

NATUS MEDICAL INC  
Form 10-Q  
November 09, 2012  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2012

.. **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: 000-33001

**NATUS MEDICAL INCORPORATED**

(Exact name of registrant as specified in its charter)

Edgar Filing: NATUS MEDICAL INC - Form 10-Q

**Delaware**  
(State or other jurisdiction)

**77-0154833**  
(I.R.S. Employer

of incorporation or organization) **Identification No.)**

**1501 Industrial Road, San Carlos, CA 94070**

(Address of principal executive offices) (Zip Code)

**(650) 802-0400**

(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 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 issued and outstanding shares of the registrant's Common Stock, \$0.001 par value, as of November 2, 2012 was 29,952,308.

**Table of Contents**

**NATUS MEDICAL INCORPORATED**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I. <u>FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2012 and 2011 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011 (unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	24
<b>PART II. <u>OTHER INFORMATION</u></b>	<b>25</b>
Item 1. <u>Legal Proceedings</u>	25
Item 1A. <u>Risk Factors</u>	25
Item 6. <u>Exhibits</u>	36
<u>Signatures</u>	37

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NATUS MEDICAL INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)****(in thousands, except share amounts)**

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,500	\$ 32,816
Accounts receivable, net of allowance for doubtful accounts of \$1,698 in 2012 and \$941 in 2011	82,030	55,260
Inventories	40,755	33,389
Prepaid expenses and other current assets	9,489	4,743
Deferred income tax	5,345	5,025
<b>Total current assets</b>	<b>157,119</b>	<b>131,233</b>
Property and equipment, net	28,511	25,350
Intangible assets	96,208	70,411
Goodwill	99,348	80,375
Other assets	7,968	6,946
<b>Total assets</b>	<b>\$ 389,154</b>	<b>\$ 314,315</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 31,885	\$ 16,365
Short-term borrowings	7,300	
Current portion of long-term debt	8,528	188
Accrued liabilities	35,000	16,560
Deferred revenue	11,765	7,604
<b>Total current liabilities</b>	<b>94,478</b>	<b>40,717</b>
Long-term liabilities:		
Long-term debt	15,173	710
Other liabilities	4,723	7,658
Deferred income tax	14,925	7,502
<b>Total liabilities</b>	<b>129,299</b>	<b>56,587</b>
Stockholders' equity:		
Common Stock, \$0.001 par value, 120,000,000 shares authorized; shares issued and outstanding 29,921,403 in 2012 and 29,439,272 in 2011	272,577	267,499
Retained earnings	6,032	7,170
Accumulated other comprehensive loss	(18,754)	(16,941)
<b>Total stockholders' equity</b>	<b>259,855</b>	<b>257,728</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 389,154</b>	<b>\$ 314,315</b>

Edgar Filing: NATUS MEDICAL INC - Form 10-Q

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

-3-

**Table of Contents****NATUS MEDICAL INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (unaudited)**

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue	\$ 80,724	\$ 51,338	\$ 201,246	\$ 168,541
Cost of revenue	36,453	23,765	89,265	73,165
Gross profit	44,271	27,573	111,981	95,376
Operating expenses:				
Marketing and selling	21,801	14,688	54,756	44,818
Research and development	8,512	6,119	21,860	18,577
General and administrative	18,809	7,809	39,250	24,828
Total operating expenses	49,122	28,616	115,866	88,223
Income (loss) from operations	(4,851)	(1,043)	(3,885)	7,153
Other income (expense), net	(228)	186	226	(28)
Income (loss) before provision for income tax	(5,079)	(857)	(3,659)	7,125
Provision for income tax (benefit) expense	(3,130)	(1,011)	(2,513)	1,507
Net income (loss)	\$ (1,949)	\$ 154	\$ (1,146)	\$ 5,618
Foreign currency translation adjustment	147	(2,672)	(1,813)	(1,074)
Comprehensive income (loss)	\$ (1,802)	\$ (2,518)	\$ (2,959)	\$ 4,544
Earnings (loss) per share:				
Basic	\$ (0.07)	\$ 0.01	\$ (0.04)	\$ 0.20
Diluted	\$ (0.07)	\$ 0.01	\$ (0.04)	\$ 0.19
Weighted average shares used in the calculation of earnings (loss) per share:				
Basic	29,062	28,643	28,947	28,477
Diluted	29,062	29,387	28,947	29,566

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

**Table of Contents****NATUS MEDICAL INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)**

(in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Operating activities:</b>		
Net income (loss)	\$ (1,146)	\$ 5,618
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	9,532	6,771
Provision for losses on accounts receivable	195	1,065
Warranty reserve	540	1,225
Loss on disposal of property and equipment	80	187
Share-based compensation	5,007	5,028
Change in fair value of contingent obligation		(1,200)
Excess tax benefit on the exercise of stock options	(125)	(299)
Changes in operating assets and liabilities:		
Accounts receivable	(12,827)	8,433
Inventories	5,131	(872)
Prepaid expenses and other assets	(4,219)	1,032
Accounts payable	9,201	(8,062)
Deferred income tax	(648)	(350)
Accrued liabilities and deferred revenue	6,261	(1,927)
<b>Net cash provided by operating activities</b>	<b>16,982</b>	<b>16,649</b>
<b>Investing activities:</b>		
Acquisition of businesses, net of cash acquired	(57,632)	(14,935)
Purchases of property and equipment	(3,799)	(2,193)
Purchase of intangible assets		(160)
Sales of marketable securities		1,005
<b>Net cash used by investing activities</b>	<b>(61,431)</b>	<b>(16,283)</b>
<b>Financing activities:</b>		
Proceeds from stock option exercises and ESPP purchases	970	1,868
Excess tax benefit on the exercise of stock options	125	299
Proceeds from short-term borrowings	7,300	2,553
Proceeds from long-term borrowings	25,000	
Payments on borrowings	(2,230)	(2,119)
<b>Net cash provided by financing activities</b>	<b>31,165</b>	<b>2,601</b>
Exchange rate effect on cash and cash equivalents	(32)	(574)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(13,316)</b>	<b>2,393</b>
Cash and cash equivalents, beginning of period	32,816	28,383
<b>Cash and cash equivalents, end of period</b>	<b>\$ 19,500</b>	<b>\$ 30,776</b>

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

### Supplemental disclosure of cash flow information:

Cash paid for interest	\$ 215	\$ 94
Cash paid for income taxes	\$ 5,007	\$ 1,912
Non-cash investing activities:		
Property and equipment included in accounts payable	\$ 1,919	\$
Contingent earnout obligations included in accrued liabilities	\$	\$ 800

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



---

**Table of Contents**

**NATUS MEDICAL INCORPORATED AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**

**1 - Basis of Presentation**

The accompanying interim condensed consolidated financial statements of Natus Medical Incorporated ( Natus, we, us, our, or the Company ) have been prepared in accordance with accounting principles generally accepted in the United States of America ( GAAP ). Except as noted below, the accounting policies followed in the preparation of the interim condensed consolidated financial statements are consistent in all material respects with those presented in Note 1 to the consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

Interim financial reports are prepared in accordance with the rules and regulations of the Securities and Exchange Commission; accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. The interim financial information is unaudited, but reflects all normal adjustments that are, in the opinion of management, necessary for the fair presentation of our financial position, results of operations, and cash flows for the interim periods presented. The condensed consolidated balance sheet as of December 31, 2011 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying financial statements should be read in conjunction with the financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

**Revenue Recognition**

Our revenue recognition policies are consistent with disclosures in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011 and updated as related to the following: We have established vendor-specific objective evidence of fair value ( VSOE ) for substantially all of the undelivered elements in our multiple element arrangements and best estimate of selling price ( ESPs ) on delivered elements. In the future we may rely on ESPs, reflecting our best estimates of what the selling prices of elements would be if they were sold regularly on a stand-alone basis, to establish the amount of revenue to allocate to the undelivered elements

**Recent Accounting Pronouncements**

*Testing Indefinite-Lived Intangibles for Impairment* In July 2012, the Financial Accounting Standards Board ( FASB ) amended guidance on *Testing Indefinite-Lived Intangibles for Impairment*. The new guidance provides an entity the option to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of its indefinite-lived intangible assets are less than their carrying amounts. If an entity determines that it is more likely than not that the fair value of each asset exceeds its carrying amount, it would not need to calculate the fair value of the asset in that year. If the entity concludes otherwise, it is required to perform an impairment test comparing the carrying value of the intangible asset with its fair value and recognize an impairment loss if necessary. The new guidance will be effective for us on January 1, 2013 and early adoption is permitted. Adoption of this guidance is not expected to have an impact on our financial position, results of operations, or cash flows.

*Intangibles Goodwill and Other* In September 2011, the FASB issued amended guidance related to *Intangibles Goodwill and Other: Testing Goodwill for Impairment*. The amendment is intended to simplify how entities test goodwill for impairment. The amendment permits an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. We became subject to this standard starting in 2012 and we will consider whether to implement these qualitative factors during our annual goodwill assessment in the fourth quarter of each year. Adoption of this guidance is not expected to have an impact on our financial position, results of operations, or cash flows.

**Table of Contents****2 - Business Combinations****Nicolet**

We acquired the Nicolet neurodiagnostic business ( Nicolet ) from CareFusion on July 2, 2012 pursuant to a Share and Acquisition Purchase Agreement. The Nicolet business develops clinically differentiated neurodiagnostic and monitoring products, including a portfolio of electroencephalography (EEG) and electromyography (EMG) systems and related accessories, as well as vascular and obstetric Doppler sensors and connectivity products.

We acquired all of the outstanding common shares of CareFusion subsidiaries comprising the Nicolet business in the United States, Ireland, and the United Kingdom, and certain assets and liabilities of Nicolet sales divisions principally in China, Brazil, Germany, Italy, the Netherlands, and Spain for \$57.9 million in cash at closing, excluding direct costs of the acquisition. The final purchase consideration is subject to an adjustment related to the amount of working capital acquired, which will be recorded as an adjustment to goodwill when finalized. A total of \$2.6 million of direct costs associated with the acquisition was expensed as incurred and reported as a component of general and administrative expenses.

The acquisition has been accounted for as a purchase business combination. Under the acquisition method of accounting, the assets acquired and liabilities assumed from Nicolet are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill. Nicolet's results of operations are included in the consolidated financial statements from the date of the acquisition.

Valuing certain components of the acquisition, primarily accounts receivable, inventories, identifiable intangible assets, real estate, deferred taxes, accrued warranty costs, accounts payable and accrued expenses required us to make significant estimates that may be adjusted in the future; consequently, the purchase price allocation is considered preliminary. Final determination of these estimates could result in an adjustment to the preliminary purchase price allocation, with an offsetting adjustment to goodwill.

The following table summarizes the preliminary purchase price allocation of the fair value of the assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash	\$ 299
Accounts receivable	15,109
Inventories	13,563
Current deferred income tax asset	306
Prepaid and other assets	569
Other long-term assets	52
Non-current deferred income tax asset	1,154
Identifiable intangible assets:	
Developed technology	11,600
Customer-related	8,300
Trademarks and trade names	9,000
Backlog	720
Land and building	1,177
Other property and equipment	1,267
Goodwill	19,072
Accounts payable	(5,194)
Accrued expenses	(9,525)
Deferred revenue	(3,943)
Non-current deferred income tax liability	(5,595)
Total purchase price	\$ 57,931

*Identifiable intangible assets.* Intangible assets included in the purchase price allocation consist of: (i) developed technology of \$11.6 million assigned a weighted average economic life of 18 years being amortized on the straight line method, (ii) customer-related intangible assets of \$8.3 million assigned an economic life of 16 years being amortized on the straight line method, (iii) trademarks and trade names of \$9.0 million that have an indefinite life and are not being amortized, and (iv) backlog of \$720,000 assigned an economic life of three months being amortized

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

on the straight line method. All straight-line method of amortization above is based on the expected pattern of future benefits related to those respective intangible assets.

-7-

**Table of Contents**

Accounts receivable, net of allowance for doubtful accounts and other liabilities are stated at their historical carrying value, which approximate fair value given the short-term nature of these assets and liabilities. The fair value of the inventory was derived from model-based valuations for which all significant inputs and value drivers are observable directly or indirectly ( Level 2 inputs ). The fair value of the non-financial assets, summarized above, were derived from significant unobservable inputs ( Level 3 inputs ) determined by management based on market analysis, income analysis and discounted cash flow model. The fair value of fixed assets was determined using market data for similar assets. The fair value of purchased identifiable intangible assets was determined using our discounted cash flow models from income projections prepared by management, using weighted average cost of capital plus a 0% premium.

*Goodwill.* Approximately \$19.1 million has been allocated to goodwill. Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the provisional values assigned to the assets acquired and liabilities assumed. None of the goodwill is expected to be deductible for tax purposes. In accordance with ASC 350-20, goodwill will not be amortized but instead will be tested for impairment at least annually (more frequently if certain indicators are present). In the event that management determines that the value of goodwill has become impaired, we will incur an accounting charge for the amount of impairment during the fiscal quarter in which the determination is made.

*Deferred income tax.* A preliminary estimate of \$306,000 has been allocated to current deferred tax assets, \$1.2 million has been allocated to non-current deferred tax assets and \$5.6 million has been allocated to non-current deferred tax liabilities, which results primarily from differences between financial reporting and the original tax basis of both tangible and intangible assets acquired.

**Embla Systems LLC**

We acquired Embla Systems LLC ( Embla ) on September 15, 2011 pursuant to an Equity Purchase Agreement. Embla, with corporate headquarters in Denver, Colorado develops, manufactures, and sells devices focused on diagnostic sleep analysis (Polysomnography or PSG ) with products sold into the hospital and dedicated sleep lab as well as home sleep testing devices. The acquisition broadened our existing PSG product offerings and allows us to further leverage our existing sales channels both in the United States and internationally.

The Company acquired all of the capital stock of Embla for \$16.1 million in cash at closing, excluding direct costs of the acquisition. The Company paid an additional \$472,000 of purchase consideration in October 2011 pursuant to a purchase price adjustment related to cash and net assets acquired. A total of \$322,000 of direct costs associated with the acquisition was expensed as incurred and reported as a component of general and administrative expenses.

The acquisition has been accounted for as a purchase business combination. Under the acquisition method of accounting, the assets acquired and liabilities assumed from Embla are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill. Embla's results of operations are included in the consolidated financial statements from the date of the acquisition.

**Pro forma financial information**

The following unaudited pro forma information combines our results of operations for the nine months ended September 30, 2012 and 2011 with the results of operations for Nicolet and Embla as if the acquisitions had occurred on January 1, 2011.

**Unaudited Pro forma Financial Information**

(in thousands)

	Nine Months Ended September 30,	
	2012	2011
Revenue	\$ 251,047	\$ 257,755
Income from operations	\$ 3,979	\$ 6,794

## **Table of Contents**

The unaudited pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisitions occurred on the dates indicated, nor does it give effect to synergies, cost savings, and other changes expected to result from the acquisitions. Accordingly, the pro forma financial results do not purport to be indicative of results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period.

Nicolet's revenue of \$24.1 million and income from operations of \$2.1 million are included in our consolidated statement of operations and comprehensive income (loss) for the period from July 2, 2012 (acquisition date) to September 30, 2012.

For purposes of preparing the unaudited pro forma financial information for the nine months ended September 30, 2012, Nicolet's consolidated statement of revenue and direct expenses for the period January 1, 2012 through July 2, 2012 was combined with the Company's Consolidated Statement of Operations and Comprehensive Income (Loss) for the nine months ended September 30, 2012. For purposes of preparing the unaudited pro forma financial information for the period January 1, 2011 through September 30, 2011, Nicolet's consolidated statement of revenue and direct expenses for the period January 1, 2011 through September 30, 2011 was combined with the Company's Consolidated Statement of Operations and Comprehensive Income (Loss) for the nine months ended September 30, 2011. Since the former owner did not maintain separate stand-alone financial statements for the Nicolet business, expenses include only cost of goods sold and operating expenses directly attributable to the operations of the business.

For purposes of preparing the unaudited pro forma financial information for the period January 1, 2011 through September 30, 2011, Embla's Consolidated Statement of Income for the period January 1, 2011 through September 15, 2011 was combined with the Company's Consolidated Statement of Operations and Comprehensive Income (Loss) for the nine months ended September 30, 2011.

The unaudited pro forma consolidated results reflect the historical information of Natus and Nicolet in 2012 and Natus, Nicolet and Embla in 2011, adjusted for the following pre-tax amounts:

Elimination of Nicolet's historical intangible asset amortization expense (approximately \$423,000 through June 30, 2012 and \$908,000 in 2011);

Additional amortization expense related to Nicolet (approximately \$564,000 through June 30, 2012 and \$1.6 million in 2011) related to the fair value of identifiable intangible assets acquired;

Decrease of Nicolet's depreciation expense (approximately \$1.0 million through June 30, 2012 and \$1.4 million in 2011) related to the fair value adjustment to property and equipment acquired;

Adjustments to general and administrative expense relating to Nicolet's direct acquisition costs (approximately \$2.6 million in 2011 and \$(2.6) million in 2012);

Adjustments to cost of goods sold relating to Nicolet's fair value inventory adjustments (approximately \$687,000 in 2011 and \$(571,000) in 2012);

Decrease of Embla's depreciation expense (approximately \$295,000 through September 14, 2011) related to the fair value adjustment to property and equipment acquired;

Elimination of Embla's historical intangible asset amortization expense (approximately \$148,000 in 2011); and

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Additional amortization expense related to Embla (approximately \$225,000 through September 14, 2011) related to the fair value of identifiable intangible assets acquired.

### **3 - Basic and Diluted Earnings (Loss) Per Common Share**

Basic earnings (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted earnings per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents are options granted and shares of restricted stock issued under our stock awards plans and are calculated under the treasury stock method. Common equivalent shares from unexercised stock options and unvested restricted stock are excluded from the computation when there is a loss as their effect is anti-dilutive or if the exercise price of such unexercised options is greater than the average market price of the stock for the period.

**Table of Contents**

Because there was a loss for the three and nine months ended September 30, 2012, no common stock equivalent shares were included in the weighted average shares outstanding used to calculate diluted earnings per share. For the three and nine months ended September 30, 2011, common stock equivalents of 744,067 and 1,088,511 shares, respectively, were included in the weighted average shares outstanding used to calculate diluted earnings per share, while common stock equivalents of 2,326,775 and 1,500,284 shares, respectively, were excluded from the calculation of diluted earnings per share because the exercise price of the underlying options was greater than the average market price of the stock for the periods.

**4 - Inventories**

Inventories consist of the following (in thousands):

	September 30, 2012	December 31, 2011
Raw materials and subassemblies	\$ 24,754	\$ 11,550
Work in process	3,075	
Finished goods	16,710	26,368
Total inventories	44,539	37,918
Less: Non-current inventories	(3,784)	(4,529)
Inventories, current	\$ 40,755	\$ 33,389

The above balances include approximately \$14.0 million of Nicolet inventory as of September 30, 2012. At September 30, 2012 and December 31, 2011, the Company has classified \$3.8 million and \$4.5 million of inventories, respectively, as non-current. This inventory consists primarily of service components used to repair products pursuant to warranty obligations and extended service contracts, including service components for products we are not currently selling. Management believes that these inventories will be utilized for their intended purpose.

**5 - Intangible Assets**

The following table summarizes the components of gross and net intangible asset balances (in thousands):

	September 30, 2012				December 31, 2011			
	Gross Carrying Amount	Accumulated Impairment	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Impairment	Accumulated Amortization	Net Book Value
Intangible assets with definite lives:								
Technology	\$ 62,633		\$ (20,185)	\$ 42,448	\$ 51,245		\$ (17,610)	\$ 33,635
Customer related	26,534		(6,093)	20,441	18,296		(4,602)	13,694
Internally developed software	7,155		(3,763)	3,392	4,414		(2,494)	1,920
Patents	2,742		(2,110)	632	2,757		(1,949)	808
Backlog	723		(712)	11				
Definite lived intangible assets	99,787		(32,863)	66,924	76,712		(26,655)	50,057
Intangible assets with indefinite lives:								
Tradenames	30,284	(1,000)		29,284	21,354	(1,000)		20,354
Total intangibles assets	\$ 130,071	\$ (1,000)	\$ (32,863)	\$ 96,208	\$ 98,066	\$ (1,000)	\$ (26,655)	\$ 70,411

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Definite lived intangible assets are amortized over their weighted average lives of 15 years for technology, 12 years for customer related intangibles, 6 years for internally developed software, and 14 years for patents. Intangible assets with indefinite lives are not subject to amortization. Substantially all of the backlog was written off during the three months ended September 30, 2012.

Internally developed software consists of \$6.2 million relating to costs incurred for development of internal use computer software and \$943,000 for development of software to be sold.

-10-



**Table of Contents**

Amortization expense related to intangible assets with definite lives was as follows (in thousands):

	<b>Three Months Ended September 30, 2012</b>	<b>Nine Months Ended September 30, 2012</b>
Technology	\$ 1,034	\$ 2,575
Customer related	595	1,491
Internally developed software	68	1,269
Patents	60	161
Backlog	712	712
 Total amortization	 \$ 2,469	 \$ 6,208

Expected amortization expense related to amortizable intangible assets is as follows (in thousands):

Three months ending December 31, 2012	\$ 1,711
2013	6,676
2014	6,376
2015	6,042
2016	5,261
2017	4,989
Thereafter	35,869
 Total expected amortization expense	 \$ 66,924

**6 - Goodwill**

The carrying amount of goodwill and the changes in those balances are as follows (in thousands):

Balance, December 31, 2011	\$ 80,375
Goodwill as a result of acquisitions	19,072
Foreign currency translation	(99)
 Balance, September 30, 2012	 \$ 99,348

**7 - Property and Equipment, net**

Property and equipment, net consist of the following (in thousands):

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Land	\$ 4,326	\$ 4,420
Buildings	11,511	10,864
Leasehold improvements	3,210	2,815

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Office furniture and equipment	11,436	10,410
Computer software and hardware	10,347	7,541
Demonstration and loaned equipment	11,885	10,646
	52,715	46,696
Accumulated depreciation and amortization	(24,204)	(21,346)
<b>Total</b>	<b>\$ 28,511</b>	<b>\$ 25,350</b>

Depreciation and amortization expense of property and equipment was approximately \$1.0 million and \$3.2 million for the three and nine months ended September 30, 2012, respectively, and was approximately \$868,000 and \$2.4 million for the three and nine months ended September 30, 2011, respectively.

### **8 - Reserve for Product Warranties**

We provide a warranty on all medical device products that is generally one year in length. We also sell extended service agreements on our medical device products. Service for domestic customers is provided by Company-owned service centers that perform all service, repair, and calibration services. Service for international customers is provided by a combination of Company-owned facilities and third-party vendors on a contract basis.

**Table of Contents**

We have accrued a warranty reserve, included in accrued liabilities on the accompanying balance sheets, for the expected future costs of servicing products during the initial warranty period. We base the liability on actual warranty costs incurred to service those products. On new products, additions to the reserve are based on a combination of factors including the percentage of service department labor applied to warranty repairs, as well as actual service department costs, and other judgments, such as the degree to which the product incorporates new technology. The reserve is reduced as costs are incurred to honor existing warranty obligations.

The details of activity in the warranty reserve are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Balance, beginning of period	\$ 2,225	\$ 1,394	\$ 2,157	\$ 696
Warranty accrued for the period	129	92	540	1,224
Warranty assumed through acquisitions	630	909	630	909
Repairs for the period	(500)	(266)	(843)	(700)
Balance, end of period	\$ 2,484	\$ 2,129	\$ 2,484	\$ 2,129

The estimates we use in projecting future product warranty costs may prove to be incorrect. Any future determination that our product warranty reserves are understated could result in increases to our cost of sales and reductions in our operating profits and results of operations.

**9 - Stockholders Equity**

The details of changes in stockholders equity are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Balance, beginning of period	\$ 259,265	\$ 275,128	\$ 257,728	\$ 263,255
Net income (loss)	(1,949)	154	(1,146)	5,618
Proceeds from stock option exercises and ESPP	200	470	970	1,868
Share-based compensation expense	2,471	1,911	5,007	5,028
Tax effect of option exercises	(279)	3	(891)	299
Foreign currency translation adjustment	147	(2,672)	(1,813)	1,074
Balance, end of period	\$ 259,855	\$ 274,994	\$ 259,855	\$ 274,994

**10 - Share-Based Compensation**

At September 30, 2012, we have two active plans that give rise to share-based compensation, the 2011 Stock Awards Plan and the 2011 Employee Stock Purchase Plan. The terms of awards granted during the nine months ended September 30, 2012 and our methods for determining grant-date fair value of the awards were consistent with those described in the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Detail of share-based compensation expense is as follows (in thousands):

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

Edgar Filing: NATUS MEDICAL INC - Form 10-Q

	2012	2011	2012	2011
Cost of revenue	\$ 49	\$ 87	\$ 161	\$ 224
Marketing and sales	400	486	927	1,196
Research and development	167	131	380	400
General and administrative	1,855	1,207	3,539	3,208
<b>Total</b>	<b>\$ 2,471</b>	<b>\$ 1,911</b>	<b>\$ 5,007</b>	<b>\$ 5,028</b>

As of September 30, 2012, unrecognized compensation expense related to the unvested portion of our stock options and other stock awards was approximately \$11.1 million, which is expected to be recognized over a weighted average period of 2.7 years.

**Table of Contents****Stock Options**

Activity in our stock options during the nine months ended September 30, 2012 is as follows:

	Shares	Weighted Average Exercise Price	Weighted- average remaining contractual life (years)	Aggregate intrinsic value (\$ 000 s)
Outstanding, beginning of period	3,789,866	\$ 11.57		
Granted	713,480	\$ 10.79		
Exercised	(87,622)	\$ 6.14		
Cancelled	(384,418)	\$ 12.36		
Outstanding, end of period	4,031,306	\$ 11.47	3.64	\$ 12,062
Exercisable, end of period	2,768,248	\$ 10.89	2.26	\$ 10,193
Vested and expected to vest, end of period	3,883,265	\$ 11.44	3.50	\$ 11,819

The intrinsic value of options exercised during the nine months ended September 30, 2012 was \$607,000.

**Restricted Stock Awards**

Activity in our restricted stock awards during the nine months ended September 30, 2012 is as follows:

	Shares	Weighted- average grant date fair value	Remaining cost expected to be recognized (\$ 000 s)
Unvested, beginning of period	588,807	\$ 15.37	
Granted	369,390	\$ 10.81	
Vested	(199,832)	\$ 15.43	
Forfeited	(24,280)	\$ 14.74	
Unvested, end of period	734,085	\$ 13.08	\$ 9,594

We award restricted stock awards (RSA s) to U.S. employees of the Company that vest 50% upon the second anniversary of the vesting start date and 25% upon each of the third and fourth anniversaries of the vesting start date. We also award RSA s to non-employee directors of the Company that vest on the first anniversary of the grant date.

At September 30, 2012 the fair market value of outstanding RSA s was \$9.6 million and the weighted average remaining recognition period of unvested RSA s was 2.8 years. At December 31, 2011 the fair market value of outstanding RSA s was \$5.6 million and the weighted average remaining recognition period was 2.5 years. The intrinsic value of RSA s equals their fair market value.

**Restricted Stock Units**

Activity in our restricted stock units during the nine months ended September 30, 2012 is as follows:

Edgar Filing: NATUS MEDICAL INC - Form 10-Q

	Shares	Weighted- average remaining contractual life (years)	Aggregate intrinsic value (\$ 000 s)
Outstanding, beginning of period	56,525		
Awarded	18,600		
Released	(13,525)		
Forfeited	(6,950)		
Outstanding, end of period	54,650	1.93	\$ 714

We award restricted stock units ( RSU s ) to non-U.S. employees of the Company that vest 50% upon the second anniversary of the vesting start date and 25% upon each of the third and fourth anniversaries of the vesting start date.

At September 30, 2012 the aggregate intrinsic value of outstanding RSU s was \$607,000 and the weighted average remaining recognition period for unvested RSU s was 3.0 years. At December 31, 2011 the aggregate intrinsic value of outstanding RSU s was \$538,000 and the weighted average remaining recognition period for unvested RSU s was 1.9 years.

**Table of Contents****11 - Other income (expense), net**

Other income (expense), net consisted of (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Investment income	\$ 11	\$ 6	\$ 20	\$ 23
Interest expense	(215)	(47)	(231)	(160)
Foreign currency exchange gain (loss)	136	67	470	(39)
Other	(160)	160	(33)	148
<b>Total other income (expense), net</b>	<b>\$ (228)</b>	<b>\$ 186</b>	<b>\$ 226</b>	<b>\$ (28)</b>

**12 - Income Taxes****Provision for Income Tax (Benefit) Expense**

We recorded provisions for income tax (benefit) of \$(3.1) million and \$(2.5) million for the three and nine months ended September 30, 2012, respectively, and provisions for income tax (benefit) expense of \$(1.0) million and \$1.5 million for the three and nine months ended September 30, 2011, respectively.

Our effective tax rate was 61.6% and 68.6% for the three and nine months ended September 30, 2012, respectively, and 117.9% and 21.2% for the three and nine months ended September 30, 2011, respectively.

Our effective tax rate for the three and nine months ended September 30, 2012 differed from statutory tax rates primarily because of the settlement of foreign and U.S. state income tax audits and from the expiration of the statute of limitations on uncertain tax positions that were recorded as a component of income tax expense in prior years, which together resulted in a tax benefit of \$3.1 million and \$2.5 million for the three and nine months ended September 30, 2012, respectively.

As of September 30, 2012 and December 31, 2011, we had unrecognized tax benefits of \$1.6 million and \$5.3 million, respectively. The decrease of unrecognized tax benefit is primarily due to reversal of tax reserves resulting from settlement of foreign and U.S. state income tax audits and the expiration of the statute of limitations on prior tax years. We do not expect that similar tax benefits will be significant in the remainder of 2012.

Our tax returns remain open to examination as follows: U.S. Federal, 2007 through 2011; U.S. states, generally 2006 through 2011; significant foreign jurisdictions, generally 2007 through 2011.

**13 - Restructuring Reserves**

In January 2011, we adopted a reorganization plan that was designed to improve efficiencies in the operations of Medix, which we acquired in October 2010. During the three months ended September 30, 2011 we also initiated similar restructuring activities in Embla, which we acquired in September 2011. We expect these restructuring activities to be substantially completed by December 31, 2012. These plans are collectively referred to as the 2011 Plans below.

In July 2012, we initiated an integration and reorganization plan related to the acquisition of Nicolet that is designed to eliminate redundant costs, improve efficiencies in operations, and to move to an indirect sales model in certain countries in Europe, where Nicolet had previously sold under a direct sales model. We expect that substantially all of the staff reductions will be completed by December 31, 2012.

The balance of the restructuring reserve is included in accrued liabilities on the accompanying balance sheets. Employee termination benefits expensed are included as a part of general and administrative expenses.





**Table of Contents**

Activity in the restructuring reserves for these plans for the nine months ended September 30, 2012 is as follows (in thousands):

	Integration and Reorganization Plans		
	2011 Plans	July 2012 Plan	Totals
Balances at December 31, 2011	\$ 774	\$	\$ 774
Expensed	1,721	6,579	8,300
Cash payments	(1,872)	(2,788)	(4,660)
Accrual reversal	(202)		(202)
Balances at September 30, 2012	\$ 421	\$ 3,791	\$ 4,212

**14 - Debt and Credit Arrangements**

At September 30, 2012 the Company had a \$50 million revolving credit facility with Wells Fargo Bank, National Association ( Wells Fargo ). The revolving credit facility contains covenants, including covenants relating to liquidity and other financial measurements, and provides for events of default, including failure to pay any interest when due, failure to perform or observe covenants, bankruptcy or insolvency events, and the occurrence of a material adverse effect, and restricts our ability to pay dividends. We have granted Wells Fargo a security interest in substantially all of our assets. We have no other significant credit facilities.

We did not draw on the facility during 2011. We funded the Nicolet acquisition with a combination of our existing cash and \$31 million borrowed under the credit facility, including \$25.0 million due in equal quarterly installments through June 30, 2015 and \$6.0 million of revolving debt. We borrowed an additional \$1.3 million of revolving debt during the quarter ended September 30, 2012.

Long-term debt is comprised of the following (2012 and 2011 columns in thousands):

	September 30, 2012	December 31, 2011
Term loan \$25 million, interest at LIBOR plus 1.5%, due June 30, 2015 with term loan principle repayable in quarterly installments of \$2.1 million	\$ 22,917	\$
Term loan \$2.9 million Canadian ( CAD ), interest at cost of funds plus 2.5%, due September 15, 2014 with principle repayable in monthly installments of \$16,000 until August 15, 2014 and one final payment of \$404,000 collateralized by a first lien on land and building owned by Xltek	784	898
Total	23,701	898
Less current portion of long-term debt	(8,528)	(188)
Total long-term debt	\$ 15,173	\$ 710

Maturities of long-term debt as of September 30, 2012 are as follows (in thousands):

2012	\$ 2,161
2013	8,525
2014	8,845

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

2015	4,170
Thereafter	
Total	23,701
Less current portion of long-term debt	(8,528)
Total long-term debt	\$ 15,173

Short-term borrowings at September 30, 2012 consists of the aforementioned \$7.3 million revolving debt associated with the Nicolet acquisition, with interest at LIBOR plus 1.5%.

At September 30, 2012 and December 31, 2011, the carrying value of total debt approximates fair market value. The fair value of the Company's debt is considered a Level 2 measurement.

**Table of Contents**

**15 - Segment, Customer and Geographic Information**

We operate in one reportable segment in which we provide healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders.

Our end-user customer base includes hospitals, clinics, laboratories, physicians, nurses, audiologists, and governmental agencies. Most of our international sales are to distributors who resell our products to end-users or sub-distributors.

Revenue and long-lived asset information by geographic region is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue:				
United States	\$ 47,398	\$ 30,792	\$ 111,964	\$ 95,944
Foreign countries	33,326	20,546	89,282	72,597
Totals	\$ 80,724	\$ 51,338	\$ 201,246	\$ 168,541

	September 30, 2012	December 31, 2011
Long-lived assets:		
United States	\$ 11,513	\$ 9,428
Foreign countries	16,998	15,922
Totals	\$ 28,551	\$ 25,350

Long-lived assets consist principally of net property and equipment. During the three and nine months ended September 30, 2012 and 2011, no single customer or foreign country contributed to more than 10% of revenue, and revenue from services was less than 10% of revenue.

During the three and nine months ended September 30, 2012, respectively, revenue from devices and systems was \$48.1 million and \$124.8 million, while revenue from supplies and services was \$30.3 million and \$72.6 million, respectively.

**16 - Fair Value Measurements**

The fair value of our assets and liabilities subject to fair value measurements are as follows (in thousands):

	Fair Value as of September 30, 2012	Fair Value Measurements as of September 30, 2012 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Bank money market investments	\$ 1,148		\$ 1,148	
Total	\$ 1,148		\$ 1,148	

Edgar Filing: NATUS MEDICAL INC - Form 10-Q

	Fair Value as of December 31, 2011	Fair Value Measurements as of December 31, 2011 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Bank money market investments	\$ 1,148		\$ 1,148	
Total	\$ 1,148		\$ 1,148	

Level 2 valuations are based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly, and include bank money market investments having a net asset value of \$1.00 per share consisting principally of commercial paper with a rating of A-1/A-1+.

Level 1 valuations are based on quoted prices in active markets for identical assets or liabilities that the Company has the ability to access. Level 3 valuations are based on inputs that are not unobservable and significant to the overall fair value measurement. At September 30, 2012 the Company has no assets or liabilities subject to Level 1 or Level 3 valuations.

**Table of Contents****ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*Natus*<sup>®</sup>, *AABR*<sup>®</sup>, *ABaer*<sup>®</sup>, *ALGO*<sup>®</sup>, *AOAE*<sup>®</sup>, *AuDX*<sup>®</sup>, *Balance Manager*<sup>®</sup>, *Balance Master*<sup>®</sup>, *Biliband*<sup>®</sup>, *Bio-logic*<sup>®</sup>, *Ceegrath*<sup>®</sup>, *CHAMP*<sup>®</sup>, *Cochlea Scan*<sup>®</sup>, *Cool Cap*<sup>®</sup>, *Ear Couplers*<sup>®</sup>, *Echo Screen*<sup>®</sup>, *Embla*<sup>®</sup>, *Embletta*<sup>®</sup>, *Enterprise*<sup>®</sup>, *EquiTest*<sup>®</sup>, *Fischer-Zoth*<sup>®</sup>, *Flexicoupler*<sup>®</sup>, *Gundrop*<sup>®</sup>, *Keypoint*<sup>®</sup>, *Keypoint AU*<sup>®</sup>, *Keypoint EU*<sup>®</sup>, *Keypoint JP*<sup>®</sup>, *MASTER*<sup>®</sup>, *Medix*<sup>®</sup>, *MedixI.C.S.A.*<sup>®</sup>, *Navigator*<sup>®</sup>, *Neatnick*<sup>®</sup>, *neoBLUE*<sup>®</sup>, *Neuromax*<sup>®</sup>, *NeuroWorks*<sup>®</sup>, *Nicolet*<sup>®</sup>, *NicoletElite*<sup>®</sup>, *Oxydome*<sup>®</sup>, *REMrand*<sup>®</sup>, *REMrlogic*<sup>®</sup>, *Sandman*<sup>®</sup>, *Sleeprite*<sup>®</sup>, *Sleepscan*<sup>®</sup>, *Smart Scale*<sup>®</sup>, *STETHODOP*<sup>®</sup>, *TECA*<sup>®</sup>, *Tootsweet*<sup>®</sup>, *Traveler*<sup>®</sup>, *Warmette*<sup>®</sup> and *VAC PAC*<sup>®</sup>, *VERSALAB*<sup>®</sup>, *Xact Trace*<sup>®</sup>, are registered trademarks of Natus Medical Incorporated and its subsidiaries. *Accuscreen*, *Bili Lite Pad*, *Bili-Lite*, *Biomark*, *Circumstraint*, *Coherence*, *Deltamed*, *inVision*, *MediLED*, *MiniMuffs*, *NATUS NatalCare*, *Neometrics* and *Smartpack* are non-registered trademarks of Natus and its subsidiaries. *Solutions for Newborn CareSM* is a non-registered service mark of Natus.

**Overview**

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) supplements the MD&A in the Annual Report on Form 10-K for the year ended December 31, 2011 of Natus Medical Incorporated ( Natus, we, us, or our Company ), and presumes that readers have read or have access to the discussion and analysis in our Annual Report. Management's discussion and analysis should be read in conjunction with our condensed consolidated financial statements and accompanying footnotes, the discussion of certain risks and uncertainties contained in Part II, Item 1A of this report, and the cautionary information regarding forward-looking statements at the end of this section. MD&A includes the following sections:

Our Business. A general description of our business;

2012 Third Quarter Overview. A summary of key information concerning the financial results for the three months ended September 30, 2012;

Application of Critical Accounting Policies. A discussion of the accounting policies that are most important to the portrayal of our financial condition and results of operations and that require significant estimates, assumptions, and judgments;

Results of Operations. An analysis of our results of operations for the periods presented in the financial statements;

Liquidity and Capital Resources. An analysis of capital resources, sources and uses of cash, investing and financing activities, off-balance sheet arrangements, contractual obligations and interest rate hedging;

Recent Accounting Pronouncements. See Note 1 to our Condensed Consolidated Financial Statements for a discussion of new accounting pronouncements that affect us; and

Cautionary Information Regarding Forward-Looking Statements. Cautionary information about forward-looking statements.

**Our Business**

Natus is a leading provider of healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders. Product offerings include computerized neurodiagnostic systems for audiology, neurology, polysomnography, and neonatology, as well as newborn care products such as hearing screening systems, phototherapy devices for the treatment of newborn jaundice, head-cooling products for the treatment of brain injury in newborns, incubators to control the newborn's environment, and software systems for managing and tracking disorders and diseases for public health laboratories.

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

We have completed a number of acquisitions since 2003, consisting of either the purchase of a company, substantially all of the assets of a company, or individual products or product lines. The businesses we have acquired are Neometrics in 2003, Fischer-Zoth in 2004, Bio-logic, Deltamed, and Olympic Medical in 2006, Xltek in 2007, Sonamed, Schwarzer Neurology, and Neurocom in 2008, Hawaii Medical and Alpine Biomed in 2009, Medix in 2010, Embla in 2011, and Nicolet in 2012.

-17-

**Table of Contents**

## Product Families

We categorize our products into the following product families, which are more fully described in our Annual Report on Form 10-K for the year ended December 31 2011:

**Neurology** Includes products for diagnostic electroencephalography (EEG), electromyography (EMG), intra-operative monitoring (IOM), diagnostic sleep analysis, or polysomnography (PSG), newborn brain monitoring, and assessment of balance and mobility disorders.

**Hearing** Includes products for newborn hearing screening and diagnostic hearing assessment.

**Newborn Care** Includes thermoregulation devices and products for the treatment of brain injury and jaundice in newborns.

*Segment and Geographic Information*

We operate in one reportable segment in which we provide healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders and balance and mobility disorders.

Our end-user customer base includes hospitals, clinics, laboratories, physicians, nurses, audiologists, and governmental agencies. Most of our international sales are to distributors who resell our products to end-users or sub-distributors.

Information regarding our sales and long-lived assets in the U.S. and in countries outside the U.S. is contained in Note 15 *Segment, Customer and Geographic Information* of our condensed consolidated financial statements included in this report.

*Revenue by Product Category*

We generate our revenue either from sales of Devices and Systems, which are generally non-recurring, and from related Supplies and Services, which are generally recurring. Other revenue consists primarily of freight revenue. The products that are attributable to these categories are described in our Annual Report on Form 10-K for the year ended December 31, 2011. Revenue from Devices and Systems and Supplies and Services, as a percent of total revenue for the three and nine months ended September 30, 2012 and 2011 is as follows:

	Three Months Ended		Nine Months	
	September 30,		Ended	
	2012	2011	2012	2011
Devices and Systems	60%	61%	62%	64%
Supplies and Services	38%	37%	36%	34%
Other	2%	2%	2%	2%
Total	100%	100%	100%	100%

During the three and nine months ended September 30, 2012 and 2011, no single customer or foreign country contributed to more than 10% of revenue, and revenue from services was less than 10% of revenue.

**2012 Third Quarter Overview**

Our business and operating results have been and continue to be affected by worldwide economic conditions. Our sales are significantly dependent on both capital spending by hospitals in the United States and healthcare spending by ministries of health within the European Union.

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Our consolidated revenue increased \$29.4 million in the third quarter ended September 30, 2012 to \$80.7 million compared to \$51.3 million in the third quarter of the previous year. Nicolet, acquired in July 2012, contributed to \$24.1 million of incremental revenue and Embla, acquired in September 2011, contributed to \$5.3 million of incremental revenue in the third quarter of 2012. We experienced revenue increases and declines across other business units in the United States, Europe, and South America that resulted in the same level of revenue in both quarters.

-18-



**Table of Contents**

We incurred a net loss of \$1.9 million or \$(0.07) per share in the three months ended September 30, 2012, compared with net income of \$154,000 or \$0.01 per diluted share in the same period in 2011. The net loss for the 2012 period included restructuring and related stock compensation costs of \$7.7 million and direct costs associated with the Nicolet acquisition completed in July 2012 of \$786,000. An increase in gross profit of 1.1 percentage points for the third quarter of 2012 compared to same period in 2011, resulted primarily from product mix.

**Application of Critical Accounting Policies**

We prepare our financial statements in accordance with accounting principles generally accepted in the United States of America ( GAAP ). In so doing, we must often make estimates and use assumptions that can be subjective, and, consequently, our actual results could differ from those estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable.

We believe that the following critical accounting policies require the use of significant estimates, assumptions, and judgments. The use of different estimates, assumptions, or judgments could have a material effect on the reported amounts of assets, liabilities, revenue, expenses, and related disclosures as of the date of the financial statements and during the reporting period:

Revenue recognition

Inventory is carried at the lower of cost or market value

Carrying value of intangible assets and goodwill

Liability for product warranties

Share-based compensation

These critical accounting policies are described in more detail in our Annual Report on Form 10-K for the year ended December 31, 2011, under Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*. There have been no changes to these policies during the three and nine months ended September 30, 2012.

**Results of Operations**

The following table sets forth, for the periods indicated, selected consolidated statements of operations data as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2012	2011	2012	2011
Revenue	100%	100.0%	100%	100%
Cost of revenue	45.2	46.3	44.4	43.4
Gross profit	54.8	53.7	55.6	56.6
Operating expenses:				
Marketing and selling	27.0	28.6	27.2	26.6
Research and development	10.5	11.9	10.9	11.0
General and administrative	23.3	15.2	19.5	14.7

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Total operating expenses	60.8	55.7	57.6	52.3
Income (loss) from operations	(6.0)	(2.0)	(2.0)	4.3
Other income (expense), net	(0.3)	0.4	0.1	
Income (loss) before provision (benefit) for income tax	(6.3)	(1.6)	(1.9)	4.3
Provision for income tax (benefit) expense	(3.9)	(2.0)	(1.3)	0.9
Net income (loss)	(2.4)%	0.4%	(0.6)%	3.4%

We acquired Nicolet in July 2012 and Embla in September 2011. Where significant, we have noted the impact of these acquisitions on our results of operations for the three and nine months ended September 30, 2012, as compared to the same periods in 2011.

**Table of Contents**

**Three Months Ended September 30, 2012 and 2011**

Our revenue increased \$29.4 million, or 57%, to \$80.7 million for the three months ended September 30, 2012, compared to \$51.3 million in the comparable 2011 period. Nicolet contributed \$24.1 million and Embla contributed \$5.3 million of incremental revenue during the 2012 quarter.

Revenue from devices and systems increased \$17 million, or 55%, to \$48.1 million in the third quarter of 2012, compared to \$31.1 million in the same period in 2011. Nicolet contributed \$12.9 million and Embla contributed \$3.3 million of incremental device and system revenue during the 2012 quarter. Devices and systems revenue from our neurology and other diagnostic products other than Nicolet and Embla increased \$200,000 or 2% to \$14.0 million and devices and systems revenue from newborn care and other device products increased \$600,000. Revenue from devices and systems was 60% and 61% of total revenue for the three months ended September 30, 2012 and 2011, respectively.

Revenue from supplies and services increased \$11.1 million, or 58%, to \$30.3 million in the third quarter of 2012 compared to \$19.2 million in the same period in 2011. Nicolet contributed \$10.0 million and Embla contributed \$2 million of incremental supplies and services revenue in the third quarter of 2012. Revenue from newborn care and hearing supplies increased by \$100,000, revenue from neurology supplies other than Nicolet and Embla decreased by \$500,000 and service fee revenue other than Nicolet and Embla decreased by \$500,000. Revenue from supplies and services was 38% of total revenue in the three months ended September 30, 2012, compared to 37% of total revenue for the third quarter of 2011.

Revenue from sales outside the U.S. increased 62%, or \$12.7 million to \$33.3 million in the third quarter of 2012 compared to \$20.6 million for the same period in 2011. Nicolet and Embla contributed \$13.3 million of international revenue, while revenue from neurology and hearing products other than Nicolet and Embla increased by \$200,000 and international revenue from newborn care and other products decreased by \$800,000.

Gross profit as a percentage of revenue was 54.8% for the three months ended September 30, 2012 compared to 53.7% for the corresponding 2011 period, reflecting increased profit margins on Natus U.S. and Xltek products. Gross profit increased \$16.7 million or 61% to \$44.3 million in 2012 from \$27.6 million in 2011.

Total operating expense increased by \$20.5 million, or 72%, to \$49.1 million in the three months ended September 30, 2012, compared to \$28.6 million in the same period in 2011. The operating expense of Nicolet and the incremental expense of Embla was \$13.0 million. In addition, restructuring costs and direct acquisition costs, respectively, were \$6.3 million and \$500,000 more in the 2012 period compared to the 2011 period. We wrote off \$700,000 of Nicolet backlog in the 2012 period with no such expense in the 2011 period.

Marketing and selling expense increased \$7.1 million, or 48%, to \$21.8 million in the three months ended September 30, 2012, compared to \$14.7 million in the same period in 2011. The marketing and selling expense of Nicolet, including the backlog write-off, and the incremental expense of Embla was \$6.8 million. The remainder of the increase was primarily related to higher commission costs.

Research and development expense increased \$2.4 million or 39%, to \$8.5 million for the three months ended September 30, 2012, compared to \$6.1 million in the same period of 2011. The research and development expense of Nicolet and the incremental expense of Embla was \$3.1 million. A decrease in other expense was primarily attributable to lower employee compensation costs resulting from cost cutting activities initiated earlier in 2012.

General and administrative expense increased \$11 million, or 141%, to \$18.8 million in the three months ended September 30, 2012, compared to \$7.8 million in the same period in 2011. The general and administrative expense of Nicolet and the incremental expense of Embla was \$3.1 million. The cost of restructuring activities and direct costs of acquisitions increased by \$6.2 million and \$500,000, respectively, in the 2012 period compared to the same period in 2011.

Other income (expense), net, consists of investment income from our investment portfolio, interest expense, net currency exchange gains and losses, and other miscellaneous income and expenses. We reported net other expense of \$228,000 in the three months ended September 30, 2012, compared to net other income of \$186,000 in the same period in 2011. We incurred other expense of \$160,000 during the three months ended September 30, 2012 compared with the same amount of other income during the three months ended September 30, 2011. In addition, interest expense was higher by \$168,000 for the three months ended September 30, 2012 quarter compared to the same quarter in 2011 resulting from bank borrowings in connection with the Nicolet acquisition.

---

**Table of Contents**

We recorded a provision for income tax benefit of \$3.1 million and \$1.0 million in the three months ended September 30, 2012 and 2011, respectively. The increase of tax benefit for the three months ended September 30, 2012 compared to the same period in the prior year is attributable primarily to the reversal of tax reserves upon settlement of a state income tax audit and the expiration of the statute of limitations on uncertain tax positions that were recorded as a component of income tax expense in prior years.

**Nine Months Ended September 30, 2012 and 2011**

Our revenue increased \$32.7 million, or 19%, to \$201.2 million for the nine month period ended September 30, 2012 compared to \$168.5 million in the comparable 2011 period. Nicolet contributed \$24.1 million and Embla contributed \$20.1 million of incremental revenue during 2012. Revenue from our newborn care products decreased \$2.3 million, revenue from neurology products other than from Nicolet and Embla decreased \$6.1 million and revenue from our hearing and other products decreased \$3.1 million in the nine month period in 2012 compared to the nine months ended September 30, 2011.

Revenue from devices and systems increased \$17.5 million, or 16% to \$124.8 million in the nine month period of 2012 compared to \$107.3 million in the same period in 2011. Nicolet contributed \$13 million and Embla contributed \$11.1 million of incremental device and system revenue during the 2012. Devices and systems revenue from our neurology and other diagnostic products other than Nicolet and Embla decreased \$5.9 million, or 11%, to \$47.0 million and devices and systems revenue from newborn hearing screening coupled with newborn care and other device products decreased \$600,000, reflecting continued weakness in worldwide capital spending coupled with pricing pressures. Revenue from devices and systems was 62% of total revenue in the nine months ended September 30, 2012 compared to 64% of total revenue for 2011.

Revenue from supplies and services increased \$14.2 million, or 24%, to \$72.6 million in the nine month period of 2012 compared to \$58.4 million in the same period in 2011. Nicolet contributed \$10.0 million and Embla contributed \$8.9 million of incremental supplies and services revenue in 2012. Revenue from newborn care and hearing supplies decreased by \$1.1 million, revenue from neurology supplies other than Nicolet and Embla decreased by \$1.3 million, and service fee revenue other than Nicolet and Embla decreased by \$2.3 million, primarily related to newborn care. Revenue from supplies and services was 36% of total revenue in the nine months ended September 30, 2012 compared to 34% of total revenue for 2011.

Revenue from sales outside the U.S. increased \$16.6 million, or 23%, to \$89.3 million in the nine month period of 2012 compared to \$72.7 million for the same period in 2011. Nicolet contributed \$11.1 million and Embla contributed \$9.7 million of international revenue, while revenue from neurology and hearing products other than Nicolet and Embla decreased by \$200,000 and international revenue from newborn care and other products decreased by \$4.0 million.

Gross profit as a percentage of revenue was 55.6% for the nine months ended September 30, 2012 compared to 56.6% for the corresponding 2011 period, with the reduction primarily the result of increases in materials costs. Gross profit increased \$16.6 million to \$112.0 million in 2012 from \$95.4 million in 2011.

Total operating expenses increased by \$27.7 million, or 31%, to \$115.9 million in the nine months ended September 30, 2012, compared to \$88.2 million in the same period in 2011. The operating expense of Nicolet and the incremental expense of Embla contributed to \$18.4 million of the increase. In addition, restructuring costs and direct acquisition costs, respectively, were \$6.8 million and \$2.6 million more in the 2012 period than the 2011 period.

Marketing and selling expense increased \$9.9 million, or 22%, to \$54.7 million in the nine months ended September 30, 2012, compared to \$44.8 million in the same period in 2011. The marketing and selling expense of Nicolet and the incremental expense of Embla was \$9.1 million. The remainder of the increase was primarily attributable to the amortization of \$700,000 of backlog recognized through purchase accounting associated with the Nicolet acquisition.

Research and development expense increased \$3.3 million, or 18%, to \$21.9 million for the nine months ended September 30, 2012, compared to \$18.6 million in the same period of 2011. The research and development expense of Nicolet and the incremental expense of Embla was \$4.9 million, partially offset by lower employee compensation costs resulting from cost cutting activities initiated early in 2012.

General and administrative expense increased \$14.4 million, or 58%, to \$39.2 million in the nine months ended September 30, 2012, compared to \$24.8 million in the same period in 2011. The general and administrative expense of Nicolet and the incremental expense of Embla was \$4.4 million. The cost of restructuring activities and direct costs of acquisitions increased by \$6.8 million and \$2.6 million, respectively, in the 2012 period compared to the same period in 2011.



---

## **Table of Contents**

Other income (expense), net, consists of investment income from our investment portfolio, interest expense, net currency exchange gains and losses, and other miscellaneous income and expenses. We reported net other income of \$226,000 in the nine months ended September 30, 2012, compared to net other expense of \$28,000 in the same period in 2011. We recognized \$470,000 of foreign exchange gains and \$39,000 of net foreign currency exchange losses during the nine months ended September 30, 2012 and 2011, respectively.

We recorded a provision for income tax benefit of \$2.5 million in the nine months ended September 30, 2012, compared to a provision for income tax expense of \$1.5 million in the same period in 2011. The tax benefit for the nine months ended September 30, 2012 compared to tax expense for same period in the prior year is primarily the result in the 2012 period of the settlement of foreign and U.S. state income tax audits and the expiration of the statute of limitations on uncertain tax positions that were recorded as a component of income tax expense in prior years.

## **Liquidity and Capital Resources**

Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing and to raise capital. Therefore, liquidity cannot be considered separately from capital resources that consist of our current funds and the potential to increase those funds in the future. We plan to use these resources in meeting our commitments and in achieving our business objectives.

As of September 30, 2012, we had cash and cash equivalents of \$19.5 million, stockholders' equity of \$259.9 million, and working capital of \$62.6 million, compared with cash and cash equivalents of \$32.8 million, stockholders' equity of \$257.7 million, and working capital of \$90.5 million as of December 31, 2011.

As of September 30, 2012, we had cash and cash equivalents outside the U.S. in certain of our foreign operations of approximately \$13.2 million. We currently intend to permanently reinvest the cash held by our foreign subsidiaries. If, however, a portion of these funds were needed for and distributed to our operations in the United States, we would be subject to additional U.S. income taxes and foreign withholding taxes. The amount of taxes due would depend on the amount and manner of repatriation, as well as the location from where the funds are repatriated.

We have a \$50 million revolving credit facility with Wells Fargo Bank, National Association (Wells Fargo). The revolving credit facility contains covenants, including covenants relating to liquidity and other financial measurements, and provides for events of default, including failure to pay any interest when due, failure to perform or observe covenants, bankruptcy or insolvency events and the occurrence of a material adverse effect, and restricts our ability to pay dividends. We have granted Wells Fargo a security interest in substantially all of our assets. We have no other significant credit facilities. We did not draw on the credit facility in 2011.

In July 2012, we acquired for a cash purchase price of \$57.9 million all of the outstanding common shares of CareFusion subsidiaries comprising the Nicolet business in the United States, Ireland, and the United Kingdom, and certain assets and liabilities of Nicolet sales divisions principally in China, Brazil, Germany, Italy, the Netherlands, and Spain. We funded this acquisition with a combination of cash on hand and a \$31.0 million borrowing under the Wells Fargo credit facility.

We believe that our current cash and cash equivalents and any cash generated from operations will be sufficient to meet our ongoing operating requirements for the foreseeable future. In addition to the Nicolet acquisition, we acquired Embla in 2011 and Medix in 2010, and completed two acquisitions in 2009, four acquisitions in 2008, one in 2007, and three in 2006. We intend to continue to acquire additional technologies, products, or businesses and these acquisitions could be significant. These actions would likely affect our future capital requirements and the adequacy of our available funds. In order to finance future acquisitions, we may be required to raise additional funds through public or private financings, strategic relationships or other arrangements. Any equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and increase our cost of capital.

Cash provided by operations increased by \$400,000 for the nine months ended September 30, 2012 to \$17.0 million, compared to \$16.6 million for the same period in 2011. The sum of our net income and certain non-cash expense items, such as reserves, depreciation and amortization, and share based compensation was approximately \$14.1 million in the 2012 period, compared to \$18.4 million in 2011. The overall impact of changes in certain operating assets and liabilities on total operating cash flows resulted in a cash inflow of \$2.9 million in 2012 compared with a cash outflow of \$1.7 million in 2011. In particular, our cash flow from operations in the first nine months of 2012 was negatively impacted by a \$12.8 million increase in accounts receivable and positively impacted by a \$5.1 million decrease in inventories, exclusive of the accounts receivable and inventory acquired from Nicolet, offset by a \$9.2 million increase in accounts payable.

---

## **Table of Contents**

Cash used in investing activities was \$61.4 million for the nine months ended September 30, 2012, compared to cash used by investing activities of \$16.3 million for the same period in 2011. We used \$57.9 million to acquire businesses during the nine months ended September 30, 2012 compared with \$14.9 million during the nine months ended September 30, 2011. We used \$3.8 million and \$2.2 million of cash to acquire property and equipment during the nine months ended September 30, 2012 and 2011, respectively. We transferred \$2.7 million of construction in process to intangible assets relating to internal software development. We received \$1.0 million for sale of marketable securities during the nine months ended September 30, 2011.

Cash provided by financing activities was \$31.2 million and \$2.6 million in the nine months ended September 30, 2012 and 2011, respectively. In June 2012 we borrowed \$31 million of cash on our credit facility to partially fund the acquisition of Nicolet and had additional borrowings of \$1.3 million as of September 30, 2012. We received cash from sales of our stock pursuant to exercise of stock options and contributions to our employee stock purchase plan in the amount of \$970,000 and \$1.9 million in the nine months ended September 30, 2012 and 2011, respectively. During the nine months ended September 30, 2012 and 2011, we realized an excess tax benefit on the exercise of employee stock options of \$125,000 and \$299,000, respectively.

Our future liquidity and capital requirements will depend on numerous factors, including the:

Extent to which we make acquisitions;

Amount and timing of revenue;

Extent to which our existing and new products gain market acceptance;

Cost and timing of product development efforts and the success of these development efforts;

Cost and timing of marketing and selling activities; and

Availability of borrowings under line of credit arrangements and the availability of other means of financing.

## **Commitments and Contingencies**

In the normal course of business, we enter into obligations and commitments that require future contractual payments. The commitments result primarily from firm, noncancellable purchase orders placed with contract vendors that manufacture some of the components used in our medical devices and related disposable supply products, as well as commitments for leased office, manufacturing, and warehouse facilities. The only material change to the table of contractual obligations presented in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, of our Annual Report on Form 10-K for the year ended December 31, 2011 has been the result of \$0 million of debt incurred from borrowings against the revolving credit facility as of September 30, 2012.

Under our bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences arising as a result of the officer or director's serving in such capacity. We have a directors and officers' liability insurance policy that limits our exposure and enables us to recover a portion of any future amounts paid resulting from the indemnification of our officers and directors. In addition, we enter into indemnification agreements with other parties in the ordinary course of business. In some cases we have obtained liability insurance providing coverage that limits our exposure for these other indemnified matters. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. We believe the estimated fair value of these indemnification agreements is minimal and have not recorded a liability for these agreements.

## **Recent Accounting Pronouncements**

See Note 1 to our Condensed Consolidated Financial Statements for a discussion of new accounting pronouncements that affect us.

**Cautionary Information Regarding Forward Looking Statements**

*This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 about Natus Medical Incorporated. These statements include, among other things, statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words may, will, continue, estimate, project, intend, believe, expect, anticipate, and other similar expressions generally identify forward-looking statements. Forward-looking statements in this Item 2 include, but are not limited to, statements regarding the following: our belief that the recovery from the worldwide economic downturn has continued, our expectation regarding expansion of our international operations, our expectations regarding our new products, the sufficiency of our current cash, cash equivalents, and short-term investment balances, and any cash generated from operations to meet our ongoing operating and capital requirements for the foreseeable future, the use of debt to fund acquisitions, our expectations of earnout arrangements related to acquisitions, and our intent to acquire additional technologies, products, or businesses.*



---

## **Table of Contents**

*Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results predicted in the forward-looking statements as well as our future financial condition and results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption "Risk Factors" contained in Part II, Item 1A of this report for a description of risks and uncertainties. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.*

### **ITEM 3. Quantitative and Qualitative Disclosures about Market Risk**

We develop products in the U.S., Canada, Argentina, and Europe and sell those products into more than 100 countries throughout the world. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. Most of our sales in Europe and Asia are denominated in U.S. Dollars and Euros and with the acquisitions of Xltek in 2007, Medix in 2010 and Nicolet in 2012, a small portion of our sales are now denominated in Canadian dollars, Argentine pesos and British pounds. As our sales in currencies other than the U.S. Dollar increase, our exposure to foreign currency fluctuations may increase.

In addition, changes in exchange rates also may affect the end-user prices of our products compared to those of our foreign competitors, who may be selling their products based on local currency pricing. These factors may make our products less competitive in some countries.

If the U.S. Dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net income would have correspondingly increased or decreased by an immaterial amount for the nine months ended September 30, 2012. Our interest income is sensitive to changes in the general level of interest rates in the U.S. However, because current market conditions have resulted in historically low rates of return on our investments, a hypothetical decrease of 10% in market interest rates would not result in a material decrease in interest income earned on our investments held as of September 30, 2012.

When able, we invest excess cash in bank money-market funds or discrete short-term investments. The fair value of short-term investments and cash equivalents ( investments ) is sensitive to changes in the general level of interest rates in the U.S., and the fair value of these investments will fall if market interest rates increase. However, since we generally have the ability to hold the investments to maturity, these declines in fair value may never be realized. If market interest rates were to increase by 10% from levels at September 30, 2012, the fair value of our investments would decline by an immaterial amount.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of September 30, 2012. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio, and changes in the relationship between short-term and long-term interest rates.

### **ITEM 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

Under the rules of the Securities and Exchange Commission, disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our chief executive officer and our chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. Our chief executive officer and chief financial officer determined that as of September 30, 2012 our disclosure controls and procedures were effective for the purpose set forth above.

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

Under the rules of the Securities and Exchange Commission, internal control over financial reporting is defined as a process designed by, or under the supervision of, an issuer's principal executive and principal financial officers, and effected by the issuer's board of directors, management and other personnel, to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.



## **Table of Contents**

During the quarter ended September 30, 2012 we completed the North American phase of our global enterprise resource planning ( ERP ) implementation, exclusive of the operations on the Nicolet business that we acquired on July 2, 2012. As a result, we implemented changes to our overall internal control over financial reporting during the period covered by this quarterly report on Form 10-Q. These changes had a material impact on our internal control over financial reporting.

There were no other changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2012, that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. Legal Proceedings**

We may from time to time become a party to various legal proceedings or claims that arise in the ordinary course of business. Our management reviews these matters if and when they arise and believes that the resolution of any such matters currently known will not have a material effect on our results of operations or financial position.

### **ITEM 1A. Risk Factors**

**We have completed a number of acquisitions and expect to complete additional acquisitions in the future. There are numerous risks associated with acquisitions and we may not achieve the expected benefit of any of our acquisitions**

Our acquisitions of products, technology assets, or businesses may have a negative impact on our business if we fail to achieve the anticipated financial, strategic, and other benefits of acquisitions or investments, and our operating results may suffer because of this.

Our significant acquisitions are as follows: Neometrics in 2003; Fischer-Zoth in 2004; Bio-logic, Deltamed, and Olympic in 2006; Xltek in 2007; Sonamed, Schwarzer Neurology, and Neurocom in 2008; Hawaii Medical and Alpine Biomed in 2009, Medix in 2010, Embla in 2011 and Nicolet in 2012.

We expect to continue to pursue opportunities to acquire other businesses in the future. The acquisitions that we have completed may not result in improved operating results for us, or in our achieving a financial condition superior to that which we would have achieved had we not completed them. Our results of operations may be adversely impacted by costs associated with our acquisitions, including one-time charges associated with restructurings. Further, our acquisitions could fail to produce the benefits that we anticipate, or could have other adverse effects that we currently do not foresee. In addition, some of the assumptions that we have relied upon, such as achievement of operating synergies, may not be realized. In this event, one or more of the acquisitions could result in reduced earnings of Natus as compared to the earnings that would have been achieved by Natus if the acquisition had not occurred.

We have assumed contingent obligations associated with earnout provisions in some of our acquisitions. We believe these provisions help us to negotiate mutually agreeable purchase terms between us and the sellers. However, a disagreement between us and a seller about the terms of an earnout provision could result in our paying more for an acquisition than we intended. For example, such disagreements arose in connection with our acquisitions of Alpine Biomed and Schwarzer Neurology. Although we resolved these disputes under terms that were not unfavorable to us, we cannot be assured of such outcomes in the future.

We used a significant portion of our existing cash resources, in addition to borrowing under our credit facility, to complete the acquisition of the Nicolet business from CareFusion. This usage of cash will have an adverse impact on our liquidity, and will force us to place more reliance on cash flow from operations for our liquidity. If our cash flow from operations is not sufficient for our needs, our business could be adversely impacted.

If our cash flow from operations is not sufficient for our needs, our business could be adversely affected. If we are required to seek additional external financing to support our need for cash to fund future acquisitions, we may not have access to financing on terms that are acceptable to us, or at all. Alternatively, we may feel compelled to access additional financing on terms that are dilutive to existing holders of our common stock or that include covenants that restrict our business, or both. If the recent lack of liquidity in credit markets persists into the future, our ability to obtain debt financing for future acquisitions may be impaired.



## Table of Contents

If we fail to successfully manage the combined operations of Natus and the businesses we have acquired, we may not realize the potential benefits of our acquisitions. Our corporate headquarters are located in San Carlos, California. We also have the following operating divisions: Olympic in Washington; Neurocom in Oregon; Bio-logic in Illinois; Neometrics in New York; Embla in Colorado; Nicolet in Wisconsin; Xltek in Canada; Medix in Argentina; Alpine Biomed in Denmark; Fischer-Zoth, Schwarzer Neurology, IT-Med, and Alpine Biomed Germany (collectively Natus Europe ) in Germany; and Deltamed and Alpine Biomed France (collectively Natus France ) in France. If we fail to manage these disparate operations effectively, our results of operations could be harmed, employee morale could decline, key employees could leave, and customers could cancel existing orders or choose not to place new ones. In addition, we may not achieve the synergies or other benefits of these and future acquisitions that we anticipate. We may encounter the following additional difficulties and delays involved in integrating and managing these operations, and the operations of companies we may acquire:

Failure of customers to continue using the products and services of the combined company;

Failure to successfully develop the acquired technology into the desired products or enhancements;

Assumption of unknown liabilities;

Failure to understand products or technologies with which we have limited previous experience;

Failure to compete effectively in new markets;

Decreased liquidity, restrictive bank covenants, and incremental financing costs associated with debt we may incur to complete future acquisitions; and

Diversion of the attention of management from other ongoing business concerns.

Our reported operating results may suffer because of impairment charges incurred to write down the carrying amount of intangible assets, including goodwill, generated as a result of the acquisitions.

### **Our growth in recent years has depended substantially on the completion of acquisitions and we may not be able to complete acquisitions of this nature or of a relative size in the future to support a similar level of growth**

The acquisitions that we have completed have been the primary source of our growth in revenue in recent years. We expend considerable effort in seeking to identify attractive acquisition candidates and, upon doing so, to convince the potential target to consider a sale to us and, ultimately, to negotiate mutually agreeable acquisition terms. If we are not successful in these efforts in the future, our growth rate will not increase at a rate corresponding to that which we have achieved in recent years. Further, as we grow larger it will be necessary to complete the acquisition of larger companies and product lines to support a growth similar to that which we have achieved in the past. The market for attractive acquisitions is competitive and others with greater financial resources than we have may be better positioned than we are to acquire desirable targets. Further, we may not be able to negotiate acquisition terms with target companies that will allow us to achieve positive financial returns from the transaction.

### **We have not filed with the SEC a timely amended Current Report on Form 8-K with respect to our Nicolet acquisition, which could adversely affect our ability to complete a registered offering of our securities**

We have determined that as a result of our acquisition of Nicolet in July 2012 we were required to file with the Securities and Exchange Commission on or before September 19, 2012 an amended Current Report on Form 8-K containing certain audited financial statements of the acquired business. We did not complete the preparation of the required financial statements prior to the due date of this amended report and are currently in the process of preparing these financial statements. Until these financial statements are submitted, we will not be able to file certain

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

registration statements under the Securities Act of 1933 ( Securities Act ) for public offerings of our securities, and thus will be unable to raise capital, or otherwise issue registered securities, in a public offering under the Securities Act. In addition, even after the filing of the amended report containing such financial statements, we may be ineligible for a period of 12 months following the due date of such report to use a Registration Statement on Form S-3 to register securities if the Securities and Exchange Commission does not provide us a waiver to do so. Were we to seek to issue securities in a public offering during this 12 month period it could be more costly and time consuming for us to do so as a result of the inability to use this abbreviated form of registration statement.

**Adverse economic conditions in markets in which we operate may harm our business**

---

## **Table of Contents**

Unfavorable changes in U.S. and international economic environments may adversely affect our business and financial results. Economic conditions in the countries in which we operate and sell products worsened and global financial markets subsequently experienced significant volatility and declines throughout much of 2009. Although these conditions improved somewhat in 2010, unfavorable conditions continue to impact the U.S. and European economies. We are unable to foresee when, or if, these factors might return to historical levels. During challenging economic times, and in tight credit markets, our customers may delay or reduce capital expenditures. This could result in reductions in sales of our products, longer sales cycles, difficulties in collection of accounts receivable, slower adoption of new technologies, and increased price competition, all of which could impact our results of operations and financial condition. In addition, we expect these factors will cause us to be more cautious in evaluating potential acquisition opportunities, which could hinder our ability to grow through acquisition while these conditions persist.

### **We have initiated changes to our information systems that could disrupt our business and our financial results.**

We plan to continuously improve our information systems to support the form, functionality, and scale of our business. These types of transitions frequently prove disruptive to the underlying business of an enterprise and may cause us to incur higher costs than we anticipate. Failure to manage a smooth transition to the new systems and the ongoing operations and support of the new systems could materially harm our business operations.

For example, we are currently in the process of implementing the rollout of a world-wide, single-platform enterprise resource planning ( ERP ) solution including customer relationship management, product lifecycle management, demand management, and business intelligence. Until we have completed this world-wide implementation, we will be dependent on multiple platforms. We may experience difficulties in implementing the ERP and we may fail to gain the efficiencies the implementation is designed to produce within the anticipated timeframe. The implementation could also be disruptive to our operations, including the ability to timely ship and track product orders to customers, project inventory requirements, manage our supply chain and otherwise adequately service our customers.

### **Future changes in technology or market conditions could result in adjustments to our recorded asset balance for intangible assets, including goodwill, resulting in additional charges that could significantly impact our operating results**

Our balance sheet includes significant intangible assets, including goodwill and other acquired intangible assets. The determination of related estimated useful lives and whether these assets are impaired involves significant judgment. Our ability to accurately predict future cash flows related to these intangible assets might be hindered by events over which we have no control. Due to the highly competitive nature of the medical device industry, new technologies could impair the value of our intangible assets if they create market conditions that adversely affect the competitiveness of our products. Further, declines in our market capitalization may be an indicator that our intangible assets or goodwill carrying values exceed their fair values which could lead to potential impairment charges that could impact our operating results. For example, in 2011 we recorded a \$20 million goodwill impairment charge related to our European reporting unit.

### **We may not be able to preserve the value of our intellectual property because we may not be able to protect access to it or we may lose our intellectual property rights due to expiration of our licenses or patents**

If we fail to protect our intellectual property rights or if our intellectual property rights do not adequately cover the technology we employ, other medical device companies could sell products with features similar to ours, and this could reduce demand for our products. We protect our intellectual property through a combination of patent, copyright, trade secret and trademark laws. Despite our efforts to protect our proprietary rights, others may attempt to copy or otherwise improperly obtain and use our products or technology. Policing unauthorized use of our technology is difficult and expensive, and we cannot be certain that the steps we have taken will prevent misappropriation. Our means of protecting our proprietary rights may be inadequate. Enforcing our intellectual property rights could be costly and time consuming and may divert our management's attention and resources. Failing to enforce our intellectual property rights could also result in the loss of those rights.

### **If health care providers are not adequately reimbursed for procedures conducted with our devices or supplies, or if reimbursement policies change adversely, we may not be successful marketing and selling our products or technologies**

---

## **Table of Contents**

Clinicians, hospitals, and government agencies are unlikely to purchase our products if they are not adequately reimbursed for the procedures conducted with our devices or supplies. Unless a sufficient amount of conclusive, peer-reviewed clinical data about our products has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If health care providers cannot obtain sufficient reimbursement from third-party payors for our products or the screenings conducted with our products, we may not achieve significant market acceptance of our products. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

Adverse changes in reimbursement policies in general could harm our business. We are unable to predict changes in the reimbursement methods used by third-party health care payors, particularly those in countries and regions outside the U.S. For example, some payors are moving toward a managed care system in which providers contract to provide comprehensive health care for a fixed cost per person. In a managed care system, the cost of our products may not be incorporated into the overall payment for patient care or there may not be adequate reimbursement for our products separate from reimbursement for other procedures.

### **Healthcare reforms, changes in healthcare policies, and changes to third-party reimbursements for our products may affect demand for our products**

In March 2010 the U. S. government signed into law the *Patient Protection and Affordable Care Act* and the *Health Care & Education Reconciliation Act*. These laws are intended to, among other things, curb rising healthcare costs, including those that could significantly affect reimbursement for our products. The policies supporting these laws include: basing reimbursement policies and rates on clinical outcomes; the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the U.S. Presidential administration or Congress.

There are numerous steps required to implement these laws. Because of the unsettled nature of these reforms, we cannot predict what additional healthcare reforms will be implemented at the federal or state level, or the effect that any future legislation or regulation will have on our business. There is also considerable uncertainty of the impact of these reforms on the medical device market as a whole. If we fail to effectively react to the implementation of health care reform, our business may be adversely affected. In addition, if the excise tax on the sale of medical devices is imposed as enacted, this could increase our costs and have an adverse effect on our results of operations, financial position, and cash flows.

### **If we fail in our efforts to educate clinicians, government agency personnel, and third-party payors on the effectiveness of our products, we may not achieve future sales growth**

It is critical to the success of our sales efforts that we educate a sufficient number of clinicians, hospital administrators, and government agencies about our products and the costs and benefits of their use. The commercial success of our products depends upon clinician, government agency, and other third-party payer confidence in the economic and clinical benefits of our products as well as their comfort with the efficacy, reliability, sensitivity and specificity of our products. We believe that clinicians will not use our products unless they determine, based on published peer-reviewed journal articles and experience, that our products provide an accurate and cost-effective alternative to other means of testing or treatment. Our customers may choose to use competitive products, which may be less expensive or may provide faster results than our devices. Clinicians are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. If clinicians, government agencies and hospital administrators do not adopt our products, we may not maintain profitability. Factors that may adversely affect the medical community's acceptance of our products include:

Publication of clinical study results that demonstrate a lack of efficacy or cost-effectiveness of our products;

Changing governmental and physician group guidelines;



## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Actual or perceived performance, quality, price, and total cost of ownership deficiencies of our products relative to other competitive products;

Our ability to maintain and enhance our existing relationships and to form new relationships with leading physicians, physician organizations, hospitals, state laboratory personnel, and third-party payers;

Changes in state and third-party payer reimbursement policies for our products; and

Repeal of laws requiring universal newborn hearing screening and metabolic screening.

-28-

---

**Table of Contents**

**Sales through group purchasing organizations and sales to high volume purchasers may reduce our average selling prices, which could reduce our operating margins**

We have entered, and expect in the future to enter into agreements with customers who purchase high volumes of our products. Our agreements with these customers may contain discounts from our normal selling prices and other special pricing considerations, which could cause our operating margins to decline. In addition, we have entered into agreements to sell our products to members of GPOs, which negotiate volume purchase prices for medical devices and supplies for member hospitals, group practices and other clinics. While we make sales directly to GPO members, the GPO members receive volume discounts from our normal selling price and may receive other special pricing considerations from us. Sales to members of all GPOs accounted for approximately 12%, 18% and 24% of our total revenue during 2011, 2010 and 2009, respectively, and sales to members of one GPO, Novation, accounted for approximately 2%, 6% and 8% of our total revenue in 2011, 2010 and 2009, respectively. Other of our existing customers may be members of GPOs with which we do not have agreements. Our sales efforts through GPOs may conflict with our direct sales efforts to our existing customers. If we enter into agreements with new GPOs and some of our existing customers begin purchasing our products through those GPOs, our operating margins could decline.

**Demand for some of our products depends on the capital spending policies of our customers, and changes in these policies could harm our business**

A majority of customers for our products are hospitals, physician offices, and clinics. Many factors, including public policy spending provisions, available resources, and economic cycles have a significant effect on the capital spending policies of these entities and therefore the amount that they can spend on our equipment products. If budget resources limit the capital spending of our customers, they will be unlikely to either purchase any new equipment from us or upgrade to any of our newer equipment products. Lack of liquidity in credit markets and uncertainty about future economic conditions can have an adverse effect on the spending patterns of our customers. These factors can have a significant adverse effect on the demand for our products.

**Our markets are very competitive and in the United States we sell certain of our products in a mature market**

We face competition from other companies in all of our product lines. Our competitors range from small privately held companies to multinational corporations and their product offerings vary in scope and breadth. We do not believe that any single competitor is dominant in any of our product lines.

The markets for certain of our products in the U.S., including the newborn hearing screening and EEG monitoring markets, are mature and we are unlikely to see significant growth for such products in the U.S. In the U.S. we derive a significant portion of our revenue from the sale of disposable supplies that are used with our hearing screening devices. Because these disposable supply products can generate high margins, we expect that our products, particularly our hearing screening disposable supply products, could face increasing competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins.

Our competitors may have certain competitive advantages, which include the ability to devote greater resources to the development, promotion, and sale of their products. Consequently, we may need to increase our efforts, and related expenses for research and development, marketing, and selling to maintain or improve our position.

We expect recurring sales to our existing customers to generate a majority of our revenue in the future, and if our existing customers do not continue to purchase products from us, our revenue may decline.

**Our operating results may decline if we do not succeed in developing, acquiring, and marketing additional products or improving our existing products**

We intend to develop additional products and technologies, including enhancements of existing products, for the screening, detection, treatment, monitoring and tracking of common medical ailments. Developing new products and improving our existing products to meet the needs of current and future customers requires significant investments in research and development. If we fail to successfully sell new products, update our existing products, or timely react to changes in technology, our operating results may decline as our existing products reach the end of their commercial life cycles.

**Table of Contents**

**Our plan to expand our international operations will result in increased costs and is subject to numerous risks; if our efforts are not successful, this could harm our business**

We have expanded our international operations through acquisitions and plan to expand our international sales and marketing efforts to increase sales of our products in foreign countries. We may not realize corresponding growth in revenue from growth in international unit sales, due to the lower average selling prices we receive on sales outside of the U.S. Even if we are able to successfully expand our international selling efforts, we cannot be certain that we will be able to create or increase demand for our products outside of the U.S. Our international operations are subject to other risks, which include:

Impact of possible recessions in economies outside the U.S.;

Political and economic instability, including instability related to war and terrorist attacks;

Contractual provisions governed by foreign law, such as local law rights to sales commissions by terminated distributors;

Decreased healthcare spending by foreign governments that would reduce international demand for our products;

Continued strengthening of the U.S. dollar relative to foreign currencies that could make our products less competitive because approximately half of our international sales are denominated in U.S. dollars;

Greater difficulty in accounts receivable collection and longer collection periods;

Difficulties of staffing and managing foreign operations;

Reduced protection for intellectual property rights in some countries and potentially conflicting intellectual property rights of third parties under the laws of various foreign jurisdictions;

Difficulty in obtaining and maintaining foreign regulatory approval;

Attitudes by clinicians, and cost reimbursement policies, towards use of disposable supplies that are potentially unfavorable to our business.

Complying with U.S. regulations that apply to international operations, including trade laws, the U.S. Foreign Corrupt Practices Act, and anti-boycott laws, as well as international laws such as the U.K. Bribery Act;

Loss of business through government tenders that are held annually in many cases; and

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Potentially negative consequences from changes in tax laws, including legislative changes concerning taxation of income earned outside of the U.S.

In particular, our international sales could be adversely affected by a strengthening of the U.S. dollar relative to other foreign currencies, which makes our products more costly to international customers for sales denominated in U.S. dollars.

### **Our operating results may suffer because of our exposure to foreign currency exchange rate fluctuations**

Substantially all of our sales contracts with our U.S. based customers provide for payment in U.S. dollars. With the exception of our Canadian operations, substantially all of the revenue and expenses of our foreign subsidiaries are denominated in the applicable foreign currency. To date we have executed only limited foreign currency contracts to hedge these currency risks. Our future revenue and expenses may be subject to volatility due to exchange rate fluctuations that could result in foreign exchange gains and losses associated with foreign currency transactions and the translation of assets and liabilities denominated in foreign currencies.

Substantially all our sales from our U.S. operations to our international distributors provide for payment in U.S. dollars. A strengthening of the U.S. dollar relative to other foreign currencies could increase the effective cost of our products to our international distributors as their functional currency is typically not the U.S. dollar. This could have a potential adverse effect on our ability to increase or maintain average selling prices of our products to our foreign-based customers.

---

**Table of Contents**

**If guidelines mandating universal newborn hearing screening do not continue to develop in foreign countries and governments do not mandate testing of all newborns as we anticipate, or if those guidelines have a long phase-in period, our sales of newborn hearing screening products may not achieve the revenue growth we have achieved in the past**

We estimate that approximately 95% of the children born in the U.S. are currently being tested for hearing impairment prior to discharge from the hospital. To date, there has been only limited adoption of newborn hearing screening prior to hospital discharge by foreign governments, and when newborn hearing screening programs are enacted by foreign governments there can be a phase-in period spanning several years. The widespread adoption of guidelines depends, in part, on our ability to educate foreign government agencies, neonatologists, pediatricians, third-party payors, and hospital administrators about the benefits of universal newborn hearing screening as well as the use of our products to perform the screening and monitoring. Our revenue from our newborn hearing screening product lines may not grow if foreign governments do not require universal newborn hearing screening prior to hospital discharge, if physicians or hospitals are slow to comply with those guidelines, or if governments provide for a lengthy phase-in period for compliance.

**Because we rely on distributors or sub-distributors to sell our products in most of our markets outside of the U.S., our revenue could decline if our existing distributors reduce the volume of purchases from us, or if our relationship with any of these distributors is terminated**

We currently rely on our distributors or sub-distributors for a majority of our sales outside the U.S. Some distributors also assist us with regulatory approvals and education of clinicians and government agencies. We intend to continue our efforts to increase our sales in Europe, Japan, and other developed countries. If we fail to sell our products through our international distributors, we would experience a decline in revenues unless we begin to sell our products directly in those markets. We cannot be certain that we will be able to attract new international distributors to market our products effectively or provide timely and cost-effective customer support and service. Even if we are successful in selling our products through new distributors, the rate of growth of our revenue could be harmed if our existing distributors do not continue to sell a large dollar volume of our products. None of our existing distributors are obligated to continue selling our products.

We may be subject to foreign laws governing our relationships with our international distributors. These laws may require us to make payments to our distributors if we terminate our relationship for any reason, including for cause. Some countries require termination payments under local law or legislation that may supersede our contractual relationship with the distributor. Any required payments would adversely affect our operating results.

**If we lose our relationship with any supplier of key product components or our relationship with a supplier deteriorates or key components are not available in sufficient quantities, our manufacturing could be delayed and our business could suffer**

We contract with third parties for the supply of some of the components used in our products and the production of our disposable products. Some of our suppliers are not obligated to continue to supply us. We have relatively few sources of supply for some of the components used in our products and in some cases we rely entirely on sole-source suppliers. In addition, the lead-time involved in the manufacturing of some of these components can be lengthy and unpredictable. If our suppliers become unwilling or unable to supply us with components meeting our requirements, it might be difficult to establish additional or replacement suppliers in a timely manner, or at all. This would cause our product sales to be disrupted and our revenue and operating results to suffer.

Replacement or alternative sources might not be readily obtainable due to regulatory requirements and other factors applicable to our manufacturing operations. Incorporation of components from a new supplier into our products may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. This process may take a substantial period of time, and we may not be able to obtain the necessary regulatory clearance or approval. This could create supply disruptions that would harm our product sales and operating results.

**We depend upon key employees in a competitive market for skilled personnel, and, without additional employees, we cannot grow or maintain profitability**

---

**Table of Contents**

Our products and technologies are complex, and we depend substantially on the continued service of our senior management team. The loss of any of our key employees could adversely affect our business and slow our product development process. Our future success also will depend, in part, on the continued service of our key management personnel, software engineers, and other research and development employees, and our ability to identify, hire, and retain additional personnel, including customer service, marketing, and sales staff. Demand for these skilled employees in our industry is very competitive due to the limited number of people available with the necessary technical skills and understanding of our product technologies. We may be unable to attract and retain personnel necessary for the development of our business.

**Our ability to market and sell products depends upon receipt of domestic and foreign regulatory approval of our products and manufacturing operations. Our failure to obtain or maintain regulatory approvals and compliance could negatively affect our business**

Our products and manufacturing operations are subject to extensive regulation in the United States by the FDA and by similar regulatory agencies in other countries. Our products are classified as medical devices. Medical devices are subject to extensive regulation by the FDA pursuant to regulations that are wide ranging and govern, among other things: design and development; manufacturing and testing; labeling; storage and record keeping; advertising, promotion, marketing, sales distribution and export; and surveillance and reporting of deaths or serious injuries.

Unless an exemption applies, each medical device that we propose to market in the U.S. must first receive one of the following types of FDA premarket review authorizations:

Clearance via Section 510(k) of the Food, Drug, and Cosmetics Act of 1938, as amended; or

Premarket approval via Section 515 of the Food, Drug, and Cosmetics Act if the FDA has determined that the medical device in question poses a greater risk of injury.

The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The premarket approval application process is much more costly, lengthy and uncertain than the 510(k) process, and must be supported by extensive data from preclinical studies and human clinical trials. The FDA may not grant either 510(k) clearance or premarket approval for any product we propose to market. Further, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a premarket approval application. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. If the FDA requires us to seek 510(k) clearance or premarket approval for modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective.

Delays in receipt of, or failure to receive, clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could adversely impact our operating results. If the FDA finds that we have failed to comply with these requirements, the Agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

Fines, injunctions and civil penalties;

Recall or seizure of our products;

Issuance of public notices or warnings;

## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

Imposition of operating restrictions, partial suspension, or total shutdown of production;

Refusal of our requests for Section 510(k) clearance or premarket approval of new products;

Withdrawal of Section 510(k) clearance or premarket approvals already granted; or

Criminal prosecution.

Domestic regulation of our products and manufacturing operations, other than that which is administered by the FDA, includes the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these Acts.

**Our business would be harmed if the FDA determines that we have failed to comply with applicable regulations governing the manufacture of our products and/or we do not pass an inspection**

---

## **Table of Contents**

We and our suppliers are required to demonstrate and maintain compliance with the FDA's Quality System Regulation. The Quality System Regulation sets forth the FDA's requirements for good manufacturing practices of medical devices and includes requirements for, among other things, the design, testing, production processes, controls, quality assurance, labeling, packaging, storage and shipping of such products. In addition, we and our suppliers must engage in extensive recordkeeping and reporting and must make available our manufacturing facility and records for periodic unscheduled inspections by federal, state and foreign agencies, including the FDA. We cannot assure you that we and our suppliers are or will continue to be in full compliance with the Quality System Regulation, and that we will not encounter any manufacturing difficulties.

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including, among other things, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or recalls of products and manufacturing restrictions, any of which could harm our business.

### **Our Olympic Cool-Cap product is subject to greater products liability exposure and FDA regulation**

The FDA classifies medical devices into one of three classes depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose lower risk are placed in either Class I or Class II. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life supporting or implantable devices, or a device deemed to not be substantially equivalent to a previously cleared 510(k) device are placed in class III, and generally require premarket approval from the FDA before they may be marketed.

Our Olympic Cool-Cap is a Class III minimally invasive medical device, and as such we may be subject to an increased product liability risk relative to our other Class I and Class II non-invasive products. In addition, this type of product is subject to greater FDA oversight than our other products and there is greater risk that sales of the product could be interrupted due to the premarket approval processes of the FDA and other regulatory bodies.

### **Our business may suffer if we are required to revise our labeling or promotional materials, or if the FDA takes an enforcement action against us for off-label uses**

We are prohibited by the FDA from promoting or advertising our medical device products for uses not within the scope of our clearances or approvals, or from making unsupported promotional claims about the benefits of our products. If the FDA determines that our claims are outside the scope of our clearances, or are unsupported, it could require us to revise our promotional claims or take enforcement action against us. If we were subject to such an action by the FDA, our sales could be delayed, our revenue could decline, and our reputation among clinicians could be harmed. Likewise, if we acquire new products, either through the purchase of products, technology assets, or businesses, that are subsequently deemed to have inadequate supporting data, we may be required to (i) obtain adequate data, which could be costly and impede our ability to market these products, or (ii) modify the labeling on these products, which could impair their marketability, as described above.

### **If we deliver products with defects, we may incur costs to repair and, possibly, recall that product and market acceptance of our products may decrease.**

The manufacturing and marketing of our products involve an inherent risk of our delivering a defective product or products that do not otherwise perform as we expect. We may incur substantial expense to repair any such products and may determine to recall such a product, even if not required to do so under applicable regulations. Any such recall would be time consuming and expensive. Product defects or recalls may adversely affect our customers' acceptance of the recalled and other of our products. As an example, in the second quarter of 2010 we discontinued selling the Sonamed Clarity newborn hearing screening product line and incurred costs associated with sales concessions awarded customers who traded in a Clarity device for one of our existing newborn hearing screening devices and the write-down of inventory. We also recorded an impairment charge to write-off the carrying value of the Sonamed and Clarity tradenames.

### **If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.**

We do not provide healthcare services, control the referral of patients for healthcare services, nor bill Medicare, Medicaid or other third-party payors; however, due to the breadth of many healthcare laws and regulations, we could be subject to healthcare fraud regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include: (i) the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for,



## Edgar Filing: NATUS MEDICAL INC - Form 10-Q

or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers, and/or (iii) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

-33-

## **Table of Contents**

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

### **Our operating results would suffer if we were subject to a protracted infringement claim**

The medical technology industry is characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. We expect that medical screening and diagnostic products may become increasingly subject to third-party infringement claims as the number of competitors in our industry grows and the functionality of products overlap. Third parties such as individuals, educational institutions, or other medical device companies may claim that we infringe their intellectual property rights. Any claims, with or without merit, could have any of the following negative consequences:

Result in costly litigation and damage awards;

Divert our management's attention and resources;

Cause product shipment delays or suspensions; or

Require us to seek to enter into royalty or licensing agreements.

A successful claim of infringement against us could result in a substantial damage award and materially harm our financial condition. Our failure or inability to license the infringed or similar technology, or design and build non-infringing products, could prevent us from selling our products and adversely affect our business and financial results.

We may also find it necessary to bring infringement actions against third parties to seek to protect our intellectual property rights. Litigation of this nature, even if successful, is often expensive and disruptive of our management's attention, and in any event may not lead to a successful result relative to the resources dedicated to any such litigation.

### **We license intellectual property rights from third parties and would be adversely affected if our licensors do not appropriately defend their proprietary rights or if we breach any of the agreements under which we license commercialization rights to products or technology from others**

We license rights from third parties for products and technology that are important to our business. If our licensors are unsuccessful in asserting and defending their proprietary rights, including patent rights and trade secrets, we may lose the competitive advantages we have through selling products that we license from third parties. Additionally, if it is found that our licensors infringe on the proprietary rights of others, we may be prohibited from marketing our existing products that incorporate those proprietary rights. Under our licenses, we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach a license agreement, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license.

### **Product liability suits against us could result in expensive and time consuming litigation, payment of substantial damages, and an increase in our insurance rates**

The sale and use of our products could lead to the filing of a product liability claim by someone claiming to have been injured using one of our products or claiming that one of our products failed to perform properly. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business reputation or financial condition. Our product liability insurance may not protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future.

**We have experienced seasonality in the sale of our products**

**Table of Contents**

We experience seasonality in our revenue. For example, our sales typically decline from our fourth fiscal quarter to our first fiscal quarter, due to patterns in the capital budgeting and purchasing cycles of our customers, many of which are government agencies, and the compensation arrangements of our direct sales employees, as those arrangements are tied to calendar-year sales plans. We may also experience declining sales in the third fiscal quarter due to summer holiday and vacation schedules. We anticipate that we will continue to experience these seasonal fluctuations, which may lead to fluctuations in our quarterly operating results. We believe that you should not rely on our results of operations for interim periods as an indication of our expected results in any future period.

**Table of Contents****ITEM 6. Exhibits**

## (a) Exhibits

Exhibit No.	Exhibit	Incorporated By Reference			
		Filing	Exhibit No.	File No.	File Date
3.1	Certificate of Amendment of the Amended & Restated Certificate of Incorporation	8-K	3.1	000-33001	09/13/2012
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.***	The following materials from the Company's Form 10-Q for the period ended September 30, 2012, formatted in Extensible Business Reporting Language (XBRL) pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (iv) Notes to Condensed Consolidated Financial Statements (unaudited), tagged as blocks of text.				

**Table of Contents**

**SIGNATURES**

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

NATUS MEDICAL INCORPORATED

Dated: November 9, 2012

By: /s/ James B. Hawkins

**James B. Hawkins**

**Chief Executive Officer**

**(Principal Executive Officer)**

Dated: November 9, 2012

By: /s/ Steven J. Murphy

**Steven J. Murphy**

**Vice President Finance and**

**Chief Financial Officer**

**(Principal Financial and**

**Accounting Officer)**

**Table of Contents****NATUS MEDICAL INCORPORATED****INDEX TO EXHIBITS**

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Filing</b>	<b>Incorporated By Reference</b>		
			<b>Exhibit No.</b>	<b>File No.</b>	<b>File Date</b>
3.1	Certificate of Amendment of the Amended & Restated Certificate of Incorporation	8-K	3.1	000-33001	09/13/2012
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.***	The following materials from the Company's Form 10-Q for the period ended September 30, 2012, formatted in Extensible Business Reporting Language (XBRL) pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (iv) Notes to Condensed Consolidated Financial Statements (unaudited), tagged as blocks of text.				