	(8,261)	(30,832)
Inventories, net	(15,596)	(17,013)
Prepaid expenses and other current assets	4,171	(17,364)
Accounts payable	(16,743)	11,977
Accrued expenses and other current liabilities	24,116	66,769
Other non-current liabilities	(21,639)	(30,448)
Net cash provided by operating activities	253,763	222,507
Cash Flows from Investing Activities:		
(Increase) decrease in restricted cash	5,771	(346,970)
Purchases of property, plant and equipment	(97,309)	(94,692)
Proceeds from sale of property, plant and equipment	22,383	846
Proceeds from disposition of business		11,491
Cash paid for acquisitions, net of cash acquired	(384,780)	(127,081)
Cash received from sales of marketable securities	271	8,392
Cash received from (paid for) equity method investments	6,556	(44,102)
Increase in other assets	(9,313)	(55,888)
Net cash used in investing activities	(456,421)	(648,004)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(2,313)	(66,338)
Cash paid for contingent purchase price consideration	(16,248)	(25,305)
Proceeds from issuance of common stock, net of issuance costs	14,260	24,159
Repurchase of preferred stock		(99,068)

Edgar Filing: ALERE INC. - Form 10-Q

Proceeds from issuance of long-term debt	198,288	1,752,708
Payments on long-term debt	(42,553)	(1,195,337)
Net proceeds under revolving credit facilities	91,162	104,808
Payments on short-term debt	(6,240)	
Repurchase of common stock		(184,867)
Cash paid for dividends	(15,970)	(68)
Excess tax benefits on exercised stock options	277	2,183
Principal payments on capital lease obligations	(4,925)	(3,084)
Other	(2,811)	(10,383)
Net cash provided by financing activities	212,927	299,408
Foreign exchange effect on cash and cash equivalents	(7,188)	1,537
Net increase (decrease) in cash and cash equivalents	3,081	(124,552)
Cash and cash equivalents, beginning of period	299,173	401,306
Cash and cash equivalents, end of period	\$ 302,254	\$ 276,754

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 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, 2011 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K, as amended, filed with the Securities and Exchange Commission. 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, 2011.

Certain reclassifications of prior period amounts have been made to conform to current period presentation. These reclassifications had no effect on net income or equity.

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

(2) Cash and Cash Equivalents

We consider all highly-liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At September 30, 2012, our cash equivalents consisted of money market funds.

(3) Inventories

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

	September 30, 2012	December 31, 2011
Raw materials	\$ 98,009	\$ 92,844
Work-in-process	77,219	72,939
Finished goods	157,284	154,486
	\$ 332,512	\$ 320,269

(4) Stock-based Compensation

We recorded stock-based compensation expense in our consolidated statements of operations for the three and nine months ended September 30, 2012 and 2011, respectively, as follows (in thousands):

	Three Months		Nine Months Ended	
	Ended		Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Cost of net revenue	\$ 269	\$ 408	\$ 801	\$ 1,124

Edgar Filing: ALERE INC. - Form 10-Q

Research and development	752	881	2,379	3,017
Sales and marketing	751	1,016	2,581	3,184
General and administrative	1,854	1,981	6,107	8,950
	3,626	4,286	11,868	16,275
Benefit for income taxes	(536)	(674)	(1,951)	(3,264)
	\$ 3,090	\$ 3,612	\$ 9,917	\$ 13,011

Table of Contents**(5) Net Income (Loss) per Common Share**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Numerator:				
Net income (loss)	\$ (3,517)	\$ 239,704	\$ (15,367)	\$ 230,539
Preferred stock dividends	(5,352)	(5,358)	(15,940)	(16,682)
Preferred stock repurchase				23,936
Less: Net income attributable to non-controlling interest	286	138	137	160
Net income (loss) available to common stockholders	\$ (9,155)	\$ 234,208	\$ (31,444)	\$ 237,633
Denominator:				
Weighted-average common shares outstanding basic	80,792	82,486	80,492	84,508
Effect of dilutive securities:				
Stock options		661		1,078
Warrants		95		120
Potentially issuable shares of common stock associated with deferred purchase price consideration		189		189
Potentially issuable shares of common stock associated Series B convertible preferred stock		10,221		10,725
Potentially issuable shares of common stock associated with convertible debt securities		3,438		3,438
Weighted-average common shares outstanding diluted	80,792	97,090	80,492	100,058
Basic net income (loss) per common share attributable to Alere Inc. and Subsidiaries	\$ (0.11)	\$ 2.84	\$ (0.39)	\$ 2.81
Diluted net income (loss) per common share attributable to Alere Inc. and Subsidiaries	\$ (0.11)	\$ 2.48	\$ (0.39)	\$ 2.56

For the three and nine months ended September 30, 2012, anti-dilutive shares of 13.7 million and 13.8 million, respectively, were excluded from the computations of diluted net loss per common share. For the three and nine months ended September 30, 2011, there were no anti-dilutive shares excluded from the computation of diluted net income per common share.

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

For the three and nine months ended September 30, 2012, Series B preferred stock dividends amounted to \$5.4 million and \$15.9 million, respectively, and for the three and nine months ended September 30, 2011, Series B preferred stock dividends amounted to \$5.4 million and \$16.7 million, respectively, which reduced earnings available to common stockholders for purposes of calculating net income (loss) per common share for each of the respective periods. As of September 30, 2012, \$5.3 million of Series B preferred stock dividends was accrued. As of October 15, 2012, payments have been made covering all dividend periods through September 30, 2012.

The Series B preferred stock dividends for the three and nine months ended September 30, 2012 were paid in cash. The Series B preferred stock dividends for the six months ended June 30, 2011 were paid in additional shares of Series B preferred stock. The Series B preferred stock

Edgar Filing: ALERE INC. - Form 10-Q

dividends for the three months ended September 30, 2011 were paid in cash.

(b) Share Repurchases

During the first quarter of 2011, we repurchased in the open market and privately-negotiated transactions 183,000 shares of our Series B preferred stock, which were convertible into approximately 1.1 million shares of our common stock, at a cost of approximately \$49.4 million, which we paid in cash. The repurchase of the preferred stock at an average cost of \$269.84 per preferred share, an amount less than the weighted-average fair value of the preferred shares at issuance, resulted in the allocation of \$13.7 million of income attributable to common stockholders. Also during the first quarter of 2011, and pursuant to the same repurchase program, we repurchased 16,700 shares of our common stock at a cost of approximately \$0.6 million, which we paid in cash.

Table of Contents

During the second quarter of 2011, we repurchased in the open market and privately-negotiated transactions, 174,788 shares of our Series B preferred stock, which were convertible into approximately 1.0 million shares of our common stock, at a cost of approximately \$49.7 million, which we paid in cash. Also during the second quarter of 2011 and pursuant to the same repurchase program, we repurchased 8,300 shares of our common stock at a cost of approximately \$0.3 million, which we paid in cash. The repurchase of the preferred stock at an average cost of \$284.28 per preferred share, an amount less than the weighted-average fair value of the preferred shares at issuance, resulted in the allocation of \$10.2 million of income attributable to common stockholders.

During the third quarter of 2011, we repurchased approximately 7.6 million shares of our common stock at a cost of approximately \$183.9 million, which we paid in cash.

(c) Changes in Stockholders' Equity and Non-controlling Interests

A summary of the changes in stockholders' equity and non-controlling interests comprising total equity for the nine months ended September 30, 2012 and 2011 is provided below (in thousands):

	Nine Months Ended September 30,					
	2012			2011		
	Total Stockholders Equity	Non- controlling Interest	Total Equity	Total Stockholders Equity	Non- controlling Interest	Total Equity
Balance, beginning of period	\$ 2,229,234	\$ 2,340	\$ 2,231,574	\$ 2,575,038	\$ 2,688	\$ 2,577,726
Issuance of common stock and warrants in connection with acquisitions				1,000		1,000
Exercise of common stock options, warrants and shares issued under employee stock purchase plan	14,261		14,261	24,159		24,159
Issuance of common stock for settlement of an acquisition-related contingent consideration obligation	1,243		1,243			
Repurchase of common stock				(184,867)		(184,867)
Repurchase of preferred stock				(99,068)		(99,068)
Preferred stock dividends	(15,970)		(15,970)	(5,391)		(5,391)
Stock-based compensation related to grants of common stock options	11,868		11,868	16,275		16,275
Excess tax benefits on exercised stock options	(437)		(437)	1,452		1,452
Purchase of subsidiary shares from non-controlling interests	(35,079)		(35,079)			
Dividend relating to non-controlling interest		(236)	(236)		(271)	(271)
Net income (loss)	(15,504)	200	(15,304)	230,379	158	230,537
Total other comprehensive income (loss)	39,675		39,675	(11,266)		(11,266)
Balance, end of period	\$ 2,229,291	\$ 2,304	\$ 2,231,595	\$ 2,547,711	\$ 2,575	\$ 2,550,286

The following table presents a summary of the changes in redeemable non-controlling interest recorded in the mezzanine section of the balance sheet for the nine months ended September 30, 2012 and 2011 (in thousands):

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Redeemable non-controlling interest, beginning of period	\$ 2,497	\$
Acquisition of non-controlling interest		2,500
Purchase of subsidiary shares from non-controlling interest	(2,433)	
Net income (loss)	(64)	2

Edgar Filing: ALERE INC. - Form 10-Q

Redeemable non-controlling interest, end of period	\$	\$	2,502
--	----	----	-------

Table of Contents

(7) Business Combinations

Acquisitions are accounted for using the acquisition method and the acquired companies' results have been included in the accompanying consolidated financial statements from their respective dates of acquisition. During the three and nine months ended September 30, 2012, we expensed acquisition-related costs of \$0.8 million and \$6.1 million, respectively, in general and administrative expense. During the three and nine months ended September 30, 2011, we expensed acquisition-related costs of \$2.9 million and \$6.2 million, respectively, in general and administrative expense.

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

Net assets acquired are recorded at their fair value on a preliminary basis and are subject to adjustment upon finalization of the fair value analysis as additional information becomes available. We are not aware of any information that indicates the final fair value analysis will differ materially from the preliminary estimates. Determination of the estimated useful lives of the individual categories of intangible assets was 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 assets are expected to contribute to future cash flows. We amortize our finite-lived intangible assets based on patterns on which the respective economic benefits are expected to be realized.

(a) Acquisitions in 2012

(i) eScreen

On April 2, 2012, we acquired eScreen, Inc., or eScreen, headquartered in Overland Park, Kansas, a technology-enabled provider of employment screening solutions for hiring and maintaining healthier and more efficient workforces. The preliminary aggregate purchase price was approximately \$295.0 million, which consisted of \$271.4 million in cash and a contingent consideration obligation with an aggregate acquisition date fair value of \$23.6 million. Included in our consolidated statements of operations for the three and nine months ended September 30, 2012 is revenue totaling approximately \$40.1 million and \$80.1 million, respectively, related to eScreen. The operating results of eScreen are included in our professional diagnostics reporting unit and business segment. The amount allocated to goodwill from this acquisition is not deductible for tax purposes.

(ii) Other acquisitions in 2012

During the nine months ended September 30, 2012, we acquired the following businesses for a preliminary aggregate purchase price of \$152.2 million, which included cash payments totaling \$106.3 million and contingent consideration obligations with an aggregate acquisition date fair value of \$45.9 million.

Reatrol Comercializacao De Produtos De Saude, LDA, subsequently renamed Alere Lda, located in Vila Nova de Gaia, Portugal, a distributor of products for drugs of abuse testing (Acquired January 2012)

Kullgren Holding AB, or Kullgren, located in Gensta, Sweden, a company that manufactures and distributes high quality intimacy and pharmaceutical products (Acquired February 2012)

Wellogic ME FZ-LLC, or Wellogic UAE, located in Dubai, United Arab Emirates, a company that provides development services to Alere Wellogic, LLC, which acquired the assets of Method Factory, Inc. (d/b/a Wellogic), or Wellogic, in December 2011 (Acquired February 2012)

Edgar Filing: ALERE INC. - Form 10-Q

certain assets, primarily including customer and patient lists, of AmMed Direct LLC, or AmMed, located near Nashville, Tennessee, a privately-owned mail-order provider of home-diabetes testing products and supplies (Acquired March 2012)

MedApps Holding Company, Inc., or MedApps, headquartered in Scottsdale, Arizona, a developer of innovative remote health monitoring solutions that deliver efficient cost-effective connectivity between patient, care provider and electronic medical records (Acquired July 2012)

Amedica Biotech, Inc., or Amedica, located in Hayward, California, a company focused on the development and manufacture of in vitro diagnostic tests (Acquired July 2012)

DiagnosisOne, Inc., or DiagnosisOne, located in Lowell, Massachusetts, a software company that provides clinical analytics technology and data-driven content to hospitals, physician groups, insurers and governments (Acquired July 2012)

Seelen Care Laege- og & Hospitalsartikler ApS, or Seelen, located in Holstebro, Denmark, a distributor of consumables, instruments and equipment to doctors, specialists and physiotherapists (Acquired August 2012)

certain assets of Diagnostik Nord, or Diagnostik, located in Schwerin, Germany, a company focused on the sale of drug screening and in vitro diagnostic medical devices and a provider of diagnostic solutions (Acquired September 2012)

Table of Contents

The operating results of Alere Lda, AmMed, MedApps, Amedica, Seelen and Diagnostik are included in our professional diagnostics reporting unit and business segment. The operating results of Wellogic UAE and DiagnosisOne are included in our health management reporting unit and business segment. The operating results of Kullgren are included in our consumer diagnostics reporting unit and business segment.

Our consolidated statements of operations for the three and nine months ended September 30, 2012 included revenue totaling approximately \$14.4 million and \$26.3 million, respectively, related to these businesses. Goodwill has been recognized in all of these acquisitions and amounted to approximately \$83.7 million. Goodwill related to the acquisitions of AmMed and Diagnostik, which totaled \$8.2 million, is deductible for tax purposes. The goodwill related to the remaining 2012 acquisitions is not deductible for tax purposes.

A summary of the preliminary fair values of the net assets acquired for the acquisitions consummated during the nine months ended September 30, 2012 is as follows (in thousands):

	eScreen	Other	Total
Current assets ⁽¹⁾	\$ 32,743	\$ 7,210	\$ 39,953
Property, plant and equipment	5,664	2,295	7,959
Goodwill	154,721	83,711	238,432
Intangible assets	204,200	93,931	298,131
Other non-current assets	481	151	632
Total assets acquired	397,809	187,298	585,107
Current liabilities	22,796	3,967	26,763
Non-current liabilities	80,023	31,145	111,168
Total liabilities assumed	102,819	35,112	137,931
Net assets acquired	294,990	152,186	447,176
Less:			
Contingent consideration	23,600	45,860	69,460
Cash paid	\$ 271,390	\$ 106,326	\$ 377,716

⁽¹⁾ Includes approximately \$2.8 million of acquired cash.

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

	eScreen	Other	Total	Weighted-average Useful Life
Core technology and patents	\$ 93,200	\$ 49,203	\$ 142,403	19.0 years
Trademarks and trade names	17,300	1,030	18,330	19.0 years
Customer relationships	79,500	39,488	118,988	19.5 years
Non-competition agreements		1,010	1,010	5.1 years
Other	14,200		14,200	10.0 years
In-process research and development		3,200	3,200	N/A
Total intangible assets	\$ 204,200	\$ 93,931	\$ 298,131	

(b) Acquisitions in 2011

Edgar Filing: ALERE INC. - Form 10-Q

During 2011, we acquired the following businesses for a preliminary aggregate purchase price of \$787.4 million, which included cash payments totaling \$603.7 million, 831,915 shares of our common stock with an acquisition date fair value of \$16.2 million, a previously-held investment with a fair value totaling \$113.2 million, contingent consideration obligations with an aggregate acquisition date fair value of \$48.7 million, deferred purchase price consideration with an acquisition date fair value of \$4.2 million and debt forgiveness with a fair value of \$1.5 million.

90% interest in BioNote, Inc., or BioNote, headquartered in South Korea, a manufacturer of diagnostic products for the veterinary industry (Acquired January 2011). We previously owned a 10% interest in BioNote.

Table of Contents

assets, including domain name, of Pregnancy.org, LLC, or Pregnancy.org, a U.S.-based company providing a website for preconception, pregnancy and newborn care content, tools and sharing (Acquired January 2011)

Home Telehealth Limited, subsequently renamed Alere Connected Health Limited, or Alere Connected Health, located in Cardiff, Wales, a company that focuses on delivering integrated, comprehensive services and programs to health and social care providers and insurers (Acquired February 2011)

Bioeasy Diagnostica Ltda., or Bioeasy, located in Belo Horizonte, Brazil, a company that markets and sells rapid diagnostic tests and systems for laboratory diagnosis, prevention and monitoring of immunological diseases and fertility (Acquired March 2011)

80.92% interest in Standing Stone, Inc., or Standing Stone, located in Westport, Connecticut, a company that focuses on disease state management by enhancing the quality of care provided to patients who require long-term therapy for chronic disease management (Acquired May 2011). During May 2012, we acquired the remaining 19.08% interest in Standing Stone.

certain assets, rights, liabilities and properties of Drug Detection Devices, Inc., or 3DL, located in Alpharetta, Georgia, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired July 2011)

Colibri Medical AB, or Colibri, located in Helsingborg, Sweden, a distributor of point-of-care drugs of abuse diagnostic products primarily to the Scandinavian marketplace (Acquired July 2011)

Laboratory Data Systems, Inc., or LDS, located in Tampa, Florida, a provider of healthcare software products, services, consulting and solutions (Acquired August 2011)

certain assets, liabilities and properties of Abatek Medical LLC, or Abatek, located in Dover, New Hampshire, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired September 2011)

Forensics Limited, or ROAR, located in Worcestershire, United Kingdom, a company that provides forensic quality toxicology services across the United Kingdom (Acquired September 2011)

Mahsan Diagnostika Vertriebsgesellschaft mbH, or Mahsan, located in Reinbek, Germany, a distributor of in vitro diagnostic drugs of abuse products primarily to the German marketplace (Acquired October 2011)

Avee Laboratories Inc. and related companies, which we refer to collectively as Avee, located in Tampa, Florida, a privately-owned provider of drug testing services in the field of pain management (Acquired October 2011)

Medical Automation Systems Inc., or MAS, located in Charlottesville, Virginia, a provider of network-based software solutions for point-of-care testing (Acquired October 2011)

Edgar Filing: ALERE INC. - Form 10-Q

Axis-Shield plc, or Axis-Shield, located in Dundee, Scotland, a U.K. publicly traded company focused on the development and manufacture of in vitro diagnostic tests for use in clinical laboratories and at the point of care (Acquired November 2011)

certain assets and properties of 1 Medical Distribution, Inc., or 1 Medical, located in Worthington, Ohio, a distributor that promotes, markets, distributes and sells drugs of abuse diagnostic products, including consumables, point-of-care diagnostic kits and related products and services (Acquired November 2011)

Arriva Medical LLC, or Arriva, located in Coral Springs, Florida, a privately-owned mail-order provider of home-diabetes testing products and supplies (Acquired November 2011)

Method Factory, Inc. (d/b/a Wellogic), or Wellogic, headquartered in Waltham, Massachusetts, a provider of software solutions designed to connect the healthcare community (Acquired December 2011)

The operating results of BioNote, Bioeasy, 3DL, Colibri, LDS, Abatek, ROAR, Mahsan, Avee, MAS, Axis-Shield, 1 Medical and Arriva are included in our professional diagnostics reporting unit and business segment. The operating results of Pregnancy.org, Alere Connected Health, Standing Stone and Wellogic are included in our health management reporting unit and business segment.

Our consolidated statements of operations for the three and nine months ended September 30, 2011 included revenue totaling approximately \$5.6 million and \$15.3 million, respectively, related to the businesses acquired during the first nine months of 2011. Goodwill has been recognized in all of the acquisitions, with the exception of 1 Medical, and amounted to approximately \$364.2

Table of Contents

million. Goodwill related to the acquisitions of Pregnancy.org, 3DL, Abatek, LDS and Wellogic, which totaled \$32.3 million, is expected to be deductible for tax purposes. The goodwill related to the remaining 2011 acquisitions is not expected to be deductible for tax purposes.

A summary of the preliminary fair values of the net assets acquired for the acquisitions consummated in 2011 is as follows (in thousands):

Current assets ⁽¹⁾	\$ 132,360
Property, plant and equipment	68,474
Goodwill	364,213
Intangible assets	416,624
Other non-current assets	27,679
 Total assets acquired	 1,009,350
 Current liabilities	 90,301
Non-current liabilities	129,132
 Total liabilities assumed	 219,433
 Less:	
Fair value of non-controlling interest	2,500
 Net assets acquired	 787,417
 Less:	
Fair value of previously-held equity investment	113,168
Contingent consideration	48,685
Fair value of common stock issued	16,183
Loan forgiveness	1,489
Deferred purchase price consideration	4,170
 Cash paid	 \$ 603,722

⁽¹⁾ Includes approximately \$23.2 million of acquired cash.

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

	Amount	Weighted-Average Useful Life
Core technology and patents	\$ 76,659	10.1 years
Database	64	3.0 years
Trademarks and trade names	14,197	10.1 years
Customer relationships	243,725	12.3 years
Non-competition agreements	8,306	5.3 years
Software	7,400	10.9 years
Other	7,767	15.6 years
In-process research and development	58,506	N/A
 Total intangible assets	 \$ 416,624	

Table of Contents*(c) Restructuring Plans of Acquisitions*

In connection with several of our acquisitions consummated during 2008 and prior, we initiated integration plans to consolidate and restructure certain functions and operations, including the costs associated with the termination of certain personnel of these acquired entities and the closure of certain of the acquired entities' leased facilities. These costs have been recognized as liabilities assumed in connection with the acquisition of these entities and are subject to potential adjustments as certain exit activities are refined. The following table summarizes the liabilities established for exit activities related to these acquisitions and the total exit costs incurred since inception of each plan (in thousands):

	Balance at December 31, 2011	Adjustments to the Reserve ⁽¹⁾	Amounts Paid	Balance at September 30, 2012	Exit Costs Since Inception
Acquisition of Matria Healthcare, Inc.:					
Severance-related costs	\$ 68	\$	\$	\$ 68	\$ 13,664
Facility costs	395	(111)	(105)	179	4,674
Total costs for Matria Healthcare, Inc.	463	(111)	(105)	247	18,338
Acquisition of Cholestech Corporation:					
Severance-related costs					5,845
Facility costs	1,304		(180)	1,124	2,732
Total costs for Cholestech Corporation	1,304		(180)	1,124	8,577
Total costs for all plans	\$ 1,767	\$ (111)	\$ (285)	\$ 1,371	\$ 26,915

⁽¹⁾ These adjustments resulted in a change in the aggregate purchase price and related goodwill for each related acquisition. Of the total \$1.4 million liability outstanding as of September 30, 2012, \$0.5 million is included in accrued expenses and other current liabilities and \$0.9 million is included in other long-term liabilities.

Although we believe our plans and estimated exit costs for our acquisitions are reasonable, actual spending for exit activities may differ from current estimated exit costs.

(8) Restructuring Plans

The following table sets forth aggregate restructuring charges recorded in our consolidated statements of operations for the three and nine months ended September 30, 2012 and 2011 (in thousands):

Statement of Operations Caption	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Cost of net revenue	\$ 1,080	\$ 80	\$ 2,069	\$ 2,310
Research and development		(1)	638	433
Sales and marketing	927	935	1,954	3,809
General and administrative	1,232	2,115	5,471	13,074
Total operating expenses	3,239	3,129	10,132	19,626

Edgar Filing: ALERE INC. - Form 10-Q

Interest expense, including amortization of original issue discounts and deferred financing costs	48	84	158	206
Equity earnings of unconsolidated entities, net of tax		199		534
Total charges	\$ 3,287	\$ 3,412	\$ 10,290	\$ 20,366

Table of Contents*(a) 2012 Restructuring Plans*

In 2012, management developed cost reduction efforts within our professional diagnostics business segment, including the integration of our businesses in Brazil. Additionally, management developed new plans to continue our efforts to reduce costs within our health management business segment, including vacating facility space. The following table summarizes the restructuring activities related to our 2012 restructuring plans for the three and nine months ended September 30, 2012 (in thousands):

	Three Months Ended September 30, 2012		
	Professional Diagnostics	Health Management	Total
Severance-related costs	\$ 691	\$ 516	\$ 1,207
Facility and transition costs		465	465
Other exit costs		5	5
Cash charges	691	986	1,677
Other non-cash charges	55		55
Total charges	\$ 746	\$ 986	\$ 1,732

	Nine Months Ended September 30, 2012		
	Professional Diagnostics	Health Management	Total
Severance-related costs	\$ 3,009	\$ 1,735	\$ 4,744
Facility and transition costs		590	590
Other exit costs		5	5
Cash charges	3,009	2,330	5,339
Other non-cash charges	55		55
Total charges	\$ 3,064	\$ 2,330	\$ 5,394

We anticipate incurring approximately \$0.3 million in additional severance-related costs under these plans related to our professional diagnostics business segment, \$1.0 million in additional facility costs under our health management business segment through 2014 and may develop additional plans over the remainder of 2012. As of September 30, 2012, \$1.7 million in severance and exit costs remain unpaid.

(b) 2011 Restructuring Plans

In 2011, management executed a company-wide cost reduction plan, which impacted our corporate and other business segment, as well as our health management and professional diagnostics business segments. Management also developed plans within our professional diagnostics business segment to consolidate operating activities among certain of our European and Asia Pacific subsidiaries, including transferring the manufacturing of our Panbio products from Australia to our Standard Diagnostics facility in South Korea. Additionally, within our health management business segment, management executed plans to further reduce costs and improve efficiencies, as well as cease operations at our GeneCare Medical Genetics Center, Inc., facility in Chapel Hill, North Carolina, and transfer the majority of our Quality Assured Services, Inc. operation in Orlando, Florida to our facility in Livermore, California. The following table summarizes the restructuring activities related to our 2011 restructuring plans for the three and nine months ended September 30, 2012 and 2011 and since inception (in thousands):

Professional Diagnostics

Edgar Filing: ALERE INC. - Form 10-Q

	Three Months		Nine Months Ended		Since Inception
	Ended September 30, 2012	Ended September 30, 2011	September 30, 2012	September 30, 2011	
Severance-related costs	\$ 639	\$ 2,120	\$ 2,914	\$ 5,721	\$ 14,961
Facility and transition costs	387	208	1,121	208	1,482
Cash charges	1,026	2,328	4,035	5,929	16,443
Fixed asset and inventory impairments	290	43	424	659	1,083
Total charges	\$ 1,316	\$ 2,371	\$ 4,459	\$ 6,588	\$ 17,526

Table of Contents**Health Management**

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Inception
	2012	2011	2012	2011	
Severance-related costs	\$	\$ 82	\$	\$ 2,274	\$ 2,254
Facility and transition costs		114		4,195	6,366
Other exit costs		16		58	154
Cash charges		130		6,527	8,774
Fixed asset and inventory impairments		528		864	949
Intangible asset impairments		60		2,935	2,935
Other non-cash charges				812	761
Total charges	\$ 130	\$ 588	\$ 170	\$ 11,138	\$ 13,419

Corporate and Other

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Inception
	2012	2011	2012	2011	
Severance-related costs	\$ 5	\$ 69	\$ 31	\$ 1,117	\$ 1,224
Cash charges	5	69	31	1,117	1,224
Fixed asset and inventory impairments				2	3
Total charges	\$ 5	\$ 69	\$ 31	\$ 1,119	\$ 1,227

We anticipate incurring approximately \$2.5 million in additional costs under these plans related to our professional diagnostics business segment, primarily related to severance and facility exit costs, and may also incur impairment charges on assets as plans are finalized. We anticipate incurring approximately \$0.9 million in additional costs under these plans related to our health management business segment, primarily related to facility lease obligations through 2014. As of September 30, 2012, \$2.9 million in cash charges remain unpaid.

(c) 2010 and 2008 Restructuring Plans

In 2010, management developed several plans to reduce costs and improve efficiencies within our health management and professional diagnostics business segments. In May 2008, management decided to close our facility located in Bedford, England and initiated steps to cease operations at this facility and transition the manufacturing operations principally to our manufacturing facilities in Shanghai and Hangzhou, China. Additionally in 2008, management developed and initiated plans to transition the businesses of Cholestech to our San Diego, California facility. The following table summarizes the restructuring activities related to these restructuring plans for the three and nine months ended September 30, 2012 and 2011 and since inception (in thousands):

Professional Diagnostics

	Three Months Ended September 30,	Nine Months Ended September 30,	Since Inception
--	--	---------------------------------------	--------------------

Edgar Filing: ALERE INC. - Form 10-Q

	2012	2011	2012	2011	
Severance-related costs	\$	\$ (107)	\$	\$ (29)	\$ 8,897
Facility and transition costs	77	266	227	828	8,539
Other exit costs	16	22	52	68	4,470
Cash charges	93	181	279	867	21,906
Fixed asset and inventory impairments					10,309
Total charges	\$ 93	\$ 181	\$ 279	\$ 867	\$ 32,215

Table of Contents**Health Management**

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Inception
	2012	2011	2012	2011	
Severance-related costs	\$	\$	\$	\$	\$ 4,647
Facility and transition costs			(84)	40	2,392
Other exit costs	11	4	41	80	329
Cash charges	11	4	(43)	120	7,368
Fixed asset and inventory impairments					165
Total charges	\$ 11	\$ 4	\$ (43)	\$ 120	\$ 7,533

We anticipate incurring an additional \$0.5 million in facility lease obligation charges related to the Cholestech plan through 2017 and do not anticipate incurring significant additional charges under the other plans. As of September 30, 2012, \$1.1 million in facility related costs remain unpaid.

In addition to the restructuring charges discussed above, certain charges associated with the Bedford facility closure were borne by SPD, our 50/50 joint venture with the Procter & Gamble Company, or P&G. Of the restructuring charges recorded by SPD, 50% has been included in equity earnings of unconsolidated entities, net of tax, in our consolidated statement of operations. The following table summarizes the 50% portion of the restructuring charges borne by SPD and included in equity earnings of unconsolidated entities, net of tax, for the three and nine months ended September 30, 2011 and since inception (in thousands):

	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011	Since Inception
Severance-related costs	\$	\$ 30	\$ 5,797
Facility and transition costs	199	432	5,396
Other exit costs			283
Cash charges	199	462	11,476
Fixed asset and inventory impairments		72	4,635
Total charges included in equity earnings of unconsolidated entities, net of tax	\$ 199	\$ 534	\$ 16,111

We do not anticipate incurring significant additional restructuring charges under this plan.

(d) Restructuring Reserves

The following table summarizes our restructuring reserves related to the plans described above, of which \$4.4 million is included in accrued expenses and other current liabilities and \$1.3 million is included in other long-term liabilities on our consolidated balance sheets (in thousands):

Severance- related Costs	Facility and	Other Exit Costs	Total
--------------------------------	-----------------	---------------------	-------

Edgar Filing: ALERE INC. - Form 10-Q

		Transition Costs		
Balance, December 31, 2011	\$ 3,380	\$ 5,215	\$ 593	\$ 9,188
Cash charges	7,690	1,879	157	9,726
Payments	(8,891)	(4,083)	(170)	(13,144)
Currency adjustments	(47)	2		(45)
Balance, September 30, 2012	\$ 2,132	\$ 3,013	\$ 580	\$ 5,725

Table of Contents**(9) Long-term Debt**

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

	September 30, 2012	December 31, 2011
A term loans ⁽¹⁾	\$ 893,750	\$ 917,188
B term loans	915,750	922,688
Incremental B-1 term loans	248,125	250,000
Incremental B-2 term loans	197,163	
Secured credit facility revolving line of credit	97,500	
3% Senior subordinated convertible notes	150,000	150,000
9% Senior subordinated notes	392,493	391,233
7.875% Senior notes	246,319	245,621
8.625% Senior subordinated notes	400,000	400,000
Other lines of credit	11,251	19,603
Other	27,714	32,210
	3,580,065	3,328,543
Less: Current portion	(52,486)	(61,092)
	\$ 3,527,579	\$ 3,267,451

⁽¹⁾ Includes A term loans and Delayed-Draw term loans under our secured credit facility.

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 consolidated statements of operations for the three and nine months ended September 30, 2012 and 2011, respectively, as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Secured credit facility ⁽¹⁾	\$ 27,474	\$ 21,160	\$ 77,422	\$ 21,380
Former secured credit facility ⁽²⁾		(279)		53,978 ⁽³⁾
3% Senior subordinated convertible notes	1,246	1,246	3,738	3,742
9% Senior subordinated notes	10,373	9,751	31,090	29,219
7.875% Senior notes	5,763	5,378	17,276	16,112
8.625% Senior subordinated notes	9,274	8,909	27,823	26,736
	\$ 54,130	\$ 46,165	\$ 157,349	\$ 151,167

⁽¹⁾ Includes A term loans, including the Delayed-Draw term loans; B term loans; Incremental B-1 term loans; Incremental B-2 term loans revolving line-of-credit loans. For the three and nine months ended September 30, 2012, the amount includes \$1.3 million and \$4.0 million, respectively, related to the amortization of fees paid for certain debt modifications.

⁽²⁾ Includes loans under First Lien Credit Agreement and Second Lien Credit Agreement.

⁽³⁾ Amount includes approximately \$29.7 million recorded in connection with the termination of our former secured credit facility and related interest rate swap agreement, coupled with the amortization of fees paid for certain debt modifications.

The following summarizes the material terms of our secured credit facility that have changed significantly since December 31, 2011. All other terms of our secured credit facility as described in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2011, but

Edgar Filing: ALERE INC. - Form 10-Q

omitted below, have not changed since that date.

On March 28, 2012, we and certain of our subsidiaries entered into a third amendment to the credit agreement that governs our secured credit facility, or the credit agreement. The third amendment provides for an additional term loan facility consisting of Incremental B-2 term loans in the aggregate principal amount of \$200.0 million and thereby increases the total amount of the credit available to us under the secured credit facility to \$2.55 billion in aggregate principal amount, consisting of term loans in the aggregate principal amount of \$2.3 billion and, subject to our continued compliance with the credit agreement, a \$250.0 million revolving line of credit; the revolving line of credit continues to include a sublimit for the issuance of letters of credit. On March 28, 2012, we borrowed the entire \$200.0 million principal amount of the Incremental B-2 term loans.

Table of Contents

Under the terms of the third amendment, we must repay the principal amount of the Incremental B-2 term loans in twenty consecutive quarterly installments, beginning on June 30, 2012 and continuing through March 31, 2017 (all previously due installments of which we have paid in full), in the amount of \$0.5 million each, and a final installment on June 30, 2017 in the amount of \$190.0 million; notwithstanding the foregoing, and subject to certain exceptions provided for in the credit agreement, in the event that any of our existing 3% senior subordinated convertible notes, 9% senior subordinated notes or 7.875% senior notes remain outstanding on the date that is six months prior to the relevant maturity date thereof, respectively, then the Incremental B-2 term loans (as well as all other term loans and all revolving credit loans under the secured credit facility) shall instead mature in full on the relevant prior date. Otherwise, the terms and conditions, including the interest rates, that apply to the Incremental B-2 term loans under the credit agreement are substantially the same as the terms and conditions, including the interest rates, that apply to the existing B term loans under the credit agreement.

(10) Derivative Financial Instruments

We manage our economic and transaction exposure to certain market-based risks through the use of derivative instruments. Our objective for holding derivative instruments has been to reduce volatility of net earnings and cash flows associated with changes in interest rates and foreign currency exchange rates. We do not hold or issue derivative financial instruments for speculative purposes.

(a) Interest Rate Risk

We used interest rate swap contracts in the management of our interest rate exposure related to our former secured credit facility. On June 30, 2011, we entered into a new secured credit facility and, in connection therewith, repaid in full all outstanding indebtedness under and terminated our former secured credit facility and related interest rate swaps.

(b) Foreign Currency Risk

In connection with our acquisition of Axis-Shield, we acquired a number of foreign currency forward contracts. The specific risk hedged in these contracts was the undiscounted foreign currency spot rate risk on forecasted foreign currency revenue. As of September 30, 2012, all of the acquired foreign currency forward contracts were settled. As of December 31, 2011, the notional value of these contracts was \$16.6 million and CHF 5.4 million, respectively. We report the effective portion of the gain or loss on a cash flow hedge as a component of other comprehensive income, and it is subsequently reclassified into net earnings in the period in which the hedged transaction affects net earnings or the forecasted transaction is no longer probable of occurring.

The following tables summarize the fair value of our derivative instruments and the effect of derivative instruments on/in our accompanying consolidated balance sheets and consolidated statements of operations (in thousands):

Derivative Instruments	Balance Sheet Caption	Fair Value at September 30, 2012	Fair Value at December 31, 2011
Foreign currency forward contracts	Accrued expenses and other current liabilities	\$	\$ 447

Derivative Instruments	Location of Gain (Loss) Recognized in Income	Amount of Gain Recognized During the Three Months Ended September 30, 2012	Amount of Loss Recognized During the Three Months Ended September 30, 2011
Foreign exchange forward contract	Other comprehensive income (loss)	\$ 10	\$ (88)
Total gain (loss)	Other comprehensive income (loss)	\$ 10	\$ (88)

Table of Contents

Derivative Instruments	Location of Gain (Loss) Recognized in Income	Amount of	Amount of
		Gain	Gain (Loss)
		Recognized	Recognized
		During the Nine	During the Nine
		Months Ended	Months Ended
		September 30, 2012	September 30, 2011
Foreign exchange forward contract	Other comprehensive income (loss)	\$ 465	\$ (80)
Interest rate swap contracts	Other comprehensive income (loss)		1,841
Total gain	Other comprehensive income (loss)	\$ 465	\$ 1,761

(11) 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. Our Level 1 assets and liabilities include investments in marketable securities.

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. Our Level 2 assets and liabilities include foreign exchange forward contracts.

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 fair value of the contingent consideration obligations related to our acquisitions is valued using Level 3 inputs.

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

Description	September 30, 2012	Quoted Prices in	Significant Other	Unobservable Inputs (Level 3)
		Active Markets (Level 1)	Observable Inputs (Level 2)	
Assets:				
Marketable securities	\$ 4,078	\$ 4,078	\$	\$
Total assets	\$ 4,078	\$ 4,078	\$	\$
Liabilities:				
Contingent consideration obligations ⁽¹⁾	\$ 171,276	\$	\$	\$ 171,276
Total liabilities	\$ 171,276	\$	\$	\$ 171,276

Edgar Filing: ALERE INC. - Form 10-Q

Description	December 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Marketable securities	\$ 3,340	\$ 3,340	\$	\$
Total assets	\$ 3,340	\$ 3,340	\$	\$
Liabilities:				
Foreign exchange forward contracts ⁽²⁾	\$ 447	\$	\$ 447	\$
Contingent consideration obligations ⁽¹⁾	140,047			140,047
Total liabilities	\$ 140,494	\$	\$ 447	\$ 140,047

Table of Contents

- (1) The fair value measurements for our contingent consideration obligations relate to acquisitions completed after January 1, 2009 and are valued using Level 3 inputs. 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.
- (2) The fair value of the foreign exchange forward contracts was measured using readily observable market inputs, such as quotations on forward foreign exchange points and foreign interest rates.

Changes in the fair value of our Level 3 contingent consideration obligations during the nine months ended September 30, 2012 were as follows (in thousands):

Fair value of contingent consideration obligations, January 1, 2012	\$ 140,047
Acquisition date fair value of contingent consideration obligations recorded	69,461
Foreign currency	314
Payments	(21,764)
Present value accretion	16,272
Adjustments, net (income) expense	(33,054)
Fair value of contingent consideration obligations, September 30, 2012	\$ 171,276

At September 30, 2012 and December 31, 2011, 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 were \$3.6 billion at September 30, 2012. The carrying amount and estimated fair value of our long-term debt were \$3.3 billion at December 31, 2011. 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.

(12) Defined Benefit Pension Plan

Our subsidiary in England, Unipath Ltd., has a defined benefit pension plan established for certain of its employees. The net periodic benefit costs are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Service cost	\$	\$	\$	\$
Interest cost	199	203	596	610
Expected return on plan assets	(152)	(156)	(457)	(468)
Amortization of prior service costs	104	106	312	320
Realized losses				
Net periodic benefit cost	\$ 151	\$ 153	\$ 451	\$ 462

(13) 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. Our reportable

Edgar Filing: ALERE INC. - Form 10-Q

operating segments are Professional Diagnostics, Health Management, Consumer Diagnostics and 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.

Table of Contents

We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three and nine months ended September 30, 2012 and 2011 is as follows (in thousands):

	Professional Diagnostics	Health Management	Consumer Diagnostics	Corporate and Other	Total
Three Months Ended September 30, 2012:					
Net revenue	\$ 531,442	\$ 135,078	\$ 24,896	\$	\$ 691,416
Operating income (loss)	\$ 63,298	\$ (14,357)	\$ 4,615	\$ (14,824)	\$ 38,732
Depreciation and amortization	\$ 85,030	\$ 24,313	\$ 1,167	\$ 239	\$ 110,749
Restructuring charge	\$ 2,139	\$ 1,095	\$	\$ 5	\$ 3,239
Stock-based compensation	\$	\$	\$	\$ 3,626	\$ 3,626
Three Months Ended September 30, 2011:					
Net revenue	\$ 429,952	\$ 129,931	\$ 25,886	\$	\$ 585,769
Operating income (loss)	\$ 64,893	\$ (12,565)	\$ 3,844	\$ (11,253)	\$ 44,919
Depreciation and amortization	\$ 63,053	\$ 26,228	\$ 1,428	\$ 208	\$ 90,917
Restructuring charge	\$ 2,587	\$ 530	\$ (57)	\$ 69	\$ 3,129
Stock-based compensation	\$	\$	\$	\$ 4,286	\$ 4,286
Nine Months Ended September 30, 2012:					
Net revenue	\$ 1,589,909	\$ 404,452	\$ 68,701	\$	\$ 2,063,062
Operating income (loss)	\$ 196,728	\$ (46,379)	\$ 7,679	\$ (49,884)	\$ 108,144
Depreciation and amortization	\$ 245,911	\$ 72,152	\$ 3,604	\$ 704	\$ 322,371
Non-cash charge associated with acquired inventory	\$ 4,681	\$	\$	\$	\$ 4,681
Restructuring charge	\$ 7,750	\$ 2,351	\$	\$ 31	\$ 10,132
Stock-based compensation	\$	\$	\$	\$ 11,868	\$ 11,868
Nine Months Ended September 30, 2011:					
Net revenue	\$ 1,254,838	\$ 408,566	\$ 72,014	\$	\$ 1,735,418
Operating income (loss)	\$ 174,459	\$ (39,652)	\$ 9,107	\$ (51,936)	\$ 91,978
Depreciation and amortization	\$ 200,645	\$ 81,871	\$ 4,007	\$ 510	\$ 287,033
Restructuring charge	\$ 7,445	\$ 11,119	\$ (57)	\$ 1,119	\$ 19,626
Stock-based compensation	\$	\$	\$	\$ 16,275	\$ 16,275
Assets:					
As of September 30, 2012	\$ 5,819,658	\$ 583,832	\$ 188,912	\$ 420,279	\$ 7,012,681
As of December 31, 2011	\$ 5,826,756	\$ 624,305	\$ 199,422	\$ 22,218	\$ 6,672,701

The following tables summarize our net revenue from the professional diagnostics and health management reporting segments by groups of similar products and services for the three and nine months ended September 30, 2012 and 2011 (in thousands):

Professional Diagnostics Segment

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Cardiology	\$ 122,372	\$ 127,943	\$ 386,795	\$ 390,652
Infectious disease	136,561	142,639	425,398	405,559
Toxicology	156,074	93,497	437,736	267,834
Diabetes	35,670		100,628	
Other	78,077	62,172	230,519	176,206
Net product sales and services revenue	528,754	426,251	1,581,076	1,240,251
License and royalty revenue	2,688	3,701	8,833	14,587
Professional diagnostics net revenue	\$ 531,442	\$ 429,952	\$ 1,589,909	\$ 1,254,838

Table of Contents**Health Management Segment**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Disease and case management	\$ 57,383	\$ 59,441	\$ 165,277	\$ 182,118
Wellness	24,290	24,427	80,881	80,369
Women s & children s health	29,136	28,509	90,220	85,550
Patient self-testing services	24,269	17,554	68,074	60,529
Health management net revenue	\$ 135,078	\$ 129,931	\$ 404,452	\$ 408,566

(14) Related Party Transactions

In May 2007, we completed the formation of SPD, our 50/50 joint venture with P&G, for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, 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 receivable from the joint venture of \$4.0 million and \$2.5 million as of September 30, 2012 and December 31, 2011, respectively. Included in the \$4.0 million receivable balance as of September 30, 2012 is approximately \$1.6 million of costs incurred in connection with our 2008 SPD-related restructuring plans. Included in the \$2.5 million receivable balance as of December 31, 2011 is approximately \$1.5 million of costs incurred in connection with our 2008 SPD-related restructuring plans. We have also recorded a long-term receivable totaling approximately \$14.5 million and \$15.5 million as of September 30, 2012 and December 31, 2011, respectively, related to the 2008 SPD-related restructuring plans. Additionally, customer receivables associated with revenue earned after the joint venture was completed have been classified as other receivables within prepaid expenses and other current assets on our accompanying consolidated balance sheets in the amount of \$7.1 million and \$7.3 million as of September 30, 2012 and December 31, 2011, 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 \$15.9 million and \$47.4 million during the three and nine months ended September 30, 2012, respectively, and \$19.4 million and \$52.0 million during the three and nine months ended September 30, 2011, respectively. Additionally, services revenue generated pursuant to the long-term services agreement with the joint venture totaled \$0.3 million and \$0.9 million during the three and nine months ended September 30, 2012, respectively, and \$0.2 million and \$0.8 million during the three and nine months ended September 30, 2011, 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, the joint venture purchases products from our manufacturing facilities in the U.K. and China. The joint venture in turn sells a portion of those tests back to us for final assembly and packaging. Once packaged, the tests are sold to P&G for distribution to third-party customers in North America. As a result of these related transactions, we have recorded \$7.1 million and \$8.9 million of trade receivables which are included in accounts receivable on our accompanying consolidated balance sheets as of September 30, 2012 and December 31, 2011, respectively, and \$13.7 million and \$19.3 million of trade accounts payable which are included in accounts payable on our accompanying consolidated balance sheets as of September 30, 2012 and December 31, 2011, respectively. During the nine months ended September 30, 2012, we received \$6.1 million in cash from SPD as a return of capital.

In connection with the formation of SPD in May 2007, we entered into an option agreement with P&G, pursuant to which P&G had the right, for a period of 60 days commencing on May 17, 2011, to require us to acquire all of P&G's interest in SPD at fair market value, and P&G had the right, upon certain material breaches by us of our obligations to SPD, to acquire all of our interest in SPD at fair market value. On July 16, 2011, P&G's option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, we recognized a gain in the amount of approximately \$288.9 million during the third quarter of 2011.

(15) Material Contingencies and Legal Settlements*(a) Legal Proceedings*

Edgar Filing: ALERE INC. - Form 10-Q

We are not a party to any pending legal proceedings that we currently believe could have a material adverse impact on our sales, operations or financial performance. However, because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future.

Table of Contents

(b) Acquisition-related Contingent Consideration Obligations

The following summarizes our principal contractual acquisition-related contingent consideration obligations as of September 30, 2012 that have changed significantly since December 31, 2011. Other acquisition-related contingent consideration obligations that were presented in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2011, but which are omitted below, represent those that have not changed significantly since that date.

AmMed

With respect to AmMed, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain operational targets within six months of the acquisition date. The maximum amount of the earn-out payment was \$2.0 million. The conditions of the earn-out were not achieved and as such no further contingent consideration obligations related to this acquisition exist as of September 30, 2012.

Amedica

With respect to Amedica, the terms of the acquisition agreement require us to make earn-out payments upon successfully meeting certain financial targets during each of calendar years 2012 and 2013. The maximum amount of the earn-out payments are \$6.9 million and \$8.1 million for calendar years 2012 and 2013, respectively.

Capital Toxicology

The initial terms of the acquisition agreement for Capital Toxicology, LLC, provided for an earn-out calculated based on the amount, if any, by which EBITDA derived from the acquired business exceeded specified targets during each of the calendar years 2011 and 2012. A portion of the earn-out for the 2011 calendar year totaling approximately \$2.1 million was earned and accrued as of December 31, 2011. During the first quarter of 2012, the acquisition agreement was modified to base the earn-out on the excess of actual cash collections from 2011 sales over 2011 expenses rather than EBITDA. This new criterion resulted in an incremental \$2.9 million accrual related to the earn-out for the 2011 calendar year based on cash collections through March 31, 2012. \$4.1 million was paid in respect of the earn-out for the 2011 calendar year during the second quarter of 2012. An additional payment of approximately \$1.5 million will be made in the fourth quarter of 2012 for the incremental cash collections from 2011 sales received prior to August 31, 2012. The maximum potential remaining amount of the earn-out payments is approximately \$8.0 million.

DiagnosisOne

With respect to DiagnosisOne, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within five years of the acquisition date. The maximum amount of the earn-out payments is \$33.0 million.

Diagnostik

With respect to Diagnostik, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within two years of the acquisition date. The maximum amount of the earn-out payments is approximately 1.4 million (approximately \$1.8 million at September 30, 2012).

eScreen

With respect to eScreen, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets during calendar years 2012 through 2014. The maximum amount of the earn-out payments is \$70.0 million.

Edgar Filing: ALERE INC. - Form 10-Q

MedApps

With respect to MedApps, the terms of the acquisition agreement require us to make earn-out payments upon achievement of certain technological and product development milestones through January 15, 2015. The maximum amount of the earn-out payments is \$22.0 million.

Standing Stone

With respect to Standing Stone, the terms of the acquisition agreement require us to pay earn-outs and employee bonuses upon successfully meeting certain operational, product development and revenue targets during the period from the date of acquisition through calendar year 2013. A cash earn-out payment totaling approximately \$5.5 million and employee bonus payments totaling approximately \$0.3 million for the achievement of the first two milestones were made during the second quarter of 2012. The maximum remaining amount of the earn-out payments is approximately \$5.5 million. The maximum remaining amount of the employee bonuses is \$0.3 million.

(c) Acquisition-related Obligations

Standing Stone

Under the terms of the acquisition agreement we acquired the remaining 19.08% of the issued and outstanding capital stock of Standing Stone, the holders of which were officers and employees of Standing Stone, in May 2012 for an aggregate purchase price of approximately \$2.6 million.

Agreements with Epocal

In November 2009, we entered into a distribution agreement with Epocal, Inc., or Epocal, to distribute the epoc[®] Blood Analysis System for blood gas and electrolyte testing for \$20.0 million, which is recorded on our accompanying consolidated balance sheet in other intangible assets, net. We also entered into a definitive agreement to acquire all of the issued and outstanding equity securities of Epocal for a total potential purchase price of up to \$255.0 million, including a base purchase price of up to \$172.5 million if Epocal achieves certain gross margin and other financial milestones on or prior to October 31, 2014, plus additional payments of up to \$82.5 million if Epocal achieves certain other milestones relating to its gross margin and product development efforts on or prior to this date. The agreement contains a working capital adjustment whereby the purchase price is increased or decreased to the extent that Epocal's working capital at closing is more or less than a specified amount. We also agreed that, if the acquisition is consummated, we will provide \$12.5 million in management incentive arrangements, 25% of which will vest over three years and 75% of which will be payable only upon the achievement of certain milestones. The acquisition will also be subject to other closing conditions, including the receipt of any required antitrust or other approvals. In April 2011, we entered into a license agreement with Epocal and amended some of the terms of the definitive agreement to acquire Epocal. The license agreement provides us with royalty-free access to certain Epocal intellectual property for use in our home-use products and provided for an upfront license payment of \$18.0 million, which we paid in 2011. The amendment of the definitive agreement increased the working capital target by \$18.0 million, which may have the effect of reducing the purchase price of the acquisition. The amendment of the agreement also added an additional potential milestone payment of \$8.0 million. As a result, the maximum purchase price under the acquisition agreement increased to \$263.0 million.

Table of Contents*(d) FDA Inspection and Office of Inspector General Subpoena*

In March 2012, the Food & Drug Administration, or FDA, began an inspection of our San Diego facility related to our Alere Triage products. During the inspection, the FDA expressed concern about the alignment between certain aspects of our labeling for the Alere Triage products and the quality control release specifications that had been in effect prior to the inspection. As a result and as previously disclosed, we implemented two recalls of Alere Triage products during the second quarter of 2012, as well as interim quality control release specifications. In June 2012, the FDA closed the inspection, and we received inspectional observations on FDA Form 483. In July 2012, we provided the FDA with a detailed response to its inspectional observations which included a plan for how we proposed to address each observation as well as a timeline for doing so. Since submitting this response, we have been working diligently to address each of these observations. Also, on or about September 28, 2012, we agreed with the FDA on a set of final release specifications for our Alere Triage meter-based products that further align the product release specifications to the package insert.

On October 9, 2012, we received a warning letter from the FDA citing the same inspectional observations set forth in the FDA Form 483 received in June. The warning letter, which was subsequently reissued as of October 22, 2012, acknowledged our July response but did not take into account the timeline that we had proposed or any of our efforts taken after our July response. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions detailed in our July response, including all of the actions then due under our timeline. We will continue to provide the FDA with further periodic updates on the status of the actions that remain to be completed over the next several months to fully address the issues that the FDA has identified.

As we anticipated, the final release specifications agreed to with the FDA for our Alere Triage products have resulted in lower manufacturing yields for those products. While we continue to make significant progress in controlling our manufacturing process to improve overall yields, we also continue to expand our manufacturing capacity to address the lower yield rates. These efforts, as well as our efforts to address the FDA's observations set forth in the FDA Form 483 and the warning letter, have increased our manufacturing costs and reduced our margins on these products.

Also, in May 2012, we received a subpoena from the Office of Inspector General of the Department of Health and Human Services. The subpoena seeks documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the government and are in the process of responding to the subpoena.

We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with these matters. Also, except for increases in manufacturing costs and decreased profitability for our Alere Triage products, we are unable to predict what impact, if any, these matters or ensuing proceedings, if any, will have on our financial condition, results of operations or cash flows.

(16) 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 as of 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.

Recently Issued Standards

In July 2012, the FASB issued Accounting Standards Update, or ASU, No. 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, or ASU 2012-02. ASU 2012-02 allows an entity the option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. An entity will be able to resume performing the qualitative assessment in any subsequent period. The adoption of this standard is not expected to have a material impact on our financial position, results of operations, comprehensive income or cash flows.

Recently Adopted Standards

Effective January 1, 2012, we adopted ASU No. 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing for Goodwill Impairment*, or ASU 2011-08. ASU 2011-08 allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the

Edgar Filing: ALERE INC. - Form 10-Q

current two-step impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. This update does not change the current guidance for testing other indefinite-lived intangible assets for impairment. The adoption of this standard did not have an impact on our financial position, results of operations, comprehensive income or cash flows.

Table of Contents

Effective January 1, 2012, we adopted ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, or ASU 2011-05. ASU 2011-05 (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. This update does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments do not affect how earnings per share is calculated or presented. Effective January 1, 2012, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, or ASU 2011-12. As these accounting standards only require enhanced disclosure, the adoption of these standards did not impact our financial position, results of operations, comprehensive income or cash flows.

Effective January 1, 2012, we adopted ASU No. 2011-04, *Fair Value Measurements (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04. ASU 2011-04 provides common requirements for measuring fair value and disclosing information about fair value measurements in accordance with U.S. GAAP and International Financial Reporting Standards.

(17) 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) Axis-Shield

During the third quarter of 2011, we acquired, in various transactions, approximately 15.0 million shares of Axis-Shield, which represented a 29.9% ownership interest in Axis-Shield as of September 30, 2011. Our equity earnings attributable to this investment for the third quarter of 2011 were immaterial. During the fourth quarter of 2011, we acquired a controlling interest of Axis-Shield.

(b) SPD

In May 2007, we completed the formation of SPD, our 50/50 joint venture with P&G for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products, outside the cardiology, diabetes and oral care fields. Upon completion of the arrangement to form SPD, we ceased to consolidate the operating results of our consumer diagnostics business related to SPD. We recorded earnings of \$2.1 million and \$8.2 million during the three and nine months ended September 30, 2012, respectively, and we recorded earnings of \$3.6 million and \$3.0 million during the three and nine months ended September 30, 2011, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our 50% share of SPD's net income for the respective periods.

(c) TechLab

In May 2006, we acquired 49% of TechLab, Inc., or TechLab, a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic-associated diarrhea and parasitology. We recorded earnings of \$0.6 million and \$1.8 million during the three and nine months ended September 30, 2012, respectively, and we recorded earnings of \$0.3 million and \$1.5 million during the three and nine months ended September 30, 2011, 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.

Table of Contents

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

Combined Condensed Results of Operations:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net revenue	\$ 54,650	\$ 61,358	\$ 165,483	\$ 178,180
Gross profit	\$ 34,411	\$ 38,294	\$ 105,175	\$ 110,659
Net income after taxes	\$ 5,399	\$ 7,858	\$ 20,083	\$ 9,142

Combined Condensed Balance Sheets:

	September 30, 2012	December 31, 2011
Current assets	\$ 84,101	\$ 84,376
Non-current assets	38,806	37,659
Total assets	\$ 122,907	\$ 122,035
Current liabilities	\$ 43,025	\$ 49,453
Non-current liabilities	7,355	6,326
Total liabilities	\$ 50,380	\$ 55,779

(18) Guarantor Financial Information

Our 9% senior subordinated notes due 2016, our 7.875% senior notes due 2016, and our 8.625% senior subordinated notes due 2018 are guaranteed by certain of our consolidated wholly owned subsidiaries, or the Guarantor Subsidiaries. The guarantees are full and unconditional and joint and several. The following supplemental financial information sets forth, on a consolidating basis, balance sheets as of September 30, 2012 and December 31, 2011, the related statements of operations and statements of comprehensive income for each of the three and nine months ended September 30, 2012 and 2011, respectively, and the statements of cash flows for the nine months ended September 30, 2012 and 2011, 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.

For comparative purposes, certain amounts for prior periods have been reclassified to conform to the current period classification.

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Three Months Ended September 30, 2012**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$	\$ 214,136	\$ 287,717	\$ (42,040)	\$ 459,813
Services revenue		148,897	77,518		226,415
Net product sales and services revenue		363,033	365,235	(42,040)	686,228
License and royalty revenue		(4,958)	4,914	5,232	5,188
Net revenue		358,075	370,149	(36,808)	691,416
Cost of net product sales	928	103,415	156,602	(37,333)	223,612
Cost of services revenue		81,134	41,239	(2,242)	120,131
Cost of net product sales and services revenue	928	184,549	197,841	(39,575)	343,743
Cost of license and royalty revenue			(3,334)	5,232	1,898
Cost of net revenue	928	184,549	194,507	(34,343)	345,641
Gross profit (loss)	(928)	173,526	175,642	(2,465)	345,775
Operating expenses:					
Research and development	6,292	17,088	17,182		40,562
Sales and marketing	1,220	74,871	84,553		160,644
General and administrative	11,392	42,706	51,739		105,837
Total operating expenses	18,904	134,665	153,474		307,043
Operating income (loss)	(19,832)	38,861	22,168	(2,465)	38,732
Interest expense, including amortization of original issue discounts and deferred financing costs	(54,324)	(9,205)	(2,856)	11,524	(54,861)
Other income (expense), net	1,534	8,298	620	(11,524)	(1,072)
Income (loss) before provision (benefit) for income taxes	(72,622)	37,954	19,932	(2,465)	(17,201)
Provision (benefit) for income taxes	(27,401)	5,099	12,558	(933)	(10,677)
Income (loss) before equity earnings of unconsolidated entities, net of tax	(45,221)	32,855	7,374	(1,532)	(6,524)
Equity in earnings (losses) of subsidiaries, net of tax	41,052	(230)		(40,822)	
Equity earnings of unconsolidated entities, net of tax	652		2,405	(50)	3,007
Net income (loss)	(3,517)	32,625	9,779	(42,404)	(3,517)
Less: Net income attributable to non-controlling interests			286		286
Net income (loss) attributable to Alere Inc. and Subsidiaries	(3,517)	32,625	9,493	(42,404)	(3,803)
Preferred stock dividends	(5,352)				(5,352)

Edgar Filing: ALERE INC. - Form 10-Q

Net income (loss) available to common stockholders	\$ (8,869)	\$ 32,625	\$ 9,493	\$ (42,404)	\$ (9,155)
---	------------	-----------	----------	-------------	------------

Table of Contents

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended September 30, 2011

(in thousands)

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$	\$ 227,479	\$ 224,801	\$ (34,026)	\$ 418,254
Services revenue		144,641	17,625		162,266
Net product sales and services revenue		372,120	242,426	(34,026)	580,520
License and royalty revenue		1,728	4,475	(954)	5,249
Net revenue		373,848	246,901	(34,980)	585,769
Cost of net product sales	1,097	100,514	127,086	(34,798)	193,899
Cost of services revenue		77,828	6,349		84,177
Cost of net product sales and services revenue	1,097	178,342	133,435	(34,798)	278,076
Cost of license and royalty revenue			2,685	(954)	1,731
Cost of net revenue	1,097	178,342	136,120	(35,752)	279,807
Gross profit (loss)	(1,097)	195,506	110,781	772	305,962
Operating expenses					
Research and development	5,063	16,195	13,514		34,772
Sales and marketing	1,973	78,667	53,736		134,376
General and administrative	7,424	52,300	32,171		91,895
Total operating expenses	14,460	147,162	99,421		261,043
Operating income (loss)	(15,557)	48,344	11,360	772	44,919
Interest expense, including amortization of original issue discounts and deferred financing costs	(46,857)	(13,418)	(4,240)	17,188	(47,327)
Other income (expense), net	4,055	14,889	(10,006)	(17,188)	(8,250)
Gain on sale of joint venture interest	16,309		272,587		288,896
Income (loss) from continuing operations before provision (benefit) for income taxes	(42,050)	49,815	269,701	772	278,238
Provision (benefit) for income taxes	(2,010)	19,156	25,475	31	42,652
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	(40,040)	30,659	244,226	741	235,586
Equity in earnings (losses) of subsidiaries, net of tax	279,392	(24)		(279,368)	
Equity earnings of unconsolidated entities, net of tax	352		3,772	(6)	4,118
Net income	239,704	30,635	247,998	(278,633)	239,704
Less: Net income attributable to non-controlling interests			138		138

Edgar Filing: ALERE INC. - Form 10-Q

Net income attributable to Alere Inc. and Subsidiaries	239,704	30,635	247,860	(278,633)	239,566
Preferred stock dividends	(5,358)				(5,358)
Net income available to common stockholders	\$ 234,346	\$ 30,635	\$ 247,860	\$ (278,633)	\$ 234,208

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS****For the Nine Months Ended September 30, 2012**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$	\$ 635,601	\$ 868,231	\$ (104,807)	\$ 1,399,025
Services revenue		447,886	204,818		652,704
Net product sales and services revenue		1,083,487	1,073,049	(104,807)	2,051,729
License and royalty revenue		8,807	10,191	(7,665)	11,333
Net revenue		1,092,294	1,083,240	(112,472)	2,063,062
Cost of net product sales	2,635	301,488	466,994	(99,453)	671,664
Cost of services revenue		238,528	95,264	(2,242)	331,550
Cost of net product sales and services revenue	2,635	540,016	562,258	(101,695)	1,003,214
Cost of license and royalty revenue			13,059	(7,665)	5,394
Cost of net revenue	2,635	540,016	575,317	(109,360)	1,008,608
Gross profit (loss)	(2,635)	552,278	507,923	(3,112)	1,054,454
Operating expenses:					
Research and development	17,361	50,850	51,798		120,009
Sales and marketing	3,096	229,649	245,799		478,544
General and administrative	37,590	147,677	162,490		347,757
Total operating expenses	58,047	428,176	460,087		946,310
Operating income (loss)	(60,682)	124,102	47,836	(3,112)	108,144
Interest expense, including amortization of original issue discounts and deferred financing costs	(158,009)	(31,090)	(10,054)	38,034	(161,119)
Other income (expense), net	(2,552)	33,563	21,593	(38,034)	14,570
Income (loss) before provision (benefit) for income taxes	(221,243)	126,575	59,375	(3,112)	(38,405)
Provision (benefit) for income taxes	(74,149)	40,637	21,870	(979)	(12,621)
Income (loss) before equity earnings of unconsolidated entities, net of tax	(147,094)	85,938	37,505	(2,133)	(25,784)
Equity in earnings (losses) of subsidiaries, net of tax	129,929	(763)		(129,166)	
Equity earnings of unconsolidated entities, net of tax	1,798		8,643	(24)	10,417
Net income (loss)	(15,367)	85,175	46,148	(131,323)	(15,367)
Less: Net income attributable to non-controlling interests			137		137
Net income (loss) attributable to Alere Inc. and Subsidiaries	(15,367)	85,175	46,011	(131,323)	(15,504)
Preferred stock dividends	(15,940)				(15,940)

Edgar Filing: ALERE INC. - Form 10-Q

Net income (loss) available to common stockholders	\$ (31,307)	\$ 85,175	\$ 46,011	\$ (131,323)	\$ (31,444)
---	-------------	-----------	-----------	--------------	-------------

Table of Contents**CONSOLIDATING STATEMENT OF OPERATIONS**

For the Nine Months Ended September 30, 2011

(in thousands)

	Issuer	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$	\$ 681,711	\$ 639,574	\$ (96,983)	\$ 1,224,302
Services revenue		443,173	50,220		493,393
Net product sales and services revenue		1,124,884	689,794	(96,983)	1,717,695
License and royalty revenue		6,948	15,028	(4,253)	17,723
Net revenue		1,131,832	704,822	(101,236)	1,735,418
Cost of net product sales	2,526	308,920	359,500	(97,027)	573,919
Cost of services revenue		232,463	18,925		251,388
Cost of net product sales and services revenue	2,526	541,383	378,425	(97,027)	825,307
Cost of license and royalty revenue			9,467	(4,253)	5,214
Cost of net revenue	2,526	541,383	387,892	(101,280)	830,521
Gross profit (loss)	(2,526)	590,449	316,930	44	904,897
Operating expenses:					
Research and development	15,041	49,865	47,756		112,662
Sales and marketing	2,922	245,481	159,570		407,973
General and administrative	35,797	172,127	84,360		292,284
Total operating expenses	53,760	467,473	291,686		812,919
Operating income (loss)	(56,286)	122,976	25,244	44	91,978
Interest expense, including amortization of original issue discounts and deferred financing costs	(108,308)	(88,472)	(12,472)	55,058	(154,194)
Other income (expense), net	9,761	41,377	(1,557)	(55,058)	(5,477)
Gain on sale of joint venture interest	16,309		272,587		288,896
Income (loss) from continuing operations before provision (benefit) for income taxes	(138,524)	75,881	283,802	44	221,203
Provision (benefit) for income taxes	(67,593)	33,211	30,062	(94)	(4,414)
Income (loss) from continuing operations before equity earnings of unconsolidated entities, net of tax	(70,931)	42,670	253,740	138	225,617
Equity in earnings of subsidiaries, net of tax	299,961	631		(300,592)	
Equity earnings of unconsolidated entities, net of tax	1,509		3,420	(7)	4,922
Net income	230,539	43,301	257,160	(300,461)	230,539
Less: Net income attributable to non-controlling interests			160		160

Edgar Filing: ALERE INC. - Form 10-Q

Net income attributable to Alere Inc. and Subsidiaries	230,539	43,301	257,000	(300,461)	230,379
Preferred stock dividends	(16,682)				(16,682)
Preferred stock repurchase	23,936				23,936
Net income available to common stockholders	\$ 237,793	\$ 43,301	\$ 257,000	\$ (300,461)	\$ 237,633

Table of Contents**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Three Months Ended September 30, 2012**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net income (loss)	\$ (3,517)	\$ 32,625	\$ 9,779	\$ (42,404)	\$ (3,517)
Other comprehensive income, before tax:					
Changes in cumulative translation adjustment	132	1	36,027	3,535	39,695
Unrealized gains on available for sale securities	141				141
Unrealized gains on hedging instruments			10		10
Minimum pension liability adjustment			(98)		(98)
Other comprehensive income, before tax	273	1	35,939	3,535	39,748
Income tax provision related to items of other comprehensive income	360				360
Other comprehensive income (loss), net of tax	(87)	1	35,939	3,535	39,388
Comprehensive income (loss)	(3,604)	32,626	45,718	(38,869)	35,871
Less: Comprehensive income attributable to non-controlling interests			286		286
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (3,604)	\$ 32,626	\$ 45,432	\$ (38,869)	\$ 35,585

Table of Contents**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME****For the Three Months Ended September 30, 2011**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net income	\$ 239,704	\$ 30,635	\$ 247,998	\$ (278,633)	\$ 239,704
Other comprehensive loss, before tax:					
Changes in cumulative translation adjustment	(877)	(147)	(46,635)	(9,078)	(56,737)
Unrealized losses on available for sale securities	(230)		(395)		(625)
Unrealized losses on hedging instruments	(87)				(87)
Minimum pension liability adjustment			246		246
Other comprehensive loss, before tax	(1,194)	(147)	(46,784)	(9,078)	(57,203)
Income tax benefit related to items of other comprehensive income	(34)		(145)		(179)
Other comprehensive loss, net of tax	(1,160)	(147)	(46,639)	(9,078)	(57,024)
Comprehensive income	238,544	30,488	201,359	(287,711)	182,680
Less: Comprehensive income attributable to non-controlling interests			138		138
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 238,544	\$ 30,488	\$ 201,221	\$ (287,711)	\$ 182,542

Table of Contents**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)****For the Nine Months Ended September 30, 2012**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net income (loss)	\$ (15,367)	\$ 85,175	\$ 46,148	\$ (131,323)	\$ (15,367)
Other comprehensive income, before tax:					
Changes in cumulative translation adjustment	(100)	78	36,756	2,123	38,857
Unrealized gains on available for sale securities	926		5		931
Unrealized gains on hedging instruments	17		448		465
Minimum pension liability adjustment			(218)		(218)
Other comprehensive income, before tax	843	78	36,991	2,123	40,035
Income tax provision related to items of other comprehensive income	360				360
Other comprehensive income, net of tax	483	78	36,991	2,123	39,675
Comprehensive income (loss)	(14,884)	85,253	83,139	(129,200)	24,308
Less: Comprehensive income attributable to non-controlling interests			137		137
Comprehensive income (loss) attributable to Alere Inc. and Subsidiaries	\$ (14,884)	\$ 85,253	\$ 83,002	\$ (129,200)	\$ 24,171

Table of Contents**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME****For the Nine Months Ended September 30, 2011**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net income	\$ 230,539	\$ 43,301	\$ 257,160	\$ (300,461)	\$ 230,539
Other comprehensive income (loss), before tax:					
Changes in cumulative translation adjustment	2	26	(14,436)	(3,708)	(18,116)
Unrealized losses on available for sale securities	(163)		(781)		(944)
Unrealized gains on hedging instruments	11,901				11,901
Minimum pension liability adjustment			326		326
Other comprehensive income (loss), before tax	11,740	26	(14,891)	(3,708)	(6,833)
Income tax provision (benefit) related to items of other comprehensive income (loss)	4,630		(197)		4,433
Other comprehensive income (loss), net of tax	7,110	26	(14,694)	(3,708)	(11,266)
Comprehensive income	237,649	43,327	242,466	(304,169)	219,273
Less: Comprehensive income attributable to non-controlling interests			160		160
Comprehensive income attributable to Alere Inc. and Subsidiaries	\$ 237,649	\$ 43,327	\$ 242,306	\$ (304,169)	\$ 219,113

Table of Contents**CONSOLIDATING BALANCE SHEET**

September 30, 2012

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	\$ 329	\$ 54,143	\$ 247,782	\$	\$ 302,254
Restricted cash		1,579	1,637		3,216
Marketable securities		784	113		897
Accounts receivable, net of allowances		196,992	311,599		508,591
Inventories, net		129,367	211,718	(8,573)	332,512
Deferred tax assets	(20,577)	22,261	5,624	2,885	10,193
Receivable from joint venture, net		1,846	2,171		4,017
Prepaid expenses and other current assets	345,055	(274,064)	68,073	(25)	139,039
Intercompany receivables	386,441	488,163	81,007	(955,611)	
Total current assets	711,248	621,071	929,724	(961,324)	1,300,719
Property, plant and equipment, net	2,114	267,557	247,560	(417)	516,814
Goodwill		1,528,228	1,503,861		3,032,089
Other intangible assets with indefinite lives		7,100	50,381		57,481
Finite-lived intangible assets, net	27,242	887,966	970,028		1,885,236
Deferred financing costs, net and other non-current assets	80,769	5,662	10,655	(55)	97,031
Receivable from joint venture, net of current portion			14,533		14,533
Investments in subsidiaries	3,598,821	50,204	2,809	(3,651,834)	
Investments in unconsolidated entities	34,792		59,229		94,021
Marketable securities	3,181				3,181
Deferred tax assets			11,576		11,576
Intercompany notes receivable	2,124,101	794,610	6,751	(2,925,462)	
Total assets	\$ 6,582,268	\$ 4,162,398	\$ 3,807,107	\$ (7,539,092)	\$ 7,012,681
LIABILITIES AND EQUITY					
Current liabilities:					
Current portion of long-term debt	\$ 45,000	\$	\$ 7,486	\$	\$ 52,486
Current portion of capital lease obligations		2,605	3,769		6,374
Accounts payable	10,665	52,749	99,754		163,168
Accrued expenses and other current liabilities	75,888	115,032	235,232	(598)	425,554
Intercompany payables	491,222	125,491	338,897	(955,610)	
Total current liabilities	622,775	295,877	685,138	(956,208)	647,582
Long-term liabilities:					
Long-term debt, net of current portion	3,504,811		22,768		3,527,579
Capital lease obligations, net of current portion		4,734	8,977		13,711
Deferred tax liabilities	(38,630)	266,120	185,769	549	413,808
Other long-term liabilities	22,600	38,042	117,819	(55)	178,406
Intercompany notes payables	241,421	1,548,960	1,135,081	(2,925,462)	
Total long-term liabilities	3,730,202	1,857,856	1,470,414	(2,924,968)	4,133,504

Edgar Filing: ALERE INC. - Form 10-Q

Stockholders equity	2,229,291	2,008,665	1,649,251	(3,657,916)	2,229,291
Non-controlling interests			2,304		2,304
Total equity	2,229,291	2,008,665	1,651,555	(3,657,916)	2,231,595
Total liabilities and equity	\$ 6,582,268	\$ 4,162,398	\$ 3,807,107	\$ (7,539,092)	\$ 7,012,681

Table of Contents**CONSOLIDATING BALANCE SHEET**

December 31, 2011

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	\$ 12,451	\$ 85,838	\$ 200,884	\$	\$ 299,173
Restricted cash		1,591	7,396		8,987
Marketable securities		770	316		1,086
Accounts receivable, net of allowances		199,547	276,277		475,824
Inventories, net		136,091	189,886	(5,708)	320,269
Deferred tax assets	10,912	22,813	7,266	1,984	42,975
Receivable from joint venture, net		2,301	202		2,503
Prepaid expenses and other current assets	(74,078)	138,329	78,659		142,910
Intercompany receivables	397,914	426,136	27,871	(851,921)	
Total current assets	347,199	1,013,416	788,757	(855,645)	1,293,727
Property, plant and equipment, net	2,542	274,588	214,206	(131)	491,205
Goodwill		1,530,324	1,295,791	(4,844)	2,821,271
Other intangible assets with indefinite lives		7,100	62,446		69,546
Finite-lived intangible assets, net	28,685	1,011,852	745,388		1,785,925
Deferred financing costs, net, and other non-current assets	88,153	5,532	4,101		97,786
Receivable from joint venture, net of current portion			15,455		15,455
Investments in subsidiaries	3,586,625	32,512	3,005	(3,622,142)	
Investments in unconsolidated entities	29,021		56,117		85,138
Marketable securities	2,254				2,254
Deferred tax assets			10,394		10,394
Intercompany notes receivable	1,934,366	(196,820)		(1,737,546)	
Total assets	\$ 6,018,845	\$ 3,678,504	\$ 3,195,660	\$ (6,220,308)	\$ 6,672,701
LIABILITIES AND EQUITY					
Current liabilities:					
Current portion of long-term debt	\$ 43,000	\$	\$ 18,092	\$	\$ 61,092
Current portion of capital lease obligations		1,550	4,533		6,083
Short-term debt	6,240				6,240
Accounts payable	6,704	53,978	94,782		155,464
Accrued expenses and other current liabilities	(259,010)	455,366	199,217		395,573
Intercompany payables	429,644	104,257	318,018	(851,919)	
Total current liabilities	226,578	615,151	634,642	(851,919)	624,452
Long-term liabilities:					
Long-term debt, net of current portion	3,243,341		24,110		3,267,451
Capital lease obligations, net of current portion		2,175	10,454		12,629
Deferred tax liabilities	(25,936)	303,837	102,730	69	380,700
Other long-term liabilities	24,407	47,135	81,856		153,398
Intercompany notes payables	321,221	658,573	754,650	(1,734,444)	

Edgar Filing: ALERE INC. - Form 10-Q

Total long-term liabilities	3,563,033	1,011,720	973,800	(1,734,375)	3,814,178
Redeemable non-controlling interest			2,497		2,497
Stockholders equity	2,229,234	2,051,633	1,582,381	(3,634,014)	2,229,234
Non-controlling interests			2,340		2,340
Total equity	2,229,234	2,051,633	1,584,721	(3,634,014)	2,231,574
Total liabilities and equity	\$ 6,018,845	\$ 3,678,504	\$ 3,195,660	\$ (6,220,308)	\$ 6,672,701

Table of Contents**CONSOLIDATING STATEMENT OF CASH FLOWS****For the Nine Months Ended September 30, 2012**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net income (loss)	\$ (15,367)	\$ 85,175	\$ 46,148	\$ (131,323)	\$ (15,367)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	(129,929)	763		129,166	
Non-cash interest expense, including amortization of original issue discounts and deferred financing costs	15,929	158			16,087
Depreciation and amortization	4,314	168,622	149,416	19	322,371
Non-cash charges for sale of inventories revalued at the date of acquisition		1,400	3,281		4,681
Non-cash stock-based compensation expense	3,119	4,309	4,440		11,868
Impairment of inventory		5	290		295
Impairment of long-lived assets		219	55		274
(Gain) loss on sale of property, plant and equipment	3	(4,037)	(160)		(4,194)
Equity earnings of unconsolidated entities, net of tax	(1,798)		(8,643)	24	(10,417)
Deferred income taxes	20,901	(35,762)	(27,855)	(903)	(43,619)
Other non-cash items	(1,156)	685	6,207		5,736
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		2,555	(10,816)		(8,261)
Inventories, net		4,829	(23,251)	2,826	(15,596)
Prepaid expenses and other current assets	(419,146)	412,393	10,899	25	4,171
Accounts payable	3,961	(685)	(20,019)		(16,743)
Accrued expenses and other current liabilities	354,452	(338,933)	9,181	(584)	24,116
Other non-current liabilities	(7,158)	(6,676)	(8,233)	428	(21,639)
Intercompany payable (receivable)	297,741	(287,831)	(7,787)	(2,123)	
Net cash provided by (used in) operating activities	125,866	7,189	123,153	(2,445)	253,763
Cash Flows from Investing Activities:					
Decrease in restricted cash		12	5,759		5,771
Purchases of property, plant and equipment	(308)	(58,785)	(104,618)	66,402	(97,309)
Proceeds from sale of property, plant and equipment	(841)	22,230	66,281	(65,287)	22,383
Cash paid for acquisitions, net of cash acquired	(364,731)		(20,049)		(384,780)
Cash received from sales of marketable securities		57	214		271
Net cash received from equity method investments	490		6,066		6,556
(Increase) decrease in other assets	(10,028)	(1,401)	2,061	55	(9,313)
Net cash provided by (used in) investing activities	(375,418)	(37,887)	(44,286)	1,170	(456,421)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(2,313)				(2,313)
Cash paid for contingent purchase price consideration	(16,248)				(16,248)
Proceeds from issuance of common stock, net of issuance costs	14,260				14,260
Proceeds from issuance of long-term debt	198,000		288		198,288
Payments on long-term debt	(33,250)		(9,303)		(42,553)
Net proceeds (payments) under revolving credit facilities	97,500		(6,338)		91,162

Edgar Filing: ALERE INC. - Form 10-Q

Payments on short-term debt	(6,240)				(6,240)
Cash paid for dividends	(15,970)				(15,970)
Excess tax benefits on exercised stock options	183	74	20		277
Principal payments on capital lease obligations		(1,402)	(3,523)		(4,925)
Other			(2,811)		(2,811)
Net cash provided by (used in) financing activities	235,922	(1,328)	(21,667)		212,927
Foreign exchange effect on cash and cash equivalents	1,508	331	(10,302)	1,275	(7,188)
Net increase (decrease) in cash and cash equivalents	(12,122)	(31,695)	46,898		3,081
Cash and cash equivalents, beginning of period	12,451	85,838	200,884		299,173
Cash and cash equivalents, end of period	\$ 329	\$ 54,143	\$ 247,782	\$	\$ 302,254

Table of Contents**CONSOLIDATING STATEMENT OF CASH FLOWS****For the Nine Months Ended September 30, 2011**

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net income	\$ 230,539	\$ 43,301	\$ 257,160	\$ (300,461)	\$ 230,539
Adjustments to reconcile net income to net cash provided by (used in) operating activities:					
Equity in earnings of subsidiaries, net of tax	(299,961)	(631)		300,592	
Non-cash interest expense, including amortization of original issue discounts and write-off of deferred financing costs	8,630	23,678	418		32,726
Depreciation and amortization	2,650	191,197	93,487	(301)	287,033
Non-cash stock-based compensation expense	4,565	6,354	5,356		16,275
Impairment of inventory		172	273		445
Impairment of long-lived assets	2	1,331	341		1,674
Impairment of intangible assets		2,935	3		2,938
Gain on sale of joint venture interest	(16,309)		(272,587)		(288,896)
(Gain) loss on sale of fixed assets	75	1,132	(111)		1,096
Gain on sales of marketable securities			(376)		(376)
Equity earnings of unconsolidated entities, net of tax	(1,509)		(3,420)	7	(4,922)
Deferred income taxes	6,270	(45,374)	8,203	(98)	(30,999)
Other non-cash items	(2,774)	3,080	(8,421)		(8,115)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net		(8,061)	(22,771)		(30,832)
Inventories, net		437	(17,431)	(19)	(17,013)
Prepaid expenses and other current assets	(2,333)	763	(15,794)		(17,364)
Accounts payable	3,201	(29)	8,805		11,977
Accrued expenses and other current liabilities	(27,881)	73,020	19,335	2,295	66,769
Other non-current liabilities	(5,455)	2,995	(27,988)		(30,448)
Intercompany payable (receivable)	(1,393,133)	925,802	467,331		
Net cash provided by (used in) operating activities	(1,493,423)	1,222,102	491,813	2,015	222,507
Cash Flows from Investing Activities:					
Decrease (increase) in restricted cash		160	(347,130)		(346,970)
Purchases of property, plant and equipment	(1,148)	(48,335)	(45,431)	222	(94,692)
Proceeds from sale of property, plant and equipment		293	553		846
Proceeds from disposition of business			11,491		11,491
Cash paid for acquisitions, net of cash acquired	(39,007)	(5,400)	(82,674)		(127,081)
Proceeds from sales of marketable securities	268	190	7,934		8,392
Net cash received from equity method investments	(2,920)		(41,182)		(44,102)
Increase in other assets	(31,824)	(15,878)	(5,133)	(3,053)	(55,888)
Net cash used in investing activities	(74,631)	(68,970)	(501,572)	(2,831)	(648,004)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(65,813)	(525)			(66,338)
Cash paid for contingent purchase price consideration	(25,305)				(25,305)
Proceeds from issuance of common stock, net of issuance costs	24,159				24,159

Edgar Filing: ALERE INC. - Form 10-Q

Repurchase of preferred stock	(99,068)			(99,068)
Proceeds from long-term debt	1,750,000	937	1,771	1,752,708
Payments on long-term debt		(1,192,344)	(2,993)	(1,195,337)
Net proceeds under revolving credit facilities	100,000		4,808	104,808
Repurchase of common stock	(184,867)			(184,867)
Excess tax benefits on exercised stock options	1,403	429	351	2,183
Principal payments on capital lease obligations		(1,783)	(1,301)	(3,084)
Other	(10,251)		(200)	(10,451)
Net cash provided by (used in) financing activities	1,490,258	(1,193,286)	2,436	299,408
Foreign exchange effect on cash and cash equivalents	(102)	27	796	816
Net decrease in cash and cash equivalents	(77,898)	(40,127)	(6,527)	(124,552)
Cash and cash equivalents, beginning of period	101,666	116,112	183,528	401,306
Cash and cash equivalents, end of period	\$ 23,768	\$ 75,985	\$ 177,001	\$ 276,754

Table of Contents

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 in this item include, without limitation, statements regarding anticipated expansion and growth in certain of our product and service offerings, the impact of our research and development activities, potential new product and technology achievements, the potential for selective acquisitions, our ability to improve our working capital and operating margins, our expectations with respect to Apollo, our integrated health management technology platform, our ability to improve care and lower healthcare costs for both providers and patients, our predictions regarding the regulatory matters relating to our Triage products and the resulting financial consequences, the impact of recent and planned changes to our quality control release specifications, our predictions regarding our ability to meet customer demand, and our funding plans for our future working capital needs and commitments. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K, as amended, for the year ended December 31, 2011 and other risk factors identified herein or from time to time in our periodic filings with the Securities and Exchange Commission. We do not undertake any obligation to update any forward-looking statements. 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 enable individuals to take charge of improving their health and quality of life at home, under medical supervision, by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global, leading products and services, as well as our new product development efforts, currently focus on cardiology, infectious disease, toxicology, diabetes, oncology and women's health. We are continuing to expand our product and service offerings in all of these categories.

As a global, leading supplier of near-patient monitoring tools, as well as value-added healthcare services, we are well positioned to improve care and lower healthcare costs for both providers and patients. Our home coagulation monitoring business, which supports doctors and patients efforts to monitor warfarin therapy using our INRatio blood coagulation monitoring system, continues to represent an early example of this. We have also continued to introduce our integrated health management technology platform, called Apollo, to our customers since its launch on January 1, 2010. Using a sophisticated data engine for acquiring and analyzing information, combined with a state of the art touch engine for communicating with individuals and their health partners, we expect Apollo to benefit healthcare providers, health insurers and patients alike by enabling more efficient and effective health management programs.

We have continued to grow through strategic acquisitions. With our November 2011 acquisitions of Axis-Shield plc, or Axis-Shield, and Arriva Medical, LLC, we have entered the diabetes diagnostics market, and we expect our presence in this field to grow. We also continued to expand our toxicology business, particularly in the growing market for pain management and medication monitoring services. We have also acquired software solutions that will further our efforts to connect healthcare providers with point of care and other patient data.

We have also continued to lay the groundwork for future revenue and earnings growth by focusing our efforts on new product development and introductions. Our important new product offerings, including the ePoc System, the Alere CD4 Analyzer and the Alere Heart Check System, have begun to penetrate the markets into which they have been launched, and we expect this trend to continue. We are also focused on expanding our global sales force. We also continued to build awareness and acceptance for our two novel biomarkers, NGAL and placental growth factor, or PLGF.

FDA and OIG Matters Relating to Alere Triage Products

In March 2012, the Food & Drug Administration, or FDA, began an inspection of our San Diego facility related to our Alere Triage products. During the inspection, the FDA expressed concern about the alignment between certain aspects of our labeling for the Alere Triage products and the quality control release specifications that had been in effect prior to the inspection. As a result and as previously disclosed, we implemented two recalls of Alere Triage products during the second quarter of 2012, as well as interim quality control release specifications. In June 2012, the FDA closed the inspection, and we received inspectional observations on FDA Form 483. In July 2012, we provided the FDA with a detailed response to its inspectional observations which included a plan for how

Table of Contents

we proposed to address each observation as well as a timeline for doing so. Since submitting this response, we have been working diligently to address each of these observations. Also, on or about September 28, 2012, we agreed with the FDA on a set of final release specifications for our Alere Triage meter-based products that further align the product release specifications to the package insert.

On October 9, 2012, we received a warning letter from the FDA citing the same inspectional observations set forth in the FDA Form 483 received in June. The warning letter, which was subsequently reissued as of October 22, 2012, acknowledged our July response but did not take into account the timeline that we had proposed or any of our efforts taken after our July response. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions detailed in our July response, including all of the actions then due under our timeline. We will continue to provide the FDA with further periodic updates on the status of the actions that remain to be completed over the next several months to fully address the issues that the FDA has identified. We intend to continue to work diligently to address all of the FDA's inspectional observations, but we cannot provide any assurance that the FDA will find our efforts satisfactory.

As we anticipated, the final release specifications agreed to with the FDA for our Alere Triage products have resulted in lower manufacturing yields for those products. While we continue to make significant progress in controlling our manufacturing process to improve overall yields, we also continue to expand our manufacturing capacity to address the lower yield rates. These efforts, as well as our efforts to address the FDA's observations set forth in the FDA Form 483 and the warning letter, have increased our manufacturing costs and reduced our margins on these products.

Also, in May 2012, we received a subpoena from the Office of Inspector General of the Department of Health and Human Services. The subpoena seeks documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the government and are in the process of responding to the subpoena.

We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with these matters. Also, except for increases in manufacturing costs and decreased profitability for our Alere Triage products, we are unable to predict what impact, if any, these matters or ensuing proceedings, if any, will have on our financial condition, results of operations or cash flows. Please see Part II, Item 1A, "Risk Factors" for a further discussion of the risks to our business, financial condition and results of operations arising from these matters.

Financial Highlights

Net revenue increased by \$105.6 million, or 18%, to \$691.4 million for the three months ended September 30, 2012, from \$585.8 million for the three months ended September 30, 2011. Net revenue increased by \$327.6 million, or 19%, to \$2.1 billion for the nine months ended September 30, 2012, from \$1.7 billion for the nine months ended September 30, 2011.

Gross profit increased by \$39.8 million, or 13%, to \$345.8 million for the three months ended September 30, 2012, from \$306.0 million for the three months ended September 30, 2011. Gross profit increased by \$149.6 million, or 17%, to \$1.1 billion for the nine months ended September 30, 2012, from \$904.9 million for the nine months ended September 30, 2011.

For the three months ended September 30, 2012, we generated a net loss available to common stockholders of \$9.2 million, or \$0.11 per basic common share. For the three months ended September 30, 2011, we generated net income available to common stockholders of \$234.2 million, or \$2.48 per diluted common share. For the nine months ended September 30, 2012, we generated a net loss available to common stockholders of \$31.4 million, or \$0.39 per basic common share. For the nine months ended September 30, 2011, we generated net income available to common stockholders of \$237.6 million, or \$2.56 per diluted common share.

During the third quarter of 2011, the Procter & Gamble Company's, or P&G's, option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, we recognized a gain totaling approximately \$288.9 million during the third quarter of 2011.

Results of Operations

Edgar Filing: ALERE INC. - Form 10-Q

Results excluding the impact of 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 trends. Our results of operations were as follows:

Net Product Sales and Services Revenue, Total and by Business Segment. Net product sales and services revenue increased by \$105.7 million, or 18%, to \$686.2 million for the three months ended September 30, 2012, from \$580.5 million for the three months ended September 30, 2011. Excluding the impact of currency translation, net product sales and services revenue for the three months ended September 30, 2012 increased by \$119.9 million, or 21%, compared to the three months ended September 30, 2011. Net product sales and services revenue increased by \$334.0 million, or 19%, to \$2.1 billion for the nine months ended

Table of Contents

September 30, 2012, from \$1.7 billion for the nine months ended September 30, 2011. Excluding the impact of currency translation, net product sales and services revenue for the nine months ended September 30, 2012 increased by \$365.5 million, or 21%, compared to the nine months ended September 30, 2011. Net product sales and services revenue by business segment for the three and nine months ended September 30, 2012 and 2011 are as follows (in thousands):

	Three Months Ended			Nine Months Ended		
	September 30, 2012	September 30, 2011	% Change	September 30, 2012	September 30, 2011	% Change
Professional diagnostics	\$ 528,754	\$ 426,251	24%	\$ 1,581,076	\$ 1,240,251	27%
Health management	135,078	129,931	4%	404,452	408,566	(1)%
Consumer diagnostics	22,396	24,338	(8)%	66,201	68,878	(4)%
Net product sales and services revenue	\$ 686,228	\$ 580,520	18%	\$ 2,051,729	\$ 1,717,695	19%

Professional Diagnostics

The following table summarizes our net product sales and services revenue from our professional diagnostics business segment by groups of similar products and services for the three and nine months ended September 30, 2012 and 2011 (in thousands):

	Three Months Ended			Nine Months Ended		
	September 30, 2012	September 30, 2011	% Change	September 30, 2012	September 30, 2011	% Change
Cardiology	\$ 122,372	\$ 127,943	(4)%	\$ 386,795	\$ 390,652	(1)%
Infectious disease	136,561	142,639	(4)%	425,398	405,559	5%
Toxicology	156,074	93,497	67%	437,736	267,834	63%
Diabetes	35,670		N/A	100,628		N/A
Other	78,077	62,172	26%	230,519	176,206	31%

Professional diagnostics net product sales and services revenue	\$ 528,754	\$ 426,251	24%	\$ 1,581,076	\$ 1,240,251	27%
---	------------	------------	-----	--------------	--------------	-----

Net product sales and services revenue from our professional diagnostics business segment increased by \$102.5 million, or 24%, to \$528.8 million for the three months ended September 30, 2012, from \$426.3 million for the three months ended September 30, 2011. Excluding the impact of currency translation, net product sales and services revenue from our professional diagnostics business segment increased by \$116.5 million, or 27%, comparing the three months ended September 30, 2012 to the three months ended September 30, 2011. Revenue increased primarily as a result of acquisitions, which contributed an aggregate of \$133.6 million of the non-currency adjusted increase. Net product sales from our North American flu-related sales decreased approximately \$6.1 million, from \$16.0 million during the three months ended September 30, 2011 to \$9.9 million during the three months ended September 30, 2012. Net product sales and services revenue from our professional diagnostics business segment were negatively impacted by the FDA recall matters related to our Alere Triage[®] meter-based products. Net product sales of meter-based Triage products in the U.S. totaled \$34.9 million during the three months ended September 30, 2012, as compared to \$48.2 million during the three months ended September 30, 2011. Excluding the impact of acquisitions, the decrease in flu-related sales during the comparable periods and the impact of the reduction in net product sales from meter-based Triage products in the U.S., the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was approximately \$3.0 million, or 1%, from the three months ended September 30, 2011 to the three months ended September 30, 2012.

Within our professional diagnostics business segment, net product sales and services revenue for our cardiology business decreased by approximately \$5.6 million, or 4%, to \$122.4 million for the three months ended September 30, 2012, from \$127.9 million for the three months ended September 30, 2011, driven principally by the impact of the FDA recall of certain of our meter-based Triage products in the U.S. Net product sales and services revenue for our infectious disease business decreased by approximately \$6.1 million, or 4%, to \$136.6 million for the three months ended September 30, 2012, from \$142.6 million for the three months ended September 30, 2011. The change was driven principally by a decrease in flu-related sales during the comparable periods as well as a decrease in both HIV and Malaria sales, both of which compare to particularly strong sales during the comparable periods, and suffered certain delays in shipments during the three months ended

Edgar Filing: ALERE INC. - Form 10-Q

September 30, 2012, but should be reversed in the fourth quarter of 2012. Our toxicology business increased by approximately \$62.6 million, or 67%, to \$156.1 million for the three months ended September 30, 2012, from \$93.5 million for the three months ended September 30, 2011, with our recent acquisitions of Avee Laboratories Inc., or Avee, eScreen, Inc., or eScreen, and Amedica Biotech, Inc., or Amedica, contributing a combined net \$62.5 million of the non-currency adjusted increase.

Table of Contents

Net product sales and services revenue from our professional diagnostics business segment increased by \$340.8 million, or 27%, to \$1.6 billion for the nine months ended September 30, 2012, from \$1.2 billion for the nine months ended September 30, 2011. Excluding the impact of currency translation, net product sales and services revenue from our professional diagnostics business segment increased by \$372.4 million, or 30%, comparing the nine months ended September 30, 2012 to the nine months ended September 30, 2011. Revenue increased primarily as a result of acquisitions, which contributed an aggregate of \$363.5 million of the non-currency adjusted increase. Partially offsetting the increase in net product sales and services revenue contributed by acquisitions was a decrease in our North American flu-related net product sales during the nine months ended September 30, 2012, as compared to the nine months ended September 30, 2011. Net product sales from our North American flu-related sales decreased approximately \$17.1 million, from \$37.8 million during the nine months ended September 30, 2011 to \$20.6 million during the nine months ended September 30, 2012, as a result of lower than normal flu levels observed in 2012 versus the more typical flu levels observed in 2011. Net product sales and services revenue from our professional diagnostics business segment were negatively impacted by the FDA recall matters related to our Alere Triage® meter-based products. Net product sales of meter-based Triage products in the U.S. totaled \$126.0 million during the nine months ended September 30, 2012, as compared to \$151.8 million during the nine months ended September 30, 2011. Excluding the impact of acquisitions, the decrease in flu-related sales during the comparable periods and the impact of the reduction in net product sales from meter-based Triage products in the U.S., the currency-adjusted organic growth for our professional diagnostics net product sales and services revenue was approximately \$53.5 million, or 5%, from the nine months ended September 30, 2011 to the nine months ended September 30, 2012.

Within our professional diagnostics business segment, net product sales and services revenue for our cardiology business decreased by approximately \$3.9 million, or 1%, to \$386.8 million for the nine months ended September 30, 2012, from \$390.7 million for the nine months ended September 30, 2011, driven by a \$19.3 million decrease in our meter-based Triage net product sales in the U.S. during the nine months ended September 30, 2012, as compared to the nine months ended September 30, 2011, partially offset by \$17.8 million contributed by the acquisition of Axis-Shield. Net product sales and services revenue for our infectious disease business increased by approximately \$19.8 million, or 5%, to \$425.4 million for the nine months ended September 30, 2012, from \$405.6 million for the nine months ended September 30, 2011, with the acquisition of Axis-Shield contributing \$23.8 million of such increase, and a \$4.5 million increase in our CD4 net product sales during the comparable periods, partially offset by a \$17.1 million decrease in our North American flu-related net product sales during the nine months ended September 30, 2012, as compared to the nine months ended September 30, 2011. Our toxicology business increased by approximately \$169.9 million, or 63%, to \$437.7 million for the nine months ended September 30, 2012, from \$267.8 million for the nine months ended September 30, 2011, with our recent acquisitions of Avee, eScreen and Amedica contributing a combined net \$154.4 million of the non-currency adjusted increase.

Health Management

The following table summarizes our net product sales and services revenue from our health management business segment by groups of similar products and services for the three and nine months ended September 30, 2012 and 2011 (in thousands):

	Three Months Ended			Nine Months Ended		
	September 30, 2012	September 30, 2011	% Change	September 30, 2012	September 30, 2011	% Change
Disease and case management	\$ 57,383	\$ 59,441	(3)%	\$ 165,277	\$ 182,118	(9)%
Wellness	24,290	24,427	(1)%	80,881	80,369	1%
Women s & children s health	29,136	28,509	2%	90,220	85,550	5%
Patient self-testing services	24,269	17,554	38%	68,074	60,529	12%
Health management net product sales and services revenue	\$ 135,078	\$ 129,931	4%	\$ 404,452	\$ 408,566	(1)%

Our health management net product sales and services revenue increased by \$5.1 million, or 4%, to \$135.1 million for the three months ended September 30, 2012, from \$130.0 million for the three months ended September 30, 2011. The increase in net product sales and services revenue was principally driven by an increase in our home coagulation monitoring programs due to the recognition of incremental patients and simultaneous reduction in patient attrition rates.

Our health management net product sales and services revenue decreased by \$4.1 million, or 1%, to \$404.5 million for the nine months ended September 30, 2012, from \$408.6 million for the nine months ended September 30, 2011. Net product sales and services revenue in our health management segment was adversely impacted by the increasingly competitive environment, including pricing pressures, the impact of health plans insourcing less differentiated services, such as disease and case management, and state budget pressures.

Table of Contents*Consumer Diagnostics*

Net product sales and services revenue from our consumer diagnostics business segment decreased by \$1.9 million, or 8%, to \$22.4 million for the three months ended September 30, 2012, from \$24.3 million for the three months ended September 30, 2011. Net product sales by our 50/50 joint venture with P&G, or SPD, were \$47.6 million during the three months ended September 30, 2012, as compared to \$54.8 million during the three months ended September 30, 2011.

Net product sales and services revenue from our consumer diagnostics business segment decreased by \$2.7 million, or 4%, to \$66.2 million for the nine months ended September 30, 2012, from \$68.9 million for the nine months ended September 30, 2011. Net product sales by SPD, were \$145.0 million during the nine months ended September 30, 2012, as compared to \$160.0 million during the nine months ended September 30, 2011.

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 was \$5.2 million for both the three months ended September 30, 2012 and 2011. License and royalty revenue decreased by approximately \$6.4 million, or 36%, to \$11.3 million for the nine months ended September 30, 2012, from \$17.7 million for the nine months ended September 30, 2011. The decrease in royalty revenue for the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011, was largely driven by an amendment to our license agreement with Quidel during 2011 whereby the license agreement was converted to a fully paid-up license. As a result of the amendment, we did not record royalty revenue from Quidel during the nine months ended September 30, 2012 and do not anticipate recording royalty revenue from Quidel in the future.

Gross Profit and Margin. Gross profit increased by \$39.8 million, or 13%, to \$345.8 million for the three months ended September 30, 2012, from \$306.0 million for the three months ended September 30, 2011. Gross profit increased by \$149.6 million, or 17%, to \$1.1 billion for nine months ended September 30, 2012, from \$904.9 million for the nine months ended September 30, 2011. The increase in gross profit during the three and nine months ended September 30, 2012 compared to the three and nine months ended September 30, 2011 was attributed to the increase in net product sales and services revenue resulting from acquisitions.

Cost of net revenue included amortization expense of \$18.4 million and \$51.6 million for the three and nine months ended September 30, 2012, respectively, compared to \$14.0 million and \$48.2 million for the three and nine months ended September 30, 2011. Included in cost of net revenue for the nine months ended September 30, 2012 was a \$4.7 million non-cash charge relating to the write-up of inventory to fair value in connection with the acquisition of Axis-Shield.

Overall gross margin for the three and nine months ended September 30, 2012 was 50% and 51%, respectively, compared to 52% for both the three and nine months ended September 30, 2011.

Gross Profit from Net Product Sales and Services Revenue, Total and by Business Segment. Gross profit from net product sales and services revenue increased by \$40.0 million, or 13%, to \$342.5 million for the three months ended September 30, 2012, from \$302.4 million for the three months ended September 30, 2011. Gross profit from net product sales and services revenue increased by \$156.1 million, or 17%, to \$1.0 billion for the nine months ended September 30, 2012, from \$892.4 million for the nine months ended September 30, 2011. Gross profit from net product sales and services revenue by business segment for the three and nine months ended September 30, 2012 and 2011 are as follows (in thousands):

	Three Months Ended			Nine Months Ended		
	September 30,		%	September 30,		%
	2012	2011	Change	2012	2011	Change
Professional diagnostics	\$ 276,906	\$ 238,414	16%	\$ 853,676	\$ 687,131	24%
Health management	60,358	58,609	3%	180,460	189,867	(5)%
Consumer diagnostics	5,221	5,421	(4)%	14,379	15,390	(7)%
Gross profit from net product sales and services revenue	\$ 342,485	\$ 302,444	13%	\$ 1,048,515	\$ 892,388	17%

Professional Diagnostics

Edgar Filing: ALERE INC. - Form 10-Q

Gross profit from our professional diagnostics net product sales and services revenue increased by \$38.5 million, or 16%, to \$276.9 million for the three months ended September 30, 2012, compared to \$238.4 million for the three months ended September 30, 2011, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above. Gross profit was negatively impacted comparing the three months ended September 30, 2012 to the three months ended September 30, 2011, as a result of a decrease in our meter-based Triage product sales and our North American flu-related sales, as discussed above. The FDA recall matter relating to our meter-based Triage products also resulted in incremental costs during the three months ended September 30, 2012 principally due to unfavorable manufacturing variances and the lost margin on the reduced volume of tests sold during the quarter.

Table of Contents

Gross profit from our professional diagnostics net product sales and services revenue increased by \$166.5 million, or 24%, to \$853.7 million for the nine months ended September 30, 2012, compared to \$687.1 million for the nine months ended September 30, 2011, principally as a result of gross profit earned on revenue from acquired businesses and organic growth, as discussed above. Gross profit was negatively impacted comparing the nine months ended September 30, 2012 to the nine months ended September 30, 2011, as a result of a decrease in our North American flu-related sales and meter-based Triage product sales, as discussed above. The FDA recall matter relating to our meter-based Triage products also resulted in incremental costs during the nine months ended September 30, 2012 related to the cost of refunds made during the period, replacement products issued at no cost, unfavorable manufacturing variances and the lost margin on the reduced volume of tests sold during the period. Included in cost of net revenue for our professional diagnostics business segment for the nine months ended September 30, 2012 was a \$4.7 million non-cash charge relating to the write-up of inventory to fair value in connection with the acquisition of Axis-Shield.

As a percentage of our professional diagnostics net product sales and services revenue, gross margin for the three and nine months ended September 30, 2012 was 52% and 54%, respectively, compared to 56% and 55% for the three and nine months ended September 30, 2011. Increased revenue from our recently acquired toxicology businesses, which contribute lower-than-segment-average gross margins, and a decrease in North American flu-related sales and meter-based Triage product sales, which contribute higher-than-segment-average gross margin, contributed to the decrease in gross margin for the respective periods.

Health Management

Gross profit from our health management net product sales and services revenue increased by \$1.7 million, or 3%, to \$60.4 million for the three months ended September 30, 2012, compared to \$58.6 million for the three months ended September 30, 2011, principally as a result of the increase in our revenue associated with our home coagulation monitoring programs during the comparable periods, as discussed above. Gross profit from our health management net product sales and services revenue decreased by \$9.4 million, or 5%, to \$180.5 million for the nine months ended September 30, 2012, compared to \$189.9 million for the nine months ended September 30, 2011, principally as a result of the decrease in revenue during the comparable periods and the increasingly competitive environment, including pricing pressures, and other adverse factors on our health management net product sales and services revenue.

As a percentage of our health management net product sales and services revenue, gross margin for both the three and nine months ended September 30, 2012 was 45%, compared to 45% and 46% for the three and nine months ended September 30, 2011, respectively. The lower margin percentage earned during the three and nine months ended September 30, 2012 is primarily a result of the increasingly competitive environment, including pricing pressures, and other adverse factors affecting our health management net product sales and services revenues, as discussed above.

Consumer Diagnostics

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$0.2 million, or 4%, to \$5.2 million for the three months ended September 30, 2012, compared to \$5.4 million for the three months ended September 30, 2011.

Gross profit from our consumer diagnostics net product sales and services revenue decreased by \$1.0 million, or 7%, to \$14.4 million for the nine months ended September 30, 2012, compared to \$15.4 million for the nine months ended September 30, 2011. The decrease in gross profit was primarily the result of a one-time cost of goods sold adjustment totaling approximately \$0.7 million related to our manufacturing agreement with SPD recorded during the nine months ended September 30, 2012.

As a percentage of our consumer diagnostics net product sales and services revenue, gross margin for the three and nine months ended September 30, 2012 was 23% and 22%, respectively, compared to 22% for both the three and nine months ended September 30, 2011, respectively.

Research and Development Expense. Research and development expense increased by \$5.8 million, or 17%, to \$40.6 million for the three months ended September 30, 2012, from \$34.8 million for the three months ended September 30, 2011. Amortization expense of \$1.3 million and \$1.4 million was included in research and development expense for the three months ended September 30, 2012 and 2011, respectively.

Research and development expense increased by \$7.3 million, or 7%, to \$120.0 million for the nine months ended September 30, 2012, from \$112.7 million for the nine months ended September 30, 2011. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling approximately \$0.6 million and \$0.4 million were included in research and development expense for the nine months ended September 30, 2012 and 2011, respectively. Amortization expense of \$5.2 million and \$11.1 million was included in research and development expense for the nine months ended September 30, 2012 and 2011, respectively. Included in the \$11.1 million of amortization expense for the nine months ended September 30, 2011 was \$7.2 million related to the write off of certain in-process research and development

Edgar Filing: ALERE INC. - Form 10-Q

projects recorded in connection with the Standard Diagnostics acquisition during the first quarter of 2010.

Research and development expense as a percentage of net revenue was 6% each of the three and nine months ended September 30, 2012 and 2011.

Sales and Marketing Expense. Sales and marketing expense increased by \$26.3 million, or 20%, to \$160.6 million for the three months ended September 30, 2012, from \$134.4 million for the three months ended September 30, 2011. The increase in sales

Table of Contents

and marketing expense primarily relates to additional spending related to newly-acquired businesses. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling approximately \$0.9 million were included in sales and marketing expense for both the three months ended September 30, 2012 and 2011, respectively. Amortization expense of \$61.1 million and \$53.0 million was included in sales and marketing expense for the three months ended September 30, 2012 and 2011, respectively.

Sales and marketing expense increased by \$70.6 million, or 17%, to \$478.5 million for the nine months ended September 30, 2012, from \$408.0 million for the nine months ended September 30, 2011. The increase in sales and marketing expense primarily relates to additional spending related to newly-acquired businesses. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling approximately \$1.9 million and \$3.8 million were included in sales and marketing expense for the nine months ended September 30, 2012 and 2011, respectively. Amortization expense of \$179.2 million and \$158.6 million was included in sales and marketing expense for the nine months ended September 30, 2012 and 2011, respectively.

Sales and marketing expense as a percentage of net revenue was 23% for both the three and nine months ended September 30, 2012, compared to 23% and 24% for the three and nine months ended September 30, 2011, respectively.

General and Administrative Expense. General and administrative expense increased by approximately \$13.9 million, or 15%, to \$105.8 million for the three months ended September 30, 2012, from \$91.9 million for the three months ended September 30, 2011. The increase in general and administrative expense relates primarily to additional spending related to newly-acquired businesses. During the three months ended September 30, 2012 and 2011, we recorded income of \$15.1 million and \$3.8 million, respectively, in connection with fair value adjustments to acquisition-related contingent consideration obligations. Acquisition-related costs of \$0.8 million and \$2.9 million were included in general and administrative expense for the three months ended September 30, 2012 and 2011, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling approximately \$1.2 million and \$2.1 million were included in general and administrative expense for the three months ended September 30, 2012 and 2011, respectively. Amortization expense of \$2.0 million and \$1.7 million was included in general and administrative expense for the three months ended September 30, 2012 and 2011, respectively.

General and administrative expense increased by approximately \$55.5 million, or 19%, to \$347.8 million for the nine months ended September 30, 2012, from \$292.3 million for the nine months ended September 30, 2011. The increase in general and administrative expense relates primarily to additional spending related to newly-acquired businesses. During the nine months ended September 30, 2012 and 2011, we recorded income of \$16.8 million and \$9.7 million, respectively, in connection with fair value adjustments to acquisition-related contingent consideration obligations. Acquisition-related costs of \$6.1 million and \$6.2 million were included in general and administrative expense for the nine months ended September 30, 2012 and 2011, respectively. Restructuring charges associated with our various restructuring plans to integrate our newly-acquired businesses totaling approximately \$5.5 million and \$13.1 million were included in general and administrative expense for the nine months ended September 30, 2012 and 2011, respectively. Amortization expense of \$6.1 million and \$9.2 million was included in general and administrative expense for the nine months ended September 30, 2012 and 2011, respectively.

General and administrative expense as a percentage of net revenue was 15% and 17% for the three and nine months ended September 30, 2012, respectively, compared to 16% and 17% for the three and nine months ended September 30, 2011.

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 increased by \$7.5 million, or 16%, to \$54.9 million for the three months ended September 30, 2012, from \$47.3 million for the three months ended September 30, 2011. The increase is principally due to higher interest expense recorded in connection with higher outstanding debt balances and applicable interest rates during the third quarter of 2012 under our secured credit facility, compared to the outstanding debt balances and applicable interest rates during the third quarter of 2011.

Interest expense increased by \$6.9 million, or 4%, to \$161.1 million for the nine months ended September 30, 2012, from \$154.2 million for the nine months ended September 30, 2011. The increase is principally due to higher interest expense recorded in connection with higher outstanding debt balances and applicable interest rates during the nine months ended September 30, 2012, compared to the outstanding debt balances and applicable interest rates during the nine months ended September 30, 2011. The increase in interest expense during the nine months ended September 30, 2012 was partially offset by interest expense and amortization of fees paid for certain debt modifications totaling \$31.2 million during the nine months ended September 30, 2011 recorded in connection with the termination of our former secured credit facility and related interest rate swap agreement.

Table of Contents

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

	Three Months Ended			Nine Months Ended		
	September 30, 2012	September 30, 2011	Change	September 30, 2012	September 30, 2011	Change
Interest income	\$ 344	\$ 927	\$ (583)	\$ 1,409	\$ 1,818	\$ (409)
Foreign exchange gains (losses), net	671	(24,740)	25,411	(5,526)	(27,532)	22,006
Other	(2,087)	15,563	(17,650)	18,687	20,237	(1,550)
Total other income (expense), net	\$ (1,072)	\$ (8,250)	\$ 7,178	\$ 14,570	\$ (5,477)	\$ 20,047

The primary reason for the increase in foreign exchange gains (losses), net for both the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011, was primarily a result of an \$18.1 million unrealized foreign currency loss associated with a cash balance established in connection with the Axis-Shield tender offer recognized during the three and nine months ended September 30, 2011. Other income of \$15.6 million for the three months ended September 30, 2011 includes a net \$11.3 million of income associated with an amendment of our license agreement with Quidel, which also includes a settlement of prior period royalties, and \$5.0 million of income associated with the settlement of a dispute over certain intellectual property rights. Other income of \$18.7 million for the nine months ended September 30, 2012 includes a \$13.5 million final royalty termination payment received from Quidel, a \$7.2 million gain recorded on the sale of property and \$1.4 million of income associated with legal settlements related to intellectual property litigation. Other income of \$20.2 million for the nine months ended September 30, 2011 includes \$13.8 million of income associated with an amendment of our license agreement with Quidel, which also includes a settlement of prior period royalties, \$5.0 million of income associated with the settlement of a dispute over certain intellectual property rights, \$0.5 million of estimated prior period royalty income and a \$1.8 million reversal of a prior period legal settlement reserve no longer deemed necessary.

Gain on Sale of Joint Venture Interest. In connection with the formation of SPD in May 2007, we entered into an option agreement with P&G, pursuant to which P&G had the right, for a period of 60 days commencing on May 17, 2011, to require us to acquire all of P&G's interest in SPD at fair market value, and P&G had the right, upon certain material breaches by us of our obligations to SPD, to acquire all of our interest in SPD at fair market value. No gain on the proceeds that we received from P&G through the formation of SPD was recognized in our financial statements until P&G's option to require us to purchase its interest in SPD expired. On July 16, 2011, P&G's option to require us to acquire its interest in SPD at fair market value expired. In connection with the expiration of the option, the gain totaling approximately \$288.9 million was recognized during the third quarter of 2011.

Provision (Benefit) for Income Taxes. The provision (benefit) for income taxes decreased by \$53.3 million to a \$10.7 million benefit for the three months ended September 30, 2012 from a \$42.7 million provision for the three months ended September 30, 2011. The effective tax rate was 62% for the three months ended September 30, 2012 compared to 15% for the three months ended September 30, 2011. The income tax provision (benefit) for the three months ended September 30, 2012 and 2011 relates to federal, foreign and state income tax provisions (benefits). The increase in the effective income tax rate and benefit for income taxes during the three months ended September 30, 2012, compared to the three months ended September 30, 2011, is primarily due to the gain on the sale of our joint venture interest, as discussed above, recorded during the third quarter of 2011 that was subject to tax at lower foreign rates, the expiration of the federal research and development tax credit during 2012, an increase in certain foreign earnings subject to U.S. taxation, an increase to certain tax reserves under the principles of accounting for uncertain tax positions in accordance with ASC 740, *Income Taxes*, and increases in certain current year state tax losses not benefitted.

The benefit for income taxes increased by \$8.2 million to a \$12.6 million benefit for the nine months ended September 30, 2012 from a \$4.4 million benefit for the nine months ended September 30, 2011. The effective tax rate was 33% for the nine months ended September 30, 2012 compared to 2% for the nine months ended September 30, 2011. The income tax benefit for the nine months ended September 30, 2012 and 2011 relates to federal, foreign and state income tax provisions (benefits). The increase in the effective income tax rate and benefit for income taxes during the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011, is primarily due to the gain on the sale of our joint venture interest, as discussed above, recorded during the nine months ended September 30, 2011 that was subject to tax at lower foreign rates, the expiration of the federal research and development tax credit during 2012, an increase in certain foreign earnings subject to U.S. taxation, an increase to certain tax reserves under the principles of accounting for uncertain tax positions in accordance with ASC 740, *Income Taxes*, and increases in certain current year state tax losses not benefitted. In addition, during the nine months ended September 30, 2011, there was a discrete benefit recorded for the reversal of valuation allowances on certain capital assets.

Edgar Filing: ALERE INC. - Form 10-Q

Equity Earnings in Unconsolidated Entities, Net of Tax. Equity earnings in unconsolidated entities is reported net of tax and includes our share of earnings in entities that we account for under the equity method of accounting. Equity earnings in unconsolidated entities, net of tax for the three and nine months ended September 30, 2012 reflects the following: (i) our 50% interest in SPD in the amount of \$2.1 million and \$8.2 million, respectively, (ii) our 40% interest in Vedalab S.A., or Vedalab, in the amount of \$0.3 million and \$0.4 million, respectively, and (iii) our 49% interest in TechLab, Inc., or TechLab, in the amount of \$0.6 million and \$1.8 million, respectively. Equity earnings in unconsolidated entities, net of tax for the three and nine months ended September 30, 2011 reflects the following: (i) our 50% interest in SPD in the amount of \$3.6 million and \$3.0 million, respectively, (ii) our 40% interest in Vedalab in the amount of \$0.2 million and \$0.4 million, respectively, and (iii) our 49% interest in TechLab in the amount of \$0.3 million and \$1.5 million, respectively.

Table of Contents

Net Income (Loss) Available to Common Stockholders. For the three months ended September 30, 2012, we generated a net loss available to common stockholders of \$9.2 million, or \$0.11 per basic common share. For the three months ended September 30, 2011, we generated net income available to common stockholders of \$234.2 million, or \$2.48 per diluted common share. Net income (loss) available to common stockholders reflects \$5.4 million of preferred stock dividends paid during both the three months ended September 30, 2012 and 2011, respectively.

For the nine months ended September 30, 2012, we generated a net loss available to common stockholders of \$31.4 million, or \$0.39 per basic common share. For the nine months ended September 30, 2011, we generated net income available to common stockholders of \$237.6 million, or \$2.56 per diluted common share. Net income (loss) available to common stockholders reflects \$15.9 million and \$16.7 million of preferred stock dividends paid during the nine months ended September 30, 2012 and 2011, respectively, and \$23.9 million of income associated with the repurchase of preferred stock during the nine months ended September 30, 2011.

See Note 5 of the accompanying consolidated financial statements for the calculation of net income (loss) per common share.

Liquidity and Capital Resources

Based upon our current working capital position, current operating plans and expected business conditions, we currently expect to fund our short- and long-term working capital needs primarily using existing cash and our operating cash flow, and we expect our working capital position to improve as we improve our future operating margins and grow our business through new product and service offerings and by continuing to leverage our strong intellectual property position. As of September 30, 2012, we had \$302.3 million of cash and cash equivalents, of which \$77.0 million was held by domestic subsidiaries and \$225.3 million was held by foreign entities. We do not plan to repatriate cash held by foreign entities due to adverse tax implications, including incremental U.S. tax liabilities and potential foreign withholding tax liabilities.

We may also utilize our secured credit facility (See Note 9) or other new sources of financing to fund a portion of our capital needs and other commitments, including our contractual contingent consideration obligations and future acquisitions. As of September 30, 2012, we had outstanding borrowings totaling \$97.5 million under the \$250.0 million revolving line of credit under our secured credit facility, leaving \$152.5 million available to us for additional borrowings. Our ability to access the capital markets may be impacted by the amount of our outstanding debt and equity and the extent to which our assets are encumbered by our outstanding secured debt. The terms and conditions of our outstanding debt instruments also contain covenants which expressly restrict our ability to incur additional indebtedness and conduct other financings. As of September 30, 2012, we had \$3.6 billion in outstanding indebtedness comprised of \$2.4 billion under our secured credit facility, \$400.0 million of 8.625% subordinated notes due 2018, \$392.5 million of 9% senior subordinated notes due 2016, \$246.3 million of 7.875% senior notes due 2016 and \$150.0 million of 3% senior subordinated convertible notes due 2016. The applicable interest rate margins under our secured credit facility represent an increase of between approximately 0.75% and 2.25% (depending on the type of loan and the type of interest rate involved and on our applicable leverage ratios) over the applicable margins under our former secured credit facility. As a result of this increase in applicable interest rates, the 1.00% floor with respect to the base Eurodollar Rate (as defined in the senior credit facility) for B term loans, Incremental B-1 term loans and Incremental B-2 term loans under our secured credit facility that are based on the Eurodollar Rate, margins and the larger amount outstanding under our secured credit facility, we anticipate that our aggregate interest expense in 2012 and future periods will exceed our aggregate interest expense in 2011.

If the capital and credit markets experience volatility or the availability of funds is limited, we may incur increased costs associated with issuing debt instruments. In addition, it is possible that our ability to access the capital and credit markets could be limited by these 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 by unexpected costs associated with integrating the operations of newly-acquired companies, executing our cost-savings strategies and prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us. We also cannot be certain that our underlying assumed levels of revenues and expenses will be realized. In addition, we intend to continue to make significant investments in our research and development efforts related to the substantial intellectual property portfolio we own. We may also choose to further expand our research and development efforts and may pursue the acquisition of new products and technologies through licensing arrangements, business acquisitions, or otherwise. 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.

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

	Nine Months Ended September 30,	
	2012	2011
Net cash provided by operating activities	\$ 253,763	\$ 222,507
Net cash used in investing activities	(456,421)	(648,004)
Net cash provided by financing activities	212,927	299,408
Foreign exchange effect on cash and cash equivalents	(7,188)	1,537
Net increase (decrease) in cash and cash equivalents	3,081	(124,552)
Cash and cash equivalents, beginning of period	299,173	401,306
Cash and cash equivalents, end of period	\$ 302,254	\$ 276,754

Summary of Changes in Cash Position

As of September 30, 2012, we had cash and cash equivalents of \$302.3 million, a \$3.1 million increase from December 31, 2011. Our primary sources of cash during the nine months ended September 30, 2012 included \$253.8 million generated by our operating activities, approximately \$198.3 million of proceeds received in connection with long-term debt issuances, \$91.2 million of net proceeds under various revolving credit facilities, \$22.4 million of proceeds received from the sale of property, plant and equipment, \$14.3 million from common stock issuances under employee stock option and stock purchase plans and \$6.6 million return of capital from equity method investments. Our primary uses of cash during the nine months ended September 30, 2012 included \$384.8 million net cash paid for acquisitions, \$97.3 million of capital expenditures, \$42.6 million related to the repayment of long-term debt obligations, \$16.2 million paid for contingent purchase price consideration, \$16.0 million for cash dividends paid on our Series B Preferred stock, \$9.3 million related to an increase in other assets and \$6.2 million related to the repayment of short-term debt obligations. Fluctuations in foreign currencies negatively impacted our cash balance by \$7.2 million during the nine months ended September 30, 2012.

Cash Flows from Operating Activities

Net cash provided by operating activities during the nine months ended September 30, 2012 was \$253.8 million, which resulted from a net loss of \$15.4 million, \$303.1 million of non-cash items and \$34.0 million of cash utilized by changes in net working capital requirements during the period. The \$303.1 million of non-cash items included, among other items, \$322.4 million related to depreciation and amortization, \$16.1 million of interest expense related to the amortization of deferred financing costs and original issue discounts, \$11.9 million related to stock-based compensation and a \$4.7 million non-cash charge relating to the write-up of inventory to fair value in connection with the acquisition of Axis-Shield, partially offset by a \$43.6 million decrease related to changes in our deferred tax assets and liabilities, which partially resulted from amortization of intangible assets, a \$10.4 million decrease attributable to equity earnings in unconsolidated entities and a \$4.2 million gain on the sale of property, plant and equipment.

Cash Flows from Investing Activities

Our investing activities during the nine months ended September 30, 2012 utilized \$456.4 million of cash, including \$384.8 million net cash paid for acquisitions, \$97.3 million of capital expenditures and \$9.3 million related to an increase in other assets, offset by \$22.4 million of proceeds received from the sale of property, plant and equipment, \$6.6 million return of capital from equity method investments, which included a \$6.1 million return of capital from SPD, and a \$5.8 million decrease in our restricted cash balance.

Cash Flows from Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2012 was \$212.9 million. Financing activities during the nine months ended September 30, 2012 primarily included approximately \$198.3 million of proceeds received in connection with long-term debt issuances, which included \$198.0 million of net proceeds received in connection with the Incremental B-2 term loans entered into as part of our

Edgar Filing: ALERE INC. - Form 10-Q

secured credit facility, \$91.2 million of net proceeds under various revolving credit facilities, which included \$97.5 million borrowed against our secured credit facility revolving line-of-credit, and \$14.3 million of cash received from common stock issuances under employee stock option and stock purchase plans. We utilized approximately \$42.6

Table of Contents

million in connection with the repayment of long-term debt obligations, \$16.2 million paid for contingent purchase price consideration, \$16.0 million for cash dividends paid on our Series B Preferred stock, \$6.2 million for the repayment of short-term debt obligations and \$4.9 million for payment of capital lease obligations.

As of September 30, 2012, we had an aggregate of \$20.1 million in outstanding capital lease obligations which are payable through 2019.

Income Taxes

As of December 31, 2011, we had approximately \$216.4 million of domestic NOL and capital loss carryforwards and \$209.5 million of foreign NOL and capital loss carryforwards, respectively, which either expire on various dates through 2031 or may be carried forward indefinitely. These losses are available to reduce federal, state and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable taxing authorities. In addition, the domestic NOL carryforward amount at December 31, 2011 included approximately \$97.1 million of pre-acquisition losses at Matria, QAS, ParadigmHealth, Biosite, Cholestech, Redwood, HemoSense, Ischemia, Ostex International, Ionian and Twist. Effective January 1, 2009, we adopted a new accounting standard for business combinations. Prior to adoption of this standard, the pre-acquisition losses were applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Upon adoption of the new accounting standard, the reduction of a valuation allowance is generally recorded to reduce our income tax expense.

Furthermore, all domestic losses are subject to the Internal Revenue Code Section 382 limitation and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our NOLs and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of September 30, 2012.

Contractual Obligations

On March 28, 2012, we entered into a third amendment to our secured credit facility, which provides for an additional term loan facility consisting of Incremental B-2 term loans in the aggregate principal amount of \$200.0 million. As of September 30, 2012, aggregate borrowings under the secured credit facility amounted to \$2.4 billion. The table below summarizes our aggregate long-term debt obligations as of September 30, 2012 (in thousands).

	Total	Payments Due by Period			Thereafter
		2012	2013-2014	2015-2016	
Long-term debt obligations	\$ 3,593,091	\$ 16,845	\$ 107,145	\$ 1,760,373	\$ 1,708,728

The following summarizes our principal contractual obligations as of September 30, 2012 that have changed significantly since December 31, 2011, other than the changes described above with respect to our secured credit facility, and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Other contractual obligations that were presented in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2011, but omitted below, represent those that have not changed significantly since that date.

(a) Acquisition-related Contingent Consideration Obligations

AmMed

With respect to AmMed Direct LLC, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain operational targets within six months of the acquisition date. The maximum amount of the earn-out payment was \$2.0 million. The conditions of the earn-out were not achieved and as such no further contingent consideration obligations related to this acquisition exist as of September 30, 2012.

Amedica

With respect to Amedica Biotech, Inc., the terms of the acquisition agreement require us to make earn-out payments upon successfully meeting certain financial targets during each of calendar years 2012 and 2013. The maximum amount of the earn-out payments are \$6.9 million and \$8.1 million for calendar years 2012 and 2013, respectively.

Capital Toxicology

Table of Contents

The initial terms of the acquisition agreement for Capital Toxicology, LLC, provided for an earn-out calculated based on the amount, if any, by which EBITDA derived from the acquired business exceeded specified targets during each of the calendar years 2011 and 2012. A portion of the earn-out for the 2011 calendar year totaling approximately \$2.1 million was earned and accrued as of December 31, 2011. During the first quarter of 2012, the acquisition agreement was modified to base the earn-out on the excess of actual cash collections from 2011 sales over 2011 expenses rather than EBITDA. This new criterion resulted in an incremental \$2.9 million accrual related to the earn-out for the 2011 calendar year based on cash collections through March 31, 2012. \$4.1 million was paid in respect of the earn-out for the 2011 calendar year during the second quarter of 2012. An additional payment of approximately \$1.5 million will be made in the fourth quarter of 2012 for the incremental cash collections from 2011 sales received prior to August 31, 2012. The maximum potential remaining amount of the earn-out payments is approximately \$8.0 million.

DiagnosisOne

With respect to DiagnosisOne, Inc., the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within five years of the acquisition date. The maximum amount of the earn-out payments is \$33.0 million.

Diagnostik

With respect to Diagnostik Nord, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets within two years of the acquisition date. The maximum amount of the earn-out payments is approximately 1.4 million (approximately \$1.8 million at September 30, 2012).

eScreen

With respect to eScreen, the terms of the acquisition agreement require us to pay earn-outs upon successfully meeting certain financial targets during calendar years 2012 through 2014. The maximum amount of the earn-out payments is \$70.0 million.

MedApps

With respect to MedApps Holding Company, Inc., the terms of the acquisition agreement require us to make earn-out payments upon achievement of certain technological and product development milestones through January 15, 2015. The maximum amount of the earn-out payments is \$22.0 million.

Standing Stone

With respect to Standing Stone, Inc., or Standing Stone, the terms of the acquisition agreement require us to pay earn-outs and employee bonuses upon successfully meeting certain operational, product development and revenue targets during the period from the date of acquisition through calendar year 2013. A cash earn-out payment totaling approximately \$5.5 million and employee bonus payments totaling approximately \$0.3 million for the achievement of the first two milestones were made during the second quarter of 2012. The maximum remaining amount of the earn-out payments is approximately \$5.5 million. The maximum remaining amount of the employee bonuses is \$0.3 million.

(b) Contingent Obligations

Standing Stone

Under the terms of the acquisition agreement we acquired the remaining 19.08% of the issued and outstanding capital stock of Standing Stone, the holders of which were officers and employees of Standing Stone, in May 2012 for an aggregate purchase price of approximately \$2.6 million.

Agreements with Epocal

In November 2009, we entered into a distribution agreement with Epocal, Inc., or Epocal, to distribute the epoc[®] Blood Analysis System for blood gas and electrolyte testing for \$20.0 million, which is recorded on our accompanying consolidated balance sheet in other intangible assets, net. We also entered into a definitive agreement to acquire all of the issued and outstanding equity securities of Epocal for a total potential purchase price of up to \$255.0 million, including a base purchase price of up to \$172.5 million if Epocal achieves certain gross margin and other financial milestones on or prior to October 31, 2014, plus additional payments of up to \$82.5 million if Epocal achieves certain other milestones relating to its gross margin and product development efforts on or prior to this date. The agreement contains a working capital adjustment whereby the purchase price is increased or decreased to the extent that Epocal's working capital at closing is more or less than a specified amount. We also agreed that, if the acquisition is consummated, we will provide \$12.5 million in management incentive arrangements, 25% of which will vest over three years and 75% of which will be payable only upon the achievement of certain milestones. The acquisition will also be subject to other closing conditions, including the receipt of any required antitrust or other approvals. In April 2011, we entered into a license agreement with Epocal and amended some of the terms of the definitive agreement to acquire Epocal. The license agreement provides us with royalty-free access to certain Epocal intellectual property for use in our home-use products and provided for an upfront license payment of \$18.0 million, which we paid in 2011. The amendment of the definitive agreement increased the working capital target by \$18.0 million, which may have the effect of reducing the purchase price of the acquisition. The amendment of the agreement also added an additional potential milestone payment of \$8.0 million. As a result, the maximum purchase price under the acquisition agreement increased to \$263.0 million.

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, 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 have been no significant changes in our critical accounting policies or management estimates since December 31, 2011. 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, as amended, for the year ended December 31, 2011.

Table of Contents**Recent Accounting Pronouncements**

See Note 16 in the notes to 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, as amended, for the year ended December 31, 2011. Market risks that were presented in our annual report but are omitted below represent those that have not changed significantly since that date. The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements.

Interest Rate Risk

We are exposed to market risk from changes in interest rates primarily through our investing and financing activities. In addition, our ability to finance future acquisition transactions or fund working capital requirements may be impacted if we are not able to obtain appropriate financing at acceptable rates.

Our investing strategy to manage interest rate exposure is to invest in short-term, highly-liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of eighteen months and an average maturity of our portfolio that should not exceed six months, with at least \$500,000 cash available at all times. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At September 30, 2012, our short-term investments approximated their market value. At September 30, 2012, under the credit agreement for our secured credit facility we had (i) term loans in an aggregate outstanding principal amount of \$2.3 billion (consisting of A term loans (including the Delayed-Draw term loans) in the aggregate principal amount of \$893.8 million, B term loans in the aggregate principal amount of \$915.8 million, Incremental B-1 term loans in the aggregate principal amount of \$248.1 million and Incremental B-2 term loans in the aggregate principal amount of \$197.2 million), (ii) \$97.5 million of outstanding borrowings under the revolving line of credit and (iii) subject to our continued compliance with the credit agreement, the ability to borrow a maximum of up to an additional \$152.5 million under a revolving line of credit, which includes a \$50.0 million sublimit for the issuance of letters of credit. Loans can be either Base Rate Loans or Eurodollar Rate Loans at our election, and interest accrues on loans and our other Obligations under the terms of the credit agreement as follows (with the terms referenced above and below in this paragraph having the meanings given to them in the credit agreement): (i) in the case of loans that are Base Rate Loans, at a rate *per annum* equal to the sum of the Base Rate and the Applicable Margin, each as in effect from time to time, (ii) in the case of loans that are Eurodollar Rate Loans, at a rate *per annum* equal to the sum of the Eurodollar Rate and the Applicable Margin, each as in effect for the applicable Interest Period, and (iii) in the case of other Obligations, at a rate *per annum* equal to the sum of the Base Rate and the Applicable Margin for Revolving Loans that are Base Rate Loans, each as in effect from time to time. The Base Rate is a floating rate which approximates the U.S. prime rate as in effect from time to time. The Eurodollar Rate is equal to the LIBOR rate and is set for a period of one, two, three or six months at our election. Applicable Margins for our A term loans (including the Delayed-Draw term loans) and revolving line of credit loans range from (i) with respect to such loans that are Base Rate Loans, 1.75% to 2.50% and (ii) with respect to such loans that are Eurodollar Rate Loans, 2.75% to 3.50%, in each case, depending upon our consolidated secured leverage ratio (as determined under the credit agreement). Applicable Margins for our B term loans, Incremental B-1 term loans and Incremental B-2 term loans range from (i) with respect to such loans that are Base Rate Loans, 2.50% to 3.25% and (ii) with respect to such loans that are Eurodollar Rate Loans, 3.50% to 4.25%, in each case, depending upon our consolidated secured leverage ratio. Interest on B term loans, Incremental B-1 term loans and Incremental B-2 term loans based on the Eurodollar Rate is subject to a 1.00% floor with respect to the base Eurodollar Rate. As of September 30, 2012, the A term loans (including the Delayed-Draw term loans), the B term loans, the Incremental B-1 term loans, the Incremental B-2 term loans and the revolving line of credit loans bore interest (including applicable margins) at 3.22%, 4.75%, 4.75%, 4.75% and 3.23% per annum, respectively.

Table of Contents

Assuming no changes in our consolidated secured leverage ratio, the effect of interest rate fluctuations on outstanding borrowings as of September 30, 2012 over the next twelve months is quantified and summarized as follows (in thousands):

	Interest Expense Increase
Interest rates payable by us increase by 100 basis points	\$ 23,523
Interest rates payable by us increase by 200 basis points	\$ 47,046

Table of Contents**ITEM 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures*

Our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective at that time. We and our management understand nonetheless that controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. In reaching their conclusions stated above regarding the effectiveness of our disclosure controls and procedures, our CEO and CFO concluded that such disclosure controls and procedures were effective as of such date at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the most recent fiscal quarter covered by this Quarterly Report on Form 10-Q 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**

Please see Part I, Item 2, Management's Discussion and Analysis of Financial Conditions and Results of Operations - FDA and OIG Matters Relating to Alere Triage Products for a description of certain legal matters.

ITEM 1A. RISK FACTORS

This section updates and supplements the risk factors detailed in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2011, and should be read in conjunction with such disclosure. The risks described below may materially impact your investment in our company or may in the future, and, in some cases, already do materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities.

We face risks and uncertainties relating to the FDA inspection and subpoena with respect to our Alere Triage products.

In March 2012, the FDA began an inspection of our San Diego facility relating to our Alere Triage products, and we have 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. As a result of the FDA inspection, and as previously disclosed, we implemented two recalls of Alere Triage products during the second quarter of 2012, as well as interim quality control release specifications. In June 2012, the FDA closed the inspection, and we received inspectional observations on FDA Form 483. In July 2012, we provided the FDA with a detailed response to its inspectional observations, which included a plan for how we proposed to address each observation as well as a timeline for doing so. Since submitting this response, we have been working diligently to address each of these observations. Also, on or about September 28, 2012, we agreed with the FDA on a set of final release specifications for our Alere Triage meter-based products that further align the product release specifications to the package insert. On October 9, 2012, we received a warning letter from the FDA citing the same inspectional observations set forth in the FDA Form 483 received in June. The warning letter, which was subsequently reissued as of October 22, 2012, acknowledged our July response but did not take into account the timeline that we had proposed or any of our efforts taken after our July response. On October 30, 2012, we responded to the warning letter and submitted evidence of our completion of most of the actions detailed in our July response, including all of the actions then due under our timeline. We will continue to provide the FDA with further periodic updates on the status of the actions that remain to be completed over the next several months to fully address the issues that the FDA has identified. We intend to continue to work cooperatively with both the FDA and OIG with respect to these matters, but we cannot assure you that the FDA and OIG will find our efforts satisfactory. It is possible that the issues arising out of the inspection and subpoena may be expanded to cover other matters. We may be unable to implement corrective actions within a timeframe and in a manner satisfactory to the FDA. We are unable to predict when these matters will be resolved or what action, if any, the government will take in connection with these matters. Also, except for increases in manufacturing costs and decreased profitability for our Alere Triage products, we are unable to predict what impact these matters or ensuing proceedings, if any, will have on our financial condition, results of operations or cash flows. Our related efforts to improve our production and quality control processes and increase production have increased our manufacturing costs, and we expect that our costs will

Edgar Filing: ALERE INC. - Form 10-Q

continue to increase as we continue to meet the final release specifications. Because our efforts to improve our manufacturing processes are ongoing and because we are continuing to seek to implement the remaining changes in accordance with the timelines set forth in our response to the FDA, we cannot predict the continuing impact of the final quality control release specifications on our manufacturing yields. We cannot guarantee that we will be able to manufacture all of the impacted products at cost-effective yield rates under the final

Table of Contents

release specifications, in which case we may be required to, or we may opt to, cease production and sale of the impacted products. In any case, we expect that our ability to supply certain Alere Triage products will continue to be limited, which is expected to adversely affect revenues from sales of these products. We are unable to predict the scope or the duration of any product shortage. We have received inquiries from regulatory authorities outside the United States regarding the Alere Triage recalls in the United States and in at least one case, remedial or corrective action was required. It is possible that foreign regulatory authorities might require us to take additional actions with respect to Alere Triage products sold outside the United States. Our revenues and market share could continue to be adversely affected by customer decisions to switch to competing products due to product shortages or damage to our reputation resulting from these matters. In connection with these matters, we may face potential enforcement proceedings by the government, potential civil or criminal fines and penalties, including disgorgement of amounts received for any adulterated products, potential withdrawals of regulatory approvals, the possibility of injunctive relief, which could limit, modify or constrain our ability to manufacture, market and sell our products, possible exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and potential product liability litigation. We are unable to predict the costs we may incur in responding to the subpoena or other potential investigations of these matters. Any of these risks and uncertainties could adversely affect our revenues, results of operations, cash flows and financial condition.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the period covered by this report, we issued 74,633 shares of our common stock upon the exercise of warrants for cash, resulting in aggregate proceeds to us of \$1,010,531. During the period covered by this report, we issued 9,157 shares of our common stock upon the net exercise of warrants to purchase 31,100 shares of our common stock, resulting in aggregate non-cash consideration to us of \$421,094. The warrants were issued in 2002 in a private placement relating to an acquisition. The shares issued upon exercise of the warrants were offered and sold, in 91 separate transactions, pursuant to the exemptions from registration afforded by Section 3(a)(9) and/or Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act.

On August 14, 2012, we issued 66,666 shares of common stock as contingent consideration payable under the share purchase agreement, as amended, governing our acquisition of Mologic Limited in October 2009 as a result of Mologic achieving certain development milestones. The shares were issued in reliance upon on the exemption from registration afforded by Section 4(a)(2) of the Securities Act and Regulation S thereunder.

ITEM 6. EXHIBITS**Exhibits:****Exhibit**

No.	Description
*31.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
*101	Interactive Data Files regarding (a) our Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011, (b) our Consolidated Statements of Comprehensive Income for the Three and Nine Months Ended September 30, 2012 and 2011, (c) our Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011, (d) our Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011 and (e) the Notes to such Consolidated Financial Statements.

* Filed herewith

Table of Contents

SIGNATURE

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

ALERE INC.

Date: November 8, 2012

/s/ David Teitel
David Teitel
Chief Financial Officer and an authorized officer