

NUVASIVE INC  
Form 10-Q  
November 07, 2008

**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, 2008**

**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)**

**(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 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 31, 2008, there were 36,142,441 shares of the registrant's common stock outstanding.

**NUVASIVE, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**September 30, 2008**  
**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

|                                                                                                                                  |    |
|----------------------------------------------------------------------------------------------------------------------------------|----|
| <u>Item 1. Financial Statements</u>                                                                                              | 3  |
| <u>Condensed Consolidated Balance Sheets as of September 30, 2008 (Unaudited) and December 31, 2007</u>                          | 3  |
| <u>Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007</u> | 4  |
| <u>Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2008 and 2007</u>           | 5  |
| <u>Notes to Condensed Consolidated Financial Statements</u>                                                                      | 6  |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                             | 14 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>                                                        | 22 |
| <u>Item 4. Controls and Procedures</u>                                                                                           | 22 |

**PART II OTHER INFORMATION**

|                                  |    |
|----------------------------------|----|
| <u>Item 1. Legal Proceedings</u> | 24 |
| <u>Item 1A. Risk Factors</u>     | 24 |
| <u>Item 6. Exhibits</u>          | 26 |
| <b><u>SIGNATURES</u></b>         | 27 |
| <u>EX-2.1</u>                    |    |
| <u>EX-10.7</u>                   |    |
| <u>EX-10.8</u>                   |    |
| <u>EX-31.1</u>                   |    |
| <u>EX-31.2</u>                   |    |
| <u>EX-32</u>                     |    |

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

**NUVASIVE, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(in thousands)*

|                                                         | <b>September 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|---------------------------------------------------------|-------------------------------|------------------------------|
|                                                         | (unaudited)                   |                              |
| <b>Assets</b>                                           |                               |                              |
| Current assets:                                         |                               |                              |
| Cash and cash equivalents                               | \$ 104,388                    | \$ 61,915                    |
| Short-term marketable securities                        | 72,157                        | 19,247                       |
| Accounts receivable, net                                | 46,072                        | 27,496                       |
| Inventory, net                                          | 58,418                        | 36,280                       |
| Prepaid expenses and other current assets               | 3,352                         | 1,240                        |
| Total current assets                                    | 284,387                       | 146,178                      |
| Property and equipment, net of accumulated depreciation | 73,159                        | 43,538                       |
| Intangible assets, net of accumulated amortization      | 57,041                        | 24,496                       |
| Long-term marketable securities                         | 45,148                        | 8,536                        |
| Other assets                                            | 8,892                         | 2,939                        |
| Total assets                                            | \$ 468,627                    | \$ 225,687                   |
| <b>Liabilities and Stockholders' Equity</b>             |                               |                              |
| Current liabilities:                                    |                               |                              |
| Accounts payable and accrued liabilities                | \$ 20,078                     | \$ 13,839                    |
| Accrued payroll and related expenses                    | 13,853                        | 12,075                       |
| Royalties payable                                       | 2,310                         | 2,076                        |
| Total current liabilities                               | 36,241                        | 27,990                       |
| Senior convertible notes                                | 230,000                       |                              |
| Long-term liabilities                                   | 27,226                        | 1,119                        |
| Commitments and contingencies                           |                               |                              |
| Stockholders' equity:                                   |                               |                              |
| Common stock                                            | 36                            | 35                           |
| Additional paid-in capital                              | 374,695                       | 364,469                      |
| Accumulated other comprehensive (loss) income           | (363)                         | 54                           |
| Accumulated deficit                                     | (199,208)                     | (167,980)                    |
| Total stockholders' equity                              | 175,160                       | 196,578                      |
| Total liabilities and stockholders' equity              | \$ 468,627                    | \$ 225,687                   |

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)*

|                                           | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                           | <b>2008</b>                                 | <b>2007</b> | <b>2008</b>                                | <b>2007</b> |
| Revenues                                  | \$ 66,915                                   | \$ 38,522   | \$ 175,501                                 | \$ 107,360  |
| Cost of goods sold                        | 12,195                                      | 6,925       | 30,845                                     | 19,342      |
| Gross profit                              | 54,720                                      | 31,597      | 144,656                                    | 88,018      |
| Operating expenses:                       |                                             |             |                                            |             |
| Sales, marketing and administrative       | 54,557                                      | 29,480      | 135,975                                    | 86,463      |
| Research and development                  | 6,396                                       | 5,702       | 19,797                                     | 16,463      |
| In-process research and development       | 16,700                                      |             | 20,876                                     |             |
| Total operating expenses                  | 77,653                                      | 35,182      | 176,648                                    | 102,926     |
| Interest and other income, net            | (146)                                       | 1,302       | 764                                        | 4,789       |
| Net loss                                  | \$ (23,079)                                 | \$ (2,283)  | \$ (31,228)                                | \$ (10,119) |
| Net loss per share:                       |                                             |             |                                            |             |
| Basic and diluted                         | \$ (0.64)                                   | \$ (0.07)   | \$ (0.88)                                  | \$ (0.29)   |
| Weighted average shares basic and diluted | 35,931                                      | 34,940      | 35,674                                     | 34,638      |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

**NUVASIVE, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(in thousands)*

|                                                                             | <b>Nine Months Ended September<br/>30,</b> |             |
|-----------------------------------------------------------------------------|--------------------------------------------|-------------|
|                                                                             | <b>2008</b>                                | <b>2007</b> |
| <b>Operating activities:</b>                                                |                                            |             |
| Net loss                                                                    | \$ (31,228)                                | \$(10,119)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                            |             |
| Depreciation and amortization                                               | 15,671                                     | 9,619       |
| Stock-based compensation                                                    | 15,719                                     | 9,977       |
| In-process research and development                                         | 20,876                                     |             |
| Leasehold abandonment                                                       | 4,486                                      |             |
| Other non-cash adjustments                                                  | 1,109                                      | 1,124       |
| Changes in operating assets and liabilities:                                |                                            |             |
| Accounts receivable                                                         | (18,986)                                   | (5,871)     |
| Inventory                                                                   | (22,136)                                   | (11,041)    |
| Prepaid expenses and other current assets                                   | (941)                                      | (28)        |
| Accounts payable and accrued liabilities                                    | 3,898                                      | 2,537       |
| Accrued payroll and related expenses                                        | 1,778                                      | 2,230       |
| Net cash used in operating activities                                       | (9,754)                                    | (1,572)     |
| <b>Investing activities:</b>                                                |                                            |             |
| Cash paid for business and technology acquisitions                          | (41,256)                                   | (6,970)     |
| Purchases of property and equipment                                         | (34,161)                                   | (14,103)    |
| Sales of short-term marketable securities                                   | 30,159                                     | 98,218      |
| Purchases of short-term marketable securities                               | (83,069)                                   | (56,131)    |
| Sales of long-term marketable securities                                    | 14,778                                     | 7,500       |
| Purchases of long-term marketable securities                                | (51,390)                                   | (16,003)    |
| Other assets                                                                | 544                                        | (167)       |
| Net cash provided by (used in) investing activities                         | (164,395)                                  | 12,344      |
| <b>Financing activities:</b>                                                |                                            |             |
| Payment of long-term liabilities                                            | (300)                                      | (300)       |
| Issuance of Senior Convertible Notes                                        | 222,414                                    |             |
| Purchase of convertible note hedges                                         | (45,758)                                   |             |
| Sale of warrants                                                            | 31,786                                     |             |
| Issuance of common stock                                                    | 8,480                                      | 4,392       |
| Net cash provided by financing activities                                   | 216,622                                    | 4,092       |
| Increase in cash and cash equivalents                                       | 42,473                                     | 14,864      |
| Cash and cash equivalents at beginning of period                            | 61,915                                     | 41,476      |
| Cash and cash equivalents at end of period                                  | \$ 104,388                                 | \$ 56,340   |

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*

NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company is a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. NuVasive's principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of cervical and motion preservation products. The Company's currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. The Company also focuses significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. The Company dedicates significant resources to sales and marketing efforts, including training spine surgeons on its unique technology and products. The Company's MAS platform combines NeuroVision®, a nerve avoidance system, MaXcess®, a minimally disruptive surgical system, and specialized implants, including fixation products for fusion and CoRoent® suite of implants.

The fusion fixation products include the Company's SpheR® pedicle screw systems, XLP® lateral fixation plate, Halo® anterior fixation plate, Helix® cervical plate and Gradient Plus® cervical plate. The Company also offers their Triad® and Extensure® lines of bone allograft, in patented saline packaging. Further, the Company has a growing offering of biologic products to promote bone growth and fusion, including the synthetic bone void filler FormaGraft®. In addition, the Company recently acquired Osteocel®, a mesenchymal stem cell-based biologic product.

The Company loans its NeuroVision systems and surgical instrument sets to surgeons and hospitals who purchase its disposables and implants for use in individual procedures. In addition, NeuroVision, MaXcess and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. The Company sells a small quantity of surgical instrument sets and NeuroVision systems to hospitals. The Company offers a range of bone allograft in patented saline packaging and spine implants such as rods, plates and screws. Implants and disposables are shipped from the Company's facilities.

*2. 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. 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 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. All intercompany transactions and balances 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, 2007 included in NuVasive's Annual Report on Form 10-K filed with the Securities and Exchange Commission. Operating results for the three- and nine- months ended September 30, 2008 and 2007 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, 2007 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. Certain previously reported amounts have been reclassified to conform to the current period's presentation.



**Table of Contents**

*3. Osteocel Biologics Business Acquisition*

On July 24, 2008, NuVasive completed the acquisition of certain assets of Osiris Therapeutics, Inc. (Osiris) (the Osteocel® Biologics Business Acquisition) for \$35.0 million in cash paid at closing pursuant to the Asset Purchase Agreement, as amended. The completion date of this transaction is referred to as the Technology Closing Date. At the Technology Closing Date, the Company also entered into a Manufacturing Agreement, as amended (collectively with the Asset Purchase Agreement, the Agreements) with Osiris.

Under the terms of the Agreements, NuVasive will make additional payments of up to \$50 million, including milestone-based contingent payments not to exceed \$37.5 million and a non-contingent \$12.5 million payment for the transfer of the manufacturing facility Osiris currently utilizes to manufacture the Osteocel product. Both the contingent and non-contingent payments are payable in either cash or a combination of cash and stock, at the Company's election. The contingent payments are based on meeting a combination of specific product delivery milestones and a sales performance milestone and are not included in the preliminary estimate of the purchase price of the Osteocel Biologics Business.

Pursuant to the Agreements, Osiris will supply, and the Company will purchase, specified quantities of Osteocel product and Osiris will meet certain performance criteria for a period not to exceed 18 months. At the conclusion of this period, NuVasive will make the non-contingent payment for the manufacturing facility and will be assigned the lease agreement for the manufacturing facility. Title to the manufacturing related assets, leasehold improvements and all other tangible assets, as defined in the Agreements, will pass to NuVasive on this date.

Pursuant to the Agreements, as amended, the sales price per cubic centimeter (cc) of the Osteocel product transferred to NuVasive was reduced for the first approximate 40,000 cc's delivered after the Technology Closing Date. NuVasive has recorded a short-term asset of \$2.5 million representing the value of the discounted purchase price contract. Management expects substantially all of the \$2.5 million to be amortized by December 31, 2008.

*Reason for the Osteocel Acquisition*

The transaction provides NuVasive with a comprehensive stem cell biologic platform with benefits similar to autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel is the only viable bone matrix product on the market that provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel allows surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel is produced for use in spinal applications through a proprietary processing method that preserves the native stem cell population that resides in marrow rich bone.

*Purchase Price*

The estimated purchase price has been allocated to the tangible and intangible assets acquired based on their respective fair values as of the Technology Closing Date. The preliminary allocation of the estimated purchase price resulted in an excess of the fair value of net tangible and intangible assets acquired over the total purchase price by approximately \$3.7 million which has been recorded as a long-term liability in accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations*.

**Table of Contents**

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

|                                                                                                |           |
|------------------------------------------------------------------------------------------------|-----------|
| Cash paid on Technology Closing Date                                                           | \$ 35,000 |
| Present value of long term deferred consideration liability, due on Manufacturing Closing Date | 11,965    |
| Estimated transaction costs and other                                                          | 544       |
| Total estimated initial purchase price                                                         | \$ 47,509 |

The following table summarizes the allocation of the estimated initial purchase price (*in thousands*):

|                                                   | Estimated<br>Fair Value | Estimated<br>Useful<br>Life |
|---------------------------------------------------|-------------------------|-----------------------------|
| Manufacturing know-how and trade secrets          | \$ 19,800               | 13 years                    |
| Developed technology                              | 7,200                   | 10 years                    |
| Discounted price purchase contract                | 2,500                   | 0.50 years                  |
| Trade name and trademarks                         | 4,700                   | 15 years                    |
|                                                   |                         | 0.25-2                      |
| Customer contracts and relationships              | 330                     | years                       |
| In-process research and development               | 16,700                  |                             |
|                                                   | 51,230                  |                             |
| Long-term liability                               | (3,721)                 |                             |
| Total estimated initial purchase price allocation | \$ 47,509               |                             |

The Company recorded an in-process research and development (IPRD) charge of \$16.7 million related to the Osteocel Biologics Business Acquisition. As of the date of the acquisition, the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in-process had no alternative future uses. Accordingly, the amount was charged to expense on the acquisition date.

The accompanying consolidated statement of operations for the three- and nine- months ended September 30, 2008 reflect the operating results of Osteocel since the date of the acquisition.

The Company has prepared the following unaudited pro forma financial statement information to compare results of the periods presented assuming the Osteocel Biologics Business Acquisition had occurred at the beginning of each of the periods presented. 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 Osteocel Biologics Business Acquisition occurred at the beginning of each of the periods presented, the pro forma unaudited results of operations would have been as follows for the three- and nine- months ended September 30, 2008 and 2007:

|                    | Three Months Ended       |                          | Nine Months Ended        |                          |
|--------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|                    | September<br>30,<br>2008 | September<br>30,<br>2007 | September<br>30,<br>2008 | September<br>30,<br>2007 |
| Revenue            | \$ 69,659                | \$ 41,143                | \$ 194,721               | \$ 115,223               |
| Net Loss           | (22,032)                 | (2,199)                  | (25,383)                 | (9,866)                  |
| Net loss per share | \$ (0.61)                | \$ (0.06)                | \$ (0.71)                | \$ (0.28)                |

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, 2008.

**Table of Contents*****4. Convertible Senior Notes***

In March 2008, the Company issued \$230.0 million principal amount of 2.25% Convertible Senior Notes (the Notes), which includes the subsequent exercise of the initial purchasers' option to purchase an additional \$30.0 million aggregate principal amount of the Notes. The net proceeds from the offering, after deducting the initial purchasers' discount and costs directly related to the offering, were approximately \$208.4 million. The Company will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013 (the Maturity Date).

The Notes will be convertible into shares of the Company's common stock, \$0.001 par value per share, based on an initial conversion rate, subject to adjustment, of 22.3515 shares per \$1,000 principal amount of the Notes (which represents an initial conversion price of approximately \$44.74 per share). Holders may convert their 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 Notes, holders of the Notes have the right to require that the Company repurchase the Notes, or a portion thereof, at the principal amount thereof plus accrued and unpaid interest.

In connection with the offering of the Notes, the Company entered into convertible note hedge transactions (the Hedge) with the initial purchasers and/or their affiliates (the 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 Counterparties warrants to acquire up to 5.1 million shares of the Company's common stock (the Warrants), subject to adjustment, at an initial strike price of \$49.13 per share, subject to adjustment. The cost of the Hedge that was not covered by the proceeds from the sale of the Warrants was approximately \$14.0 million and is reflected as a reduction of additional paid-in capital as of September 30, 2008. The impact of the Hedge is to raise the effective conversion price of the Notes to approximately \$49.13 per share (or approximately 20.3542 shares per \$1,000 principal amount of the Notes). The Hedge is expected to reduce the potential equity dilution upon conversion of the Notes if the daily volume-weighted average price per share of the Company's common stock exceeds the strike price of the Hedge. The 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 Warrants.

***5. Acquisition of Pedicle Screw Technology***

In March 2008, the Company completed a buy-out of royalty obligations on SpheRx® pedicle screw and related technology products and acquired new pedicle screw intellectual property totaling \$6.3 million. Of the total purchase price, \$2.1 million, representing the present value of the expected future cash flows associated with the terminated royalty obligations, was allocated to intangible assets to be amortized on a straight-line basis over a seven-year period. The remaining \$4.2 million was allocated to in-process research and development as the associated projects had not yet reached technological feasibility and had no alternative future uses.

***6. Balance Sheet Reserves***

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

|                                            | <b>September 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|--------------------------------------------|-------------------------------|------------------------------|
| Reserves for accounts receivable           | \$ 1,257                      | \$ 926                       |
| Reserves for excess and obsolete inventory | \$ 3,637                      | \$ 3,614                     |

**Table of Contents****7. Intangible Assets**

Identifiable intangible assets subject to amortization consisted of the following as of September 30, 2008 (*in thousands*):

|                                          | <b>Gross<br/>Carrying<br/><br/>Amount</b> | <b>Accumulated<br/><br/>Amortization</b> | <b>Intangible<br/>Assets<br/>Subject to<br/>Amortization,<br/>net</b> |
|------------------------------------------|-------------------------------------------|------------------------------------------|-----------------------------------------------------------------------|
| Trade name and trademarks                | \$ 4,700                                  | \$ (53)                                  | \$ 4,647                                                              |
| Customer relationships                   | 9,730                                     | (1,166)                                  | 8,564                                                                 |
| Developed technology                     | 25,625                                    | (2,686)                                  | 22,939                                                                |
| Manufacturing know-how and trade secrets | 19,800                                    | (258)                                    | 19,542                                                                |
|                                          | <b>\$59,855</b>                           | <b>\$ (4,163)</b>                        | <b>\$ 55,692</b>                                                      |

Future estimated amortization expense related to acquired intangible assets subject to amortization is as follows (*in thousands*):

|                |                  |
|----------------|------------------|
| Remaining 2008 | \$ 1,178         |
| 2009           | 4,573            |
| 2010           | 4,510            |
| 2011           | 4,423            |
| 2012           | 4,423            |
| Thereafter     | 36,585           |
|                | <b>\$ 55,692</b> |

**8. Net Loss Per Share**

NuVasive computes net loss per share using the weighted-average number of common shares outstanding during the period. The effect of stock options, conversion of the senior convertible notes, and warrants is anti-dilutive and therefore excluded from the calculation. Although these securities are currently not included in the net loss per share calculation, they could be dilutive when, and if, the Company reports future earnings.

| <b>(in thousands, except per share amounts)</b>       | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                                       | <b>2008</b>                                 | <b>2007</b> | <b>2008</b>                                | <b>2007</b> |
| Numerator:                                            |                                             |             |                                            |             |
| Net loss                                              | \$ (23,079)                                 | \$ (2,283)  | \$ (31,228)                                | \$ (10,119) |
| Denominator for basic and diluted net loss per share: |                                             |             |                                            |             |
| Weighted average common shares outstanding            | 35,931                                      | 34,940      | 35,674                                     | 34,638      |
| Basic and diluted net loss per share                  | \$ (0.64)                                   | \$ (0.07)   | \$ (0.88)                                  | \$ (0.29)   |

**9. Comprehensive Income**

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

|                                       | <b>Nine Months Ended<br/>September 30,</b> |            |
|---------------------------------------|--------------------------------------------|------------|
|                                       | 2008                                       | 2007       |
| Net income                            | \$(31,228)                                 | \$(10,119) |
| Other comprehensive loss:             |                                            |            |
| Unrealized gain (loss) on investments | (318)                                      | 28         |
| Translation adjustments               | (99)                                       | (25)       |
| Total comprehensive income            | \$(31,645)                                 | \$(10,116) |

**Table of Contents****10. Marketable Securities**

Effective January 1, 2008, the Company adopted FASB Statement No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. On February 6, 2008, the FASB deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. The Company measures certain assets at fair value and thus there was no impact on the Company's consolidated financial statement at the adoption of SFAS 157. SFAS 157 requires disclosure that establishes a framework for measuring fair value and expands disclosure about fair value measurements. The statement requires fair value measurement 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.

The Company measures available-for-sale securities at fair value on a recurring basis. All of the Company's assets measured at fair value on a recurring basis subject to the disclosure requirements of SFAS 157 as of September 30, 2008 are categorized as Level 1. The Company recorded an immaterial unrealized loss in each of the nine-month periods ended September 30, 2008 and 2007. The unrealized loss is included as a component of other comprehensive income (loss) within stockholders' equity.

**11. Stock-Based Compensation**

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options granted to employees and shares issued under the Employee Stock Purchase Plan, or ESPP, using a Black-Scholes option-pricing model. The assumptions used to estimate the fair value of stock awards granted in the three- and nine-month periods ended September 30, 2008 and 2007 are as follows:

|                         | <b>Three and Nine<br/>Months<br/>Ended September<br/>30, 2008</b> | <b>Three and Nine<br/>Months<br/>Ended September<br/>30, 2007</b> |
|-------------------------|-------------------------------------------------------------------|-------------------------------------------------------------------|
| <b>Stock Options</b>    |                                                                   |                                                                   |
| Volatility              | 42%                                                               | 50%                                                               |
| Expected term (years)   | 2.5 to 4.5                                                        | 2.5 to 4.5                                                        |
| Risk free interest rate | 2.46% to 3.41%                                                    | 4.23% to 4.92%                                                    |
| Expected dividend yield | 0.0%                                                              | 0.0%                                                              |
| <b>ESPP</b>             |                                                                   |                                                                   |
| Volatility              | 42% to 65%                                                        | 50%                                                               |
| Expected term (years)   | 0.5 to 2                                                          | 0.5 to 2                                                          |
| Risk free interest rate | 4.01% to 4.86%                                                    | 4.45% to 4.86%                                                    |
| Expected dividend yield | 0.0%                                                              | 0.0%                                                              |

The compensation cost that has been included in the statement of operations for all stock-based compensation arrangements was as follows:

| <b>Three Months Ended<br/>September 30,</b> | <b>Nine Months Ended<br/>September 30,</b> |
|---------------------------------------------|--------------------------------------------|
|---------------------------------------------|--------------------------------------------|

Edgar Filing: NUVASIVE INC - Form 10-Q

| <b>(in thousands, except per share amounts)</b> | <b>2008</b> | <b>2007</b> | <b>2008</b> | <b>2007</b> |
|-------------------------------------------------|-------------|-------------|-------------|-------------|
| Sales, marketing and administrative expense     | \$ 4,499    | \$ 2,801    | \$ 13,541   | \$ 8,323    |
| Research and development expense                | 922         | 563         | 2,178       | 1,654       |
| Stock-based compensation expense                | \$ 5,421    | \$ 3,364    | \$ 15,719   | \$ 9,977    |
| Effect on basic and diluted net loss per share  | \$ (0.15)   | \$ (0.10)   | \$ (0.44)   | \$ (0.29)   |

Stock-based compensation for stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award*



**Table of Contents**

*Plans* (FIN 28). As of September 30, 2008, there was \$21.2 million of unrecognized stock-based compensation expense. This cost is expected to be recognized over a weighted-average period of approximately 1.3 years.

***12. New Building Lease***

On November 6, 2007, the Company entered into a 15-year lease agreement for the purpose of relocating the Company's corporate headquarters to an approximately 140,000 square foot two-building campus style complex in San Diego. Rental payments consist of base rent that escalates at an annual rate of three percent over the 15-year period of the lease, plus building related expenses paid to the landlord. In addition, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. In connection with the lease, the Company issued a \$3.1 million irrevocable transferrable letter of credit. Relocation to the new facility began in March 2008 and was completed during August 2008.

The Company expects to sublease its previous corporate headquarters through August 2012, the date on which the related lease agreement expires, however expects that the space will remain vacant for approximately 24 months with no associated sublease during that time. Upon moving the final phase of shareowners (employees) and operations to the new headquarters during August of 2008, the Company recorded a loss equal to the estimated present value of expected net future cash flows in the amount of \$4.8 million. The Company has assumed, in performing the calculation of the loss, that the facility will remain vacant for approximately 24 months given the current market conditions. As of the date of this filing, the Company has not yet entered into a sublease agreement and cannot be assured that a sublease, if any, will provide the anticipated sublease income used to calculate the above charge. The charge related to the estimated fair value of expected net future cash flows is reflected in the consolidated statement of operations as sales, marketing and administrative expense.

The table below provides the minimum cash payments required under the new and old building leases for rent and related operating expenses.

| <b>Year<br/>(in thousands)</b> | <b>Previous Headquarters</b> | <b>New Headquarters</b> | <b>Total</b> |
|--------------------------------|------------------------------|-------------------------|--------------|
| 2008                           | \$ 310                       | \$ 644                  | \$ 954       |
| 2009                           | 1,267                        | 5,151                   | 6,418        |
| 2010                           | 1,305                        | 5,801                   | 7,106        |
| 2011                           | 1,344                        | 6,003                   | 7,347        |
| 2012                           | 921                          | 6,214                   | 7,135        |
| Thereafter                     |                              | 82,339                  | 82,339       |
|                                | \$ 5,147                     | \$ 106,152              | \$ 111,299   |

***13. Impact of Recently Issued Accounting Standards***

In December 2007, the Financial Accounting Standards Board (FASB) issued Statement No. 141 (Revised 2007), *Business Combinations* (SFAS No. 141(R)), which establishes principles and requirements for the reporting entity in a business combination, including recognition and measurement in the financial statements of the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree. This statement also establishes disclosure requirements to enable financial statement users to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. SFAS No. 141(R) will become effective for our fiscal year beginning in 2009. The Company is currently evaluating the effect, if any, the adoption of SFAS No. 141(R) could have on the consolidated financial statements.

In December 2007, Statement of Financial Accounting Standards No. 160, *Reporting of Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160) was issued and is effective for financial statements for fiscal years beginning on or after December 1, 2008, and interim periods within those years.

SFAS 160 improves the relevance, comparability and transparency of financial information provided to investors by requiring all entities to report noncontrolling (minority) interests in subsidiaries in the same way. Additionally, SFAS 160 eliminates the diversity that currently exists in accounting

**Table of Contents**

for transactions between an entity and noncontrolling interests by requiring they be treated as equity transactions. As of September 30, 2008, we did not hold any noncontrolling interests in subsidiaries.

*14. Legal Proceedings*

*Medtronic Sofamor Danek USA, Inc. Litigation*

On August 18, 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, alleging that certain of the Company's products infringe, or contribute to the infringement of twelve U.S. patents owned by Medtronic (Medtronic Patents). Medtronic is seeking unspecified monetary damages and a court injunction against future infringement by NuVasive. On October 6, 2008, Medtronic filed an amended complaint dropping their claims of infringement relating to three of the named U.S. Patents. On October 13, 2008, the Company answered the complaint denying the allegations and filed counterclaims seeking dismissal of Medtronic's complaint and a declaration that NuVasive have not infringed and currently does not infringe any valid claim of the Medtronic Patents, including those previously dropped by Medtronic. As of September 30, 2008, the probability of an outcome cannot be reasonably determined, nor can the Company reasonably estimate a potential loss, therefore, in accordance with SFAS 5, the Company has not recorded an accrual related to this litigation.

## Table of Contents

### **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 consolidated financial statements and the notes to those statements included in this report. This discussion may contain 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 ending December 31, 2007. 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 the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed \$4.2 billion in the United States in 2008. 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 cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We also focus significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources to our sales and marketing efforts, including training spine surgeons on our unique technology and products.

Our MAS platform combines three categories of our product offerings:

NeuroVision<sup>®</sup> a proprietary software-driven nerve avoidance system;

MaXcess<sup>®</sup> a unique split-blade design retraction system providing enhanced surgical access to the spine; and

Specialized implants, including our fixation products for fusion and CoRoent<sup>®</sup> suite of implants.

Our fusion fixation products include our SpheRx<sup>®</sup> pedicle screw systems, XLP lateral fixation plate, Halo anterior fixation plate, Helix cervical plate and Gradient Plus cervical plate. We also offer our Tru<sup>®</sup> and Extensure<sup>®</sup> lines of bone allograft, in our patented saline packaging, and a synthetic bone void filler, FormaGraft<sup>®</sup>, designed to aid in bone growth with fusion procedures. Osteocel<sup>®</sup>, the most recent addition to our comprehensive product portfolio, is part of our biologics offering that we expect to contribute to the growth of our biologics platform over the next several years.

We have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion. We completed the enrollment of our pivotal clinical trial in August for NeoDisc, our cervical disc replacement device. The trial protocol requires a two-year follow up period on all patients before submitting to the FDA for potential approval.

Since inception, we have been unprofitable. As of September 30, 2008, we had an accumulated deficit of \$199.2 million.

**Revenues.** The majority of our revenues are derived from the sale of implants and disposables and we expect this trend to continue in the near term. We loan our NeuroVision systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures; there are no minimum purchase requirements of disposables and implants related to these loaned surgical instruments. In addition, we place NeuroVision, MaXcess and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. These extended loan transactions represent less than 20% of our total stock of loaner surgical assets. Our implants and disposables are currently sold and shipped from our San Diego and Memphis facilities. We recognize revenue for disposables or implants used upon receiving a purchase order from the hospital indicating product use or implantation. In



## **Table of Contents**

addition, we sell a small number of MAS instrument sets, MaXcess devices, and NeuroVision systems. To date, we have derived less than 5% of our total revenues from these sales.

*Sales and Marketing.* Through September 30, 2008, substantially all of our operations are located in the United States and substantially all of our sales to date have been generated in the United States. We distribute our products through a sales force comprised of independent exclusive sales agents and our own directly employed sales professionals. 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. In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Late in 2007, we began an expansion in international markets focusing initially on European markets. We expect our international sales force to be made up of a combination of distributors and direct sales personnel.

### **Critical Accounting Policies**

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, long-term assets, income taxes, and stock-based compensation. 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.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition.* We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon receipt of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of our instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

*Allowance for Doubtful Accounts.* We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers. As a result of this review, the allowance is adjusted on a specific identification basis. Increases to the allowance for doubtful accounts result in a corresponding sales, marketing and administrative expense. We maintain a relatively large customer base that mitigates the risk of concentration with one customer. However, if the overall condition of the healthcare industry were to deteriorate, or if the historical data used to calculate the allowance provided for doubtful accounts does not reflect our customer's future ability to pay outstanding receivables, significant additional allowances could be required.

*Excess and Obsolete Inventory and Instruments.* We calculate an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft implants have a four-year shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. Our MAS inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and

are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold.

**Table of Contents**

A stated goal of our business is to focus on continual product innovation and to obsolete our own products. While we believe this provides a competitive edge, it also results in the risk that our products and related capital instruments will become obsolete prior to the end of their anticipated useful lives. If we introduce new products or next-generation products prior to the end of the useful life of a prior generation, we may be required to dispose of existing inventory and related capital instruments and/or write off the value or accelerate the depreciation of these assets.

*Long-Term Assets.* Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on the estimated useful lives of three to seven years for machinery and equipment and three years for loaner instruments. We own land and a building in Memphis, Tennessee that we use as a warehouse and distribution facility. The building is depreciated over a period of 20 years. Maintenance and repairs are expensed as incurred. Intangible assets, consisting of purchased and licensed technology and a supply agreement, are amortized on a straight-line basis over their estimated useful lives ranging from ten to 20 years.

We evaluate our long-term assets for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If this evaluation indicates that the value of the long-term asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the long-term asset is not recoverable, we reduce the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. We have not recognized any material impairment losses on long-term intangible assets through September 30, 2008.

*Accounting for Income Taxes.* Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a full valuation allowance on our net deferred tax assets as of September 30, 2008 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future.

*Valuation of Stock-Based Compensation.* On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for shareowner (employee) and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. Option awards issued to non-employees are recorded at their fair value as determined in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating the stock-based compensation expense, we estimate the fair value of all share-based awards to shareowners (employees) and directors at the date of grant using the Black-Scholes option-pricing model and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on an accelerated basis.

The determination of fair value using the Black-Scholes option-pricing model is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividend and expected term. Stock-based compensation expense is recognized only for those awards that are ultimately expected to vest, and we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). If there is a difference between the assumptions used in determining stock-based compensation cost and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs. These changes, if any, may materially impact our results of operations in the period such changes are made.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States (GAAP). See our unaudited condensed consolidated financial statements and notes thereto included in this report, and our audited consolidated





**Table of Contents**

financial statements and notes thereto for the year ended December 31, 2007 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, which contain accounting policies and other disclosures required by GAAP.

***Osteocel® Biologics Business Acquisition***

On July 24, 2008, NuVasive completed the acquisition of certain assets of Osiris Therapeutics, Inc. (Osiris) (the Osteocel® Biologics Business Acquisition) for \$35.0 million in cash paid at closing pursuant to the Asset Purchase Agreement, as amended. The completion date of this transaction is referred to as the Technology Closing Date. At the Technology Closing Date, the Company also entered into a Manufacturing Agreement, as amended, (collectively with the Asset Purchase Agreement, the Agreements) with Osiris.

Under the terms of the Agreements, NuVasive will make additional payments of up to \$50 million, including milestone-based contingent payments not to exceed \$37.5 million and a non-contingent \$12.5 million payment for the transfer of the manufacturing facility Osiris currently utilizes to manufacture the Osteocel product. Both the contingent and non-contingent payments are payable in either cash or a combination of cash and stock, at the Company's election. The contingent payments are based on meeting a combination of specific product delivery milestones and a sales performance milestone and are not included in the preliminary estimate of the purchase price of the Osteocel Biologics Business.

Pursuant to the Agreements, Osiris will supply, and the Company will purchase, specified quantities of Osteocel product and Osiris will meet certain performance criteria for a period not to exceed 18 months. At the conclusion of this period, NuVasive will make the non-contingent payment for the manufacturing facility and will be assigned the lease agreement for the manufacturing facility. Title to the manufacturing related assets, leasehold improvements and all other tangible assets, as defined in the Agreements, will pass to NuVasive on this date. NuVasive will record the fair value of the assets acquired as of the Manufacturing Closing Date and estimates their value will be approximately \$5 million to \$10 million.

Pursuant to the Agreements, as amended, the sales price per cubic centimeter (cc) of the Osteocel product transferred to NuVasive was reduced for the first approximate 40,000 cc's delivered after the Technology Closing Date. NuVasive has recorded a short-term asset of \$2.5 million representing the value of the discounted purchase price contract. Management expects substantially all of the \$2.5 million to be amortized by December 31, 2008.

The transaction provides NuVasive with a comprehensive stem cell biologic platform with benefits similar to autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel is the only viable bone matrix product on the market that provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel allows surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel is produced for use in spinal applications through a proprietary processing method that preserves the native stem cell population that resides in marrow rich bone.

The acquisition has been accounted for using the purchase method of accounting in accordance with Financial Accounting Standards Board Opinion No. 141, *Business Combinations* (FAS 141). Accordingly, NuVasive's cost to acquire the Osteocel Biologics Business has been allocated to the tangible assets, intangible assets and in-process research and development acquired, based upon their respective estimated fair values as of the date of the Technology Closing Date. The fair value estimates are preliminary and may change upon finalization of the purchase price allocation.

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

|                        | September 30, |           |           |          |
|------------------------|---------------|-----------|-----------|----------|
| (dollars in thousands) | 2008          | 2007      | \$ Change | % Change |
| Three months ended     | \$ 66,915     | \$ 38,522 | \$28,393  | 73.7%    |
| Nine months ended      | \$175,501     | \$107,360 | \$68,141  | 63.5%    |

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS platform, including NeuroVision, MaXcess disposables, and our specialized implants such as our XLP lateral plate, SpheRx® pedicle screw systems, and CoRoent® suite of products. The continued adoption of minimally invasive procedures for spine has led to the continued expansion of our innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or 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 through product introductions in 2008 and 2007 have contributed to revenue growth in both years. We expect revenue to continue to increase, which can be attributed to the continued adoption of our XLIF procedure and deeper penetration into existing accounts as our sales force executes on the strategy of selling the full mix of our products. In addition, the expansion of our biologics offering through the acquisition of the Osteocel Biologics Business, and our new product introductions and sales force initiatives are expected to lead to continued revenue growth. Included in revenues for the quarter ended September 30, 2008 is \$4.4 million of Osteocel revenue. Excluding Osteocel revenue, revenues for the first three quarters of 2008 increased 62.3% compared to the same period in 2007.

***Cost of Goods Sold***

|                        | September 30, |          |           |          |
|------------------------|---------------|----------|-----------|----------|
| (dollars in thousands) | 2008          | 2007     | \$ Change | % Change |
| Three months ended     | \$12,195      | \$ 6,925 | \$ 5,270  | 76.1%    |
| % of revenue           | 18.2%         | 18.0%    |           |          |
| Nine months ended      | \$30,845      | \$19,342 | \$11,503  | 59.5%    |
| % of revenue           | 17.6%         | 18.0%    |           |          |

Cost of goods sold consists of purchased goods and overhead costs, including depreciation expense for instruments.

The increase in cost of goods sold in total dollars in the three- and nine-month periods ended September 30, 2008 compared to the same periods in 2007 resulted primarily from (i) increased material costs of \$4.9 million and \$9.8 million, respectively, primarily to support revenue growth and new product launches; and (ii) increased depreciation expense of \$0.3 million and \$1.4 million, respectively, incurred on the increased amount of surgical instruments held for use in surgeries. We expect cost of goods sold, as a percentage of revenue, to increase slightly through the remainder of 2008. We expect our gross margin to range between 81% and 82% for the remainder of 2008.

***Operating Expenses***

*Sales, Marketing and Administrative.*

|                        | September 30, |          |           |          |
|------------------------|---------------|----------|-----------|----------|
| (dollars in thousands) | 2008          | 2007     | \$ Change | % Change |
| Three months ended     | \$ 54,557     | \$29,480 | \$25,077  | 85.1%    |
| % of revenue           | 81.5%         | 76.5%    |           |          |
| Nine months ended      | \$135,975     | \$86,463 | \$49,512  | 57.3%    |

% of revenue

77.5%

80.5%

18

---

**Table of Contents**

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, surgeon training costs, shareowner (employee) related expenses for our administrative functions, third party professional service fees, amortization of acquired intangible assets, and facilities and insurance expenses.

The increases in sales, marketing and administrative expenses principally result from growth in our revenue and the overall growth in the Company, including expenses that fluctuate with sales and expenses associated with investments in our infrastructure and headcount growth. Increases in costs based on revenue, such as sales force compensation and shipping costs, were \$ 3.8 million, and \$13.4 million, for the three- and nine- month periods ended September 30, 2008, respectively, compared to the same periods in 2007. In addition, in the third quarter of 2008, \$4.8 million and \$2.6 million were included in sales, marketing and administrative expenses for a charge related to vacating the Company's previous corporate headquarters and incremental transition costs related to the Company's ERP system, respectively. These charges are described in further detail below. Increases in costs based on overall company growth and administrative support, such as compensation and other shareowner (employee) related costs, were \$8.3 million and \$13.9 million, respectively, for the three- and nine-month periods ended September 30, 2008, compared to the same periods in 2007. We also incurred an increase in equipment and facility costs of \$2.5 million and \$4.7 million for the three- and nine-month period ended September 30, 2008, respectively, compared to the same period in 2007, also a result of company growth and the relocation to our new facility.

Total costs related to our sales force, as a percent of revenue, decreased to 30.3% from 31.6% for the three months ended September 30, 2008 compared to the same period in 2007. The decrease in costs as a percentage of revenue was primarily attributable to the increased revenues and to certain costs associated with our transition to sales force exclusivity that were incurred in the 2007 period but not incurred in the 2008 period.

On a long-term basis, as a percentage of revenue, we expect sales, marketing and administrative costs to continue to decrease over time as we continue to see the synergies of investments we have made. However, we have incurred other significant expenses that are designed to increase the scalability of our business over time. For example, we purchased and began the implementation of a new enterprise resource planning, or ERP, software system, in 2007. We completed the implementation of our new ERP system during the third quarter of 2008. We capitalized the majority of the aggregate \$10.9 million anticipated cost of the ERP project and are amortizing it over a 7-year period. During the quarter, we determined that additional consulting time was important for a successful transition and therefore incurred \$2.6 million in Q3 2008 which was an incremental non-capitalizable expense related to the ongoing support costs for the implementation. We anticipate an additional charge of approximately \$1.5 million in the fourth quarter of 2008. These third and fourth quarter investments minimize the potential for transitional risk of moving to a new SAP based system and will assist in driving expected efficiencies in 2009. We expect to move to a more traditional and leverage-able on-going support model in 2009, without significant incremental costs.

In addition, we entered into a lease of a two-building campus-style headquarters complex in November 2007 to accommodate our Company's growth. Relocation to the new facility was completed in August 2008, and, as a result, we began to incur increased facility costs beginning on the relocation dates. Specifically, we expect to incur approximately \$1.9 million in incremental facility costs in 2008 plus a charge of \$4.8 million related to vacating our previous corporate headquarters, as discussed below.

We expect to sublease our previous corporate headquarters through August 2012, the date on which the related lease agreement expires, however expect that the space will remain vacant for approximately 24 months with no associated sublease during that time. At the completion of moving the final phase of shareowners (employees) and operations from our previous facility to our new headquarters during August 2008, we recorded a loss equal to the present value of expected net future cash flows in the amount of \$4.8 million. We assumed, in performing the calculation of the loss, that the facility will remain vacant for approximately 24 months given the current market conditions. As of the date of this filing, we have not yet entered into a sublease agreement and cannot be assured that a sublease, if any, will provide the anticipated sublease income used to estimate the charge recorded.

**Table of Contents***Research and Development.***September 30,**

| <b>(dollars in thousands)</b> | <b>2008</b> | <b>2007</b> | <b>\$ Change</b> | <b>% Change</b> |
|-------------------------------|-------------|-------------|------------------|-----------------|
| Three months ended            | \$ 6,396    | \$ 5,702    | \$ 694           | 12.2%           |
| % of revenue                  | 9.6%        | 14.8%       |                  |                 |
| Nine months ended             | \$ 19,797   | \$ 16,463   | \$ 3,334         | 20.3%           |
| % of revenue                  | 11.3%       | 15.3%       |                  |                 |

Research and development expense consists primarily of product research and development, clinical trial costs, regulatory and clinical functions, and employee (shareowner) related expenses.

The increase in research and development costs in the periods presented are primarily due to increases in compensation and other shareowner related expenses of \$0.5 million and \$2.1 million for the three- and nine-month periods ended September 30, 2008, respectively, compared to the same periods in 2007, primarily due to increased headcount to support our product development and enhancement efforts. We expect research and development costs to continue to increase in absolute dollars for the foreseeable future in support of our ongoing development activities and planned clinical trial activities; however, as a percentage of revenue these costs are expected to decrease in the near term and then stabilize over time.

*In-Process Research and Development.*

In 2008, we recorded in-process research and development (IPRD) charges of \$4.2 million related to the acquisition of pedicle screw technology in the first quarter of 2008 and \$16.7 million related to the Osteocel Biologics Business Acquisition during the third quarter of 2008. As of the respective dates of the acquisitions, the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in-process had no alternative future uses. Accordingly, the amounts were charged to expense on the acquisition dates.

*Interest and Other Income, Net***September 30,**

| <b>(dollars in thousands)</b> | <b>2008</b> | <b>2007</b> | <b>\$ Change</b> | <b>% Change</b> |
|-------------------------------|-------------|-------------|------------------|-----------------|
| Three months ended            | \$ (146)    | \$ 1,302    | \$ (1,448)       | (111.2%)        |
| % of revenue                  | (0.2)%      | 3.4%        |                  |                 |
| Nine months ended             | \$ 764      | \$ 4,789    | \$ (4,025)       | (84.0%)         |
| % of revenue                  | 0.4%        | 4.5%        |                  |                 |

Interest and other income, net, consists primarily of interest income earned on marketable securities offset by interest expense incurred related to the Company's convertible debt offering signed in March 2008. For the nine months ended September 30, 2007, this category also includes, other income of \$0.4 million related to our relinquishment of a right of first refusal to certain technology associated with the 2005 acquisition of RSB Spine LLC and other income of \$0.3 million for an insurance claim settlement. Excluding these items, interest and other income, net, decreased in the periods presented due to (i) \$1.7 million and \$3.8 million in interest expense for the three- and nine-month periods ended September 30, 2008, respectively, related to the convertible debt offering, and (ii) higher balances in marketable securities offset by lower interest rates resulting in an increase of \$0.2 million and \$0.3 million for the three- and nine-month periods ended September 30, 2008, respectively.

*Stock-Based Compensation***Three Months Ended  
September 30,****Nine Months Ended  
September 30,**

| <b>(in thousands)</b>                       | <b>2008</b> | <b>2007</b> | <b>2008</b> | <b>2007</b> |
|---------------------------------------------|-------------|-------------|-------------|-------------|
| Sales, marketing and administrative expense | \$ 4,499    | \$ 2,801    | \$ 13,541   | \$ 8,323    |
| Research and development expense            | 922         | 563         | 2,178       | 1,654       |

# Edgar Filing: NUVASIVE INC - Form 10-Q

|                                        |          |          |           |          |
|----------------------------------------|----------|----------|-----------|----------|
| Total stock-based compensation expense | \$ 5,421 | \$ 3,364 | \$ 15,719 | \$ 9,977 |
|----------------------------------------|----------|----------|-----------|----------|

We granted approximately 1.8 million and 1.3 million options in the first nine months of 2008 and 2007, respectively, with a per option grant date weighted average fair value of \$14.49 and \$10.48, respectively. We recognize stock-based compensation expense on an accelerated basis in accordance with FIN 28, which effectively results in the recognition of approximately 60% of the total compensation expense for a particular option within 12 months of its grant date. The increases in stock-based compensation expense in the three- and nine-month periods ended September 30, 2008 compared to the same periods in 2007 are due primarily to additional options granted in the 2008 periods and the increased weighted average fair value per option in 2008, in addition to increased participation in our Employee Stock Purchase Plan.

## **Table of Contents**

### **Liquidity and Capital Resources**

Since our inception in 1997, we have incurred significant losses and as of September 30, 2008, we had an accumulated deficit of approximately \$199.2 million. We have not yet achieved profitability, and do not expect to be profitable in 2008. We expect our sales, marketing and administrative expense and research and development expense will continue to grow and, as a result, we will need to generate significant net sales to achieve profitability. To date, our operations have been funded primarily with proceeds from the sale of our equity securities.

In March 2008, we issued \$230.0 million principal amount of 2.25% Convertible Senior Notes due 2013 (the Notes). The net proceeds from the offering, after deducting the initial purchasers' discount and costs directly related to the offering, were approximately \$208.4 million. We will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013.

Cash, cash equivalents and short-term and long-term marketable securities, was \$221.7 million at September 30, 2008 and \$89.7 million at December 31, 2007. The increase was due primarily to the net proceeds from our convertible debt financing transaction in March of 2008.

Net cash used in operating activities was \$9.8 million in the first three quarters of 2008 compared to \$1.6 million used in operating activities in the same period in 2007. We spent an incremental \$11.1 million during the first nine months of 2008 as compared to the same period in 2007 for inventory to support our increased operations and growing business and preparation for the introduction of NeuroVision M5, which represents a significant upgrade to our core MAS platform, which was introduced at the beginning of the fourth quarter of 2008.

Net cash used by investing activities was \$164.4 million in the first three quarters of 2008 compared to \$12.3 million provided by investing activities in the same period in 2007. The increase in net cash used by investing activities of \$176.7 million is primarily due to the net change of \$123.1 million in the cash used by the activity in our investment portfolio and to a \$20.1 million increase in capital asset purchases. Included in the \$20.1 million increase of capital expenditures over the prior year, is approximately \$8.4 million and \$10.9 million of expenditures related to the new facility and for the implementation of our new ERP system, respectively.

Net cash provided by financing activities was \$216.6 million in the first nine months of 2008 compared to \$4.1 million in the same period in 2007. The change in net cash provided by financing activities of \$212.5 million is primarily due to the receipt of net proceeds of \$208.4 million from the issuance of convertible debt in March 2008.

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 working capital requirements and of our capital expenditures for additional loaner assets, our operating results, and cash used in any future acquisitions. In addition, we expect to incur additional capital expenditures for leasehold improvements for the new headquarters facility. We have sufficient cash and investments on hand to finance our operations for the foreseeable future.

### ***Commitments***

#### ***Convertible Senior Notes***

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



**Table of Contents**

approximately \$208.4 million. We will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013 (the Maturity Date).

*Osteocel Biologics Business Acquisition*

In connection with the Osteocel Biologics Business Acquisition, we are required to make a non-contingent \$12.5 million payment to Osiris Therapeutics, Inc. (Osiris) for the transfer of the manufacturing facility Osiris currently utilizes to manufacture the Osteocel product. Also, we will make additional milestone-based contingent payments to Osiris not to exceed \$37.5 million based on meeting a combination of specific product delivery milestones and a sales performance milestone. Both the contingent and non-contingent payments to Osiris are payable in either cash or a combination of cash and stock, at our election.

*Building Leases*

On November 6, 2007, the Company entered into a 15-year lease agreement for the purpose of relocating our corporate headquarters to an approximately 140,000 square foot two-building campus style complex. Rental payments consist of base rent of \$2.43 per square foot, escalating at an annual rate of three percent over the 15-year period of the lease, plus related operating expenses. Relocation to the new facility began in the first quarter of 2008 and was completed in August 2008. In addition, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. Under the terms of this lease, and the lease of our previous headquarters, NuVasive is required to make minimum lease payments, including operating expenses as follows:

| <b>Year</b><br><b>(in thousands)</b> | <b>Previous</b><br><b>Headquarters</b> | <b>New</b><br><b>Headquarters</b> | <b>Total</b> |
|--------------------------------------|----------------------------------------|-----------------------------------|--------------|
| 2008                                 | \$ 310                                 | \$ 644                            | \$ 954       |
| 2009                                 | 1,267                                  | 5,151                             | 6,418        |
| 2010                                 | 1,305                                  | 5,801                             | 7,106        |
| 2011                                 | 1,344                                  | 6,003                             | 7,347        |
| 2012                                 | 921                                    | 6,214                             | 7,135        |
| Thereafter                           |                                        | 82,339                            | 82,339       |
|                                      | \$ 5,147                               | \$ 106,152                        | \$ 111,299   |

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

Our exposure to interest rate risk at September 30, 2008 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At September 30, 2008, we did not hold any material asset-backed investment securities and in 2007 and 2008, we did not realize any losses related to asset-backed investment securities.

*Interest Rate Risk.* Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments.

*Foreign Currency Exchange Risk.* We have operated mainly in the United States of America, and the majority of our sales since inception have been made in U.S. dollars. Further, the majority of our sales to international markets have been to independent distributors in transactions conducted in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

**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 recognizes 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 is 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, 2008. Based on such evaluation, our management has concluded as of September 30, 2008, the Company's disclosure controls and procedures are effective.

**Table of Contents**

*Changes in Internal Control over Financial Reporting.* We are involved in ongoing evaluations of internal controls. In anticipation of the filing of this Form 10-Q, our Chief Executive Officer and Chief Financial Officer, with the assistance of other members of our management, performed an evaluation of any change in internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is likely to materially affect, our internal controls over financial reporting. During the third quarter of 2008, we implemented an Enterprise Resource Planning (ERP) system which is expected to improve and enhance internal controls over financial reporting. This ongoing implementation has materially changed how transactions are being processed and has also changed the structure and operation of some internal controls. While the ERP changes materially affected our internal control over financial reporting during the current quarter, the implementation has proceeded to date without material adverse effects on our internal control over financial reporting.

Except for the ERP implementation described above, there have been no other changes in our internal control over financial reporting during the three months ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

As previously reported, we have been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA's willed body program. We had been dismissed from these lawsuits by the trial court but the decision was appealed and in July 2008, the appellate court reversed the trial court's decision to dismiss us from these lawsuits. We are currently appealing the decision of the appellate court to the Supreme Court of California, which has agreed to hear our appeal.

On August 18, 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, alleging that certain of our products (the XLIF procedure, CoRoent XL, Gradient, MaXcess, SpheRx Guide Assembly, SpheRx DBR, SpheRx DBR Guide, and Helix) infringe, or contribute to the infringement of, twelve U.S. patents: Nos. 5,860,973; 5,772,661; 6,936,051; 6,936,050; 6,916,320; 6,945,933; 7,008,422; 6,530,929; 6,235,028; 6,969,390; 6,428,542; 6,592,586 owned by Medtronic (Medtronic Patents). Medtronic is seeking unspecified monetary damages and a court injunction against future infringement by NuVasive. On October 6, 2008, Medtronic filed an amended complaint dropping their claims of infringement relating to U.S. Patent Nos. 7,008,422; 6,530,929; 6,235,028. On October 13, 2008, we answered the complaint denying the allegations and filed counterclaims seeking dismissal of Medtronic's complaint and a declaration that we have not infringed and currently does not infringe any valid claim of the Medtronic Patents, including U.S. Patent Nos. 7,008,422; 6,530,929; 6,235,028 previously dropped by Medtronic. Additionally, we made counterclaims against Medtronic seeking the following relief: (i) Medtronic be 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.

**Item 1A. Risk Factors**

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2007 (the Risk Factors) together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. If any of the risks described in this report or in our annual report 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. There have been no material changes to the Risk Factors except as described below.

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

On August 18, 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, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by Medtronic. Medtronic is a large, publicly-traded corporation with significantly greater financial resources than us.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to the 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 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, and 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.



## **Table of Contents**

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 attorney's fees and costs, which may be substantial.

An unfavorable outcome for us in this patent litigation would significantly harm our business and may cause us to materially change our business model as we may be unable to commercialize some of our potential products or may have to cease some of our business operations. In addition, costs of defense and any damages resulting from the litigation may materially adversely affect our business and financial results. The 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.

### ***The recent financial crisis and general slowdown of the economy may adversely affect our liquidity and the liquidity of our customers.***

At September 30, 2008, we had \$104.3 million in cash and cash equivalents and \$117.3 million in investments in marketable debt securities. We have historically invested these amounts in U.S. treasuries and government agencies, corporate debt, money market funds, commercial paper and municipal bonds 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. It is unclear whether the recent declines are temporary or long-term in nature. If there are further declines in the value of our investment portfolio that are not temporary and we are unable to find alternative sources of liquidity, our results of operations, liquidity and financial condition may be adversely affected.

The liquidity of our customers and suppliers may also be affected by the current financial crisis. 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 current financial crisis and the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

### ***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;

Difficulties in integration of the operations, technologies, 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 assumption of certain known and unknown liabilities of the acquired companies; and

Difficulties in retaining key relationships with 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. Specifically, our recent Osteocel acquisition is the largest acquisition we have ever completed, with a potential total acquisition price of \$85 million. If we failed to properly value that business, or fail to generate expected revenues or profits from operation of that business, our results of operations will suffer.

Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have little experience as a company developing or marketing a particular product or technology (as is the case with the Osteocel biologic product). For example, we may not be able to successfully integrate an acquired company's operations, technologies, products and services, information systems and personnel into our

business, which will be required if we assume ownership of the Osteocel processing facility. Acquisitions may also further strain our existing financial and managerial controls, and divert management's attention away from our other business concerns.

***Our recent acquisition of the Osteocel business from Osiris Therapeutics may prove difficult to successfully integrate and could negatively impact our business.***

We recently acquired the Osteocel biologics business from Osiris Therapeutics, Inc. As part of this acquisition, we inherited the right and obligation to continue supplying the Osteocel product to the existing primary distributor of Osteocel, Orthofix N.V. Orthofix has an obligation to purchase a pre-determined amount of Osteocel from us, and our revenue projections for 2008 are largely dependent on these purchases. We do not have a history of dealing with Orthofix, and any failure of Orthofix to meet their contractual obligations will negatively impact our results of operations.

In addition, as part of the acquisition, Osiris will continue to act as our exclusive supplier of Osteocel for a period of 18 months. In that capacity, we will be highly dependent on Osiris for supply of Osteocel and any failure on their part to process and supply such product will negatively impact our ability to meet our obligations to existing distributors and to build inventory for future launch of our own sales.

The Osteocel product is processed from allograft, which is donated human tissue. Allograft is a supply-constrained material and there is ongoing risk that there will be insufficient supply to produce the necessary quantity of Osteocel. Allograft also carries with it the possibility of disease transmission, which could result in negative patient outcomes and negative publicity for our company.

Lastly, Orthofix unsuccessfully attempted to stop our acquisition of Osteocel by seeking a temporary restraining order to delay the acquisition. Although this attempt failed, it is possible that Orthofix will take further legal action to disrupt the acquisition or integration of the product, and may specifically assert that it has rights to Osteocel beyond 2008. If Orthofix attempts to assert any of these claims, such claims could result in fees related to litigation, settlement or judgment, which fees could negatively impact our results of operations.

**Table of Contents**

**Item 6. Exhibits**

**EXHIBIT INDEX**

| <b>Exhibit No</b> | <b>Description</b>                                                                                                                                                             |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1+              | Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.                                                      |
| 3.1 (1)           | Restated Certificate of Incorporation                                                                                                                                          |
| 3.2 (1)           | Restated Bylaws                                                                                                                                                                |
| 10.1(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Alexis V. Lukianov                                                                         |
| 10.2(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Keith C. Valentine                                                                         |
| 10.3(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Kevin C. O Boyle                                                                           |
| 10.4(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Patrick Miles                                                                              |
| 10.5(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Jeffrey P. Rydin                                                                           |
| 10.6(2)+          | Manufacturing Agreement, dated July 24, 2008 by and between the Company and Osiris Therapeutics, Inc.                                                                          |
| 10.7+             | Amendment to Manufacturing Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.                                                       |
| 10.8#             | Amendment No. 1 to 2004 Employee Stock Purchase Plan                                                                                                                           |
| 31.1              | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934                                             |
| 31.2              | Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934                                             |
| 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 |
| (1)               | Incorporated by reference to our Quarterly Report on Form 10-Q filed with                                                                                                      |



the Securities  
and Exchange  
Commission on  
August 13,  
2004.

- (2) Incorporated by  
reference to our  
Quarterly  
Report on Form  
10-Q filed with  
the Securities  
and Exchange  
Commission on  
August 8, 2008.

# Indicates  
management  
contract or  
compensatory  
plan.

+ Confidential  
portions omitted  
and filed  
separately with  
the U.S.  
Securities and  
Exchange  
Commission  
pursuant to  
Rule 24b-2  
promulgated  
under the  
Securities  
Exchange Act  
of 1934, as  
amended.

\* 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.

**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 7, 2008

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

Date: November 7, 2008

By: /s/ Kevin C. O Boyle  
Kevin C. O Boyle  
*Executive Vice President and Chief Financial Officer*  
27

---

**Table of Contents**

**EXHIBIT INDEX**

| <b>Exhibit No</b> | <b>Description</b>                                                                                                                                                             |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1+              | Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.                                                      |
| 3.1 (1)           | Restated Certificate of Incorporation                                                                                                                                          |
| 3.2 (1)           | Restated Bylaws                                                                                                                                                                |
| 10.1(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Alexis V. Lukianov                                                                         |
| 10.2(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Keith C. Valentine                                                                         |
| 10.3(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Kevin C. O Boyle                                                                           |
| 10.4(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Patrick Miles                                                                              |
| 10.5(2)#          | Compensation Letter Agreement, dated August 5, 2008, by and between the Company and Jeffrey P. Rydin                                                                           |
| 10.6(2)+          | Manufacturing Agreement, dated July 24, 2008 by and between the Company and Osiris Therapeutics, Inc.                                                                          |
| 10.7+             | Amendment to Manufacturing Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.                                                       |
| 10.8#             | Amendment No. 1 to 2004 Employee Stock Purchase Plan                                                                                                                           |
| 31.1              | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934                                             |
| 31.2              | Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934                                             |
| 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 |
| (1)               | Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange                                                                          |

Commission on  
August 13,  
2004.

- (2) Incorporated by  
reference to our  
Quarterly  
Report on Form  
10-Q filed with  
the Securities  
and Exchange  
Commission on  
August 8, 2008

# Indicates  
management  
contract or  
compensatory  
plan.

+ Confidential  
portions omitted  
and filed  
separately with  
the U.S.  
Securities and  
Exchange  
Commission  
pursuant to  
Rule 24b-2  
promulgated  
under the  
Securities  
Exchange Act  
of 1934, as  
amended.

\* 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.