

NUVASIVE INC  
Form 10-Q  
November 04, 2011  
Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

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

Commission file number 000-50744

**NUVASIVE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0768598**  
(I.R.S. Employer  
Identification No.)

7475 Lusk Boulevard

San Diego, CA 92121

(Address of principal executive offices, including zip code)

(858) 909-1800

(Registrant's telephone number, including area code)

## Edgar Filing: NUVASIVE INC - Form 10-Q

**(Former name, former address and former fiscal year, if changed since last report)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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  Smaller reporting company

(Do not check if a 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

As of October 28, 2011, there were 42,244,073 shares of the registrant's common stock outstanding.

**Table of Contents**

NUVASIVE, INC.

**QUARTERLY REPORT ON FORM 10-Q**

**September 30, 2011**

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of September 30, 2011 (Unaudited) and December 31, 2010 3

Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010 4

Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 5

Notes to Unaudited Condensed Consolidated Financial Statements 6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 19

Item 3. Quantitative and Qualitative Disclosures About Market Risk 30

Item 4. Controls and Procedures 30

**PART II OTHER INFORMATION**

Item 1. Legal Proceedings 30

Item 1A. Risk Factors 31

Item 6. Exhibits 44

**SIGNATURES** 45

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NUVASIVE, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS***(in thousands, except par value)*

	September 30, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 220,943	\$ 92,597
Short-term marketable securities	151,363	86,458
Accounts receivable, net	78,637	76,632
Inventory	122,588	107,577
Deferred tax assets	4,425	4,425
Prepaid expenses and other current assets	5,100	4,082
Total current assets	583,056	371,771
Property and equipment, net	118,125	102,165
Long-term marketable securities	46,593	50,635
Intangible assets, net	100,044	107,121
Goodwill	103,070	103,070
Deferred tax assets, non-current	76,260	52,033
Restricted cash and investments	68,463	5,529
Other assets	19,187	9,705
Total assets	\$ 1,114,798	\$ 802,029
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 52,191	\$ 58,995
Accrued payroll and related expenses	17,872	17,266
Litigation liability	101,200	
Acquisition-related liabilities	33,628	32,715
Total current liabilities	204,891	108,976
Senior Convertible Notes	427,974	230,000
Long-term acquisition-related liabilities		326
Deferred tax liabilities	3,685	3,685
Other long-term liabilities	13,088	12,810
Commitments and contingencies		
Noncontrolling interests	11,015	11,877
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, none outstanding		
Common stock, \$0.001 par value; 120,000 and 70,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 39,904 and 39,528 issued and outstanding at September 30, 2011 and December 31, 2010, respectively	40	40
Additional paid-in capital	625,387	545,114

Edgar Filing: NUVASIVE INC - Form 10-Q

Accumulated other comprehensive income (loss)	(54)	616
Accumulated deficit	(171,228)	(111,415)
<b>Total stockholders' equity</b>	<b>454,145</b>	<b>434,355</b>
Total liabilities and stockholders' equity	\$ 1,114,798	\$ 802,029

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

## NUVASIVE, INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

*(in thousands, except per share data)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue	\$ 132,880	\$ 120,262	\$ 390,312	\$ 348,933
Cost of goods sold (excluding amortization of purchased technology)	26,015	21,580	75,049	62,037
Gross profit	106,865	98,682	315,263	286,896
Operating expenses:				
Sales, marketing and administrative	85,482	77,717	254,025	230,104
Research and development	10,092	10,085	31,119	31,989
Amortization of intangible assets	1,504	1,342	4,241	4,047
Litigation award	101,200		101,200	
Total operating expenses	198,278	89,144	390,585	266,140
Interest and other expense, net:				
Interest income	257	200	591	567
Interest expense	(7,276)	(1,668)	(10,962)	(5,005)
Other income (expense), net	1,726	(6)	2,303	81
Total interest and other expense, net	(5,293)	(1,474)	(8,068)	(4,357)
(Loss) income before income tax expense	(96,706)	8,064	(83,390)	16,399
Income tax (benefit) expense	(29,031)	(40)	(22,715)	1,399
Consolidated net (loss) income	\$ (67,675)	\$ 8,104	\$ (60,675)	\$ 15,000
Net loss attributable to noncontrolling interests	\$ (123)	\$ (438)	\$ (862)	\$ (1,353)
Net (loss) income attributable to NuVasive, Inc.	\$ (67,552)	\$ 8,542	\$ (59,813)	\$ 16,353
Net (loss) income per share attributable to NuVasive, Inc.:				
Basic	\$ (1.69)	\$ 0.22	\$ (1.50)	\$ 0.42
Diluted	\$ (1.69)	\$ 0.21	\$ (1.50)	\$ 0.40
Weighted average shares outstanding:				
Basic	39,892	39,394	39,766	39,180
Diluted	39,892	40,396	39,766	40,389

See accompanying notes to unaudited condensed consolidated financial statements.



**Table of Contents**

## NUVASIVE, INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

*(in thousands)*

	Nine Months Ended September 30,	
	2011	2010
<b>Operating activities:</b>		
Consolidated net (loss) income	\$ (60,675)	\$ 15,000
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	24,847	27,404
Stock-based compensation	23,789	21,304
Allowance for excess and obsolete inventory	4,642	1,682
Allowance for doubtful accounts and sales return reserves, net of write offs	1,261	(1,039)
Accretion of contingent consideration	587	570
Amortization of debt issuance costs	2,588	1,120
Amortization of debt discount	3,076	
Gain recognized on change in fair value of derivatives	(2,387)	
Deferred income tax expense	6,238	
Other non-cash adjustments	3,545	2,924
Changes in operating assets and liabilities, net of effects from acquisitions:		
Accounts receivable	(3,152)	(11,465)
Inventory	(19,933)	(10,043)
Prepaid expenses and other assets	(1,061)	(3,878)
Accounts payable and accrued liabilities	504	6,502
Litigation liability	101,200	
Accrued payroll and related expenses	584	(5,973)
Income taxes payable	(32,237)	(186)
Net cash provided by operating activities	53,416	43,922
<b>Investing activities:</b>		
Purchases of property and equipment	(39,435)	(36,622)
Purchases of marketable securities	(244,209)	(150,045)
Sales of marketable securities	124,205	142,313
Purchases of restricted investments	(4,535)	
Payment for specific rights in connection with supply agreement, net of refund received	(5,000)	
Other assets	(1,100)	(659)
Net cash used in investing activities	(170,074)	(45,013)
<b>Financing activities:</b>		
Proceeds from the sale of warrants	47,898	
Proceeds from the issuance of convertible debt, net of issuance costs	391,334	
Purchase of convertible note hedges	(80,097)	
Repurchase of 2013 Senior Convertible Notes	(118,702)	
Proceeds from the issuance of common stock	4,461	12,768
Other assets	(349)	(7,722)
Tax benefits related to stock-based compensation awards	638	1,118
Net cash provided by financing activities	245,183	6,164
Effect of exchange rate changes on cash	(179)	104



Edgar Filing: NUVASIVE INC - Form 10-Q

Increase in cash and cash equivalents	128,346	5,177
Cash and cash equivalents at beginning of period	92,597	65,413
Cash and cash equivalents at end of period	\$ 220,943	\$ 70,590

See accompanying notes to unaudited condensed consolidated financial statements.

---

**Table of Contents**

**NuVasive, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

***1. Description of Business and Basis of Presentation***

***Description of Business***

NuVasive<sup>®</sup>, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company is focused on developing minimally disruptive surgical products and procedures for the spine. The Company began commercializing its products in 2001. Its currently-marketed product portfolio is focused on applications for spine fusion surgery. Its principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>®</sup>, as well as a growing offering of biologics, cervical and motion preservation products. In the spine surgery market, the Company's currently-marketed products are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. The Company also focuses significant research and development efforts on expanding its MAS product platform, advancing the applications of its unique technology to additional procedures, and developing motion preservation products. The Company dedicates significant resources toward training spine surgeons on its unique technology and products.

The Company's primary business model is to loan its MAS systems to surgeons and hospitals who purchase disposables and implants for use in individual procedures. In addition, for larger customers, the Company's proprietary nerve monitoring systems, MaXcess<sup>®</sup> and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them. The Company also offers a range of bone allograft in patented saline packaging, disposables and spine implants, which include its branded CoRoent<sup>®</sup> products and fixation devices such as rods, plates and screws. Implants and disposables are shipped from the Company's inventories. The Company sells an immaterial quantity of MAS instrument sets, MaXcess and nerve monitoring systems to hospitals.

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Pursuant to these rules and regulations, the Company has condensed or omitted certain information and footnote disclosures it normally includes in its annual consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP). In the opinion of management, the consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented.

The accompanying unaudited condensed consolidated financial statements as of September 30, 2011 and December 31, 2010 and for the three and nine months ended September 30, 2011 and 2010 include the accounts of the Company and its wholly owned subsidiaries, as well as the accounts of a variable interest entity, Progentix Orthobiology, B.V. (Progentix), which is consolidated pursuant to existing guidance issued by the Financial Accounting Standards Board (FASB). All significant intercompany accounts and transactions have been eliminated in consolidation.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2010 included in NuVasive's Annual Report on Form 10-K filed with the SEC. Operating results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

***Change in Accounting Estimate***

During the first quarter of 2011, the Company completed a review of the estimated useful life of its surgical instrument sets. Based on historical useful life information, as well as forecasted product life cycles and demand expectations, the useful life of certain surgical instrument sets was extended from three to four years. In accordance with authoritative guidance, this was accounted for as a change in accounting estimate and was made on a prospective basis effective January 1, 2011. For the three and nine months ended September 30, 2011, depreciation expense, which is included in sales, marketing and administrative expenses, was lower by approximately \$1.2 million and \$5.0 million, respectively, than it would have been had the useful life of these assets not been extended. The effect of this change on basic and diluted earnings per share for the three and nine months ended September 30, 2011 was \$0.02 and \$0.09 per share, respectively.



---

## **Table of Contents**

### ***Reclassifications and Adjustments***

Certain reclassifications have been made to the prior year condensed consolidated financial statements to conform to the current year presentation.

During the three months ended June 30, 2011, the Company identified an immaterial error in the consolidated financial statements for the year ended December 31, 2010 related to the accrual of payroll expenses. Based on a quantitative and qualitative analysis of the error as required by authoritative guidance, management concluded that the correction, which increased expenses by approximately \$1.3 million in the nine months ended September 30, 2011, had no material impact on any of the Company's previously issued financial statements, would be immaterial to the expected full year results for 2011 and had no effect on the trend of financial results. Of the \$1.3 million, approximately \$1.0 million and \$0.3 million was charged to sales, marketing and administrative expenses and research and development expenses, respectively.

### ***2. Significant Accounting Policies***

#### ***Derivative Financial Instruments***

On June 28, 2011, the Company issued \$402.5 million principal amount of 2.75% Senior Convertible Notes due 2017 (the 2017 Notes). Prior to September 28, 2011, the 2017 Notes were settleable only in cash. On September 28, 2011, stockholder approval was obtained to increase the number of the Company's authorized shares of common stock from 70 million to 120 million. Prior to obtaining stockholder approval, in accordance with authoritative guidance, the cash conversion feature of the 2017 Notes (the 2017 Notes Embedded Conversion Derivative) required bifurcation from the 2017 Notes and was accounted for as a derivative liability.

In connection with the issuance of the 2017 Notes, the Company entered into convertible note hedge transactions (the 2017 Hedge) entitling the Company to purchase up to 9,553,096 shares of the Company's common stock at an initial stock price of \$42.13 per share, each of which is subject to adjustment. Prior to obtaining the stockholder approval to increase the number of the Company's authorized shares of common stock discussed above, the 2017 Hedge was settleable only in cash. In accordance with authoritative guidance, the 2017 Hedge was accounted for as a derivative asset.

In accordance with authoritative guidance, upon obtaining stockholder approval to increase the number of authorized shares of the Company's common stock, as the Company can now settle the 2017 Notes in cash, stock, or a combination thereof, solely at the Company's election, the derivative liability and asset were marked to fair value and reclassified to stockholders' equity.

During the three and nine months ended September 30, 2011, the Company recognized non-cash income of approximately \$2.4 million related to the net change in the fair values of the derivative liability and asset. This \$2.4 million consists of a \$39.5 million gain related to the change in the fair value of the derivative liability and a loss of \$37.1 million related to the change in fair value of the derivative asset. Gains and losses are included as a component of other income (expense), net.

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

##### ***Fair Value Measurements Disclosures***

Effective January 1, 2011, the Company adopted the FASB's updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately information related to purchases, sales, issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs, or Level 3, to be included in the rollforward of activity. The guidance is effective for interim or annual financial reporting periods beginning after December 15, 2010. The Company has updated its disclosures to comply with the updated guidance; however, adoption of the updated guidance did not have an impact on the Company's consolidated results of operations or financial position.

**Table of Contents****3. Investment in Progentix Orthobiology, B.V.**

In 2009, the Company completed the purchase of forty percent (40%) of the capital stock of Progentix, a company organized under the laws of the Netherlands, from existing shareholders (the Progentix Shareholders) pursuant to a Preferred Stock Purchase Agreement for \$10 million in cash (the Initial Investment). Concurrent with the Initial Investment, NuVasive and Progentix also entered into a Senior Secured Facility Agreement, whereby Progentix may borrow up to \$5.0 million from NuVasive to fund ongoing clinical and regulatory efforts (the Loan). At September 30, 2011, the Company had advanced Progentix the full \$5.0 million in accordance with the Loan Agreement. The Loan accrues interest at a rate of six percent (6%) per year. Other than its obligations under the Loan Agreement, NuVasive is not obligated to provide additional funding, nor has any additional funding been provided, to Progentix.

Also concurrent with the Preferred Stock Purchase Agreement, NuVasive, Progentix and the Progentix Shareholders entered into an Option Purchase Agreement, as amended (the Option Agreement), whereby NuVasive may be obligated (the Put Option), upon the achievement of an annual sales run rate on Progentix products in excess of a specified amount between June 14, 2011 and June 13, 2013 (the Option Period), to purchase the remaining sixty percent (60%) of capital stock of Progentix from its shareholders (the Remaining Shares) for an amount up to \$35.0 million, subject to certain reductions, payable in a combination of cash and NuVasive common stock, at NuVasive's sole discretion. In accordance with the Option Agreement, NuVasive has the right to purchase the Remaining Shares (the Call Option) during the Option Period for an amount up to \$35.0 million, subject to certain reductions, payable in a combination of cash and NuVasive common stock, at NuVasive's sole discretion. Also in accordance with the Option Agreement, an option expired in June 2011 that could have required NuVasive to purchase the Remaining Shares and make additional milestone-related payments totaling up to \$70.0 million, subject to certain adjustments. NuVasive and Progentix also entered into a Distribution Agreement, as amended, whereby Progentix appointed NuVasive as its exclusive distributor for certain Progentix products. The Distribution Agreement will be in effect for a term of ten years unless terminated earlier in accordance with its terms.

In accordance with authoritative guidance, the Company has determined that Progentix is a variable interest entity (VIE) as it does not have the ability to finance its activities without additional subordinated financial support and its equity investors will not absorb their proportionate share of expected losses and will be limited in the receipt of the potential residual returns of Progentix. Additionally, pursuant to this guidance, NuVasive is considered its primary beneficiary as NuVasive has both (1) the power to direct the economically significant activities of Progentix and (2) the obligation to absorb losses of, or the right to receive benefits from, Progentix. Accordingly, the financial position and results of operations of Progentix have been included in the Company's consolidated financial statements from the date of the Initial Investment. The liabilities recognized as a result of consolidating Progentix do not represent additional claims on the Company's general assets. The creditors of Progentix have claims only on the assets of Progentix, which are not material, and the assets of Progentix are not available to NuVasive.

Pursuant to authoritative guidance, the equity interests in Progentix not owned by the Company, which includes shares of both common and preferred stock, are reported as noncontrolling interests on the consolidated balance sheet of the Company. The preferred stock represents 18% of the noncontrolling equity interests and provides for a cumulative 8% dividend, if and when declared by Progentix's Board of Directors. As the rights and conversion features of the preferred stock are substantially the same as those of the common stock, the preferred stock is classified as noncontrolling interest and shares in the allocation of the losses incurred by Progentix. Losses incurred by Progentix are charged to the Company and to the noncontrolling interest holders based on their ownership percentage. The Remaining Shares and the Option Agreement that was entered into between NuVasive, Progentix and the Progentix Shareholders are not considered to be freestanding financial instruments as defined by authoritative guidance. Therefore the Remaining Shares and the Option Agreement are accounted for as a combined unit on the consolidated financial statements as a redeemable noncontrolling interest that was initially recorded at fair value and classified as mezzanine equity.

Total assets and liabilities of Progentix as of September 30, 2011 included in the accompanying condensed consolidated balance sheet are as follows (*in thousands*):

Total current assets	\$ 834
Identifiable intangible assets, net	15,455
Goodwill	12,654
Other long-term assets	422
Accounts payable & accrued expenses	470
Other long-term liabilities	553
Deferred tax liabilities, net	3,685
Noncontrolling interests	11,015

**Table of Contents**

The following is a reconciliation of equity (net assets) attributable to the noncontrolling interests (*in thousands*):

Noncontrolling interests at December 31, 2010	\$ 11,877
Net loss attributable to the noncontrolling interests	(862)
Noncontrolling interests at September 30, 2011	\$ 11,015

**4. Balance Sheet Reserves**

The balances of the reserves for accounts receivable and inventory are as follows (*in thousands*):

	September 30, 2011	December 31, 2010
Reserves for accounts receivable and sales returns	\$ 3,533	\$ 2,573
Reserves for excess and obsolete inventory	11,324	6,682

The Company's inventory consists primarily of purchased finished goods, which includes specialized implants and disposables, and is stated at the lower of cost or market determined by a weighted average cost method. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for the identified items.

**5. Marketable Securities and Fair Value Measurements**

Marketable securities consist of certificates of deposit, corporate debt securities, commercial paper, U.S. government treasury securities and securities of government-sponsored entities. The Company classifies all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income in stockholders' equity until realized. A decline in the market value of any marketable security below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of marketable securities, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations.

The composition of marketable securities is as follows (*in thousands, except years*):

	Contractual Maturity (in Years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2011:					
Classified as current assets					
Certificates of deposit	Less than 1	\$ 777	\$ 1	\$	\$ 778
Corporate notes	Less than 1	21,206	9	(1)	21,214
Commercial paper	Less than 1	9,997			9,997
U.S. government treasury securities	Less than 1	34,760	5	(1)	34,764
Securities of government-sponsored entities	Less than 1	84,618	4	(12)	84,610

Edgar Filing: NUVASIVE INC - Form 10-Q

Short-term marketable securities		151,358	19	(14)	151,363
Classified as non-current assets					
Corporate notes	1 to 2	5,075	3		5,078
Securities of government-sponsored entities	1 to 2	41,506	17	(8)	41,515
Long-term marketable securities		46,581	20	(8)	46,593
Classified as restricted investments					
U.S. government treasury securities	Less than 1 to 2	12,030	11		12,041
Securities of government-sponsored entities	Less than 1 to 2	50,716	22	(13)	50,725
Restricted investments		62,746	33	(13)	62,766
Total marketable securities at September 30, 2011		\$ 260,685	\$ 72	\$ (35)	\$ 260,722

**Table of Contents**

	Contractual				
	Maturity		Gross	Gross	Fair
	(in Years)	Amortized	Unrealized	Unrealized	Value
		Cost	Gains	Losses	
December 31, 2010:					
Classified as current assets					
Certificates of deposit	Less than 1	\$ 938	\$ 1	\$ (1)	\$ 938
Corporate notes	Less than 1	12,076	3		12,079
U.S. government treasury securities	Less than 1	16,550	12	(1)	16,561
Securities of government-sponsored entities	Less than 1	56,870	24	(14)	56,880
Short-term marketable securities		86,434	40	(16)	86,458
Classified as non-current assets					
Certificates of deposit	1 to 2	456			456
Corporate notes	1 to 2	3,123		(9)	3,114
U.S. government treasury securities	1 to 2	4,023			4,023
Securities of government-sponsored entities	1 to 2	43,056	6	(20)	43,042
Long-term marketable securities		50,658	6	(29)	50,635
Total marketable securities at December 31, 2010		\$ 137,092	\$ 46	\$ (45)	\$ 137,093

As of September 30, 2011, the Company had no significant investment positions that were in an unrealized loss position. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company maintains an investment portfolio of various holdings, types and maturities. The Company does not have derivative financial investments. The Company places its cash investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issue, issuer or type of instrument.

The Company measures certain assets and liabilities in accordance with authoritative guidance which requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy during the nine months ended September 30, 2011. The Company had one transfer from Level 3 of the fair value measurement hierarchy, as the liability became fixed during the nine months ended September 30, 2011.

The fair values of the Company's assets and liabilities at September 30, 2011, which are measured at fair value on a recurring basis, were determined using the following inputs (*in thousands*):

	Quoted Price in Significant Other		
	Active	Observable	Significant
	Market	Inputs	Unobservable
	(Level 1)	(Level 2)	Inputs (Level 3)
	Total		
Marketable Securities and Restricted Investments:			



Edgar Filing: NUVASIVE INC - Form 10-Q

Certificates of deposit	\$ 778	\$ 778	\$	\$
Corporate notes	26,292	26,292		
Commercial paper	9,997	9,997		
U.S. government treasury securities	46,805	46,805		
Securities of government-sponsored entities	176,850	176,850		
<b>Total marketable securities and restricted investments</b>	<b>\$ 260,722</b>	<b>\$ 260,722</b>	<b>\$</b>	<b>\$</b>
Contingent Consideration:				
Acquisition-related liabilities	\$ (31,828)	\$	\$	\$ (31,828)

**Table of Contents**

The fair and carrying value of the Company's Senior Convertible Notes is discussed in Note 7.

**Contingent Consideration Liability**

In connection with the acquisition of Cervitech<sup>®</sup>, Inc. (Cervitech) in May 2009, the Company is required to pay an additional amount not to exceed \$33.0 million in the event that the PCM<sup>®</sup> cervical total disc replacement device receives U.S. Food and Drug Administration approval. The fair value of the contingent consideration is determined using a probability-weighted discounted cash flow model, the significant inputs which are not observable in the market. The key assumptions in applying this approach are the interest rate, the timing of expected approval and the probability assigned to the milestone being achieved. Based on the expected timing of the milestone being achieved, the estimated fair value of the contingent consideration decreased to \$31.3 million at September 30, 2011. Changes in fair value are recorded in the statement of operations as sales, marketing and administrative expenses.

In connection with an immaterial acquisition in 2010, the Company is required to pay an additional amount not to exceed \$3.0 million in the event three specified milestones are met. The fair value of the contingent consideration is determined using a probability-weighted discounted cash flow model, the significant inputs of which are not observable in the market. The key assumptions in applying this approach are the interest rate and the probabilities assigned to the milestones being achieved. During the three and nine months ended September 30, 2011, approximately \$1.8 million of the total milestone payment became fixed and is no longer considered contingent consideration. Based on the probabilities assigned to the milestone being achieved, the estimated fair value of the remaining contingent consideration totaled approximately \$0.5 million at September 30, 2011. Changes in fair value are recorded in the statement of operations as sales, marketing and administrative expenses.

**Derivative Financial Instruments**

Prior to their reclassification to stockholders' equity on September 28, 2011, the 2017 Hedge and the 2017 Notes Embedded Conversion Derivative were classified as Level 3 because these assets and liabilities were not actively traded and were valued using significant unobservable inputs. Significant inputs to these models were the Company's stock price, risk free interest rate, credit rating, bond yield, and expected volatility of the Company's stock price.

The following table sets forth the changes in the estimated fair value for the Company's assets and liabilities measured using significant unobservable inputs (Level 3) (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Assets:</b>				
Fair value measurement at beginning of period	\$ 80,098	\$	\$	\$
Derivative asset purchased in connection with 2017 Notes			80,098	
Change in fair value measurement included in operating expenses and other income (expense)	(37,124)		(37,124)	
Derivative asset reclassified to stockholders' equity	(42,974)		(42,974)	
Fair value measurement at end of period	\$	\$	\$	\$
<b>Liabilities:</b>				
Fair value measurement at beginning of period	\$ 122,855	\$ 30,876	\$ 33,041	\$ 30,694
Derivative liability recorded in connection with 2017 Notes			88,900	
Change in fair value measurement included in operating expenses and other income (expense)	(39,837)	388	(38,923)	570
Derivative liability reclassified to stockholders' equity	(49,390)		(49,390)	
Contingent consideration settled	(1,800)		(1,800)	
Fair value measurement at end of period	\$ 31,828	\$ 31,264	\$ 31,828	\$ 31,264

**Table of Contents****6. Goodwill and Intangible Assets**

Goodwill and intangible assets as of September 30, 2011 consisted of the following (*in thousands, except years*):

	Weighted- Average Amortization Period (in years)	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
<b>Intangible Assets Subject to Amortization:</b>				
Purchased technology:				
Developed technology	14	\$ 37,535	\$ (9,941)	\$ 27,594
Manufacturing know-how and trade secrets	12	21,121	(5,519)	15,602
Trade name and trademarks	14	6,200	(1,294)	4,906
Customer relationships	13	10,035	(3,533)	6,502
	14	\$ 74,891	\$ (20,287)	\$ 54,604
<b>Intangible Assets Not Subject to Amortization:</b>				
In-process research and development				45,440
Goodwill				103,070
Total intangible assets, net				\$ 203,114

Goodwill and intangible assets as of December 31, 2010 consisted of the following (*in thousands, except years*):

	Weighted- Average Amortization Period (in years)	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
<b>Intangible Assets Subject to Amortization:</b>				
Purchased technology:				
Developed technology	14	\$ 39,975	\$ (7,946)	\$ 32,029
Manufacturing know-how and trade secrets	12	21,104	(4,207)	16,897
Trade name and trademarks	14	6,100	(956)	5,144
Customer relationships	13	10,035	(2,984)	7,051
	14	\$ 77,214	\$ (16,093)	\$ 61,121
<b>Intangible Assets Not Subject to Amortization:</b>				
In-process research and development				46,000
Goodwill				103,070
Total intangible assets, net				\$ 210,191

Total expense related to the amortization of intangible assets was \$1.5 million and \$1.3 million for the three months ended September 30, 2011 and 2010, respectively, and \$4.2 million and \$4.0 million for the nine months ended September 30, 2011 and 2010, respectively. In-process research and development will be amortized beginning on the regulatory approval date of the respective acquired products and will be amortized over the estimated useful life determined at that time.

## Edgar Filing: NUVASIVE INC - Form 10-Q

Total future amortization expense related to intangible assets subject to amortization at September 30, 2011 is set forth in the table below (*in thousands*):

Remaining 2011	\$ 1,460
2012	5,836
2013	5,818
2014	5,781
2015	5,450
2016	5,256
Thereafter through 2027	25,003
Total future amortization expense	\$ 54,604

**Table of Contents****7. Senior Convertible Notes**

The carrying values of the Company's Senior Convertible Notes are as follows (*in thousands*):

	September 30, 2011	December 31, 2010
<b>2.75% Senior Convertible Notes due 2017:</b>		
Principal amount	\$ 402,500	\$
Unamortized debt discount	(85,824)	
	316,676	
<b>2.25% Senior Convertible Notes due 2013</b>	<b>111,298</b>	<b>230,000</b>
<b>Total Senior Convertible Notes</b>	<b>\$ 427,974</b>	<b>\$ 230,000</b>

**2.75% Senior Convertible Notes due 2017**

In June 2011, the Company issued \$402.5 million principal amount of 2.75% Senior Convertible Notes due 2017 (the 2017 Notes), which includes the issuance of \$52.5 million principal amount for the exercise of the initial purchasers' option to purchase additional notes. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately \$359.0 million. The 2017 Notes have a stated interest rate of 2.75% and mature on July 1, 2017. Prior to September 28, 2011, the date on which stockholder approval to increase the number of the Company's authorized shares of common stock from 70 million to 120 million was obtained, the 2017 Notes were settleable only in cash. Subsequent to the receipt of this approval, the 2017 Notes may be settled in cash, stock, or a combination thereof, solely at the Company's election. The initial conversion rate of the 2017 Notes is 23.7344 shares per \$1,000 principal amount, subject to adjustment (which represents an initial conversion price of approximately \$42.13 per share).

Interest on the 2017 Notes began accruing in June 2011 and is payable semi-annually each January 1st and July 1st, beginning January 1, 2012. The fair value, based on quoted market prices, of the outstanding 2017 Notes at September 30, 2011 is approximately \$338.1 million.

Prior to January 1, 2017, holders may convert their notes only under the following conditions: a) During any calendar quarter beginning October 1, 2011, if the reported sale price of the Company's common stock for at least 20 days of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day; b) During the five business day period in which the trading price of the 2017 Notes falls below 98% of the product of (i) the last reported sale price of the Company's common stock and (ii) the conversion rate on that date; and c) Upon the occurrence of specified corporate events, as defined in the 2017 Notes. From January 1, 2017 and until the close of business on the second scheduled trading day immediately preceding the July 1, 2017, holders may convert their 2017 Notes at any time, regardless of the foregoing circumstances. The Company may not redeem the 2017 Notes prior to maturity.

Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the 2017 Notes do not contain any financial covenants and do not restrict the Company from paying dividends or issuing or repurchasing any of its other securities.

In accordance with authoritative guidance, the cash conversion feature of the 2017 Notes (the 2017 Notes Embedded Conversion Derivative) required bifurcation from the 2017 Notes and was initially accounted for as a derivative liability. The fair value of the 2017 Notes Embedded Conversion Derivative at the time of issuance of the 2017 Notes was \$88.9 million, and was recorded as the original debt discount for purposes of accounting for the debt component of the 2017 Notes. On September 28, 2011, upon obtaining stockholder approval of the additional authorized shares of the Company's common stock, in accordance with authoritative literature, the derivative liability was marked to fair value and reclassified to stockholders' equity. The original debt discount will be recognized as interest expense using the effective interest method over the term of the 2017 Notes.

In connection with the offering of the 2017 Notes, the Company entered into convertible note hedge transactions (the 2017 Hedge) with the initial purchasers and/or their affiliates (the Counterparties) entitling the Company to purchase up to 9,553,096 shares of the Company's common stock at an initial stock price of \$42.13 per share, each of which is subject to adjustment. Prior to obtaining the stockholder approval to increase the number of the Company's authorized common shares discussed above, the 2017 Hedge was settleable only in cash and was accounted for as a derivative asset. The cost of the 2017 Hedge was \$80.1 million. On September 28, 2011, upon obtaining stockholder approval of the additional authorized shares of the Company's common stock, in accordance with authoritative literature, the derivative asset was marked to fair value and

## Edgar Filing: NUVASIVE INC - Form 10-Q

reclassified to stockholders' equity. The 2017 Hedge expires on July 1, 2017. The 2017 Hedge is expected to reduce the potential equity dilution upon conversion of the 2017 Notes if the daily volume-weighted average price per share of the Company's common stock exceeds the strike price of the 2017 Hedge.

**Table of Contents**

In addition, the Company sold warrants to the Counterparties to acquire up to 477,654 shares of the Company's Series A Participating Preferred Stock (the 2017 Warrants), at an initial strike price of \$988.51 per share, subject to adjustment. Each share of Series A Participating Preferred Stock is initially convertible into 20 shares of the Company's common stock. The 2017 Warrants expire on various dates from September 2017 through January 2018 and may be settled in cash or net shares. The Company received \$47.9 million in cash proceeds from the sale of the 2017 Warrants, which has been recorded as an increase in additional paid-in-capital. The 2017 Warrants could have a dilutive effect on the Company's earnings per share to the extent that the price of the Company's common stock during a given measurement period (the quarter or year-to-date period) exceeds the strike price of the 2017 Warrants.

***2.25% Senior Convertible Notes due 2013***

In March 2008, the Company issued \$230.0 million principal amount of 2.25% unsecured Senior Convertible Notes (the 2013 Notes), which includes the subsequent exercise of the initial purchasers' option to purchase an additional \$30.0 million aggregate principal amount of the 2013 Notes. The net proceeds from the offering, after deducting the initial purchasers' discounts and costs directly related to the offering, were approximately \$208.4 million.

During the three and nine months ended September 30, 2011, the Company repurchased, in privately negotiated transactions, approximately \$118.7 million in principal of its 2013 Notes. The aggregate purchase price totaled approximately \$119.0 million (representing a price of approximately 99.4% of the principal face value of the 2013 Notes, plus accrued interest). The repurchases were made using a portion of the net proceeds from the issuance of the 2017 Notes. Including the write off of a portion of the deferred financing costs related to the 2013 Notes, the Company recorded a loss on the extinguishment of debt of approximately \$0.7 million. At September 30, 2011, approximately \$111.3 million of the 2013 Notes' original aggregate principal amount of \$230.0 million remains outstanding.

The Company pays 2.25% interest per annum on the principal amount of the 2013 Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. Any of the 2013 Notes not converted prior to March 15, 2013, the Maturity Date, will be paid in cash. The fair value, based on quoted market prices, of the outstanding 2013 Notes at September 30, 2011 is approximately \$108.0 million.

The 2013 Notes are convertible into shares of the Company's common stock, based on an initial conversion rate, subject to adjustment, of 22.3515 shares per \$1,000 principal amount of the 2013 Notes (which represents an initial conversion price of approximately \$44.74 per share). Holders may convert their 2013 Notes at their option on any day up to and including the second scheduled trading day immediately preceding the Maturity Date. If a fundamental change to the Company's business occurs, as defined in the 2013 Notes, holders of the 2013 Notes have the right to require that the Company repurchase the 2013 Notes, or a portion thereof, at the principal amount plus accrued and unpaid interest.

In connection with the offering of the 2013 Notes, the Company entered into convertible note hedge transactions (the 2013 Hedge) with the initial purchasers and/or their affiliates (the 2013 Counterparties) entitling the Company to purchase up to 5.1 million shares of the Company's common stock at an initial stock price of \$44.74 per share, each of which is subject to adjustment. In addition, the Company sold to the 2013 Counterparties warrants to acquire up to 5.1 million shares of the Company's common stock (the 2013 Warrants), at an initial strike price of \$49.13 per share, subject to adjustment. The cost of the 2013 Hedge that was not covered by the proceeds from the sale of the 2013 Warrants was approximately \$14.0 million and was recorded as a reduction of additional paid-in capital as of December 31, 2008. The impact of the 2013 Hedge is to raise the effective conversion price of the 2013 Notes to approximately \$49.13 per share (or approximately 20.3542 shares per \$1,000 principal amount of the 2013 Notes). The 2013 Hedge is expected to reduce the potential equity dilution upon conversion of the 2013 Notes if the daily volume-weighted average price per share of the Company's common stock exceeds the strike price of the 2013 Hedge. The 2013 Warrants could have a dilutive effect on the Company's earnings per share to the extent that the price of the Company's common stock during a given measurement period (the quarter or year to date period) exceeds the strike price of the 2013 Warrants.

***8. Series A Preferred Securities***

On June 28, 2011, in connection with the issuance of the 2017 Warrants, the Company amended its Restated Certificate of Incorporation to designate 477,654 shares of the Company's authorized preferred stock, par value \$0.001 per share, as Series A Participating Preferred Stock (the Series A Preferred Stock). The Series A Preferred Stock will automatically convert into shares of the Company's common stock.

**Table of Contents**

The holders of Series A Preferred Stock (collectively, the Preferred Holders) are entitled to receive dividends when and if declared by the Board of Directors. The preferred dividends are payable in preference and in priority to any dividends on the Company's common stock.

Shares of Series A Preferred Stock are convertible into 20 shares of common stock, subject to certain antidilution adjustments. Preferred Holders vote on an equivalent basis with common stockholders on an as-converted basis.

The Preferred Holders are entitled to receive liquidation preferences at the rate of \$648.20 per share. Liquidation payments to the Preferred Holders have priority and are made in preference to any payments to the holders of common stock.

**9. Net (Loss) Income Per Share**

The Company computes basic net (loss) income per share using the weighted-average number of common shares outstanding during the period. Diluted net (loss) income per share assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's stock options, unvested restricted stock units, warrants and the shares to be issued upon the conversion of the 2013 Notes and the 2017 Notes. No shares related to the assumed conversion of the 2013 Notes or the 2017 Notes were included in the diluted net (loss) income per share calculation for the three and nine months ended September 30, 2011 and 2010 because the inclusion of such shares would have had an anti-dilutive effect. The shares to be issued upon exercise of all outstanding warrants were excluded from the diluted net (loss) income calculation for the three and nine months ended September 30, 2011 and 2010 because the inclusion of such shares would have had an anti-dilutive effect.

The following table sets forth the computation of basic and diluted (loss) earnings per share (*in thousands, except per share data*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Numerator:</b>				
Net (loss) income attributable to NuVasive, Inc.	\$ (67,552)	\$ 8,542	\$ (59,813)	\$ 16,353
<b>Denominator for basic and diluted net (loss) income per share:</b>				
Weighted average common shares outstanding for basic	39,892	39,394	39,766	39,180
<b>Dilutive potential common stock outstanding:</b>				
Stock options		807		1,046
Restricted stock units		195		163
Weighted average common shares outstanding for diluted	39,892	40,396	39,766	40,389
Basic net (loss) income per share attributable to NuVasive, Inc.	\$ (1.69)	\$ 0.22	\$ (1.50)	\$ 0.42
Diluted net (loss) income per share attributable to NuVasive, Inc.	\$ (1.69)	\$ 0.21	\$ (1.50)	\$ 0.40

The following outstanding common stock equivalents were not included in the calculation of diluted net (loss) income per share because their effects were anti-dilutive (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Weighted stock options and RSUs	6,223	4,043	6,076	2,874
Warrants	5,141	5,141	5,141	5,141
2013 Notes	3,619	5,141	4,628	5,141
2017 Notes	9,553		3,289	
<b>Total</b>	<b>24,536</b>	<b>14,325</b>	<b>19,134</b>	<b>13,156</b>





**Table of Contents****10. Comprehensive (Loss) Income**

The components of comprehensive (loss) income are as follows (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Consolidated net (loss) income	\$(67,675)	\$8,104	\$(60,675)	\$15,000
Other comprehensive (loss) income:				
Unrealized gain (loss) on investments	11	(10)	36	85
Translation adjustments	(1,763)	1,480	(707)	410
Total consolidated comprehensive (loss) income	(69,427)	9,574	(61,346)	15,495
Plus: Net loss attributable to noncontrolling interests	(123)	(438)	(862)	(1,353)
Comprehensive (loss) income attributable to NuVasive, Inc.	\$(69,304)	\$10,012	\$(60,484)	\$16,848

**11. Stock-Based Compensation**

The Company estimates the fair value of stock options and shares issued to employees under the Employee Stock Purchase Plan (ESPP Plan) using a Black-Scholes option-pricing model on the date of grant. The fair value of restricted stock units (RSUs) is based on the stock price on the date of grant. The fair value of equity instruments that are expected to vest are recognized and amortized on an accelerated basis over the requisite service period.

The weighted-average assumptions used to estimate the fair value of stock options granted and stock purchase rights under the ESPP Plan are as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
<b>Stock Options</b>				
Volatility	49%		49%	47%
Expected term (years)	5.0		5.3	4.5
Risk free interest rate	1.8%		2.1%	2.4%
Expected dividend yield	0.0%		0.0%	0.0%
<b>ESPP</b>				
Volatility	55%	55%	58%	53%
Expected term (years)	1.4	1.4	1.2	1.4
Risk free interest rate	0.3%	0.8%	0.2%	0.9%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

The compensation costs included in the consolidated statement of operations for all stock-based compensation arrangements are as follows (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Sales, marketing and administrative expense	\$7,497	\$6,494	\$21,956	\$18,846
Research and development expense	621	827	1,833	2,458
Total stock-based compensation expense	\$8,118	\$7,321	\$23,789	\$21,304

The Company issued 8,000 and 104,000 shares of common stock upon exercise of stock options during the three and nine months ended September 30, 2011, respectively, and issued 524,000 shares of common stock upon exercise of stock options during the year ended December 31, 2010. The Company issued 28,000 and 148,000 shares of common stock upon the vesting of RSUs during the three and nine months ended September 30, 2011, respectively, and issued 73,000 shares of common stock upon the vesting of RSUs during the year ended

December 31, 2010.

***12. Income Taxes***

The Company recorded an income tax benefit of \$29.0 million and \$40,000 for the three months ended September 30, 2011 and 2010, respectively, and recorded an income tax benefit of \$22.7 million and income tax expense of \$1.4 million for the nine months ended September 30, 2011 and 2010, respectively. The effective income tax benefit rate for the nine months ended September 30, 2011 was 27%, which is based on an estimate of the Company's annual effective income tax rate. The Company updates its annual effective income tax rate each quarter and if the estimated effective income tax rate changes, a cumulative adjustment is made.

## **Table of Contents**

As a result of the litigation award accrual totaling \$101.2 million recorded in the three and nine months ended September 30, 2011, the Company evaluated the need for a valuation allowance of its deferred tax assets by reviewing all available positive and negative evidence. Based on this review, the Company concluded that it was more likely than not that the Company would be able to realize the benefit of its U.S. federal deferred tax assets and its deferred tax assets for all states except California in the future. This conclusion was primarily based on historical and projected operating performance, as well as the Company's expectation that operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the federal deferred tax assets well within the statutory carryover periods. Accordingly, the Company did not establish a valuation allowance on its federal or non-California state deferred tax assets as of September 30, 2011.

Based on this same evidence and consideration of the state of California's past and current suspension of the use of net operating loss carryforwards, the state of California's statutory carryover periods and the Company's apportionment election beginning in 2011, the Company concluded that it is more likely than not that the Company will not be able to utilize its California deferred tax assets. Therefore, the Company established a full valuation allowance on its California deferred tax assets as of September 30, 2011. Accordingly, the income tax benefit reported for the three and nine months ended September 30, 2011, includes income tax expense totaling \$4.8 million in connection with the establishment of this valuation allowance.

In addition, certain future tax deductions will no longer be realized as a result of the repurchase of \$118.7 million of the 2013 Notes. Accordingly, the income tax benefit for the three and nine months ended September 30, 2011 includes a charge totaling \$1.5 million representing the write off of deferred tax assets associated with these future deductions.

There was no material change to the Company's unrecognized tax benefits and interest accrued related to unrecognized tax benefits during the nine months ended September 30, 2011.

### ***13. Business Segment and Product Information***

The Company's business operates in one segment based upon the Company's organizational structure, the way in which the operations are managed and evaluated and the lack of availability of separate financial results. Substantially all of the Company's assets and sales are in the United States.

The Company's spine surgery product line offerings, which include thoracolumbar product offerings, cervical offerings, and a set of motion preservation products still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. The Company's biologic product line offerings include allograft (donated human tissue), Osteocel® Plus, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion, and FormaGraft®, a collagen synthetic product used to aid the fusion process. Revenue by product line offerings was as follows (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Spine Surgery Products	\$ 107,340	\$ 97,477	\$ 317,638	\$ 284,169
Biologics	25,540	22,785	72,674	64,764
<b>Total Revenue</b>	<b>\$ 132,880</b>	<b>\$ 120,262</b>	<b>\$ 390,312</b>	<b>\$ 348,933</b>

### ***14. Legal Proceedings***

#### ***Medtronic Sofamor Danek USA, Inc. Litigation***

In August 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States District Court for the Southern District of California (Medtronic Litigation), alleging that certain of NuVasive's products infringe, or contribute to the infringement of, twelve U.S. patents assigned or licensed to Medtronic. Three of the patents were later withdrawn by Medtronic, leaving nine patents. NuVasive brought counterclaims against Medtronic alleging infringement of certain of NuVasive's patents. The case has been administratively broken into serial phases. The first phase of the case includes three Medtronic patents and one NuVasive patent. Trial on the first phase of the case began in August 2011 and on September 20, 2011, a jury from the U.S. District Court, Southern District of California delivered an unfavorable verdict against NuVasive with respect to three Medtronic patents and a favorable verdict in favor of NuVasive with respect to one NuVasive patent. Judgment was entered by the Court on September 29, 2011. The jury awarded monetary damages of approximately \$101.2 million to Medtronic which includes lost profits and back royalties. As Medtronic has filed for a permanent injunction and an increase in damages, additional fees and costs, potential future royalties and injunctive relief may be awarded as part of a final judgment

## Edgar Filing: NUVASIVE INC - Form 10-Q

which is expected in the coming months. While the Company intends to timely appeal the unfavorable verdict, in accordance with the authoritative guidance on the evaluation of loss contingencies, during the three and nine months ended September 30, 2011, the Company recorded an accrual for the \$101.2 million verdict. In addition, the Company is currently planning to accrue ongoing royalties on future sales at the royalty rates stated in the jury verdict. The \$101.2 million is recorded as a separate line item within operating expenses as the split between lost profit and royalty amounts are not known. The Company may be required to secure the amount of the judgment during the appeals process.

**Table of Contents**

With respect to the favorable verdict delivered regarding the one NuVasive patent, the jury awarded the Company monetary damages of approximately \$0.7 million for reasonable royalty damages. In accordance with the authoritative guidance on the evaluation of gain contingencies, this amount has not been recorded at September 30, 2011.

***Trademark Infringement Litigation***

In September 2009, Neurovision Medical Products, Inc. (NMP) filed suit against NuVasive in the U.S. District Court for the Central District of California (Case No. 2:09-cv-06988-R-JEM) alleging trademark infringement and unfair competition. NMP sought cancellation of NuVasive's NeuroVision trademark registrations, injunctive relief and damages based on NMP's common law use of the Neurovision mark. On November 23, 2009, the Company denied the allegations in NMP's complaint. After trial of the matter, on October 25, 2010 an unfavorable jury verdict was delivered against the Company relating to its use of the NeuroVision trade name. The verdict awarded damages to NMP of \$60.0 million. On January 3, 2011, the Court ordered a judgment be entered in the case in the amount of \$60.0 million, and granted a permanent injunction prohibiting the Company's use of the NeuroVision name for marketing purposes. The Company sought emergency relief, and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction. The Company has appealed the judgment and permanent injunction. During pendency of the appeal, the Company has been required to escrow funds to secure the amount of the judgment, plus interest, attorneys' fees and costs. On June 16, 2011, the Company entered into an escrow arrangement and transferred \$62.5 million of cash and investments into a restricted escrow account. These funds are included in restricted cash and investments on the Company's September 30, 2011 condensed consolidated balance sheet. Any payment of damages will be delayed while the appeals process runs its course, which could take up to two years. The Company continues to believe that the verdict is not supported by the facts or by applicable law. The Company, based on its own assessment as well as that of outside counsel, believes that the trial court committed a number of prejudicial legal errors and that these errors were significant, making the possibility of reversal of the judgment on appeal and/or a new trial probable. At September 30, 2011, in accordance with the authoritative guidance on the evaluation of contingencies, the Company has not recorded an accrual related to this litigation. The Company may be required to record an expense related to this damage award in the future.

***Contingencies***

The Company is party to certain claims and legal actions arising in the normal course of business. The Company does not expect any such claims and legal actions to have a material adverse effect on its business, results of operations or financial condition.

***15. Subsequent Event***

***Impulse Monitoring, Inc. Acquisition***

On October 7, 2011 (the Closing Date), the Company completed the purchase of all of the outstanding shares of Impulse Monitoring, Inc., (IMI), a Delaware corporation, pursuant to an Agreement and Plan of Merger dated September 28, 2011 (the Merger Agreement) for an initial payment of approximately \$80.0 million consisting of cash totaling approximately \$40.5 million and the issuance of 2,336,200 shares of NuVasive common stock to certain stockholders of IMI. IMI, a company headquartered in Maryland, is a leading provider of outsourced intraoperative monitoring (IOM) services to hospitals and became a wholly owned subsidiary of the Company upon completion of the acquisition. The acquisition allows the Company to increase its IOM service business, which is a long-standing service providing solutions for the detection of neurological compromise and identification of functional neural structures during surgeries that involve spine, cardio, ENT, brain and general orthopedic. The acquisition complements the Company's existing nerve monitoring systems, which are designed for discreet and directional nerve avoidance and detection, making lateral access to the spine during the XLIF® procedure more safe and reproducible.

***Purchase Price***

The acquisition of IMI will be recorded using the acquisition method of accounting in accordance with the authoritative guidance for business combinations.

The estimated initial purchase price is estimated as follows (*in thousands*):

Cash paid to sellers	\$ 40,500
Market value of NuVasive common stock issued on Closing Date	39,500

Total estimated initial purchase price	\$ 80,000
--	-----------

The preliminary allocation of the estimated initial purchase price is based on management's preliminary valuation of the fair value of tangible assets, intangible assets and acquired and liabilities assumed as of the Closing Date and such estimates are subject to revision. As of the date of this Form 10-Q, the Company has not completed the detailed valuations necessary to finalize the estimate of the fair

**Table of Contents**

value of the assets acquired and the liabilities assumed from IMI and the related allocations of the estimated initial purchase price. Thus, the estimated initial purchase price allocation below is preliminary, and is subject to further adjustment. The final purchase price allocation is pending the completion of the Company's internal review of the valuation work, which is expected to be completed during the fourth quarter of 2011. The provisional items pending finalization are the valuation of the acquired intangible assets, goodwill, property and equipment, total other current assets, liabilities assumed, and income tax related matters.

The acquisition of IMI occurred subsequent to September 30, 2011. Accordingly, the assets acquired and liabilities assumed from IMI, the consideration paid to acquire IMI, and the results of IMI's operations are not reflected in the Company's condensed consolidated financial statements as of the three and nine months ended September 30, 2011.

The following preliminary allocation of the estimated initial purchase price is subject to change, and the final amounts may differ. The following table summarizes the allocation of the estimated initial purchase price (*in thousands*):

	Estimated Fair Value	Estimated Useful Life
Cash	\$ 5,100	
Total other current assets	6,900	
Property, plant and equipment	1,100	
Developed technology	700	5 years
Non-compete agreement	400	2 years
Trade name	500	3 years
Customer relationships	24,700	10 years
Goodwill	58,400	
Current liabilities	(9,100)	
Deferred income tax liabilities	(8,700)	
<b>Total estimated initial purchase price allocation</b>	<b>\$ 80,000</b>	

Goodwill totaling \$58.4 million represents the excess of the estimated initial purchase price over the fair value of tangible and identifiable intangible assets acquired and is due primarily to customers and synergies expected from combining the assembled workforce with the Company's existing IOM workforce. This acquisition was nontaxable and, as a result, there is no tax basis in goodwill. Accordingly, none of the goodwill associated with the IMI acquisition is deductible for tax purposes.

**Results of Operations**

The Company has prepared the following unaudited pro forma financial statement information to compare results of the periods presented assuming the IMI acquisition had occurred as of January 1, 2010. These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be an indicator of the results of operations that would have actually resulted had the acquisition occurred at the beginning of each of the periods presented, or of future results of operations. Assuming the IMI acquisition occurred as of January 1, 2010, the pro forma unaudited results of operations would have been as follows for the three and nine months ended September 30, 2011 and 2010 (using the preliminary allocation of the estimated purchase price above which is subject to change) (*in thousands, except per share data*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue	\$ 143,293	\$ 128,281	\$ 419,714	\$ 372,331
Net (loss) income attributable to NuVasive, Inc.	\$ (66,426)	\$ 8,656	\$ (57,882)	\$ 13,838
Net (loss) income per share - basic	\$ (1.57)	\$ 0.21	\$ (1.37)	\$ 0.33
Net (loss) income per share - diluted	\$ (1.57)	\$ 0.20	\$ (1.37)	\$ 0.32

The above pro forma unaudited results of operations do not include pro forma adjustments relating to costs of integration or post-integration cost reductions that may be incurred or realized by the Company in excess of actual amounts incurred or realized through September 30, 2011.

For the three and nine months ended September 30, 2011, the Company's condensed consolidated results of operations include acquisition-related expenses of \$0.5 million which are included in sales, marketing and administrative expenses.



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

**Forward-Looking Statements May Prove Inaccurate**

*You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the notes to those statements included in this report. This discussion may contain*

---

## **Table of Contents**

*forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under heading Risk Factors, and elsewhere in this report, and similar discussions in our other Securities and Exchange Commission filings, including our Annual Report on Form 10-K for the year ended December 31, 2010. We do not intend to update these forward looking statements to reflect future events or circumstances.*

### **Overview**

We are a medical device company focused on developing minimally disruptive surgical products and procedures for the spine. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, including biologics, a combined market estimated to exceed \$7.7 billion globally in 2011. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>®</sup>, as well as a growing offering of biologics, cervical and motion preservation products. Our spine surgery product line offerings, which include products for the thoracolumbar spine, the cervical spine, and a set of motion preservation product offerings still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. Our biologic product line offerings include allograft (donated human tissue), OsteoCel<sup>®</sup> Plus, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion, and FormaGraft<sup>®</sup>, a collagen synthetic product used to aid the fusion process. We focus significant research and development efforts to expand our MAS product platform, advance the applications of our unique technology to additional procedures and develop motion preserving products such as our total disc replacement products. We dedicate significant resources toward training spine surgeons on our unique technology and products. Currently, we are training over 500 surgeons annually, which includes surgeons new to our MAS product platform as well as surgeons previously trained on our MAS product platform who are attending advanced training programs.

Our MAS platform, with the unique advantages provided by our nerve monitoring systems, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF<sup>®</sup>, in which surgeons access the spine for a fusion procedure from the side of the patient's body, rather than from the front or back. Our MaXcess<sup>®</sup> instruments provide access to the spine in a manner that affords direct visualization and our nerve monitoring systems allow surgeons to avoid critical nerves.

In the past certain insurance providers have adopted policies of not providing reimbursement for the XLIF procedure. We have worked with our surgeon customers and certain surgical societies who, in turn, have worked with these insurance providers to supply the information required to categorize the XLIF procedure as a procedure entitled to reimbursement under their policies. Most major insurance companies provide reimbursement for XLIF procedures, however certain smaller regional carriers have policies against coverage of XLIF. NuVasive cannot offer definitive time frames or final outcomes regarding reversal of the non-coverage policies, as the process is dictated by the third-party insurance providers. To date, we have not experienced significant lack of payment for our procedures based on these policies.

Factors arising from third parties such as prolonged interaction with regulatory agencies, general pushback from private payers on any of our procedures, devices, or services, industry specific taxes, and other external factors may have a material impact on our business. We have begun to incur incremental expenditures to address these types of issues regionally and nationally as deemed necessary. Such advocacy for improvements in the regulatory approval process, payer coverage of new technologies, and policies that facilitate innovation to improve spine care are likely to become an ongoing expense.

In recent years, we have significantly expanded our product offering relating to procedures in the cervical spine as well as in the area of biologics. Our cervical product offering now provides a full set of solutions for cervical fusion surgery, including both allograft and CoRoent<sup>®</sup> implants, as well as cervical plating and posterior fixation products. In 2009, we acquired Cervitech<sup>®</sup>, Inc. (Cervitech), a company focused on gaining regulatory approval of the PCM<sup>®</sup> cervical disc system, a motion preserving total disc replacement device. This strategic acquisition allows us the potential to accelerate our entry into the growing mechanical cervical disc replacement market. In the first quarter of 2010, we filed a PMA application with the U.S. Food and Drug Administration (FDA) for approval of the PCM cervical disc system. If obtained, approval, which is expected during the latter half of 2012, would further strengthen our cervical product offering and should enable us to continue our trend of increasing our market share.

In 2009 we purchased forty percent (40%) of the capital stock of Progentix Orthobiology, B.V. (Progentix), a company organized under the laws of the Netherlands, from existing shareholders for \$10.0 million in cash (the Initial Investment). Progentix has as its objective the development and exploitation of knowledge and technology in the field of synthetic bone graft materials to aid in the healing and generation of human bone.

We have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion.



---

**Table of Contents**

The majority of our revenues are derived from the sale of disposables and implants, and we expect this trend to continue for the foreseeable future. We loan our proprietary software-driven nerve monitoring systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures. In addition, we place our proprietary software-driven nerve monitoring systems, MaXcess and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them. Our implants and disposables are currently sold and shipped from our primary distribution and warehousing operations facility located in Memphis, Tennessee. We recognize revenue for disposables or implants used upon receiving acknowledgement of a purchase order from the hospital indicating product use or implantation. In addition, we sell an immaterial number of MAS instrument sets, MaXcess devices, and our proprietary software-driven nerve monitoring systems. To date, we have derived less than 5% of our total revenues from these sales.

While we continue to expand internationally, through September 30, 2011, substantially all of our operations are located in the United States and substantially all of our sales have been generated in the United States. We sell our products in the United States through a sales force comprised of exclusive independent sales agents and our own directly-employed sales professionals; both selling only NuVasive spine surgery products. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. Beginning late in 2007 and continuing today, we are continuing our expansion of international sales efforts with the focus on European, Asian and Latin American markets. Our international sales force is comprised of directly-employed exclusive shareowners as well as exclusive distributors and independent sales agents.

**2011 Activity**

In June 2011, we issued \$402.5 million principal amount of 2.75% Senior Convertible Notes due 2017 (the 2017 Notes), which includes the issuance of \$52.5 million principal amount upon the exercise of the initial purchasers' option to purchase additional notes. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately \$359.0 million. We pay 2.75% interest per annum on the principal amount of the 2017 Notes. The 2017 Notes mature on July 1, 2017 and may be settled in cash, stock, or a combination thereof, solely at our election. Interest on the 2017 Notes began accruing in June 2010 and is payable semi-annually each January 1st and July 1st, beginning January 1, 2012. The completion of this financing transaction affords us greater flexibility and liquidity.

In August 2011, we repurchased, in privately negotiated transactions, approximately \$118.7 million in principal of its 2013 Notes. The repurchases were made using a portion of the net proceeds from the issuance of the 2017 Notes. Including the write off of a portion of the deferred financing costs related to the 2013 Notes, we recorded a loss on the extinguishment of debt of approximately \$0.7 million. At September 30, 2011, approximately \$111.3 million of the 2013 Notes' original aggregate principal amount of \$230.0 million remains outstanding.

In September 2011, in connection with the Medtronic Sofamor Danek USA, Inc. (Medtronic) litigation, a jury from the U.S. District Court, Southern District of California delivered an unfavorable verdict to us and awarded monetary damages of approximately \$101.2 million to Medtronic. While we intend to timely appeal the unfavorable verdict, we may be required to secure the amount of the judgment during the appeals process.

In October 2011, we completed the purchase of all of the outstanding shares of Impulse Monitoring, Inc. (IMI) for an initial payment of approximately \$80.0 million consisting of cash totaling approximately \$40.5 million and the issuance of 2,336,200 shares of NuVasive common stock to certain stockholders of IMI. IMI, a company headquartered in Maryland, is a leading provider of outsourced intraoperative monitoring (IOM) services to hospitals and became a wholly owned subsidiary of the Company upon completion of the acquisition. This acquisition allows the Company further entry into the IOM market.

**Table of Contents****Results of Operations****Revenue**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended:				
Spine Surgery Products	\$107,340	\$ 97,477		
Biologics	25,540	22,785		
Total Revenue	\$132,880	\$120,262	\$12,618	10%
Nine months ended:				
Spine Surgery Products	\$317,638	\$284,169		
Biologics	72,674	64,764		
Total Revenue	\$390,312	\$348,933	\$41,379	12%

Our spine surgery product line offerings, which include products for the thoracolumbar spine, the cervical spine, and a set of motion preservation product offerings still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. Our biologics product line offerings include allograft (donated human tissue), Osteocel Plus, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion, and FormaGraft, a collagen synthetic product used to aid the fusion process.

The continued adoption of minimally invasive procedures for spine has led to the continued expansion of our innovative lateral procedure known as XLIF, in which surgeons access the spine for a fusion procedure from the side of the patient's body, rather than from the front or back. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions has contributed to strong revenue growth. In addition, increased market acceptance in our international markets contributed to the increase in revenues noted for the periods presented. We expect the continued adoption of our XLIF procedure and deeper penetration into existing accounts and our newer international markets as our sales force executes on the strategy of selling the full mix of our products; however, recent changes in payer and hospital behavior in the United States have created less predictability in the U.S. lumbar portion of the spine market and impacted the overall spine market's growth rate. Accordingly, we believe that our growth in revenue in 2011 will be more weighted towards increased sales of our cervical offerings, our biologics product line and in our international businesses.

Our total revenues increased \$12.6 million and \$41.4 million in the three and nine months ended September 30, 2011, respectively, representing total revenue growth of 10% and 12% for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010. Revenue from our Spine Surgery Products increased \$9.9 million and \$33.5 million, or 10% and 12%, in the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010. Revenue from our Biologics product line increased \$2.8 million and \$7.9 million, or 12%, in both the three and nine months ended September 30, 2011, compared to the same periods in 2010. Total revenues were impacted by small unfavorable changes in price of approximately 1% and 2% in the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010.

**Cost of Goods Sold, excluding amortization of purchased technology**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended	\$26,015	\$21,580	\$ 4,435	21%
% of revenue	20%	18%		
Nine months ended	\$75,049	\$62,037	\$13,012	21%
% of revenue	19%	18%		

Cost of goods sold consists of purchased goods, inventory-related costs and royalty expenses.

## Edgar Filing: NUVASIVE INC - Form 10-Q

Cost of goods sold as a percentage of revenue increased slightly for the three and nine months ended September 30, 2011 compared to the same periods in 2010, primarily from an increase in excess and obsolete inventory reserves, as well as continued shifts in the geographic mix and from estimated royalty expense accruals associated with the recent judgment in the Medtronic litigation.

We expect cost of goods sold, as a percentage of revenue, to increase to approximately 20.5% primarily due to the acquisition of IMI, as well as estimated on-going royalty expense accruals related to the Medtronic litigation.

**Table of Contents***Operating Expenses**Sales, Marketing and Administrative*

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended	\$ 85,482	\$ 77,717	\$ 7,765	10%
% of revenue	64%	65%		
Nine months ended	\$254,025	\$230,104	\$23,921	10%
% of revenue	65%	66%		

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for personnel engaged in sales, marketing and customer support functions; distributor commissions; depreciation expense for surgical instrument sets; shipping costs; surgeon training costs; shareowner (employee) related expenses for our administrative functions; and third-party professional service fees.

The increases in sales, marketing and administrative expenses principally result from growth in our revenue and the overall growth of the Company, including: expenses that tend to vary based on revenue such as commissions, depreciation expense for loaned surgical instrument sets, worldwide sales force headcount and shipping; expenses associated with investments in our worldwide infrastructure such as operating systems and real estate; legal expenses; and non-sales related headcount growth, offset by the decrease in depreciation expense due to the change in useful life of certain surgical instrument sets. As a percentage of revenue, sales, marketing and administrative expenses decreased slightly for the three and nine months ended September 30, 2011 compared to the same periods in 2010 principally as a result of increased operating leverage in our expenses relative to the 10% and 12% growth in revenue for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010.

Excluding the impact resulting from a change in an accounting estimate related to the useful life of certain surgical instrument sets, costs that tend to vary based on revenue increased \$3.1 million and \$7.7 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010. This increase includes expenses totaling \$0.4 million recorded in the nine months ended September 30, 2011 resulting from the correction of an immaterial error related to the accrual of payroll expenses. This increase is less than our increased revenue growth of 10% and 12% in the first three and nine months of 2011 as compared to the same periods in 2010. Effective January 1, 2011, we changed the useful life of certain surgical instrument sets from three to four years. This change, which was accounted for as a change in accounting estimate, resulted in approximately \$1.2 million and \$5.0 million less depreciation expense for the three and nine months ended September 30, 2011, respectively, than would have been recorded had the useful life of these assets not been extended.

Compensation and other shareowner related expenses for our marketing and administrative support functions increased \$3.5 million and \$12.9 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010, which include expenses totaling \$0.6 million recorded in the nine months ended September 30, 2011 resulting from the correction of an immaterial error related to the accrual of payroll expenses. These increases are due to increased compensation and other shareowner related expenses resulting from additions to our headcount and an increase in performance-based compensation. Stock-based compensation increased \$1.0 million and \$3.1 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010, primarily related to an increase in stock-based awards granted to shareowners associated with the continued increase in headcount and our fiscal 2011 annual grants.

Acquisition-related costs decreased \$0.2 million and increased \$1.0 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010 primarily attributable to changes in the contingent consideration liabilities incurred in the three and nine months ended September 30, 2011, and expenses incurred related to other acquisition-related activities.

Legal costs were relatively consistent for the three and nine months ended September 30, 2011 compared to the same periods in 2010; however, expenses incurred in 2010 in connection with the defense of the NeuroVision trademark infringement litigation were offset by increased expenses incurred in connection with the Medtronic litigation during 2011. In addition, during the nine months ended September 30, 2010, expenses were lower due to a recovery of an international receivable totaling \$1.5 million for which no comparable reduction in expenses occurred during the same period in 2011.

On a long-term basis, as a percentage of revenue, we expect total sales, marketing and administrative costs to continue to decrease moderately over time.





**Table of Contents****Research and Development**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended	\$10,092	\$10,085	\$ 7	%
% of revenue	8%	8%		
Nine months ended	\$31,119	\$31,989	\$(870)	(3%)
% of revenue	8%	9%		

Research and development expenses consist primarily of product research and development, clinical trial and study costs, regulatory and clinical functions, and shareowner related expenses.

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, enhanced the applications of the XLIF procedure, expanded our offering of cervical products, and moved us closer to entering into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications, which are currently in different phases of clinical trials and related studies. We anticipate continuing to incur costs related to such clinical trials and studies through at least 2011.

Compensation and other shareowner related expenses, including stock-based compensation, increased \$0.4 million and \$1.0 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010, which includes expenses totaling \$0.6 million recorded in the nine months ended September 30, 2011 resulting from the correction of an immaterial error related to the accrual of payroll expenses. These increases are primarily due to increased compensation and other shareowner related expenses resulting from additions to our headcount to support our product development and enhancement efforts, offset by a decrease in stock-based compensation.

In addition to the items discussed above, expenses for the three and nine months ended September 30, 2011 increased by \$0.2 million and \$0.7 million, respectively, compared to the same periods in 2010 related to expenses incurred to acquire technology as well as an asset acquisition-related milestone payment in 2011. These increased expenses were offset by a decrease of \$0.3 million and \$1.0 million for the three and nine months ended September 30, 2011 for expenses incurred in 2010 in connection with a supply agreement related to the bone graft product being developed by Progentix with no comparable expense during the same periods in 2011, and a decrease of \$0.4 million and \$1.3 million for the three and nine months ended September 30, 2011, respectively, of expenses incurred by Progentix.

For the foreseeable future, as a percentage of revenue, we expect total research and development costs to remain around 8% in support of our ongoing development and planned clinical trial and study related activities.

**Amortization of Intangible Assets**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended:	\$1,504	\$1,342	\$162	12%
% of total revenue	1%	1%		
Nine months ended:	\$4,241	\$4,047	\$194	5%
% of total revenue	1%	1%		

Amortization of intangible assets relates to amortization of finite-lived intangible assets acquired. Although amortization expense for the three and nine months ended September 30, 2011 compared to the same periods in 2010 remained relatively constant, we expect expenses recorded in connection with the amortization of intangible assets to continue to increase in absolute dollars for the foreseeable future as amortization of acquired in-process research and development commences once acquired research and development projects reach technological feasibility.

**Table of Contents****Litigation Award**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended	\$101,200	\$	\$101,200	%
% of revenue	76%	%		
Nine months ended	\$101,200	\$	\$101,200	%
% of revenue	26%	%		

Litigation award expenses represent the monetary damages awarded to Medtronic during September 2011 which includes lost profits and back royalties.

**Interest and Other Expense, Net**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended:				
Interest income	\$ 257	\$ 200		
Interest expense	(7,276)	(1,668)		
Other income (expense), net	1,726	(6)		
Total interest and other expense, net	\$(5,293)	\$(1,474)	\$(3,819)	259%
% of revenue	4%	1%		
Nine months ended:				
Interest income	\$ 591	\$567		
Interest expense	(10,962)	(5,005)		
Other income, net	2,303	81		
Total interest and other expense, net	\$(8,068)	\$(4,357)	\$(3,711)	85%
% of revenue	2%	1%		

Interest and other expense, net, consists principally of interest expense incurred on our outstanding \$428.0 million Senior Convertible Notes, offset by income earned on marketable securities and other income (expense) items. Interest expense increased \$5.6 million and \$6.0 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010, primarily as a result of the additional cash and non-cash interest expense associated with the 2017 Notes offering which closed on June 28, 2011, slightly offset by reduced interest incurred resulting from the repurchase of approximately \$118.7 million of the 2013 Notes during August 2011.

Other income (expense) increased \$1.7 million and \$2.2 million for the three and nine months ended September 30, 2011, respectively, compared to the same periods in 2010, primarily as a result of the \$2.4 million net non-cash gain recorded in the three and nine months ended September 30, 2011 related to the changes in the fair values of the derivative asset and liability recorded in connection with the 2017 Notes offering, offset by the net loss of approximately \$0.7 million related to the write off of unamortized debt issuance costs associated with the repurchase of a portion of the 2013 Notes.

Interest and other expense, net, is expected to increase in the foreseeable future as a result of the additional cash and non-cash interest expense associated with the 2017 Notes offering.

**Income Tax (Benefit) Expense**

September 30,

Edgar Filing: NUVASIVE INC - Form 10-Q

<b>(dollars in thousands)</b>	<b>2011</b>	<b>2010</b>	<b>\$ Change</b>	<b>% Change</b>
Three months ended:	\$(29,031)	\$ (40)	\$(28,991)	72478%
Effective income tax (benefit) rate	(30)%	(1)%		
Nine months ended:	\$(22,715)	\$1,399	\$(24,114)	1724%
Effective income tax (benefit) rate	(27)%	9%		

We recorded an income tax benefit of \$29.0 million and \$40,000 for the three months ended September 30, 2011 and 2010, respectively, and recorded an income tax benefit of \$22.7 million and income tax expense of \$1.4 million for the nine months ended September 30, 2011 and 2010, respectively. The effective income tax benefit rate for the nine months ended September 30, 2011 was 27%, which is based on an estimate of our annual effective income tax rate. We update our annual effective income tax rate each quarter and if the estimated effective income tax rate changes, a cumulative adjustment is made.

**Table of Contents**

As a result of the litigation award accrual totaling \$101.2 million recorded in the three and nine months ended September 30, 2011, we evaluated the need for a valuation allowance on our deferred tax assets by reviewing all available positive and negative evidence. Based on our review, we concluded that it was more likely than not that we would be able to realize the benefit of our U. S. federal deferred tax assets and our deferred tax assets for all states except California in the future. This conclusion was primarily based on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the federal deferred tax assets well within the statutory carryover periods. Accordingly, we did not establish a valuation allowance on our federal or non-California state deferred tax assets as of September 30, 2011.

Based on this same evidence and consideration of the state of California's past and current suspension of the use of net operating loss carryforwards, the state of California's statutory carryover periods and our apportionment election beginning in 2011, we concluded that it is more likely than not that we will not be able to utilize our California deferred tax assets. Therefore, we established a full valuation allowance on our California deferred tax assets as of September 30, 2011. Accordingly, the income tax benefit reported for the three and nine months ended September 30, 2011, includes income tax expense totaling \$4.8 million in connection with the establishment of this valuation allowance.

In addition, certain future tax deductions will no longer be realized as a result of the repurchase of \$118.7 million of our 2013 Notes. Accordingly, the income tax benefit for the three and nine months ended September 30, 2011 includes a charge totaling \$1.5 million, representing the write off of deferred tax assets associated with these future deductions.

**Stock-Based Compensation**

(dollars in thousands)	September 30,		\$ Change	% Change
	2011	2010		
Three months ended:				
Sales, marketing and administrative expense	\$ 7,497	\$ 6,494		
Research and development expense	621	827		
Total stock-based compensation expense	\$ 8,118	\$ 7,321	\$ 797	11%
% of revenue	6%	6%		
Nine months ended:				
Sales, marketing and administrative expense	\$ 21,956	\$ 18,846		
Research and development expense	1,833	2,458		
Total stock-based compensation expense	\$ 23,789	\$ 21,304	\$ 2,485	12%
% of revenue	6%	6%		

Stock-based compensation related to stock awards is recognized and amortized on an accelerated basis in accordance with authoritative guidance. The increase in stock-based compensation of approximately \$0.8 million and \$2.5 million for the three and nine months ended September 30, 2011 is primarily attributed to an increase in the number of awards granted to shareowners associated with the continued increase in headcount year over year for the periods presented, and the fiscal 2011 annual grants that occurred during the three months ended March 31, 2011.

**Liquidity, Cash Flows and Capital Resources**

Our principal sources of liquidity are our existing cash, cash equivalents and marketable securities, cash generated from operations and proceeds from our convertible debt financings issued in March 2008 and June 2011.

In March 2008, we issued \$230.0 million principal amount of 2.25% Senior Convertible Notes due 2013 (the 2013 Notes). The net proceeds from the offering, after deducting the initial purchasers' discounts and costs directly related to the offering, were approximately \$208.4 million. We pay 2.25% interest per annum on the principal amount of the 2013 Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. In August 2011, we repurchased approximately \$118.7 million of the 2013 Notes. At September 30, 2011, approximately \$111.3 million of the 2013 Notes remain outstanding. Any 2013 Notes not converted prior to March 15, 2013, the maturity date, will be paid in cash.

## Edgar Filing: NUVASIVE INC - Form 10-Q

In June 2011, we issued \$402.5 million principal amount of the 2017 Notes, which includes the issuance of \$52.5 million principal amount upon the exercise of the initial purchasers' option to purchase additional notes. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately \$359.0 million. We pay 2.75% interest per annum on the principal amount of the 2017 Notes. The 2017 Notes mature on July 1, 2017 and may be settled in cash, stock, or a combination thereof, solely at our election. Interest on the 2017 Notes began accruing in June 2010 and is payable semi-annually each January 1st and July 1st, beginning January 1, 2012.

**Table of Contents**

As more fully discussed in Note 14 to the unaudited condensed consolidated financial statements included in this Report, we were required to escrow funds to secure the recent \$60.0 million judgment against us in connection with the NeuroVision trademark infringement litigation. On June 16, 2011, we entered into an escrow arrangement and transferred \$62.5 million of cash and investments, representing the \$60.0 million judgment amount, plus interest, attorneys' fees and costs, into a restricted escrow account. These funds are included in restricted cash and investments in our September 30, 2011 condensed consolidated balance sheet.

Additionally, in connection with the Medtronic litigation, a jury from the U.S. District Court, Southern District of California delivered an unfavorable verdict to us and awarded monetary damages of approximately \$101.2 million to Medtronic. While we intend to timely appeal the unfavorable verdict, we may be required to secure the amount of the judgment during the appeals process.

Cash, cash equivalents and marketable securities was \$418.9 million and \$229.7 million at September 30, 2011 and December 31, 2010, respectively. We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to meet our anticipated cash needs for at least the next 12 months. Our future capital requirements will depend on many factors including our rate of revenue growth, the timing and extent of spending to support development efforts, the expansion of sales, marketing and administrative activities, the timing of introductions of new products and enhancements to existing products, the continuing market acceptance of our products and the expenditures associated with possible future acquisitions or other business combination transactions.

We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results and working capital requirements. We have historically invested our cash primarily in U.S. treasuries and government agencies, corporate debt, and money market funds. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets or even our own funds.

**Cash Flows**

The following table summarizes, for the periods indicated, selected items in our condensed consolidated statements of cash flows (*in thousands*):

	September 30,		
	2011	2010	\$ Change
<b>Nine months ended:</b>			
Cash provided by operating activities	\$ 53,416	\$ 43,922	\$ 9,494
Cash used in investing activities	(170,074)	(45,013)	(125,061)
Cash provided by financing activities	245,183	6,164	239,019
Effect of exchange rate changes on cash	(179)	104	(283)
Increase in cash and cash equivalents	\$ 128,346	\$ 5,177	\$ 123,169

**Cash flows from operating activities**

Cash provided by operating activities was \$53.4 million for the nine months ended September 30, 2011, as compared to \$43.9 million for the same period in 2010. The \$9.5 million increase in cash provided by operating activities for the nine months ended September, 30 2011 as compared to the same period in 2010 is primarily due to improved collections from accounts receivable, an increase in accrued compensation and related expenses, and a decrease in amounts paid for other prepaid assets, offset by the use of \$9.9 million more cash to build inventory.

**Cash flows from investing activities**

Cash used in investing activities was \$170.1 million for the nine months ended September 30, 2011, as compared to cash used in investing activities of \$45.0 million for the same period in 2010. The \$125.1 million increase in cash used in investing activities for the nine months ended September 30, 2011 as compared to the same period in 2010 is due to an increase in our net purchases of marketable securities of \$112.3 million, payments made in connection with a supply agreement, and increased investments in restricted cash and purchases of surgical instrument sets which are deployed to support our increasing revenue volume.

**Cash flows from financing activities**

## Edgar Filing: NUVASIVE INC - Form 10-Q

Cash provided by financing activities was \$245.2 million for the nine months ended September 30, 2011, as compared to \$6.2 million for the same period in 2010. The \$239.0 million increase in cash provided by financing activities for the nine months ended

---

## **Table of Contents**

September 30, 2011 as compared to the same period in 2010 is primarily due to net proceeds totaling approximately \$359.0 million from the issuance of \$402.5 million Senior Convertible Notes on June 28, 2011, offset by the repurchase of \$118.7 million our outstanding 2013 Notes.

### **Contractual Obligations and Commitments**

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our Senior Convertible Notes, operating leases and other contractual obligations. Our future contractual obligations and commitments are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and there have been no material changes during the nine months ended September 30, 2011 except as follows:

In June 2011, we issued \$402.5 million principal amount of the 2017 Notes. We pay 2.75% interest per annum on the principal amount of the 2017 Notes. The 2017 Notes mature on July 1, 2017 and may be settled in cash, stock, or a combination thereof, solely at our election. Interest on the 2017 Notes began accruing in June 2010 and is payable semi-annually each January 1st and July 1st, beginning January 1, 2012.

In August 2011, we repurchased approximately \$118.7 million of the 2013 Notes. At September 30, 2011, approximately \$111.3 million of the 2013 Notes original aggregate principal amount of \$230.0 million remains outstanding.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, valuation of goodwill, intangibles and other long-term assets, income taxes, stock-based compensation, and legal proceedings. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and there have been no material changes during the nine months ended September 30, 2011 except as follows:

#### ***Change in Accounting Estimate***

Effective January 1, 2011, we changed the estimated useful lives of instrument sets that we loan to or place with hospitals from three to four years.

#### ***Financial Instruments and Fair Value***

Inputs to valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs have created the following fair-value hierarchy:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

This hierarchy requires us to minimize the use of unobservable inputs and to use observable market data, if available, when determining fair value. We recognize transfers between levels of this hierarchy based on the fair values of the respective financial instruments at the end of the reporting period in which the transfer occurred. Changes in fair value are recognized in earnings each period for financial instruments that are carried at fair value.

The types of instruments that trade in markets that are not considered to be active, but are valued based on quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency are generally classified within Level 2 of the fair value hierarchy.





---

## **Table of Contents**

As more fully discussed in Notes 2 and 5 to the unaudited condensed consolidated financial statements included in this Report, in June 2011, in connection with the offering of the 2017 Notes, we entered into convertible note hedge transactions, and recorded an embedded conversion derivative liability and derivative asset. The fair values of these derivatives were determined using an option pricing model based on unobservable inputs and were classified within Level 3. The significant inputs to the model included our stock price, risk free interest rate, bond yield, credit rating, and expected volatility of our stock price. On September 28, 2011, upon obtaining stockholder approval to increase the number of authorized shares of our common stock, in accordance with authoritative literature, the derivative asset and liability were marked to fair value and reclassified to stockholders' equity.

Certain contingent consideration liabilities are classified within Level 3 of the fair value hierarchy because they use unobservable inputs. For those liabilities, fair value is determined using a probability-weighted discounted cash flow model, the significant inputs which are not observable in the market.

### ***Income Taxes***

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

As a result of the litigation award accrual totaling \$101.2 million recorded in the three and nine months ended September 30, 2011, we evaluated the need for a valuation allowance on our deferred tax assets by reviewing all available positive and negative evidence. Based on our review, we concluded that it was more likely than not that we would be able to realize the benefit of our U.S. federal deferred tax assets and our deferred tax assets for all states except California in the future. This conclusion was primarily based on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the federal deferred tax assets well within the statutory carryover periods. Accordingly, we did not establish a valuation allowance on our federal or non-California state deferred tax assets as of September 30, 2011.

Based on this same evidence and consideration of the state of California's past and current suspension of the use of net operating loss carryforwards, the state of California's statutory carryover periods and our apportionment election beginning in 2011, we concluded that it is more likely than not that we will not be able to utilize our California deferred tax assets. Therefore, we established a full valuation allowance on our California deferred tax assets as of September 30, 2011. Accordingly, the income tax benefit reported for the three and nine months ended September 30, 2011, includes income tax expense totaling \$4.8 million in connection with the establishment of this valuation allowance.

In addition, certain future tax deductions will no longer be realized as a result of the repurchase of \$118.7 million of our 2013 Notes. Accordingly, the income tax benefit for the three and nine months ended September 30, 2011 includes a charge totaling \$1.5 million, representing the write off of deferred tax assets associated with these future deductions.

### ***New accounting requirements***

Effective January 1, 2011, we adopted the FASB's updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately information related to purchases, sales, issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs, or Level 3, to be included in the rollforward of activity. The guidance is effective for interim or annual financial reporting periods beginning after December 15, 2010. We updated our disclosures to comply with the updated guidance; however, adoption of the updated guidance did not have an impact on our consolidated results of operations or financial position.

### ***Off-Balance Sheet Arrangements***

We have not engaged in any off-balance sheet activities.

---

## **Table of Contents**

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in its Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

### **Item 4. Controls and Procedures**

*Disclosure Controls and Procedures.* We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information 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. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2011. Based on such evaluation, our management has concluded that as of September 30, 2011, the Company's disclosure controls and procedures are effective.

*Changes in Internal Control over Financial Reporting.* There has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

There have been no material changes to the Legal Proceedings discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, except as follows:

As reported by us previously, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic), on August 18, 2008, filed a patent infringement lawsuit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of NuVasive's products or methods, including the XLIF<sup>®</sup> procedure, infringe, or contribute to the infringement of, twelve U.S. patents. Three of the patents were later withdrawn by Medtronic leaving the following nine patents in the lawsuit: Nos. 5,860,973; 5,772,661; 6,936,051; 6,936,050; 6,916,320; 6,945,933; 6,969,390; 6,428,542; 6,592,586 assigned or licensed to Medtronic (Medtronic Patents). Medtronic is seeking monetary damages and a court injunction against future infringement by NuVasive. NuVasive answered the complaint denying the allegations, and filed counterclaims seeking dismissal of Medtronic's complaint and a declaration that NuVasive has not infringed and currently does not infringe any valid claim of the Medtronic Patents.

Additionally, NuVasive made counterclaims against Medtronic seeking the following relief: (i) Medtronic being permanently enjoined from charging that NuVasive has infringed or is infringing the Medtronic Patents; (ii) a declaration that the Medtronic Patents are invalid; (iii) a declaration that the 5,860,973 and 5,772,661 patents are unenforceable due to inequitable conduct; and (iv) costs and reasonable attorneys' fees.

NuVasive filed an amended counterclaim on September 4, 2009, alleging that NuVasive's U.S. Patent Nos. 7,207,949; 7,582,058; and 7,470,236 are infringed by Medtronic's NIM-Eclipse System and accessories and Quadrant products, and DLIF (Direct Lateral Interbody Fusion) surgical technique. Medtronic, on June 23, 2009, filed a request for inter partes reexamination with the Patent Office on NuVasive's U.S. Patent No. 7,207,949. On October 14, 2009, Medtronic filed a request for inter partes reexamination on NuVasive's U.S. Patent No. 7,582,058. The Patent Office granted both requests and issued rejections of the claims. Both reexaminations are pending.

Given the number of patents asserted in the litigation, the parties agreed to proceed on a limited number of patents. The court determined to proceed only with patents that are not the subject of active reexamination proceedings. As a result, the first phase of the case included three Medtronic patents and one NuVasive patent. Trial on the first phase of the case began in August 2011 and on September 20, 2011, a jury from the U.S. District Court, Southern District of California delivered an unfavorable verdict against



---

## **Table of Contents**

NuVasive with respect to three Medtronic patents and a favorable verdict in favor of NuVasive with respect to one NuVasive patent. Judgment was entered by the Court on September 29, 2011. The jury awarded monetary damages of approximately \$101.2 million to Medtronic which includes lost profits and back royalties. As Medtronic has filed for a permanent injunction and an increase in damages, additional fees and costs, potential future royalties and injunctive relief may be awarded as part of a final judgment which is expected in the coming months. While the Company intends to timely appeal the unfavorable verdict, in accordance with the authoritative guidance on the evaluation of loss contingencies, during the three and nine months ended September 30, 2011, the Company recorded an accrual for the \$101.2 million verdict. In addition, the Company is currently planning to accrue ongoing royalties on future sales at the royalty rates stated in the jury verdict. The \$101.2 million is recorded as a separate line item within operating expenses as the split between lost profit and royalty amounts are not known. The Company may be required to secure the amount of the judgment during the appeals process.

With respect to the favorable verdict delivered regarding the NuVasive patent, the jury awarded the Company monetary damages of approximately \$0.7 million for reasonable royalty damages. In accordance with the authoritative guidance on the evaluation of gain contingencies, this amount has not been recorded at September 30, 2011.

### **Trademark Infringement Litigation**

In September 2009, Neurovision Medical Products, Inc. (NMP) filed suit against NuVasive in the U.S. District Court for the Central District of California (Case No. 2:09-cv-06988-R-JEM) alleging trademark infringement and unfair competition. NMP sought cancellation of NuVasive's NeuroVision trademark registrations, injunctive relief and damages based on NMP's common law use of the Neurovision mark. On November 23, 2009, the Company denied the allegations in NMP's complaint. After trial of the matter, on October 25, 2010 an unfavorable jury verdict was delivered against the Company relating to its use of the NeuroVision trade name. The verdict awarded damages to NMP of \$60.0 million. On January 3, 2011, the Court ordered a judgment be entered in the case in the amount of \$60.0 million, and granted a permanent injunction prohibiting the Company's use of the NeuroVision name for marketing purposes. The Company sought emergency relief, and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction, and has consolidated this issue with our appeal of the verdict. During pendency of the appeal, the Company has been required to escrow funds to secure the amount of the judgment, plus interest, attorneys' fees and costs. On June 16, 2011, the Company entered into an escrow arrangement and transferred \$62.5 million of cash and investments into a restricted escrow account. Any payment of damages will be delayed while the appeals process runs its course, which could take up to two years. The Company continues to believe that the verdict is not supported by the facts or by applicable law. The Company, based on its own assessment as well as that of outside counsel, believes that the trial court committed a number of prejudicial legal errors and that these errors were significant, making the possibility of reversal of the judgment on appeal and/or a new trial probable. Accordingly, at September 30, 2011, in accordance with the authoritative guidance on the evaluation of contingencies, the Company has not recorded an accrual related to this litigation. The Company may be required to record an expense related to this damage award in the future.

### **Item 1A. Risk Factors**

An investment in our common stock involves significant risks. Before making an investment decision, and in consultation with your own financial and legal advisors, you should carefully read and consider the risk factors described below as well as the other information included or incorporated by reference in this report, including the information contained in our Annual Report on Form 10-K for the year ended December 31, 2010 under the headings Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations. Due to some changes in our business environment, namely our litigation with Medtronic, our issuance of the 2017 Notes and our acquisition of Impulse Monitoring, Inc., we have included all of our risk factors and marked with an asterisk (\*) those risk factors that reflect material changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2010.

If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

#### **Risks Related to Our Business and Industry**

***Changes to third party reimbursement policies and practices can negatively impact our ability to sell our products at prices necessary to expand our operations and increase profitability.***

We believe that future reimbursement may be subject to changes in policies and practices, such as more restrictive criteria to qualify for surgery or reduction in payment amount to hospitals and surgeons for approved surgery, both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our existing products or our products

currently under development and limit our ability to sell our products on a profitable basis.

---

## **Table of Contents**

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines.

There can be no assurance that third party payers' reimbursement policies and practices will not adversely affect our ability to sell our products profitably.

***Non-coverage decisions concerning our technologies by third party payers may negatively impact our ability to sell our complete product portfolio, expand our operations and increase profitability.***

Sales of our products will depend on the availability of adequate reimbursement from third party payers. Healthcare providers, such as hospitals that purchase medical devices for treatment of their patients, generally rely on third party payers to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Likewise, spine surgeons rely primarily on third party reimbursement for the surgical fees they earn. Spine surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of their involvement in the surgical procedures.

Certain third party payers have stated non-coverage decisions concerning our technologies and implementation of such policies could significantly alter our ability to sell our products. For example, several smaller regional third party payers, such as Blue Cross Blue Shield of Florida and Medica of Minnesota, continue to have reimbursement policies that label XLIF® surgeries as experimental. Additional payers may also state that our technologies are not covered. The inability to successfully market our technologies due to lack of reimbursement coverage may adversely impact our ability to acquire new physician clients, increase market penetration with existing clients, or retain existing clients across NuVasive product lines and, therefore, may adversely impact our ability to sell our complete product portfolio, expand our operations and increase profitability.

***We are currently involved in a patent litigation action involving Medtronic, and, if we do not prevail on our appeal of the Medtronic verdict, we could be liable for substantial damages and might be prevented from making, using, selling, offering to sell, importing or exporting certain of our products.***

On August 18, 2008, Medtronic filed suit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by Medtronic. Trial in the first phase of the case began on August 20, 2011 and on September 20, 2011, a jury delivered an unfavorable verdict against us with respect to three Medtronic patents and a favorable verdict was delivered in favor of us with respect to a NuVasive patent. Judgment was entered by the court on September 29, 2011. The jury awarded monetary damages of approximately \$660,000 to NuVasive which includes back royalty payments. Additionally, the jury awarded monetary damages of \$101.2 million to Medtronic which includes lost profits and back royalties. Additional fees and costs, potential future royalties and injunctive relief (if requested) may be awarded as part of a final judgment which is expected in the coming months. While we intend to timely appeal the unfavorable verdict, we may be required to secure the amount of the judgment during the appeals process. See also the section entitled "Legal Proceedings" in our Annual Report on Form 10-K for the year ended December 31, 2010 and incorporated by reference herein for more information on this action.

***Pricing pressure from our competitors may impact our ability to sell our products at prices necessary to expand our operations, invest in innovative technologies and increase profitability. \****

The market for spine surgery products is large and growing. This has attracted numerous new companies and technologies, and encouraged more established companies to intensify competitive pressure, in addition to large, well-established manufacturers that also create pricing pressure. New entrants to our markets include numerous niche companies with singular product focus, as well as companies owned partially by spine surgeons, who have significant market knowledge and access to the surgeons who use our products. As a result of this increased competition, we believe there will be continued pricing pressure. If competitive forces drive down the price we are able to charge for some of our products, and we are not able to counter that pressure as we have historically with the rapid introduction of new offerings, our profit margins will shrink, which will hamper our ability to generate profits and cash flow, and, as a result, to invest in and grow our business, including the investment into new and innovative technologies.

***We are in a highly competitive market segment and face competition from large, well-established medical device manufacturers as well as new market entrants. \****

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. With respect to our nerve monitoring systems, we





---

**Table of Contents**

compete with Medtronic and VIASYS Healthcare, a division of CareFusion, both of which have significantly greater resources than we do, as well as numerous regional nerve monitoring companies. With respect to MaXcess®, our minimally disruptive surgical system, our largest competitors are Medtronic, DePuy Spine, Inc., a Johnson & Johnson company, and Synthes, Inc, which has agreed to be acquired by Johnson & Johnson. We compete with many of the same companies with respect to our other products. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. At any time, these companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products.

Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

significantly greater name recognition;

established relations with a greater number of spine surgeons, hospitals, other healthcare providers and third party payers;

larger and more well established distribution networks with significant international presence;

products supported by long-term clinical data;

greater experience in obtaining and maintaining FDA and other regulatory approvals or clearances for products and product enhancements;

more expansive portfolios of intellectual property rights; and

greater financial and other resources for product research and development, sales and marketing and litigation.

In addition, the spine industry is becoming increasingly crowded with new market entrants, including companies owned at least partially by spine surgeons. Many of these new competitors focus on a specific product or market segment, making it more difficult for us to expand our overall market position. If these companies become successful, we expect that competition will become even more intense, leading to greater pricing pressure and making it more difficult for us to expand.

***Our future success depends on our strategy of obsoleting our own products and our ability to timely acquire, develop and introduce new products or product enhancements that will be accepted by the market.***

We have the objective of staying ahead of the spine market by obsoleting our own products with new products and enhancements. It is important to our business that we continue to build upon our product offering to surgeons and hospitals, and enhance the products we currently offer. As such, our success will depend in part on our ability to acquire, develop and introduce new products and enhancements to our existing products to keep pace with the rapidly changing spine market. We cannot assure you that we will be able to successfully acquire, develop, obtain regulatory approval for or market new products or that any of our future products or enhancements will be accepted by the surgeons who use our products or the payers who financially support many of the procedures performed with our products. Additionally, in our quest to obsolete our products, we must effectively manage our inventory, the demand for new and current product and the regulatory process for new products in order to avoid unintended adverse financial and accounting consequences.

If we do not effectively manage our strategy of obsoleting our products by acquiring or developing new products or product enhancements that we can introduce in time to meet market demand or if there is insufficient demand for these products or enhancements, or if we do not manage the product transitions well which would result in margin reducing writeoffs for obsolete inventory, our results of operations may suffer.

*If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval, we will be unable to commercialize these products. \**

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, PCM and lateral TDR (XL TDR), will require a PMA submission to the FDA based on their product classification. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

As a result, to receive regulatory approval for NeoDisc, PCM, XL TDR or other devices requiring PMA approval, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory approval and, ultimately, the commercialization of that device.

---

**Table of Contents**

Our NeoDisc, PCM, and XL TDR devices are currently the subject of an Investigational Device Exemption (IDE) clinical study. There is no assurance that these devices will be approved for sale in the United States by the FDA. The clinical study may prove that the device does not provide the intended benefit or that there are unintended negative side effects of the device that make it unsafe or not effective. In addition, the NeoDisc device includes embroidery technology, which has not been thoroughly studied for use as permanent implants in the spine. Any failure or delay in obtaining regulatory approval for these devices will hamper our ability to commercialize the device in the United States.

Jurisdictions outside of the United States have regulatory schemes that differ from that of the United States in various respects. In each jurisdiction where we have introduced or plan to introduce our products, we have or intend to submit all required information to the relevant agencies, perform all required clinical trials, and otherwise to comply with the regulatory schemes in non-U.S. jurisdictions, but there can be no assurances that we will be successful in our efforts to comply with these diverse, unfamiliar and sometimes complex laws and regulations, and failure to do so could harm our business.

***If our acquisitions are unsuccessful, our business may be harmed.***

As part of our business strategy, we have acquired companies, technologies, and product lines to maintain our objectives of developing or acquiring innovative technologies. Acquisitions involve numerous risks, including the following:

the possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges and/or a dilution of future earnings per share;

difficulties in integration of the operations, technologies, personnel, and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;

the applicability of additional laws, regulations and policies that have particular application to the IOM service business, including those relating to patient privacy, insurance fraud and abuse, false claims, prohibitions against self-referrals, anti-kickbacks and prohibitions against the corporate practice of medicine and fee-splitting;

the assumption of certain known and unknown liabilities of the acquired companies; and

difficulties in retaining key relationships with shareowners (employees), customers, partners and suppliers of the acquired company. Any of these factors could have a negative impact on our business, results of operations or financing position. In October 2011, we acquired IMI, a provider of IOM services. In 2009, we invested in Progentix, a private company working to develop a synthetic bone graft material. This includes an ongoing option for us to acquire all of Progentix as well as a put option by Progentix if certain commercial revenue milestones are achieved by us.

Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology (as is the case with the Progentix products) or providing professional IOM services (as is the case with IMI). For example, we may not be able to successfully integrate an acquired company's operations, business processes, technologies, products and services, information systems and personnel into our business. Acquisitions may also further strain our existing financial and managerial controls, and divert management's attention away from our other business concerns.

***Our reliance on single source suppliers could limit our ability to meet demand for our products in a timely manner or within our budget.***

We rely on third party suppliers and manufacturers to supply and manufacture our products. To be successful, our contract manufacturers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

## Edgar Filing: NUVASIVE INC - Form 10-Q

We currently use one or two manufacturers for each of our devices or components. Our dependence on one or two manufacturers involves several risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our manufacturers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate revenue.

---

## **Table of Contents**

Invibio, Inc. (Invibio) is our exclusive supplier of polyetheretherketone (PEEK), which comprises our PEEK partial vertebral body product called CoRoent. We have a supply agreement with Invibio, pursuant to which we have agreed to purchase our entire supply of PEEK for our current product lines from Invibio. We also have an exclusive supply arrangement with Sparton Medical Corporation (Sparton) pursuant to which Sparton is our exclusive supplier of our proprietary neuromonitoring systems. In the event we experience delays, shortages, or stoppages of supply with either supplier, we would be forced to locate a suitable alternative supplier which could take significant time and result in significant expense. Any inability to meet our customers' demands for these products could lead to decreased sales and harm our reputation and result in the loss of customers to our competitors, which could cause the market price of our common stock to decline.

Maxigen Biotech, Inc. (MBI) is our sole supplier of our FormaGraft® product. We may require that MBI significantly expand its manufacturing capacity to meet our potential forecasted needs, and no assurance can be given that MBI will be able to meet our requirements. If we experience difficulties in dealing with MBI, we may not be able to secure an adequate source of supply of FormaGraft, which could adversely affect our operational results.

We acquired PCM, a motion preserving total disc replacement device, through our acquisition of Cervitech®, Inc. (Cervitech). Our supply of the product comes from two sources: Waldemar Link GmbH & Co. KG, a company that was affiliated with Cervitech prior to the acquisition, and Sandvik Medical Solutions Limited. Upon approval of the PCM product by the FDA, we plan on using Sandvik Medical Solutions Limited as our sole supplier of PCM. At such time, we will determine whether to establish alternate suppliers and there is no assurance that we will be able to establish a new supplier which could adversely affect our operating results.

Further, Tissue Banks International, Inc., AlloSource, Inc. and Community Tissue Services collectively supply us with all of our allograft implants. The processing of human tissue into allograft implants is very labor intensive and it is therefore difficult to maintain a steady supply stream. AlloSource is also our exclusive supplier of OsteoCel Plus, which is processed from allograft. Allograft, which is donated human tissue, is a supply-constrained material and there is ongoing risk that there will be insufficient supply to produce the necessary quantity of OsteoCel Plus and our other allograft products. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our allograft products are at times in particularly short supply. Allograft also carries with it the possibility of disease transmission, which could result in negative patient outcomes and negative publicity for us. We cannot be certain that our supply of allograft from Tissue Banks International, Inc. and AlloSource, Inc. will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft from these sources in amounts sufficient to meet our needs, we may not be able to locate and engage replacement sources of allograft on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of allograft could reduce our revenues.

***We are dependent on the services of Alexis V. Lukianov and Keith C. Valentine, and the loss of either of them could harm our business.***

Our continued success depends in part upon the continued service of Alexis V. Lukianov, our Chairman and Chief Executive Officer, and Keith C. Valentine, our President and Chief Operating Officer, who are critical to the overall management of NuVasive as well as to the development of our technology, our culture and our strategic direction. We have entered into employment arrangements with Messrs. Lukianov and Valentine, but neither of these agreements guarantees the service of the individual for a specified period of time. The loss of either Messr. Lukianov or Valentine could have a material adverse effect on our business, results of operations and financial condition. We have not obtained and do not expect to obtain any key-person life insurance policies.

***If we fail to properly manage our anticipated international growth, our business could suffer.***

We have invested, and expect to increase our investment for the foreseeable future, in our expansion into international markets. To execute our anticipated growth in international markets we must:

manage the complexities associated with a larger, faster growing and more geographically diverse organization;

expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;

expand our sales presence in international markets generally to avoid revenue concentration in a small number of markets that would subject us to the risk of business disruption as a result of economic or political problems in concentrated locations;

Edgar Filing: NUVASIVE INC - Form 10-Q

expand our sales and marketing resources for international expansion and to launch products targeted for international markets; and

---

**Table of Contents**

upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create the scalability and properly handle the transaction volumes that our growing geographically diverse organization demands.

We expect that our operating expenses will continue to increase as we continue to expand into international markets. We have only limited experience in expanding into international markets as well as marketing and operating our products and services in such markets. Certain international markets, such as Japan, require a lot of time and resources to receive product approvals and clearances to sell and promote products. After we receive the appropriate approvals and clearances, international markets may be slower than domestic markets in adopting our products and are expected to yield lower profit margins when compared to our domestic operations.

Additionally, our international endeavors may involve significant risks and uncertainties, including distraction of management from domestic operations, insufficient revenue to offset expenses associated with our international strategy, and unidentified issues not discovered in our due diligence. Because expansion into international markets is inherently risky, no assurance can be given that such strategies and initiatives will be successful and will not materially adversely affect our financial condition and operating results. Even if our international expansion is successful, our expenses may increase at a greater pace than our revenues and our operating results could be harmed.

Further, our anticipated growth internationally will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

***If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market our products could suffer.***

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved PMA.

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 PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. Additionally, any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary.

Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities. Additionally, surgeons use several of our products for unapproved uses. While surgeons are permitted by the FDA to use our products for unapproved uses, there is a heightened risk of an enforcement action against us by a governmental enforcement authority when surgeons engage in that practice.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products in foreign countries, we may be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our foreign independent sales agencies to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

---

**Table of Contents**

*The safety of our products is not yet supported by long-term clinical data and our products may therefore prove to be less safe and effective than initially thought.*

We obtained clearance to offer almost all of our products that require FDA clearance or approval through the FDA's 510(k) clearance process. The FDA's 510(k) clearance process is less rigorous than the PMA process and requires less supporting clinical data. As a result, we currently lack the breadth of published long-term clinical data supporting the safety of our products and the benefits they offer that might have been generated in connection with the PMA process. For these reasons, spine surgeons may be slow to adopt our products; we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, affect our ability to have sustainable reimbursement for our products from third party payers, significantly reduce our ability to achieve expected revenues and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to costly product liability litigation.

*If we or our suppliers fail to comply with the FDA's quality system regulations, the manufacture of our products could be delayed and we may be subject to an enforcement action by the FDA.*

We and our suppliers are required to comply with the FDA's quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We have undergone FDA inspections regarding our allograft implant business and FDA inspections regarding our medical device activities. In connection with these inspections as well as prior inspections, the FDA requested minor corrective actions, which we have implemented. There can be no assurance the FDA will not subject us to further enforcement action and the FDA may impose additional inspections at any time.

Additionally, we are the legal manufacturer of record for the products that are distributed and labeled by NuVasive, regardless of whether the products are manufactured by us or our suppliers. Thus, a failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement action against us by the FDA, which may include any of the following sanctions:

fining, injunctions, and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or premarket approval of new products;

withdrawing 510(k) clearance or premarket approvals that are already granted; and

criminal prosecution.

**Risks Related to Our Financial Results and Need for Financing**

*We may be unable to grow our revenue or earnings as anticipated, which may have a material adverse effect on our future operating results.*

\*



## Edgar Filing: NUVASIVE INC - Form 10-Q

We have experienced rapid growth since our inception, and have increased our revenues from \$38.4 million in 2004, the year of our initial public offering, to \$478.2 million in 2010. Our ability to achieve future growth will depend upon, among other things, the success of our growth strategies, which we cannot assure you will be successful. In addition, we may have more difficulty maintaining our prior rate of growth of revenues or recent earnings. Our future success will depend upon various factors, including the strength of our brand image, the market success of our current and future products, competitive conditions and our ability to manage increased revenues, if any, or implement our growth strategy. In addition, we anticipate significantly expanding our infrastructure and adding personnel in connection with our anticipated growth, which we expect will cause our selling, general and administrative expenses to increase in absolute dollars and which may cause our selling, general and administrative expenses to increase as a percentage of revenue. Because these expenses are generally fixed, particularly in the short-to-medium term, operating results may be adversely impacted if we do not achieve our anticipated growth.

***The current adverse global economic conditions may adversely affect our liquidity and the liquidity of our customers.***

At September 30, 2011, we had approximately \$220.9 million in cash and cash equivalents and approximately \$198.0 million in investments in marketable securities. On June 16, 2011, we entered into an escrow arrangement in connection with the NeuroVision

---

## **Table of Contents**

trademark infringement litigation and have transferred \$62.5 million of our cash and investments into a restricted escrow account. On September 20, 2011, a jury reached a verdict and awarded monetary damages of approximately \$101.2 million to Medtronic as part of a verdict against us in conjunction with an ongoing patent lawsuit. While we intend to appeal the verdict, we may be required to secure the amount of the judgment during the appeals process.

We have historically invested our cash primarily in U.S. treasuries and government agencies, corporate debt, money market funds, and commercial paper meeting certain criteria. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets or even our own funds.

The liquidity of our customers and suppliers may also be affected by adverse global economic conditions. If our suppliers experience credit or liquidity problems, important sources of raw materials or manufactured goods may be affected. If our customers' liquidity and creditworthiness is negatively impacted by the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

***Upon the achievement of certain milestones, equity adjustments and stock repurchases related to our acquisitions, we may be required to make payments which may affect our liquidity and our financial results. \****

In connection with our recent acquisitions, we may be obligated to make payments in the future upon the achievement of certain milestones. At September 30, 2011, we had \$33.0 million in outstanding potential milestone obligations under our agreement with the stockholders of Cervitech and could potentially be required to purchase the remaining sixty (60) percent of Progentix Orthobiology B.V. for an aggregate amount up to \$30.0 million. If we are required to make those payments, particularly at a time when we are experiencing financial difficulty, our liquidity, financial results and financial condition may be adversely affected.

In connection with the acquisition of Impulse Monitoring, Inc., we may be obligated to (i) make additional cash payments and/or issue additional common stock of ours in the event that the net proceeds of the sales during the thirty (30) trading days after the closing of the acquisition are less than the aggregate value of the shares issued by us to the selling stockholders, as valued at the closing price per share of our common stock on the last full trading day on the NASDAQ prior to the closing of the acquisition, or (ii) repurchase any unsold shares held by the selling stockholders if on December 31, 2011, we have been unable to have an effective registration statement on Form S-3 effective with the SEC for more than the number of trading days required for such selling stockholders to sell these shares or any additional shares of our common stock that we may issue as part of any adjustment payment. In the event that an adjustment payment is required and we decide to issue additional shares of our common stock, we may be required to provide a further adjustment payment should the net proceeds of all sales during this thirty (30) trading day period and an extended sale period remain less than the value of shares issued by us to the selling stockholders at the closing of the acquisition.

***The sale of our 2.75% Senior Convertible Notes due 2017 significantly increased our amount of long-term debt, and our financial condition and results of operations could be adversely affected if we do not efficiently manage our liabilities. \****

In June 2011, we issued \$402.5 million aggregate principal amount of our 2.75% Senior Convertible Notes due 2017 (the 2017 Notes). As a result of the sale of the 2017 Notes, we have a substantially greater amount of long-term debt than we have maintained in the past. Our maintenance of such increased level of debt could adversely affect our flexibility to take advantage of corporate opportunities and could adversely affect our financial condition and results of operations.

### **Risks Related to Our Intellectual Property and Litigation**

***We are currently involved in several additional litigation actions which could cause us to incur significant legal expenses and/or prevent us from making, using, selling, offering to sell, importing or exporting certain of our products. \****

In addition to our litigation with Medtronic, on April 20, 2010, we filed a lawsuit against Orthofix, Inc. and its related entities (Orthofix) and Musculoskeletal Transplant Foundation for infringement of a patent licensed as part of our purchase of Osteocel Plus®. In December 2010, the parties entered into a license agreement covering the subject product marketed by Orthofix, Trinity Evolution®, and the lawsuit was settled by the parties. Similarly, on October 5, 2010, we initiated a patent infringement lawsuit against Globus Medical, Inc. (Globus) to protect our investment in our XLIF procedure and MaXcess retractor system. The lawsuit against Globus is in its early stages, and the outcome of this litigation is difficult to predict.

## Edgar Filing: NUVASIVE INC - Form 10-Q

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from modeling, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. We may also be subject

---

**Table of Contents**

to negative publicity due to litigation. Pending or future patent litigation against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual property, unless we develop alternative non-infringing technology or that party grants us or any strategic partners or licensees rights to use its intellectual property, and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, or if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all, and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Furthermore, if we are found to infringe patent claims of a third party, we may, among other things, be required to pay damages, including up to treble damages and attorneys' fees and costs, which may be substantial.

An unfavorable outcome for us in patent or other intellectual property litigation could significantly harm our business if such outcome makes us unable to commercialize some of our current or potential products or cease some of our business operations. In addition, costs of defense and any damages resulting from litigation may materially adversely affect our business and financial results. Litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

***Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain. \****

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending U.S. and foreign patent applications may not issue as patents at all or not in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable to ours. Moreover, competitors may challenge our issued patents through the reexamination process (domestically) and/or opposition proceedings (internationally), such as was done by Medtronic on two of our U.S. patents related to aspects of our XLIF surgical technique. We asserted these patents against Medtronic as part of our ongoing patent litigation. Patent reexamination was granted by the U.S. Patent Office in each case. If the U.S. Patent Office cancels or narrows the claims in these patents, it could prevent or hinder us from being able to enforce them against competitors.

Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our officers, shareowners, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. To the extent that our employees, consultants, or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition, recently enacted changes to the U.S. patent laws, together with proposed changes to the rules of the U.S. Patent Office to comport with the newly enacted laws may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. Of significance in the newly enacted patent laws, the United States has shifted from a first to invent to a first inventor to file system. Consequently, the pool of prior art available to inhibit or limit our ability to obtain issued patents on the technology utilized in our products is expected to expand and the grace period for filing a patent application will be reduced in some ways. It will be possible for a situation to arise in which a competitor is able to obtain patent rights to technology which we invented first. Furthermore, the newly enacted patent laws provide for post grant review of issued patents and expanded reexamination proceedings that may provide our competitors with additional opportunities to challenge the validity of our issued patents.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

---

## **Table of Contents**

In addition, certain product categories, including pedicle screws, have been the subject of significant patent litigation in recent years and since we currently offer pedicle screws in both of our SpheRx and Armada product lines, any related litigation could harm our business.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages, including treble damages in some cases. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop technologies similar to ours. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we make an effort to ensure that our products do not infringe other parties' rights, our products and methods may be covered by patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any of our strategic partners or licensees may force us or such strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual property, unless that party grants us or our strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all, and any licenses may require substantial royalties or other payments by us. Even if our strategic partners, licensees or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

***We are currently involved in a trademark litigation action involving the NeuroVision brand name and, if we do not prevail on our appeal of the verdict, we could be liable for substantial damages.***

A judgment in our ongoing trademark dispute regarding the NeuroVision brand name was handed down by the U.S. District Court for the Central District of California. An unfavorable jury verdict was delivered against us in our use of the NeuroVision name. The verdict, which we are appealing, awarded damages to the plaintiff of \$60.0 million. We sought emergency relief and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction. During pendency of the appeal, we entered into an escrow to secure the amount of the judgment, interest and attorneys' fees. This could result in a material reduction in the liquidity required to run or grow our business. While this case relates solely to the use of the NeuroVision brand name and does not involve our proprietary neuromonitoring technology underlying the NeuroVision system or future products, it may require us to rebrand and re-market the NeuroVision brand name. This could result in a significant impact on our marketing costs and other related financial costs. There is a chance that the acceptance of a new brand name will be lengthy and may not be well received by our customers. The appeals process could be expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to this trademark litigation. The litigation required during the appeals process may significantly divert the attention of our technical and management personnel. We are unable to predict the outcome of our appeal. In the event that we are unsuccessful in our appeal, we could be required to pay significant damages which are not covered under any of our insurance plans. In the event this outcome occurred, our business, liquidity, financial condition and results of operations would be materially adversely affected.

***If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, we sell allograft products, derived from cadaver bones, which pose the potential risk of biological contamination. If any such contamination is found to exist, sales of allograft products could decline, our reputation would be harmed, and we may be subject to liability.

Currently, we maintain product liability insurance in the amount of \$10 million. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the



---

**Table of Contents**

future. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves which may harm our financial condition. If longer-term patient results and experience indicate that our products or any component cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Finally, even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management's attention from managing our business.

***We are subject to rigorous governmental regulations regarding the development, manufacture, and sale of our products and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations and financial condition.***

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities, including regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging, marketing and distribution of our products.

We are required to register with the FDA as a device manufacturer and tissue bank. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) and Good Tissue Practices (GTPs) requirements, which require manufacturers of medical devices and tissue banks to adhere to certain regulations, including testing, quality control and documentation procedures. Our compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products, and are subject to periodic inspections by notified bodies to obtain and maintain these certifications. If we or our suppliers fail to adhere to QSR, ISO or similar requirements, this could delay product production and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which in turn could have a material adverse effect on our financial condition, results of operations, or prospects.

Medical devices must receive FDA clearance or approval before they can be commercially marketed. In addition, the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized, and can prevent or limit further marketing of a product based upon the results of post-marketing programs. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Furthermore, most major markets for medical devices outside the United States require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time-consuming, and approvals may not be granted for future products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products or product improvements could result in delayed realization of product revenues or in substantial additional costs, which could have a material adverse effect on our business or results of operations or prospects. At any time after approval of a product, the FDA may conduct periodic inspections to determine compliance with both QSR requirements and/or current Medical Device Reporting regulations. Product approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. Although we believe our marketing, promotional materials and training programs for physicians do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of any device or product we manufacture or distribute. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations and financial condition.





**Table of Contents**

***Any claims relating to our making improper payments or providing improper gifts or benefits to physicians or other potential violations of laws or regulations governing interactions between us and health care professionals and our involvement in federal health care programs could be time consuming and costly.***

Our relationship with health care professionals, such as physicians, hospitals and those that may market our products (e.g., distributors, etc.), are subject to scrutiny under various state and federal laws, rules and regulation (e.g., anti-kickback statute, self-referral/Stark laws, false claims, etc.), often referred to collectively as healthcare fraud and abuse laws. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if they are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in governmental healthcare programs. Despite implementation of a comprehensive healthcare compliance program, we cannot provide assurance that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with health care professionals nor can we make any assurances that authorities will not challenge or investigate our current or future activities under these laws.

In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the Foreign Corrupt Practices Act. Despite implementation of a comprehensive global compliance program, we may be subject to more regulation, enforcement, inspections and investigations by governmental authorities in the future. Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, exclude or debar us from federal health care programs, impose compliance obligations, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice (DOJ). Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects.

Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. Although we believe our marketing, promotional materials and training programs for physicians do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business, as well as could result in a material adverse effect on the market price of our common stock and on our business, results of operations and financial condition. For example, Synthes, Inc., in 2010, settled with the DOJ and the Office of Inspector General (the OIG) for \$22 million relating to allegations that it illegally tested bone cement on patients and, in 2009, Guidant Corporation/Boston Scientific settled with the DOJ and the OIG for \$22 million relating to alleged improper payments made to physicians for certain post-market surveys.

Additionally, we must comply with a variety of other laws, such as the (i) Healthcare Insurance Portability and Accountability Act of 1996 (HIPAA) and the HITECH Act which protects the privacy of individually identifiable healthcare information; (ii) the Physician Payment Sunshine Act which requires medical device companies to begin reporting all compensation, gifts and benefits provided to certain health care professionals in 2013; and (iii) the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

***We or our suppliers may be the subject of claims for non-compliance with FDA regulations in connection with the processing or distribution of allograft products.***

It is possible that allegations may be made against us or against donor recovery groups or tissue banks, including those with which we have a contractual relationship, claiming that the acquisition or processing of tissue for allograft products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action against us, or could cause negative publicity for us or our industry in general. These actions or any negative publicity could cause us to incur substantial costs, divert the attention of our management from our business, harm our reputation and cause the market price of our shares to decline.

**Table of Contents**

**Risks Related to the Securities Markets and Ownership of Our Common Stock**

*We expect that the price of our common stock will fluctuate substantially, potentially adversely affecting the ability of investors to sell their shares. \**

The market price of our common stock has been and may continue to be subject to wide fluctuations. For example, the closing price for our stock on the last day of the past four quarters was: \$17.06 on September 30, 2011, \$32.88 on June 30, 2011, \$25.32 on March 31, 2011, and \$25.65 on December 31, 2010. Fluctuation in the stock price may occur due to many factors, including:

general market conditions and other factors related to the economy or otherwise, including factors unrelated to our operating performance or the operating performance of our competitors. These conditions might include people's expectations, favorable or unfavorable, as to the likely unit growth of the spine sector;

negative stock market reactions to the results of litigation;

negative publicity regarding spine surgeon's practices or outcomes, whether warranted or not, that cast the sector in a negative light;

the introduction of new products or product enhancements by us or our competitors;

changes in the availability of third party reimbursement in the United States or other countries;

disputes or other developments with respect to intellectual property rights or other potential legal actions;

our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;

quarterly variations in our or our competitor's results of operations;

sales of large blocks of our common stock, including sales by our executive officers and directors;

announcements of technological or medical innovations for the treatment of spine pathology;

changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;

the acquisition or divestiture of businesses, products, assets or technology;

litigation, including intellectual property litigation and any associated negative verdicts or ruling;

## Edgar Filing: NUVASIVE INC - Form 10-Q

announcements of actions by the FDA or other regulatory agencies; and

changes in earnings estimates or recommendations by us or by securities analysts.

Market price fluctuations may negatively affect the ability of investors to sell our shares at consistent prices.

***Sales of a significant number of shares of our common stock in the public markets, or the perception of such sales, could depress the market price of our common stock. \****

Sales of a substantial number of shares of our common stock or other equity-related securities in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock or other equity-related securities would have on the market price of our common stock.

***Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.***

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;

**Table of Contents**

prohibit our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and

require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***We do not intend to pay cash dividends.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' source of potential gain for the foreseeable future.

**Item 6. Exhibits**

**EXHIBIT INDEX**

<b>Exhibit No</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the Commission) on August 13, 2004)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to our Form 8-K filed with the Commission on September 28, 2011 (file no. 0001193125-11-258797))
3.3	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008)
10.1	Agreement and Plan of Merger by and among NuVasive, Inc., Catamaran Acquisition Corporation, Impulse Monitoring, Inc. and Tullis-Dickerson & Co., Inc., as Stockholders' Agent, dated September 28, 2011 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 7, 2011 (file no. 0001193125-11-266851))
10.2	Stock Plan Sale Agreement, dated September 28, 2011, by and among NuVasive, Inc., the holders of Series A preferred stock and Series B preferred stock of Impulse Monitoring, Inc. listed on Exhibit A thereto, and Robert W. Baird & Co. Incorporated (incorporated by reference to our Form S-3 filed with the Commission on October 7, 2011 (file no. 0001193125-11-266861))
10.3	Amendment to 2004 Equity Incentive Plan (filed herewith)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32 *	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

## Edgar Filing: NUVASIVE INC - Form 10-Q

101**	XBRL Instance Document
101**	XBRL Taxonomy Extension Schema Document
101**	XBRL Taxonomy Calculation Linkbase Document
101**	XBRL Taxonomy Definition Linkbase Document
101**	XBRL Taxonomy Label Linkbase Document
101**	XBRL Taxonomy Presentation Linkbase Document

Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. Application has been made to the Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. This exhibit has been filed separately with the Commission without redactions in connection with registrant's confidential treatment request.

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

**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.

**NUVASIVE, INC.**

Date: November 4, 2011

By: /s/ ALEXIS V. LUKIANOV  
Alexis V. Lukianov  
*Chairman and Chief Executive Officer*

Date: November 4, 2011

By: /s/ MICHAEL J. LAMBERT  
Michael J. Lambert  
*Executive Vice President and Chief Financial Officer*

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the Commission) on August 13, 2004)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to our Form 8-K filed with the Commission on September 28, 2011 (file no. 0001193125-11-258797))
3.3	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008)
10.1	Agreement and Plan of Merger by and among NuVasive, Inc., Catamaran Acquisition Corporation, Impulse Monitoring, Inc. and Tullis-Dickerson & Co., Inc., as Stockholders Agent, dated September 28, 2011 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 7, 2011 (file no. 0001193125-11-266851))
10.2	Stock Plan Sale Agreement, dated September 28, 2011, by and among NuVasive, Inc., the holders of Series A preferred stock and Series B preferred stock of Impulse Monitoring, Inc. listed on Exhibit A thereto, and Robert W. Baird & Co. Incorporated (incorporated by reference to our Form S-3 filed with the Commission on October 7, 2011 (file no. 0001193125-11-266861))
10.3	Amendment to 2004 Equity Incentive Plan (filed herewith)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32 *	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 **	XBRL Instance Document
101 **	XBRL Taxonomy Extension Schema Document
101 **	XBRL Taxonomy Calculation Linkbase Document
101 **	XBRL Taxonomy Definition Linkbase Document
101 **	XBRL Taxonomy Label Linkbase Document
101 **	XBRL Taxonomy Presentation Linkbase Document

Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. Application has been made to the Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. This exhibit has been filed separately with the Commission without redactions in connection with registrant's confidential treatment request.

## Edgar Filing: NUVASIVE INC - Form 10-Q

- \* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.
  
- \*\* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.