

NUVASIVE INC  
Form 10-Q  
August 08, 2007

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended June 30, 2007**

**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.)**

**4545 Towne Centre Court**  
**San Diego, CA 92121**

**(Address of principal executive offices, including zip code)**

**(858) 909-1800**

**(Registrant's telephone number, including area code)**

**N/A**

**(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, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

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 July 31, 2007, there were 34,880,690 shares of the registrant's common stock outstanding.

**NUVASIVE, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**June 30, 2007**  
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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

**NUVASIVE, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(unaudited and in thousands, except per share data)*

	<b>June 30, 2007</b>	<b>December 31, 2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 44,218	\$ 41,476
Short-term investments	44,460	73,930
Accounts receivable, net	23,261	18,960
Inventory, net	26,763	18,636
Prepaid expenses and other current assets	1,628	1,716
Total current assets	140,330	154,718
Property and equipment, net of accumulated depreciation	33,917	30,573
Intangible assets, net of accumulated amortization	25,335	8,441
Long-term investments	9,987	1,996
Other assets	451	456
Total assets	\$ 210,020	\$ 196,184
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 10,694	\$ 8,937
Accrued payroll and related expenses	8,056	8,477
Royalties payable	1,424	1,068
Total current liabilities	20,174	18,482
Long-term liabilities	1,112	1,399
Commitments and contingencies		
Stockholders' equity:		
Common stock, 70,000 shares authorized 34,842 and 33,929 issued and outstanding at June 30, 2007 and December 31, 2006, respectively	35	34
Additional paid-in capital	353,311	333,009
Accumulated other comprehensive loss	(61)	(25)
Accumulated deficit	(164,551)	(156,715)
Total stockholders' equity	188,734	176,303
Total liabilities and stockholders' equity	\$ 210,020	\$ 196,184

See accompanying notes to unaudited condensed consolidated financial statements.

**NUVASIVE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(unaudited and in thousands, except per share data)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenues	\$35,618	\$ 22,724	\$68,838	\$ 42,409
Cost of goods sold	6,710	5,087	12,417	8,967
Gross Profit	28,908	17,637	56,421	33,442
Operating expenses:				
Sales, marketing and administrative	28,027	22,996	56,067	44,015
Research and development	5,925	4,448	11,677	8,438
Development milestone expense		10,500		10,500
Total operating expenses	33,952	37,944	67,744	62,953
Interest and other income, net	1,628	1,837	3,487	2,935
Net loss	\$ (3,416)	\$ (18,470)	\$ (7,836)	\$ (26,576)
Net loss per share:				
Basic and diluted	\$ (0.10)	\$ (0.56)	\$ (0.23)	\$ (0.85)
Weighted average shares basic and diluted	34,654	33,113	34,485	31,394

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	<b>2007</b>	<b>2006</b>
<b>Operating activities:</b>			
Net loss	\$	(7,836)	\$ (26,576)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization		5,933	3,545
Stock-based compensation		6,613	6,823
Other non-cash adjustments		1,179	1,273
Changes in operating assets and liabilities:			
Accounts receivable		(4,621)	(2,157)
Inventory		(8,868)	(5,333)
Prepaid expenses and other current assets		(39)	(819)
Accounts payable and accrued liabilities		1,926	3,158
Accrued payroll and related expenses		(421)	(307)
Development milestone payable			10,500
Net cash used in operating activities		(6,134)	(9,893)
<b>Investing activities:</b>			
Cash paid for acquisition of Radius Medical, LLC		(6,970)	
Purchases of property and equipment		(8,527)	(8,561)
Sales of short-term investments		79,050	10,950
Purchases of short-term investments		(49,580)	(45,455)
Sales of long-term investments		6,000	
Purchases of long-term investments		(13,991)	
Other assets		5	(291)
Net cash provided by (used in) investing activities		5,987	(43,357)
<b>Financing activities:</b>			
Payment of long-term liabilities		(300)	(300)
Issuance of common stock, including net proceeds from secondary offering		3,189	143,065
Net cash provided by financing activities		2,889	142,765
Increase in cash and cash equivalents		2,742	89,515
Cash and cash equivalents at beginning of period		41,476	12,545
Cash and cash equivalents at end of period	\$	44,218	\$ 102,060
<b>Supplemental disclosure of non-cash transaction:</b>			
Issuance of common stock in connection with acquisition of Radius Medical LLC	\$	10,501	\$

See accompanying notes to unaudited condensed consolidated financial statements.

**NuVasive, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

*1. Description of Business*

*Description of Business.* NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company designs, develops and markets products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. Its current product portfolio is focused on applications for lumbar, thoracic and cervical spine fusion. The principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, as well as a growing offering of cervical and lumbar motion preservation products. The Company's products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. MAS combines NeuroVision®, a nerve avoidance system, MaXcess®, a minimally invasive surgical system, and specialized implants.

The Company loans its NeuroVision systems to surgeons and hospitals who purchase 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 also sells a small quantity of surgical instrument sets and NeuroVision systems to hospitals. The Company also 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 or from limited disposable inventories stored at sales agents' sites.

The Company also focuses significant efforts on a research and development pipeline emphasizing both MAS and motion preservation products such as total disc replacement. In particular, the Company has a pivotal clinical study underway (which began in the third quarter of 2006) with respect to our NeoDisc cervical disc replacement device.

*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 management's opinion, 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.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2006 included in NuVasive's Annual Report on Form 10-K filed with the Securities and Exchange Commission. Operating results for the three and six months ended June 30, 2007 and 2006 are not necessarily indicative of the results that may be expected for any other interim period or for the full year ending December 31, 2007. The balance sheet at December 31, 2006 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.

*3. Acquisition of Radius Medical LLC*

On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by NuVasive of substantially all of Radius' right, title and interest in and to the assets used by Radius in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. The Company has included the results of the acquired Radius operations in its statement of operations from the date of the acquisition. The Company does not consider the Radius acquisition material to its results of operations or financial position, and therefore is not presenting pro forma information.



*Reasons for the Radius Acquisition.* The transaction provides NuVasive with a biologic product, Formagraft®, a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. Formagraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with the Company's objectives of developing or acquiring innovative technologies.

In connection with the transaction, Radius received net cash payments of approximately \$5.0 million and 451,677 unregistered shares of NuVasive common stock, which were subsequently registered. NuVasive also funded at closing \$2 million in cash into an escrow account, which will be maintained for a period of eighteen months from the acquisition date to secure the indemnification obligations of Radius and its members under the Purchase Agreement. At the end of this eighteen month period, the funds held in escrow that are not subject to pending indemnification claims will be disbursed to Radius.

As part of the acquisition, NuVasive also acquired, as of January 23, 2007, all of Radius' right, title and interest in and to that certain Supply Agreement dated November 4, 2004, by and between Maxigen Biotech, Inc. (MBI) and Radius, as amended to date (the MBI Supply Agreement). MBI is a Taiwanese company that manufactures Formagraft and owns a portion of the core technology underlying Formagraft. Under the MBI Supply Agreement and following NuVasive's succession to Radius' interest therein, MBI has agreed to exclusively sell to NuVasive (and NuVasive has agreed to exclusively purchase from MBI) such quantities as NuVasive may order of all current and future products manufactured by MBI for use as synthetic bone graft substitutes consisting of certain collagens or ceramics, and grants exclusive distributor rights to NuVasive for North America, EU countries, South American and Central American countries, Australia, New Zealand and their respective territories (with additional territories on a non-exclusive basis). NuVasive will be required to purchase a minimum of \$0.9 million of product from MBI per calendar year. MBI has also granted to NuVasive an exclusive, perpetual, royalty-free license to use all such MBI products, and all related proprietary rights and proprietary information relating thereto, including without limitation, rights to conduct research and development, develop modifications, improvements or additional products and to use and sell such improvements and additional products. Radius was required to pay MBI a one-time license fee in consideration for the above described license, which obligation was satisfied by Radius.

*Purchase Price.* The total purchase consideration consisted of (*in thousands, except share and per share data*):

Net cash paid to Radius	\$ 4,970
NuVasive common stock issued on the closing date (451,667 shares at \$23.25 per share)	10,501
Cash deposited in escrow	2,000
Acquisition-related costs, consisting primarily of professional fees	306
Total purchase price	\$ 17,777

The Company has allocated the total purchase consideration to the assets acquired based on their respective fair values at the acquisition date. The following table summarizes the preliminary allocation of the purchase price (*in thousands*).

MBI Supply Agreement	\$ 9,400
Licensed technology	7,145
Inventory	132
Goodwill	1,100
Total purchase price	\$ 17,777

In connection with the acquisition of Radius, NuVasive made a separate \$2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. The Company accounts for this investment at cost.

#### 4. Allowances

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The balances of the allowances for doubtful accounts and excess and obsolete inventory are as follows:

<b>(in thousands)</b>	<b>June 30, 2007</b>	<b>December 31, 2006</b>
Allowance for doubtful accounts	\$ 915	\$ 737
Allowance for excess and obsolete inventory	\$ 3,973	\$ 2,856

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### 5. Net Loss Per Share

NuVasive computes net loss per share using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. Due to the net loss reported in all periods, the effect of stock options and warrants is anti-dilutive and is therefore excluded. Although these options and warrants are currently not included in the net loss per share calculation, they could be dilutive when, and if, the Company reports future earnings.

(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Numerator:				
Net loss	\$ (3,416)	\$ (18,470)	\$ (7,836)	\$ (26,576)
Denominator for basic and diluted net loss per share:				
Weighted average common shares outstanding	34,654	33,113	34,485	31,394
Basic and diluted net loss per share	\$ (0.10)	\$ (0.56)	\$ (0.23)	\$ (0.85)

### 6. Comprehensive Loss

Comprehensive loss which includes the unrealized gain (loss) on short-term investments and foreign currency translation adjustments for the three and six month periods ended June 30, 2007 and 2006, did not differ significantly from the reported net loss.

### 7. Stock Based Compensation

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options 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 options granted in the three and six month periods ended June 30, 2007 and 2006 are as follows:

	Three and Six Months Ended June 30, 2007	Three and Six Months Ended June 30, 2006
<b>Stock Options</b>		
Volatility	50%	65%
Expected term (years)	2.5 to 4.5	2.5 to 4.5
Risk free interest rate	4.51% to 4.92%	4.5% to 5.1%
Expected dividend yield	0%	0%
<b>ESPP</b>		
Volatility	50%	65%
Expected term (years)	0.5	0.5
Risk free interest rate	4.45% to 4.86%	5%
Expected dividend yield	0%	0%

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

(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Sales, marketing and administrative expense	\$ 2,894	\$ 2,481	\$ 5,522	\$ 5,270
Research and development expense	575	741	1,091	1,553
Stock-based compensation expense	\$ 3,469	\$ 3,222	\$ 6,613	\$ 6,823

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 Plans* (FIN 28). As of June 30, 2007, there was \$14.5 million of unrecognized stock-based compensation expense. This cost is expected to be recognized over a weighted-average period of approximately 1.4 years.

#### 8. Reclassifications

Certain reclassifications to prior period information have been made for consistent presentation. Specifically, in 2006 the Company classified all bonus expense in sales, marketing and administrative expense in the statement of operations. Beginning in 2007, such expense is classified according to employee function. Expense of \$0.3 million and \$0.4 million for the three and six months periods ended June 30, 2006, respectively, has been reclassified from sales, marketing and administrative expense to research and development expense to conform to this presentation change.

#### 9. Income Taxes

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The adoption of FIN 48 did not impact the Company's consolidated financial condition, results of operations or cash flows. At January 1, 2007, the Company had net deferred tax assets of \$58.6 million. The deferred tax assets are primarily composed of federal and state tax net operating loss (NOL) carryforwards, federal and state research and development (R&D) credit carryforwards, amortization of capital assets, and stock compensation. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset.

**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 in our Annual Report on Form 10-K for the year ending December 31, 2006. 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 \$3.6 billion in the United States. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>tm</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, like our SpheRx<sup>®</sup> pedicle screw system and CoRoent<sup>®</sup> suite of implants.

We also offer a suite of traditional spine surgery products, including a line of precision-machined cervical and lumbar allograft implants, a titanium surgical mesh system, and related instrumentation. Our Triad<sup>®</sup> and Extensure<sup>TM</sup> lines of bone allograft, in our patented saline packaging, are human bone that has been processed and precision shaped for transplant. We also offer fusion plates such as our SmartPlate<sup>®</sup> Gradient CLP, a dynamic cervical plate.

We also have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion. In particular, we have a pivotal clinical study underway with respect to our NeoDisc cervical disc replacement device.

Since inception, we have been unprofitable. As of June 30, 2007, we had an accumulated deficit of \$164.6 million.

**Revenues.** The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue in the near term. We loan our 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 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 historically represent less than 10% of our total stock of loaner surgical assets. Our implants and disposables are currently sold and shipped from our San Diego and Memphis facilities or from limited disposable inventories stored at our sales agents' sites. We recognize revenue for disposables or implants used upon receiving a purchase order from the

hospital indicating product use or implantation. In 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.* 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 agencies and our own sales personnel. 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. Our exclusive sales force includes independent exclusive sales agents and directly-employed sales professionals.

*Acquisition of Radius Medical LLC.* On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by us of substantially all of Radius' right, title and interest in and to the assets used by Radius in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. The transaction provides us with a biologic product, Formagraft®, a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. Formagraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with our objective of developing or acquiring innovative technologies.

### **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) and regulations of the Securities and Exchange Commission. 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 and income taxes. 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) collectibility 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 NeuroVision units and 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.

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 consist of purchased technology acquired in 2005 and 2007 and the license agreement asset acquired in 2007, and are amortized on a straight-line basis over their estimated useful lives ranging from 14 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 impairment losses on long-term intangible assets through June 30, 2007.

*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 December 31, 2006 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 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, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. 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 consolidated financial statements and notes thereto included in this report, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2006 included in Annual Report on Form 10-K filed with the Securities and Exchange Commission, which contain accounting policies and other disclosures required by GAAP.

## **Results of Operations**

### **Revenues**

	June 30,			%
<i>(dollars in thousands)</i>	2007	2006	\$ Change	Change
Three months ended	\$35,618	\$22,724	\$12,894	56.7%
Six months ended	\$68,838	\$42,409	\$26,429	62.3%

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 SpheRx pedicle screw system and CoRoent suite of products. In addition, in mid-2006, we completed our transition to an exclusive sales force, which has increased the amount of effort focused on selling our products as well as the overall market penetration.

Over time, the percentage contribution to total revenue from our non-MAS products has decreased. This is due in large part to the focus of the product development and commercialization efforts to our MAS platform.

### **Cost of Goods Sold**

	June 30,			%
<i>(dollars in thousands)</i>	2007	2006	\$ Change	Change
Three months ended	\$ 6,710	\$5,087	\$1,623	31.9%
% of revenue	18.8%	22.4%		
Six months ended	\$12,417	\$8,967	\$3,450	38.5%
% of revenue	18.0%	21.1%		

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

Cost of goods sold as a percentage of revenue has decreased over time due to (i) a higher portion of our sales coming from products with higher margins and (ii) efficiencies gained with growth. The increase in cost of goods sold in total dollars in the three and six month periods ended June 30, 2007 compared to the same periods in 2006, resulted primarily from (i) increased material costs of \$0.9 million and \$1.4 million, respectively, primarily to support revenue growth; (ii) increased depreciation expense of \$0.6 million and \$1.6 million, respectively, incurred on the increased amount of surgical instrument sets we hold for use in surgeries; and (iii) for the six month period ended June 30, 2007, increased reserves taken against inventory as a result of planned product introductions and enhancements. We expect cost of goods sold, as a percentage of revenue, to remain relatively consistent for the foreseeable future.

**Operating Expenses***Sales, Marketing and Administrative.***June 30,**

<i>(dollars in thousands)</i>	<b>2007</b>	<b>2006</b>	<b>\$ Change</b>	<b>% Change</b>
Three months ended	\$28,027	\$22,996	\$ 5,031	21.9%
% of revenue	78.7%	101.2%		
Six months ended	\$56,067	\$44,015	\$12,052	27.4%
% of revenue	81.4%	103.8%		

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 headcount increases in the second half of 2006 and in 2007. Increases in costs dependent on revenue, such as sales force compensation, royalty expense, and shipping costs were \$2.8 million and \$7.0 million for the three and six month periods ended June 30, 2007, respectively. Total costs related to our sales force, as a percent of revenue, decreased from 50% to 38% in the six months ended June 30, 2007 compared to the same period in 2006, respectively. Increases in costs as a result of overall company growth and administrative, support and marketing headcount increases, such as compensation and other shareowner related costs, stock-based compensation, and computer, facility and machinery and equipment costs, were \$1.0 million and \$2.4 million for the three and six month periods ended, June 30, 2007, respectively. In addition, amortization increased \$0.3 million and \$0.5 million in the three and six month periods ending June 30, 2007 compared to the same period in 2006, respectively, as a result of the technology and license agreement assets acquired in the acquisition of Radius Medical LLC.

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. Our exclusive sales force consists of independent sales agents and directly-employed sales personnel. 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 begin to see the synergies of investments we have made (such as our sales force exclusivity transition).

*Research and Development.***June 30,**

<i>(dollars in thousands)</i>	<b>2007</b>	<b>2006</b>	<b>\$ Change</b>	<b>% Change</b>
Three months ended	\$ 5,925	\$4,448	\$1,477	33.2%
% of revenue	16.6%	19.6%		
Six months ended	\$11,677	\$8,438	\$3,239	38.4%
% of revenue	17.0%	19.9%		

Research and development expense consists primarily of product research and development, clinical trial costs, regulatory and clinical functions, and shareowner-related expenses. In the third quarter of 2006, we commenced patient enrollment in our NeoDisc clinical trial, which resulted in increased research and development costs subsequent to this date. We expect to see an increase in NeoDisc related costs in the second half of 2007 associated with accelerated enrollment.

The increases in research and development costs in the periods presented are primarily due to increases in (i) compensation and other shareowner related expenses of \$0.7 million and \$1.7 million for the three and six month periods ended June 30, 2007, respectively, compared to the same periods in 2006 primarily due to increased headcount to support our product development and enhancement efforts; and (ii) NeoDisc trial costs of \$0.8 million

and \$1.8 million for the three and six month periods ended June 30, 2007, respectively, compared to the same periods in 2006.

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 moderately over time.

***Interest and Other Income, Net***

<i>(dollars in thousands)</i>	June 30,		<b>\$ Change</b>	<b>% Change</b>
	<b>2007</b>	<b>2006</b>		
Three months ended	\$ 1,628	\$ 1,837	\$ (209)	(11.4)%
% of revenue	4.6%	8.1%		
Six months ended	\$ 3,487	\$ 2,935	\$ 552	18.8%
% of revenue	5.1%	6.9%		

Interest and other income, net consists primarily of interest income. This category also includes, in the first quarter of 2007, 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, in the second quarter of 2007, other income of \$0.3 million for an insurance claim settlement. Excluding these items of other income, interest and other income, net decreased in the periods presented due to lower investment balances in the 2007 periods.

***Stock-Based Compensation***

<i>(in thousands, except per share amounts)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Sales, marketing and administrative expense	\$ 2,894	\$ 2,481	\$ 5,522	\$ 5,270
Research and development expense	575	741	1,091	1,553
Stock-based compensation expense	\$ 3,469	\$ 3,222	\$ 6,613	\$ 6,823

We granted 1.2 million options in the first six months of 2007 compared to 1.3 million options granted in the first six months of 2006 at per option weighted average valuations of \$10.26 and \$9.62, respectively. We recognize stock-based compensation expense on an accelerated basis in accordance with FIN 48, 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 changes in stock-based compensation expense in the 2007 periods presented compared to the same periods in 2006 are due primarily to the increased weighted average valuation per option in 2007. For the six month period ended June 30, 2007 compared to the same period in 2006, the impact of the increased valuation is offset by lower consultant options expense.

We decreased the expected future volatility estimate used in the valuation of the options granted in 2007 to 50% from the 65% used to value options granted in 2006. The decreased expected future volatility estimate reflects management's evaluation of NuVasive's historical stock price data, particularly since the date of our initial public offering in May 2004. The remaining assumptions used to estimate the fair value of stock options granted in the periods presented are comparable with the 2006 full year assumptions.

***Acquisition of Radius Medical LLC***

On January 23, 2007, we acquired assets used by Radius Medical LLC, or Radius, in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. In connection with the transaction, we made net cash payments totaling \$5.0 million and issued 451,677 unregistered shares of our common stock, which were subsequently registered. We also funded at closing \$2.0 million in cash into an escrow account for the benefit of Radius, which will be maintained for a period of 18 months. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc. (MBI) with respect to product manufacture. MBI is a Taiwanese company who manufactures Formagraft and owns a portion of the core technology.



In connection with the acquisition of Radius, we made a separate \$2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. We account for this investment at cost.

### **Liquidity and Capital Resources**

Since our inception in 1997, we have incurred significant losses and as of June 30, 2007, we had an accumulated deficit of approximately \$164.6 million. We have not yet achieved profitability, and do not expect to be profitable in 2007 after considering stock compensation expense. We expect our research and development, sales, marketing and general and administrative expenses 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.

Cash, cash equivalents and short-term and long-term investments, excluding our investment in MBI, was \$96.7 million at June 30, 2007 and \$117.4 million at December 31, 2006. The decrease was due primarily to the cash used to fund our operations, the acquisition of Radius Medical LLC and our \$2.0 million investment in MBI.

Net cash used in operating activities was \$6.1 million in the first half of 2007 compared to \$9.9 million in the 2006 period. The decrease in net cash used in operating activities of \$3.8 million was primarily a result of our improved operating results in the period offset by increases in net accounts receivable and inventory balances to support our growing business.

Net cash provided by investing activities was \$6.0 million in the first half of 2007 compared to net cash used in investing activities of \$43.4 million in the 2006 period. The increase in net cash provided by investing activities of \$49.3 million is primarily due to the net change of \$58.0 million in the cash provided by the activity in our investment portfolio offset by cash of \$7.0 million used in the acquisition of Radius Medical LLC and our \$2.0 million investment in MBI.

Net cash provided by financing activities was \$2.9 million in the first half of 2007 compared to \$142.8 million in the 2006 period. The decrease in net cash provided by financing activities of \$139.9 million is primarily due to the receipt of net proceeds of \$142.0 million from the issuance of common stock in February 2006.

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. We have sufficient cash and investments on hand to finance our operations (as currently conducted) for the foreseeable future.

### **Commitments**

During the second quarter, we entered into material agreements for the acquisition and integration of a new enterprise resource planning software, or ERP, system. These agreements include a software license agreement with SAP America, Inc., pursuant to which we acquired software rights for the ERP software platform. The acquisition cost of the software platform is not material to our business. Pursuant to this agreement, SAP agreed to provide ERP software to us, provide ongoing support during the software implementation process, and to provide longer term technical and professional support. In addition, we executed a customer agreement with International Business Machines Corporation, or IBM, pursuant to which we engaged IBM to act as the primary implementer of our ERP software. IBM will provide implementation, consulting, and software customization services during the course of our ERP implementation and beyond. The costs expected to be incurred under the IBM contract will be material to our business; however, at this time the costs are not quantifiable with a reasonable certainty. We will quantify these costs in future quarters. We expect to capitalize as long-term assets substantially all of the costs incurred in connection with these agreements and subsequently amortize such assets over a useful life of 7 years.

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

Our exposure to interest rate risk at June 30, 2007, 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.

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. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

*Interest Rate Risk.* Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment activities is to preserve the principal while at the same time maximizing yields without significantly increasing the risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in instruments that meet high credit quality standards, as specified in our investment policy. None of our investments are held for trading purposes. Our policy also limits the amount of credit exposure to any one issue, issuer and type of instrument.

### **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 June 30, 2007. Based on such evaluation, our management has concluded as of June 30, 2007, the Company's disclosure controls and procedures are effective.

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

## **PART II. OTHER INFORMATION**

### **Item 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 for the year ended December 31, 2006 together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. The risks described in our annual report have not materially changed since that report was filed. 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.

**Item 4. Submission of Matters to a Vote of Security Holders**

Our Annual Meeting of Stockholders was held on May 24, 2007. Our stockholders acted upon the following three proposals at the meeting:

1. To elect three Class III directors to hold office until the 2010 Annual Meeting of Stockholders and until their successors are elected and qualified.
2. To ratify the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2007.
3. To approve, solely to preserve our ability to receive corporate income tax deductions that may become available pursuant to Internal Revenue Code Section 162(m), the material terms of our 2004 Equity Incentive Plan as well as limits on the number of stock awards and amount of cash awards that may be granted to any employee during any given fiscal year.

With respect to the first proposal, our stockholders voted and approved the election of three Class III directors to hold office until the 2010 Annual Meeting of Stockholders or until their earlier resignation or removal. The directors elected and the votes cast were as follows:

Names of Directors Elected	Number of Shares:	For	Withheld
Alexis V. Lukianov:		25,202,117	389,348
Jack R. Blair:		25,289,185	302,280
James C. Blair, Ph.D.		24,551,246	1,040,219

The following are the other members of our board of directors whose terms continued after the meeting: Lesley H. Howe; Robert J. Hunt; Peter C. Farrell, Ph.D.; and Hansen Yuan, M.D. In addition, as previously announced, on June 6, 2007 Eileen M. More was elected as a new director of the Company to fill an existing vacancy, serving a term that expires at the Annual Meeting of Stockholders in 2009.

At the Annual Meeting, our stockholders also voted upon and ratified the Audit Committee's selection of Ernst & Young, LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2007, by the following vote:

<u>Number of Shares Voted</u>			
For	Against	Abstain	Broker Non-Votes
25,540,942	46,007	4,516	0

In addition, at the Annual Meeting, our stockholders approved the material terms of our 2004 Equity Incentive Plan. This approval was requested solely to preserve our ability to receive corporate income tax deductions that may become available pursuant to Internal Revenue Code Section 162(m), and included new limits on the number of stock awards and amount of cash awards that may be granted to any employee during any given fiscal year. The votes cast were as follows:

<u>Number of Shares Voted</u>			
For	Against	Abstain	Broker Non-Votes



19,791,518

690,948

198,942

4,910,057

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**Item 5. Other Information.**

During the second quarter, we entered into agreements for the acquisition and integration of a new enterprise resource planning software, or ERP, system. These agreements include a software license agreement with SAP America, Inc., pursuant to which we acquired software rights for the ERP software platform. The acquisition cost of the software platform is not material to our business. Pursuant to this agreement, SAP agreed to provide ERP software to us, provide ongoing support during the software implementation process, and to provide longer term technical and professional support. In addition, we executed a customer agreement with International Business Machines Corporation, or IBM, pursuant to which we engaged IBM to act as the primary implementer of our ERP software. IBM will provide implementation, consulting, and software customization services during the course of our ERP implementation and beyond. The costs expected to be incurred under the IBM contract will be material to our business; however, at this time the costs are not quantifiable with a reasonable certainty. We will quantify these costs in future quarters.

**Item 6. Exhibits**

**EXHIBIT INDEX**

<b>Exhibit No</b>	<b>Description</b>
3.1 (1)	Restated Certificate of Incorporation
3.2 (1)	Restated Bylaws
10.1	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.2	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
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.
	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.

**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: August 8, 2007

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

Date: August 8, 2007

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

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