

---

---

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 March 31, 2005**

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 000-30713



**Intuitive Surgical, Inc.**

(Exact name of Registrant as specified in its Charter)

**Delaware**

**77-0416458**

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification Number)

**950 Kifer Road**

**Sunnyvale, California 94086**

(Address of Principal Executive Offices including Zip Code)

**(408) 523-2100**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file 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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES ☒ NO ☐

The Registrant had 34,745,803 shares of Common Stock, \$0.001 par value per share, outstanding as of April 30, 2005.

---

---

**Intuitive Surgical, Inc.**  
**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Page No.**

Item 1. Financial Statements (Unaudited):

Condensed consolidated balance sheets as of March 31, 2005 and December 31, 2004 [1](#)

Condensed consolidated statements of operations for the three-month periods ended March 31, 2005 and March 31, 2004 [2](#)

Condensed consolidated statements of cash flows for the three-month periods ended March 31, 2005 and March 31, 2004 [3](#)

Notes to condensed consolidated financial statements [4](#)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations [13](#)

Item 3. Quantitative and Qualitative Disclosures About Market Risk [36](#)

Item 4. Controls and Procedures [36](#)

**PART II. OTHER INFORMATION**

Item 1. Legal Proceedings [37](#)

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds [41](#)

Item 3. Defaults Upon Senior Securities [42](#)

Item 4. Submission of Matters to a Vote of Security Holders [42](#)

Item 5. Other Information [42](#)

Item 6. Exhibits [42](#)

**PART I -- FINANCIAL INFORMATION**

Item 1. Financial Statements

**INTUITIVE SURGICAL, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**  
**(UNAUDITED)**

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
		<b>(See Note 1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 11,025	\$ 5,771
Investments.....	138,427	126,267
Accounts receivable, net.....	31,407	35,443
Inventory.....	7,566	5,966
Prepays.....	3,945	3,032
Restricted cash.....	319	205
Total current assets.....	<u>192,689</u>	<u>176,684</u>
Property, plant and equipment, net.....	26,857	27,065
Restricted cash.....	--	319
Intangible assets, net.....	5,755	6,221
Goodwill.....	143,332	143,332
Other assets.....	567	608
Total assets.....	<u><u>\$ 369,200</u></u>	<u><u>\$ 354,229</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable.....	\$ 6,482	\$ 4,485
Accrued compensation and employee benefits.....	5,907	10,321
Deferred revenue.....	16,862	15,372
Restructuring accrual.....	462	541
Other accrued liabilities.....	8,181	7,057
Current portion of notes payable.....	347	609
Total current liabilities.....	<u>38,241</u>	<u>38,385</u>
Deferred revenue.....	420	505
Other accrued liabilities.....	342	407
Total non-current liabilities.....	<u>762</u>	<u>912</u>
Commitments and contingencies.....	--	--
Stockholders' equity:		
Preferred stock, 2,500,000 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of March 31, 2005 and and December 31, 2004, respectively.....	--	--
Common stock, 100,000,000 shares authorized, \$0.001 par value, 34,717,702 and 34,234,795 shares issued and outstanding as of March 31, 2005 and December 31, 2004, respectively.....	35	34
Additional paid-in capital.....	437,315	430,362
Accumulated deficit.....	(105,964)	(114,936)
Treasury stock, at cost, no shares and 4,461 shares at March 31, 2005 and December 31, 2004, respectively.....	--	(136)
Accumulated other comprehensive loss.....	(1,189)	(392)
Total stockholders' equity.....	<u>330,197</u>	<u>314,932</u>
Total liabilities and stockholders' equity.....	<u><u>\$ 369,200</u></u>	<u><u>\$ 354,229</u></u>

See accompanying notes to condensed consolidated financial statements.

---

**INTUITIVE SURGICAL, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)**  
**(UNAUDITED)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Sales:		
Products.....	\$ 34,183	\$ 22,471
Services.....	7,431	4,588
Total sales.....	<u>41,614</u>	<u>27,059</u>
Cost of sales:		
Products.....	11,155	8,813
Services.....	3,196	2,410
Total cost of sales.....	<u>14,351</u>	<u>11,223</u>
Gross profit.....	<u>27,263</u>	<u>15,836</u>
Operating costs and expenses:		
Selling, general, and administrative.....	14,204	10,243
Research and development.....	4,145	5,310
Total operating costs and expenses.....	<u>18,349</u>	<u>15,553</u>
Income from operations.....	<u>8,914</u>	<u>283</u>
Other income, net .....	723	606
Income before taxes.....	<u>9,637</u>	<u>889</u>
Income tax expense.....	533	36
Net income.....	<u>\$ 9,104</u>	<u>\$ 853</u>
Net income per share:		
Basic.....	<u>\$ 0.26</u>	<u>\$ 0.03</u>
Diluted .....	<u>\$ 0.25</u>	<u>\$ 0.02</u>
Shares used in computing net income per share:		
Basic.....	<u>34,517</u>	<u>33,282</u>
Diluted.....	<u>37,021</u>	<u>34,137</u>

See accompanying notes to condensed consolidated financial statements.

---

**INTUITIVE SURGICAL, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(IN THOUSANDS)**  
**(UNAUDITED)**

	<b>For the Three Months</b>	
	<b>Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>OPERATING ACTIVITIES:</b>		
Net income.....	\$ 9,104	\$ 853
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation.....	1,201	1,374
Benefit for doubtful accounts and write-offs.....	(58)	(106)
Gain on sales of property and equipment.....	--	(13)
Amortization of deferred compensation and stock compensation.....	--	15
Amortization of intangible assets.....	466	467
Changes in operating assets and liabilities:		
Accounts receivable.....	4,094	(399)
Prepays.....	(922)	(469)
Inventory.....	(1,601)	805
Other assets.....	39	(41)
Accounts payable.....	2,016	(1,228)
Accrued compensation and employee benefits.....	(4,384)	(1,647)
Restructuring accrual.....	(79)	38
Other accrued liabilities.....	1,067	(2,060)
Deferred revenue.....	1,405	1,496
Net cash provided by (used in) operating activities.....	<u>12,348</u>	<u>(915)</u>
<b>INVESTING ACTIVITIES:</b>		
Acquisition of property and equipment.....	(1,001)	(537)
Disposition of property and equipment.....	--	27
Release of restricted cash.....	204	269
Purchase of investments.....	(53,117)	(28,778)
Proceeds from sales and maturities of investments.....	40,125	28,147
Net cash used in investing activities.....	<u>(13,789)</u>	<u>(872)</u>
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock.....	6,958	4,116
Repayment of notes payable.....	(262)	(292)
Net cash provided by financing activities.....	<u>6,696</u>	<u>3,824</u>
Effect of exchange rate changes on cash and cash equivalents.....	(1)	(26)
Net increase in cash and cash equivalents.....	<u>5,254</u>	<u>2,011</u>
Cash and cash equivalents, beginning of period.....	5,771	11,335
Cash and cash equivalents, end of period.....	<u>\$ 11,025</u>	<u>\$ 13,346</u>

See accompanying notes to condensed consolidated financial statements.

**INTUITIVE SURGICAL, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(UNAUDITED)**

In this report, “Intuitive Surgical,” “Intuitive,” and the “Company” refer to Intuitive Surgical, Inc.

**NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all normal, recurring adjustments considered necessary for a fair presentation have been included. The consolidated balances at December 31, 2004 were derived from the audited financial statements included in Intuitive Surgical, Inc.’s Annual Report on Form 10-K (“Annual Report”) for the year ended December 31, 2004. The financial statements included in this report should be read in conjunction with the audited financial statements for the year ended December 31, 2004 included in the Annual Report. The results for the interim period ended March 31, 2005 are not necessarily indicative of the results to be expected for the full year ending December 31, 2005 or future operating periods. The condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from these estimates.

***Revenue Recognition***

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured.

In certain cases, revenue from direct system sales is earned pursuant to multiple-element arrangements that require judgment in the areas of customer acceptance, collectibility, the separability of units of accounting, and the fair value of individual elements. Effective July 1, 2003, the Company adopted the provisions of Emerging Issues Task Force (“EITF”) Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables,” on a prospective basis. The principles and guidance outlined in EITF 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and (b) determine how the arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The Company determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, service, installation, and training. Each of these elements represents individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements generally do not contain a general right of return relative to the delivered item. The Company determines fair value based on the price of the deliverable when it is sold separately or based on third-party evidence. In accordance with the guidance in EITF 00-21, the Company uses the residual method to allocate the arrangement consideration when it does not have fair value of the system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. Assuming all other criteria for revenue recognition have been met, the Company recognizes revenue for system sales when delivery and acceptance occurs, for installation and training when the services are rendered, and for service ratably over the service period, which is generally one year.

The Company’s distributors do not have price protection rights. The Company records an allowance for sales returns based on historical returns.

Revenue from sales of instruments and accessories is recognized upon delivery. Revenue related to future commitments under separately priced service contracts is deferred and recognized ratably over the service period. All costs associated with the provision of service and maintenance, including salaries, benefits, travel, spare parts and equipment, are recognized in cost of sales as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the condensed consolidated balance sheets.

The Company's *da Vinci* Surgical System, *Hermes* Control Center and *AESOP* Endoscope Positioner contain a software component. The Company believes that this software element is an incidental part of each system. The software element within the Company's products is not sold or marketed separately to customers, and the software does not operate independently of each system. Furthermore, the software development effort does not represent a significant cost to the Company relative to the overall development cost of the product. As such, the software the Company provides is incidental to each system as a whole and the software revenue guidance provided in Statement of Position ("SOP") 97-2, "Software Revenue Recognition," is not applicable to the Company's revenues.

### ***Stock-Based Compensation***

The Company applies Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock option plans. Accordingly, no compensation expense has been recorded for stock option grants issued with an exercise price equal to the market value of the underlying stock on the date granted. The Company has recorded stock-based compensation, primarily related to deferred compensation arising from the Company's initial public offering in 2000 and its acquisition of Computer Motion, Inc. ("Computer Motion") in June 2003. As required under Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," the Company has provided the following pro forma net income (loss) and pro forma net income (loss) per share disclosures for stock-based awards as if the fair value-based method defined in SFAS 123, "Accounting for Stock-Based Compensation," had been applied, amortizing expense ratably over the service period (amounts in thousands, except per share amounts):

		<b>Three Months Ended</b>	
		<b>March 31,</b>	
		<b>2005</b>	<b>2004</b>
Net income, as reported.....	\$	9,104	\$ 853
Add: Total stock-based employee compensation expense included in reported net income, net of \$0 related tax effect.....		--	15
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of \$0 related tax effect.....		(3,006)	(2,460)
Pro forma net income (loss).....	\$	<u>6,098</u>	<u>\$ (1,592)</u>
Net income (loss) per share:			
Basic - as reported.....	\$	0.26	\$ 0.03
Basic - pro forma.....	\$	0.18	\$ (0.05)
Diluted - as reported.....	\$	0.25	\$ 0.02
Diluted - pro forma.....	\$	0.16	\$ (0.05)

The fair value for each stock option award granted was estimated at the date of grant using the Black-Scholes option-pricing model, assuming no expected dividends and the following weighted average assumptions:

	Three Months Ended	
	March 31,	
	2005	2004
<b>Stock Option Plans:</b>		
Average risk free interest rate.....	3.65 %	2.66 %
Average expected life (years).....	4.0	4.0
Volatility.....	58 %	73 %

**Stock Purchase Plan:**

Average risk free interest rate.....	1.96 %	1.30 %
Average expected life (years).....	1.3	1.2
Volatility.....	49 %	62 %

***Recent Accounting Pronouncements***

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, "Share Based Payment" ("SFAS 123R"). This statement is a revision to SFAS 123, supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." SFAS 123R requires a public entity to expense the cost of employee services received in exchange for an award of equity instruments. SFAS 123R also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. SFAS 123R is effective for the fiscal years beginning after June 15, 2005. The Company will be required to adopt SFAS 123R at the beginning of the first quarter of 2006.

SFAS 123R permits public companies to choose between the following two adoption methods:

1. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date; or
2. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, the Company generally recognizes no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions. The impact on the results of operations and earnings per share had the Company adopted SFAS 123 is described in the stock-based compensation section above. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on the Company's overall financial position. SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company has not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations, nor the method of adoption for this new standard.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs," an amendment of ARB No. 43, Chapter 4, "Inventory Pricing." This standard clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and waste material (spoilage). Such abnormal expenses must be recognized in the period in which they are incurred. In addition, SFAS No. 151 requires the allocation of fixed production overhead to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect the adoption of this new accounting pronouncement to have a material impact on its financial position or results of operations.

In March 2004, the FASB issued EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," which provides new guidance for assessing impairment losses on debt and



equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF Issue No. 03-1; however, the disclosure requirements remain effective. The Company will evaluate the effect, if any, of EITF Issue No. 03-1 when final guidance is released.

## NOTE 2. CONCENTRATIONS OF RISK

Financial instruments which subject the Company to potential risk consist of its cash equivalents, short-term investments, and accounts receivable. The counterparties to the agreements relating to the Company's investment securities consist of various major corporations and financial institutions of high credit standing. The Company believes the financial risks associated with these financial instruments are minimal. For the three months ended March 31, 2005 and 2004, no customer accounted for more than 10% of total sales. The Company does not require collateral. The Company provides reserves for potential credit losses but has not experienced significant losses to date.

The Company's *da Vinci* Surgical System, *Hermes* Control Center, *AESOP* Endoscope Positioner and related instruments and accessories accounted for all of the Company's product sales for the three months ended March 31, 2005 and 2004. Purchases of key parts and components used to manufacture the Company's products are from limited supply sources. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

The Company operates in one segment: the development and marketing of products designed for use in surgery. The distribution of sales by geographic location is as follows (in thousands):

Three Months Ended			
March 31,			
	2005		2004
Domestic.....	\$ 36,857	\$	20,506
International.....	4,757		6,553
Total sales.....	<u>\$ 41,614</u>	<u>\$</u>	<u>27,059</u>

## NOTE 3. CASH AND CASH EQUIVALENTS

Intuitive Surgical considers all highly liquid investments with an original maturity from date of purchase of 90 days or less to be cash equivalents for the purpose of balance sheet and statement of cash flows presentation. The carrying value of cash and cash equivalents approximates market value at March 31, 2005 and December 31, 2004, respectively. Approximately \$3.2 million and \$1.7 million of money market instruments were included in cash and cash equivalents at March 31, 2005 and December 31, 2004, respectively.

## NOTE 4. SHORT-TERM INVESTMENTS

All short-term investments are classified as available-for-sale, and, therefore, are carried at fair market value. The Company views its available-for-sale portfolio as available for use in its current operations. Accordingly, all investments are classified as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair market value based upon quoted market prices of the securities. Unrealized gains and losses on such securities are reported as a separate component of stockholders' equity. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

The following table presents the fair value of available-for-sale securities included in short-term investments as of the respective dates (in thousands):

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
U.S. corporate debt.....	\$ 73,522	\$ 54,430
U.S. government debt.....	40,906	33,188
Municipal debt.....	23,000	38,649
Commercial paper.....	999	--
Total.....	<u>\$ 138,427</u>	<u>\$ 126,267</u>

## NOTE 5. INVENTORY

Inventory is stated at the lower of cost or market value. Cost is computed using standard costs, which approximates actual cost on a first-in, first-out basis. Inventory consists of the following (in thousands):

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
Raw materials.....	\$ 2,666	\$ 2,404
Work-in-process.....	1,330	1,183
Finished goods.....	3,570	2,379
Total.....	<u>\$ 7,566</u>	<u>\$ 5,966</u>

## NOTE 6. GOODWILL AND INTANGIBLE ASSETS

### *Goodwill and Intangible Assets*

Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. Goodwill is not deductible for tax purposes. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," goodwill and intangible assets with indefinite useful lives can no longer be amortized; rather, they will be tested for impairment at least annually in the fourth quarter of each year (more frequently if certain indicators are present). Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. In the event management determines that goodwill has been impaired, the Company will record an accounting charge for the impairment during the fiscal quarter in which the determination is made. Of the total purchase price related to the Company's acquisition of Computer Motion on June 30, 2003, \$143.3 million was allocated to goodwill and \$8.6 million was allocated to amortizable intangible assets, comprised of developed technology of \$3.5 million, core technology of \$3.3 million, customer relationships of \$1.3 million, and other intangible assets totaling \$0.5 million.

Other purchased intangible assets represent patents, which are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over the expected useful life of six or seven years.

Net intangible assets is comprised of the following (in thousands):

March 31, 2005				
	Accumulated			
	Gross	Amortization	Impairment	Net
Developed technology.....	\$ 3,500	\$ 250	\$ 3,250	\$ --
Core technology.....	3,300	825	--	2,475
Customer relationships.....	1,300	567	--	733
Patents.....	7,310	4,892	--	2,418
Other intangible assets.....	500	80	291	129
Total intangible assets, net.....	<u>\$ 15,910</u>	<u>\$ 6,614</u>	<u>\$ 3,541</u>	<u>\$ 5,755</u>

December 31, 2004				
	Accumulated			
	Gross	Amortization	Impairment	Net
Developed technology.....	\$ 3,500	\$ 250	\$ 3,250	\$ --
Core technology.....	3,300	707	--	2,593
Customer relationships.....	1,300	501	--	799
Patents.....	7,310	4,616	--	2,694
Other intangible assets.....	500	74	291	135
Total intangible assets, net.....	<u>\$ 15,910</u>	<u>\$ 6,148</u>	<u>\$ 3,541</u>	<u>\$ 6,221</u>

Amortization expense related to intangible assets was \$0.5 million for each of the three months ended March 31, 2005 and 2004.

Estimated future amortization expense related to intangible assets at March 31, 2005 is as follows (in thousands):

Fiscal Year	
2005 (remaining 9 months).....	\$ 1,401
2006.....	1,275
2007.....	1,078
2008.....	811
2009.....	811
Thereafter.....	379
Total.....	<u>\$ 5,755</u>

### *Impairment of Goodwill*

The Company has elected to perform an annual analysis of goodwill during the fourth quarter of each year. Based on the Company's 2004 impairment analysis, no impairments were identified, and no indicators of impairment were identified during the three months ended March 31, 2005.

### *Impairment of Long-Lived Assets*

SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," requires recognition of impairment of long-lived assets when circumstances indicate an impairment has occurred and in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets. Accordingly, the Company evaluates asset recoverability when an event occurs that may impair recoverability of the asset. The Company determines the recoverability of the carrying amount of each asset by reviewing the following factors: the undiscounted value of expected operating cash flows; the estimated useful or contractual life of the asset; and the contract or product supporting the asset. No impairment losses were incurred during the three months ended March 31, 2005 and 2004.

## **NOTE 7. PRODUCT WARRANTY PROVISIONS**

The Company's standard policy is to warrant all shipped systems against defects in design, materials and workmanship by replacing failed parts during the first year of ownership. The Company's estimate of costs to service the warranty obligations is based on historical experience and current product performance trends. A review of warranty obligations is performed regularly to determine the adequacy of the reserve. Based on the outcome of this review, revisions to the estimated warranty liability are recorded as appropriate.

The following table reconciles the changes to the product warranty liability, which is included in other accrued liabilities on the accompanying condensed consolidated balance sheets, for the period indicated (in thousands):

	<b>Balance at Beginning of Period</b>	<b>Warranty Usage</b>	<b>Warranty Expensed</b>	<b>Balance at End of Period</b>
Three months ended March 31, 2005.....	\$ 136	\$ (18)	\$ 7	\$ 125

The Company from time to time enters into agreements to indemnify its customers against liability and damages arising from patent claims against the Company's products. The term of these agreements vary, but generally, a maximum obligation is not explicitly stated within the agreements. Historically, the Company has not been obligated to make any significant payments related to its customer indemnification clauses and no liabilities have been recorded for this obligation on its balance sheets as of March 31, 2005 or December 31, 2004.

#### NOTE 8. RESTRUCTURING CHARGES

Upon the consummation of the acquisition of Computer Motion, Intuitive's management approved plans to restructure the operations of the combined entity. The restructuring plan eliminated redundant activities and infrastructure. The Company now has a single sales and marketing organization and has consolidated all manufacturing and administrative functions in Sunnyvale, California. Based upon the restructuring plan, the Company recorded a \$3.4 million accrual in accordance with EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination." In accordance with EITF No. 95-3, the restructuring accrual has been recorded as a component of the purchase price. The accrual was comprised of \$2.6 million for employee severance costs, which was substantially paid out by the end of 2004, and \$0.8 million to exit existing lease commitments. The Company has estimated vacancy periods of between one month and three years between exiting various sites and realizing subleasing proceeds. The Company increased the accrual for the estimated losses to be incurred to sublet vacated facilities by \$0.2 million in 2004 due to the change in assumptions used to calculate the losses on subleasing the vacated facilities. This amount was recorded as adjustments to goodwill.

Subsequent to the Computer Motion acquisition, based on the Company's cost structure and future development plans, the Company determined to completely shut down the Goleta research and development facility. This plan called for exiting the last Goleta rented facility and terminating all of the Goleta-based employees. In accordance with SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," the Company recorded \$0.4 million of one-time employee termination costs, which were paid out by the end of 2004. In 2004, the Company completed the shutdown of the Goleta research and development facilities and accrued \$0.5 million of lease commitment costs to exit the leased facility. The Company later decreased its restructuring liability by \$0.2 million due to the changes in estimates of subleasing proceeds. The charges incurred were recorded in research and development expenses on the condensed consolidated statement of operations. The Company expects to fully utilize the accrual by the third quarter of 2007, when existing lease commitments expire.

The following table summarizes the restructuring activity for the periods indicated (in thousands):

	<b>EITF No. 95-3</b>		<b>SFAS No. 146</b>		
	<b>Employee Severance</b>	<b>Lease Commitments</b>	<b>Employee Severance</b>	<b>Lease Commitments</b>	<b>Total</b>
Cost accrued.....	\$ 2,629	\$ 816	\$ 410	\$ 525	\$ 4,380
Cash payments, net of subleasing proceeds.....	(2,781)	(593)	(410)	(207)	(3,991)
Currency impact.....	(23)	(23)	--	--	(46)
Adjustments.....	175	200	--	(177)	198
Balance at December 31, 2004.....	--	400	--	141	541
Cash payments, net of subleasing proceeds.....	--	(53)	--	(26)	(79)
Balance at March 31, 2005.....	\$ --	\$ 347	\$ --	\$ 115	\$ 462

#### NOTE 9. COMPREHENSIVE INCOME

Comprehensive income includes net income and other comprehensive income (loss), which primarily consists of unrealized gains and losses on available-for-sale securities and cumulative translation adjustments. Total accumulated other comprehensive income loss is displayed as a separate component of stockholders' equity in the

accompanying condensed consolidated balance sheets. The components of comprehensive income consist of the following (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net income, as reported.....	\$ 9,104	\$ 853
Other comprehensive income (loss):		
Foreign currency translation		
adjustments.....	36	(30)
Change in unrealized gain (loss)		
on available-for-sale securities.....	(833)	244
Comprehensive income.....	<u>\$ 8,307</u>	<u>\$ 1,067</u>

The components of accumulated other comprehensive loss were as follows (in thousands):

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
Accumulated net unrealized loss on		
available-for-sales securities.....	\$ (1,259)	\$ (427)
Foreign currency translation		
adjustments.....	70	35
Total accumulated other comprehensive		
loss.....	<u>\$ (1,189)</u>	<u>\$ (392)</u>

#### **NOTE 10. NET INCOME PER SHARE**

Basic net income per share is computed by dividing the net income for the period by the weighted-average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted-average number of common shares outstanding and potential number of common shares outstanding during the period less the weighted-average number of common shares subject to repurchase if their effect is dilutive.

The following table presents the computation of basic and diluted net income per share (in thousands, except per share data).

Three Months Ended		
March 31,		
	2005	2004
Net income.....	\$ 9,104	\$ 853
Basic:		
Weighted-average shares outstanding.....	34,517	33,282
Basic net income per common share.....	\$ 0.26	\$ 0.03
Diluted:		
Weighted-average shares outstanding		
used in basic calculation.....	34,517	33,282
Add common stock equivalents.....	2,504	855
Weighted-average shares used in		
computing diluted net income		
per common share.....	37,021	34,137
Diluted net income per common share.....	\$ 0.25	\$ 0.02

Potential weighted-average common shares excluded from the computation of diluted net income per share as their effect would be antidilutive were 439,000 shares and 1,817,000 shares, respectively, for the three months ended March 31, 2005 and 2004. The exercise price of these options exceeded the average market price during the three month periods mentioned above. These shares could, however, potentially dilute basic income per share in the future.

## NOTE 11. COMMITMENTS AND CONTINGENCIES

### OPERATING LEASES

The Company leases office space for research and development in Milford, Connecticut and sales office space in St. Germain en Laye, France. In connection with the acquisition of Computer Motion, the Company assumed leases in Goleta, California. These leases have varying terms, the longest of which extends to September 2007. As of March 31, 2005, the Company sublet approximately 92% of its office space in Goleta.

Future minimum lease commitments, net of sublease income of \$1.1 million during the next three years, under the Company's operating leases as of March 31, 2005 are as follows (in thousands):

2005 (remaining 9 months).....	\$ 522
2006.....	626
2007.....	341
2008.....	59
2009.....	36
Total.....	\$ 1,584

Rent expense was approximately \$44,000 and \$0.8 million for the three months ended March 31, 2005 and 2004, respectively.

### CONTINGENCIES

The discussion of the Company's legal proceedings is incorporated by reference from Part II: Other Information - Item 1. Legal Proceedings of this report.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this report, "Intuitive Surgical," "Intuitive," the "Company," "we," "us," and "our" refer to Intuitive Surgical, Inc.

This management's discussion and analysis of financial condition as of March 31, 2005 and results of operations for the three months ended March 31, 2005 and March 31, 2004 should be read in conjunction with the management's discussion and analysis of financial condition and results of operations included in the Annual Report.

Except for historical information, the discussion in this report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. The cautionary statements made in this report should be read as applying to all related forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to these differences include those discussed in "Factors Affecting Operating Results" below as well as those discussed elsewhere.

Intuitive Surgical®, *da Vinci*®, InSite®, EndoWrist®, *Zeus*®, *Hermes*®, and *Aesop*® are registered trademarks of Intuitive Surgical, Inc.

## OVERVIEW

We design, manufacture and market the *da Vinci* Surgical System, an advanced surgical system that we believe represents a new generation of surgery—the third generation. The *da Vinci* Surgical System consists of a surgeon's console, a patient-side cart, a high performance vision system and proprietary "wristed" instruments. The *da Vinci* Surgical System seamlessly translates the surgeon's natural hand movements on instrument controls at a console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports. We believe that the *da Vinci* Surgical System is the only commercially available technology that can provide the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and 3-D visualization characteristic of open surgery, while simultaneously allowing the surgeons to work through the small ports of minimally invasive surgery, or MIS. By placing computer-enhanced technology between the surgeon and the patient, we believe that the *da Vinci* Surgical System enables surgeons to perform better surgery in a manner never before experienced. The *da Vinci* Surgical System is sold for use in multiple surgical specialties, principally urology, cardiac and general surgery.

To date, the majority of our revenues have come from the sales of the *da Vinci* Surgical System, which are high revenue dollar items. A smaller percentage of our revenues have come from sales of EndoWrist instruments and accessories, which are lower revenue dollar items. In addition, a portion of our revenue comes from the ongoing service of installed *da Vinci* Surgical Systems. Due to the high dollar revenue per system sold, a small variation in system unit sales may cause revenue to vary significantly from quarter to quarter. During the useful life of each installed *da Vinci* Surgical System, we expect to generate revenue through sales of the EndoWrist instrument and accessories and ongoing service. Over the past three years, revenue generated from the sale of instruments, accessories, service and training increased from \$15.7 million, or 22% of sales, in 2002 to \$29.9 million, or 33% of sales, in 2003 to \$60.0 million, or 43% of sales, in 2004. We have seen a continuation of this trend in 2005 as first quarter recurring revenue grew to \$20.3 million, or 49% of sales, from \$12.5 million, or 46% of sales, during the first quarter of 2004. We expect that recurring revenue will continue to grow and become a larger part of overall revenue in the future.

## RESULTS OF OPERATIONS

### *Product Sales (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 34.2	\$ 22.5	\$ 11.7	52 %

Product sales for the quarter ended March 31, 2005 were \$34.2 million, compared to \$22.5 million during the quarter ended March 31, 2004. The increase resulted from higher system, instrument, and accessory sales. System sales increased to \$21.3 million in the quarter ended March 31, 2005 from \$14.6 million in the quarter ended March 31, 2004, reflecting growth in system unit sales of *da Vinci* Surgical Systems and *da Vinci* fourth arms. We sold 19 *da Vinci* Surgical Systems during the quarter ended March 31, 2005, compared to 14 in the quarter ended March 31, 2004. We sold 19 fourth arms during the quarter ended March 31, 2005, compared to 11 during the quarter ended March 31, 2004. Instrument and accessory sales for the quarter ended March 31, 2005 were \$12.9 million, compared to \$7.9 million for the quarter ended March 31, 2004. The increase was driven by a larger number of installed systems during the quarter ended March 31, 2005 and higher utilization per system. Increased use of the *da Vinci* Surgical System for radical prostatectomies contributed substantially to the higher first quarter 2005 product sales.

*Service Sales (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 7.4	\$ 4.6	\$ 2.8	62 %

Service sales, comprised of system service, installation and customer training, increased to \$7.4 million for the quarter ended March 31, 2005 from \$4.6 million for the quarter ended March 31, 2004. The increase resulted primarily from a larger base of *da Vinci* Surgical Systems generating service revenue in 2005. The base of *da Vinci* Surgical Systems generating service revenue grew to approximately 279 entering the first quarter of 2005, compared to approximately 180 entering the first quarter of 2004. The increase of 99 systems was comprised of 28 systems sold in the first half of 2003 coming out of the warranty period onto service contracts and 76 systems sold in 2004, with first year service deferred according to EITF 00-21, which we adopted prospectively during the third quarter of 2003, offset by 5 system retirements. In addition, the average service revenue per site increased during the first quarter of 2005 due to a higher percentage of four-arm systems in the installed base. Four-arm systems carry higher service revenue contracts.

*Product Sales Gross Profit (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 23.0	\$ 13.6	\$ 9.4	69 %
Percentage of product sales.....	67.4 %	60.8 %		

Product gross profit for the quarter ended March 31, 2005 was \$23.0 million, or 67.4% of sales, compared to \$13.6 million, or 60.8% of sales during the quarter ended March 31, 2004. The higher gross profit for the quarter ended March 31, 2005 was driven by higher product revenue during the quarter, as described above. The higher product gross profit percentage was driven by leveraging manufacturing overhead costs across higher product revenue, lower product material costs, and a higher average *da Vinci* Surgical System average selling price. The average *da Vinci* Surgical System selling price was approximately \$925,000 during the quarter ended March 31, 2005, up from approximately \$865,000 during the quarter ended March 31, 2004. The higher average selling price during the quarter ended March 31, 2005 resulted primarily from customer channel mix, as only 1 of 19 first quarter 2005 system sales was through a distributor, compared to 3 of 14 during the quarter ended March 31, 2004. In addition, the first quarter 2004 average selling price was negatively impacted by one *da Vinci* Surgical System sale, which was reduced in price as a result of a *Zeus* trade-in.

*Service Sales Gross Profit (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 4.2	\$ 2.2	\$ 2.0	94 %
Percentage of service sales.....	57.0 %	47.5 %		

Service sales gross profit for the quarter ended March 31, 2005 was \$4.2 million, or 57.0% of service sales, compared to \$2.2 million, or 47.5% of service sales for the quarter ended March 31, 2004. Higher first quarter 2005 gross service margin was driven by increased service revenue, as described above, in combination with increased leverage of the service and training organization expenses across a larger base of installed systems.

*Selling, General and Administrative Expenses (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 14.2	\$ 10.2	\$ 4.0	39 %

Selling, general and administrative expenses include personnel costs for sales, marketing and administrative personnel, tradeshow expenses, legal expenses, regulatory fees and general corporate expenses. Selling, general and administrative expenses for the quarter ended March 31, 2005 were \$14.2 million, up 39% from \$10.2 million for the quarter ended March 31, 2004. The year-over-year increase was primarily due to sales organization headcount



growth to support higher sales and higher variable compensation associated with achieving higher revenues and profitability.

We expect selling, general and administrative expenses to continue to increase in the future to support our expanding business.

*Research and Development Expenses (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 4.1	\$ 5.3	\$ (1.2)	(22)%

Research and development expenses include costs associated with the design, development, testing and enhancement of our products. These enhancements represent significant improvements to our products. Research and development expenses also include expenditures for clinical trials and purchases of laboratory supplies.

Research and development expenses for the quarter ended March 31, 2005 were \$4.1 million, compared to \$5.3 million for the quarter ended March 31, 2004. The decrease was primarily due to the elimination of expenses relating to our former Goleta, California site during the first quarter of 2004. During the first quarter of 2004, the Goleta site incurred \$1.0 million of general operating expenses, comprised of salaries, materials, depreciation, and other expenses. In addition, we recorded a \$0.7 million restructuring charge during the quarter ended March 31, 2004 to completely shut down the Goleta site and terminate all remaining Goleta-based employees. Excluding the impact of the Goleta expenses, higher research and development expenses for the quarter ended March 31, 2005 were primarily due to higher product development expenses.

Research and development costs are expensed as incurred. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses will continue to increase in the future.

*Other Income, Net (dollars in millions)*

	March 31, 2005	March 31, 2004	Change	% Change
Three months ended.....	\$ 0.7	\$ 0.6	\$ 0.1	19 %

Other income for the quarter ended March 31, 2005 was \$0.7 million, up 19% from \$0.6 million for the quarter ended March 31, 2004. Other income for the quarter ended March 31, 2005 of \$0.7 million was comprised of \$1.0 million of interest income, netted against \$0.3 million of foreign exchange losses resulting from euro-based transactions. Other income increased by \$0.1 million compared to the quarter ended March 31, 2004 primarily due to higher interest earned of \$0.3 million, resulting from a higher first quarter 2005 average cash and investment balance, partially offset by higher foreign exchange losses of \$0.2 million.

*Income Tax Expense*

Income tax expense for the quarter ended March 31, 2005 was \$0.5 million, or 5.5% of pre-tax income, compared to \$36,000, or 4.0% of pre-tax income, during the first quarter of 2004. Our tax rate is less than the statutory rate due to the utilization of net operating loss carryforwards.

**LIQUIDITY AND CAPITAL RESOURCES**

Our operations have been financed through the sale of our equity securities and cash generated from operations. Sales of convertible preferred stock have yielded proceeds of approximately \$127.3 million and public offerings of our common stock have yielded proceeds of approximately \$124.5 million. We have also financed operations through employee stock purchase and option plans as well as equipment financing arrangements. As of March 31, 2005, we had total stockholders equity of \$330.2 million and outstanding equipment financing debt of \$0.3 million. As of March 31, 2005, we had cash, cash equivalents and short-term investments of \$149.5 million, compared to \$132.0 million as of December 31, 2004. Working capital as of March 31, 2005 was \$154.4 million, compared to \$138.3 million as of December 31, 2004. The increase in cash and investments and in working capital resulted primarily from our \$9.1 net income and \$7.0 million of net proceeds realized from stock option and warrant exercises and our employee stock purchase plan in the quarter ended March 31, 2005.

Net cash provided by operating activities was \$12.3 million for the quarter ended March 31, 2005, compared to net cash used in operating activities of \$0.9 million for the quarter ended March 31, 2004. Higher cash provided by operating activities was driven by higher first quarter 2005 net income of \$8.3 million and higher working capital provided of \$5.1 million. Cash provided by operating activities during the quarter ended March 31, 2005 was comprised of net income of \$9.1 million, non-cash expenses of \$1.6 million, and working capital of \$1.6 million. The \$0.9 million of cash used in operations during the first quarter of 2004 was primarily the result of working capital consumed of \$3.5 million, due in large part to net payments of 2003 year end accounts payable and other liabilities, offset by our net income of \$0.9 million and non-cash expenses of \$1.7 million.

Net cash used in investing activities was \$13.8 million for the quarter ended March 31, 2005, compared to \$0.9 million for the quarter ended March 31, 2004. Net cash used in investing activities during the first quarter of 2005 resulted mainly from the net investment of cash provided by operations into marketable securities of \$13.0 million and acquisitions of property and equipment of \$1.0 million. Net cash used in investing activities during the first quarter of 2004 resulted mainly from investments in fixed assets of \$0.5 million.

Net cash provided by financing activities was \$6.7 million for the quarter ended March 31, 2005, compared to \$3.8 million for the quarter ended March 31, 2004. First quarter 2005 cash provided resulted primarily from \$7.0 million net proceeds realized from stock option and warrant exercises and our employee stock purchase plan, partially offset by repayments of long-term debt of \$0.3 million. First quarter 2004 cash provided resulted primarily from net proceeds realized from stock option exercises and our employee stock purchase plan of \$4.1 million, partially offset by repayments of long-term debt of \$0.3 million.

Our capital requirements depend on numerous factors, including market acceptance of our products, the resources we devote to developing and supporting our products, and other factors. We expect to devote substantial capital resources to continue our research and development efforts, to expand our customer support and product development activities and for other general corporate activities. We believe that our current cash and cash equivalents and short-term investment balances, together with revenue to be derived from the sale of our products, will be sufficient to meet our liquidity requirements for the foreseeable future.

#### *Contractual Obligations and Commercial Commitments*

The following table summarizes all significant contractual payment obligations, net of sublease income of \$1.1 million during the next three years, by payment due date:

#### **Payments by Periods (in millions)**

Contractual Obligation	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	\$1.6	\$0.7	\$0.8	\$0.1	\$0.0

#### **CRITICAL ACCOUNTING POLICIES**

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of assets and liabilities. On an on-going basis, we evaluate our critical accounting policies and estimates, including those related to revenue recognition, bad debts, income taxes and intangible assets. We base our estimates on historical experience and on various other assumptions that 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 that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our Annual Report.

#### **FACTORS AFFECTING OPERATING RESULTS**

#### **OUR FUTURE OPERATING RESULTS MAY BE BELOW SECURITIES ANALYSTS' OR INVESTORS' EXPECTATIONS, WHICH COULD CAUSE OUR STOCK PRICE TO DECLINE.**

Due to the nascent nature of our industry, we have limited insight into trends that may emerge in our market and affect our business. The revenue and income potential of our market are unproven, and we may be unable to continue to generate significant revenues. In addition, our costs may be higher than we anticipated. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer. Further, future revenue from sales of our products is difficult to forecast because the market for new surgical technologies is

still evolving. Our results of operations will depend upon numerous factors, including:

- the extent to which our products gain market acceptance;
- actions relating to regulatory matters;
- our timing and ability to develop our manufacturing and sales and marketing capabilities;
- demand for our products;
- the size and timing of specific sales and any collection delays related to those sales;
- product quality problems;
- the progress of surgical training in the use of our products;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- third-party payor reimbursement policies;
- our ability to protect our proprietary rights and defend against third party challenges;
- our ability to license additional intellectual property rights; and
- the progress and results of clinical trials.

Our operating results in any particular period will not be a reliable indication of our future performance. It is likely that in some future quarters, our operating results will be below the expectations of securities analysts or investors. If this occurs, the price of our common stock, and the value of your investment, will likely decline.

**WE EXPERIENCE LONG AND VARIABLE SALES CYCLES, WHICH COULD HAVE A NEGATIVE IMPACT ON OUR RESULTS OF OPERATIONS FOR ANY GIVEN QUARTER.**

Our *da Vinci* Surgical System has a lengthy sales and purchase order cycle because it is a major capital item and generally requires the approval of senior management at purchasing institutions. These factors may contribute to substantial fluctuations in our quarterly operating results, particularly during the periods in which our sales volume is low. Because of these fluctuations, it is likely that in some future quarters our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations also mean that you will not be able to rely upon our operating results in any particular period as an indication of future performance.

**BECAUSE A SMALL NUMBER OF CUSTOMERS HAVE AND ARE LIKELY TO CONTINUE TO ACCOUNT FOR A SUBSTANTIAL PORTION OF OUR REVENUES, OUR REVENUES COULD DECLINE DUE TO THE LOSS OR DELAY OF A SINGLE CUSTOMER.**

A relatively small number of customers account for a significant portion of our total revenues. During the three months ended March 31, 2005 and 2004, approximately 50% and 52%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems, which are high revenue dollar items. During the three months ended March 31, 2005 and 2004, no customer accounted for more than 10% of total sales. However, due to the high average selling price of the *da Vinci* Surgical System, our failure to add new customers that make significant purchases of our products could reduce our future revenues. The loss or delay of individual orders could have a significant impact on revenues and operating results.

**IF OUR PRODUCTS DO NOT ACHIEVE MARKET ACCEPTANCE, WE WILL NOT BE ABLE TO GENERATE THE REVENUE NECESSARY TO SUPPORT OUR BUSINESS.**

The *da Vinci* Surgical Systems and our other products represent a fundamentally new way of performing surgery. Achieving physician, patient and third-party payor acceptance of *Intuitive* surgery as a preferred method of performing surgery will be crucial to our success. If our products fail to achieve market acceptance, hospitals will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that physicians' and third-party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing surgical techniques. Even if we can prove the effectiveness of our products through clinical trials, surgeons may elect not to use our

products for any number of other reasons. For example, cardiologists may continue to recommend conventional open-heart surgery simply because such surgery is already widely accepted. In addition, surgeons may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third-party payors.

We expect that there will be a learning process involved for surgical teams to become proficient in the use of our products. Broad use of our products will require training of surgical teams. Market acceptance could be delayed by the time required to complete this training. We may not be able to rapidly train surgical teams in numbers sufficient to generate adequate demand for our products. We cannot be certain that our training programs will be cost effective or sufficient to meet our customers' needs.

**BECAUSE OUR MARKETS ARE HIGHLY COMPETITIVE, CUSTOMERS MAY CHOOSE TO PURCHASE OUR COMPETITORS' PRODUCTS OR MAY NOT ACCEPT INTUITIVE SURGERY, WHICH WOULD RESULT IN REDUCED REVENUE AND LOSS OF MARKET SHARE.**

*Intuitive* surgery is a new technology that will compete with established and emerging treatment options in both disease management and reconstructive medical procedures. These competitive treatment options may take the form of traditional minimally invasive surgery, open surgery, interventional approaches, or pharmacological regimens. Some of these procedures are widely accepted in the medical community and in many cases have a long history of use. Technological advances could make such treatments more effective or less expensive than using our products, which could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future technologies.

In addition, we may face competition from companies that develop robotic and computer-assisted surgical systems in the future. Our revenues may be reduced or eliminated if our competitors develop and market products that are more effective or less expensive than our products. If we are unable to compete successfully, our revenues will suffer. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.

**INTERNATIONAL SALES OF OUR PRODUCTS ACCOUNT FOR A SIGNIFICANT PORTION OF OUR REVENUES, WHICH EXPOSES US TO RISKS INHERENT IN INTERNATIONAL OPERATIONS. OUR GROWTH MAY BE LIMITED IF WE ARE UNABLE TO SUCCESSFULLY MANAGE OUR INTERNATIONAL ACTIVITIES.**

Our business currently depends in large part on our activities in Europe and other foreign markets. Sales to markets outside of the United States accounted for approximately 11% of sales for the three months ended March 31, 2005 and 24% of sales for the three months ended March 31, 2004.

We are subject to a number of challenges that specifically relate to our international business activities. These challenges include:

- failure of local laws to provide the same degree of protection against infringement of our intellectual property;
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets;
- the risks associated with foreign currency exchange rate fluctuation;
- the expense of establishing facilities and operations in new foreign markets; and
- building an organization capable of supporting geographically dispersed operations.

Currently, a majority of our international sales are denominated in United States dollars. As a result, an increase in the value of the United States dollar relative to foreign currencies could make our products less competitive in international markets. If we are unable to meet and overcome these challenges, our international operations may not be successful, which would limit the growth of our business.

**IF DEFECTS ARE DISCOVERED IN OUR PRODUCTS, WE MAY INCUR ADDITIONAL UNFORESEEN COSTS, HOSPITALS MAY NOT PURCHASE OUR PRODUCTS AND OUR REPUTATION MAY SUFFER.**

Our products incorporate mechanical parts, electrical components and computer software, any of which can contain

errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products as a result of performance problems. We cannot assure you that our products will not experience errors or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

- delays in product shipments;
- loss of revenue;
- delay in market acceptance;
- diversion of our resources;
- damage to our reputation;
- product recalls;
- increased service or warranty costs; or
- product liability claims.

#### **WE MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE.**

We have manufactured a limited number of our products for sales to customers. We may be unable to maintain reliable, high-volume manufacturing capacity. Even if this capacity can be maintained, the cost of doing so may increase the cost of our products and reduce our ability to compete. We may encounter difficulties in scaling up production of our products, including:

- problems involving production yields;
- quality control and assurance;
- component supply shortages;
- shortages of qualified personnel; and
- compliance with state, federal and foreign regulations.

Manufacturing our products is a complex process. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace could be damaged.

#### **OUR RELIANCE ON SOLE AND SINGLE SOURCE SUPPLIERS COULD HARM OUR ABILITY TO MEET DEMAND FOR OUR PRODUCTS IN A TIMELY MANNER OR WITHIN BUDGET.**

Some of the components necessary for the assembly of our products are currently provided to us by sole source suppliers or single source suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. The disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture our products in a timely manner or within budget.

#### **IF WE ARE UNABLE TO PROTECT THE INTELLECTUAL PROPERTY CONTAINED IN OUR PRODUCTS FROM USE BY THIRD PARTIES, OUR ABILITY TO COMPETE IN THE MARKET WILL BE HARMED.**

Our commercial success will depend in part on obtaining patent and other intellectual property protection for the

technologies contained in our products, and on successfully defending our patents and other intellectual property against third party challenges. We will incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. We also do not know whether we will be able to develop additional patentable proprietary technologies. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or reexaminations. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

**OTHERS MAY ASSERT THAT OUR PRODUCTS INFRINGE THEIR INTELLECTUAL PROPERTY RIGHTS, WHICH MAY CAUSE US TO ENGAGE IN COSTLY DISPUTES AND, IF WE ARE NOT SUCCESSFUL IN DEFENDING OURSELVES, COULD ALSO CAUSE US TO PAY SUBSTANTIAL DAMAGES AND PROHIBIT US FROM SELLING OUR PRODUCTS.**

There may be United States and foreign patents issued to third parties that relate to computer-assisted surgery, remote surgery, and minimally invasive surgery. Some of these patents may be broad enough to cover one or more aspects of our present technology, and may cover aspects of our future technology. We do not know whether any of these patents, if challenged, would be held valid, enforceable and infringed. From time to time, we receive, and likely will continue to receive, letters from third parties inviting us to license their patents. We may be sued by, or become involved in an administrative proceeding with, one or more of these third parties. We cannot be certain that a court or administrative body would agree with any arguments or defenses we have concerning invalidity, unenforceability or noninfringement of any third-party patent. In addition to the issued patents of which we are aware, other parties may have filed, and in the future are likely to file, patent applications covering surgical products that are similar or identical to ours. We cannot be certain that any patents issuing from applications filed by a third party will not cover our products or will not have priority over our patent applications.

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages, including treble damages, and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our patents from infringement or claims of invalidity or unenforceability, or to defend against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could cause our stock price to decline.

**THE RIGHTS AND MEASURES WE RELY ON TO PROTECT THE INTELLECTUAL PROPERTY UNDERLYING OUR PRODUCTS MAY NOT BE ADEQUATE TO PREVENT THIRD PARTIES FROM USING OUR TECHNOLOGY, WHICH COULD HARM OUR ABILITY TO COMPETE IN THE MARKET.**

In addition to patents, we typically rely on a combination of trade secret, copyright and trademark laws, nondisclosure agreements and other contractual provisions and technical security measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If they do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection outside the United States. We also realize that our trade secrets may become known through other means not currently foreseen by us. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our intellectual property rights, or may design around our proprietary technologies.

**OUR PRODUCTS RELY ON LICENSES FROM THIRD PARTIES, AND IF WE LOSE ACCESS TO THESE TECHNOLOGIES, OUR REVENUES COULD DECLINE.**

We rely on technology that we license from others, including technology that is integral to our products. We have entered into license agreements with Heartport, Inc., now part of Johnson & Johnson, IBM Corporation, MIT, Olympus Optical Co., Ltd., SRI International, and Brookhill-Wilk, LLC. Any of these agreements may be terminated for breach. If any of these agreements is terminated, we may be unable to reacquire the necessary license on satisfactory terms, or at all. The loss or failure to maintain these licenses could prevent or delay further development or commercialization of our products.

**THE USE OF OUR PRODUCTS COULD RESULT IN PRODUCT LIABILITY CLAIMS THAT COULD BE EXPENSIVE, DIVERT MANAGEMENT'S ATTENTION AND HARM OUR BUSINESS.**

Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. Particularly as sales of our products increase, we may be unable to maintain product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. A product liability claim or any product recalls could also harm our reputation or result in a decline in revenues.

**TERMINATION OF RELATIONSHIPS WITH FORMER DISTRIBUTORS OF COMPUTER MOTION COULD RESULT IN LITIGATION.**

As part of our integration strategy related to our acquisition of Computer Motion, we terminated Computer Motion's relationships with a number of companies that served as Computer Motion's distributors prior to the acquisition. As a result, two former distributors (one in Italy and the other in Israel) have filed breach of contract suits against us. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such litigation at this time and, therefore, cannot estimate the range of possible loss. These proceedings could be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in these lawsuits, these proceedings could consume substantial amounts of our financial and managerial resources. See Part II: Other Information - Item 1: Legal Proceedings.

**PUBLIC ANNOUNCEMENTS OF LITIGATION EVENTS MAY CAUSE OUR STOCK PRICE TO DECLINE.**

During the course of our administrative proceedings and/or lawsuits, there may be public announcements of the results of hearings, motions, and other interim proceedings or developments in the litigation. If securities analysts or investors perceive these results to be negative, it could have a substantial negative effect on the trading price of our stock.

**OUR PRODUCTS ARE SUBJECT TO A LENGTHY AND UNCERTAIN DOMESTIC REGULATORY PROCESS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY DOMESTIC REGULATORY APPROVALS, WE WILL NOT BE ABLE TO MARKET AND SELL OUR PRODUCTS IN THE UNITED STATES.**

Our products and operations are subject to extensive regulation in the United States by the U.S. Food and Drug Administration ("FDA"). The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market certain products for use in the United States, we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfather status. If we significantly modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or premarket approval application ("PMA"), for the modified product before we are permitted to market the products in the U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfather status, we will be required to obtain FDA approval by submitting a PMA.

The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions, or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, all of which could delay or preclude sale of new products in the United States. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies, in support of a 510(k) submission. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex and burdensome application than a 510(k). To support a PMA, the FDA would

likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, or the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products we develop, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition and results of operations.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a device, a company must, among other things, apply for and obtain Institutional Review Board (“IRB”) approval of the proposed investigation. In addition, if the clinical study involves a “significant risk” (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an investigational device exemption (“IDE”) application. Most of our products to date have been considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the U.S. for any new devices we intend to market in the United States in the future. If we obtain such approvals, we may not be able to comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

**COMPLYING WITH FDA REGULATIONS IS AN EXPENSIVE AND TIME-CONSUMING PROCESS, AND OUR FAILURE TO COMPLY FULLY COULD SUBJECT US TO SIGNIFICANT ENFORCEMENT SANCTIONS.**

Because our products, including the *da Vinci* Surgical System, are commercially distributed, numerous postmarket regulatory requirements apply, including the following:

- Quality System Regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations;
- the FDA’s general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or “off-label” uses;
- the Reports of Corrections and Removals regulation, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FFDCA that may pose a risk to health; and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public warning letter to more severe civil and criminal sanctions. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

We have modified the labeling, advertising and user training for the *da Vinci* Surgical System to call out specific procedures that we believe are within the scope of our existing 510(k) clearances. We cannot assure you that the FDA would agree that all such specific procedures are within the scope of the existing general clearance or that we have compiled adequate information to support the safety and efficacy of using the *da Vinci* Surgical System for all such specific procedures. We also have modified the hardware and software in the *da Vinci* Surgical System since clearance in ways that we believe do not require new 510(k) clearance. We cannot be certain that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes. Computer Motion also modified the hardware and software in its products subsequent to 510(k) clearance without seeking new clearance. We cannot be certain that the FDA would agree with the determinations not to seek new 510(k) clearance for any of these changes. The FDA could impose enforcement sanctions and/or require us to obtain 510(k) clearance for any modification to our products or Computer Motion’s products. We may be prohibited from marketing the modified device until such 510(k) clearance is granted.



In December 2002, the FDA inspected our Sunnyvale manufacturing facility and issued a Form FDA 483 setting forth three observed compliance deficiencies relating to the QSR and two observed deficiencies relating to the Reports of Corrections and Removals regulation. In January 2003, we wrote to the FDA indicating our response to each observation with proposed corrective actions. That same month, the FDA informed us that the adequacy of our promised corrections and actions would be verified during the next inspection of our facility. To date, the FDA has not returned for another inspection and we continue to evaluate and upgrade our QSR compliance. We cannot assure you that, upon reinspection, the FDA will find that our promised corrective actions are appropriate or that they have been adequately implemented. We also cannot assure you that the FDA will not find other deficiencies in our compliance with the QSR and other postmarket regulations.

In June 2003, we acquired Computer Motion and have integrated its FDA compliance quality system into our own. As a result of the integration and review, we identified deficiencies in Computer Motion's complaint handling, MDR reporting and Corrections and Removals reporting in several years preceding our acquisition of Computer Motion that required submission of retroactive reports to the FDA. We reported 52 MDRs, although we believe many of the complaints likely would not have been reportable if more information had been available. To our knowledge, none of the reported events resulted in a death or serious injury, prolonged hospitalization, or medical intervention to prevent death or serious injury. Computer Motion did respond to complaint trends, and it addressed the trends through corrective actions. Accordingly, the incident of many of the types of events in the reports had been mitigated by June 2003. Our review also suggested that significant complaint trends identified by Computer Motion over the period of four years were addressed by corrective actions, which have proven to be effective over time. Computer Motion's product modifications were completed without 510(k) clearance, and we believe that no new 510(k) clearances are required. We cannot assure you that the FDA would agree with our determinations not to seek new 510(k) clearance of any of these changes.

We cannot assure you that the FDA will not seek to impose enforcement sanctions on us for Computer Motion's violations preceding our acquisition of Computer Motion, that the FDA will agree that since the acquisition we have corrected all regulatory problems, or that our review of Computer Motion's complaint handling will not lead us to initiate recalls or field actions to remedy problems with Computer Motion products already in the field.

**OUR PRODUCTS ARE SUBJECT TO VARIOUS INTERNATIONAL REGULATORY PROCESSES AND APPROVAL REQUIREMENTS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY INTERNATIONAL REGULATORY APPROVALS, WE WILL NOT BE ABLE TO MARKET AND SELL OUR PRODUCTS IN FOREIGN COUNTRIES.**

To be able to market and sell our products in other countries, we must obtain regulatory approvals and comply with the regulations of those countries. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals are expensive, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products. If we fail to obtain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

The European Union requires that manufacturers of medical products obtain the right to affix the CE mark to their products before selling them in member countries of the European Union. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. In January 1999, we received permission to affix the CE mark to our *da Vinci* Surgical System and *EndoWrist* instruments.

If we modify existing products or develop new products in the future, including new instruments, we may need to apply for permission to affix the CE mark to such products. In addition, we will be subject to annual regulatory audits in order to maintain the CE mark permissions we have already obtained. We cannot be certain that we will be able to obtain permission to affix the CE mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the European Union.

**IF INSTITUTIONS OR SURGEONS ARE UNABLE TO OBTAIN REIMBURSEMENT FROM THIRD-PARTY PAYORS FOR PROCEDURES USING OUR PRODUCTS, OR IF REIMBURSEMENT IS INSUFFICIENT TO COVER THE COSTS OF PURCHASING OUR PRODUCTS, WE MAY BE UNABLE TO GENERATE SUFFICIENT SALES TO SUPPORT OUR BUSINESS.**

Domestic institutions typically bill the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. If hospitals do not obtain sufficient

reimbursement from third-party payors for procedures performed with our products, or if government and private payors' policies do not permit reimbursement for surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. Reimbursement practices vary significantly by country. Many international markets have government-managed healthcare systems that control reimbursement for new products and procedures. Other foreign markets have both private insurance systems and government-managed systems that control reimbursement for new products and procedures. Market acceptance of our products may depend on the availability and level of reimbursement in any country within a particular time. In addition, health care cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our products and these efforts are expected to continue.

**IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE OR EUROPEAN MANUFACTURING STANDARDS, WE MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF OUR MANUFACTURING OPERATIONS, WHICH COULD RESULT IN PRODUCT DELIVERY DELAYS AND LOST REVENUE.**

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Good Manufacturing Practice requirements contained in the FDA's Quality System Regulations, or QSR. We are also required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe. If we fail to continue to comply with Good Manufacturing Practice requirements or ISO standards, we may be required to cease all or part of our operations until we comply with these regulations. We continue to be subject to FDA and other regulatory inspections at any time. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards in future inspections and audits by regulatory authorities.

The FDA inspected the Goleta facilities of Computer Motion in 1998 and noted deficiencies in Computer Motion's systems for reviewing and reporting product-related complaints and defect information. We have determined that these deficiencies may not have been addressed. While the Goleta manufacturing facility has been closed and production of certain products has been transferred to our Sunnyvale facility, these issues raised by the FDA must nonetheless be resolved. The complaint records prior to acquisition of Computer Motion were reviewed and appropriate Medical Device Reports were filed with the FDA. Complaints received subsequent to our acquisition of Computer Motion are handled in accordance with Intuitive Surgical quality system requirements, which we believe is in accordance with FDA requirements, although we cannot assure you that FDA will agree, nor can we assess what regulatory impact, if any, this may have on our company.

As required, we are licensed by the State of California to manufacture medical devices. We are subject to periodic inspections by the California Department of Health Services and, if we are unable to maintain this license following any future inspections, we will be unable to manufacture or ship products.

**IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, OUR ABILITY TO COMPETE WILL BE HARMED.**

We are highly dependent on the principal members of our management and technical staff. Our product development plans depend, in part, on our ability to attract and retain engineers with experience in electronics, mechanics, software and optics. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among technology and healthcare companies, and universities. The loss of any of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are not subject to any meaningful market risks related to currency, commodity prices or similar matters. We are sensitive to short-term interest rate fluctuations to the extent that such fluctuations impact the interest income we receive on the investment of the remaining proceeds from our public offerings and cash generated from operations.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. To

minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in a variety of securities. We classify our cash equivalents and marketable securities as “fixed-rate” if the rate of return on such instruments remains fixed over their term. These “fixed-rate” investments include commercial paper and government and non-government debt securities. We classify our cash equivalents and marketable securities as “variable-rate” if the rate of return on such investments varies based on the change in a predetermined index or set of indices during their term. These “variable-rate” investments primarily include auction-rate securities with rates that re-set generally every 30 days. The weighted average maturity of all of our fixed-rate investments as of March 31, 2005 was approximately 2 years. At March 31, 2005 and December 31, 2004, approximately 11% and 25%, respectively, of our fixed-rate investment portfolio was composed of investments with maturities of one year or less.

The majority of our revenue, expense, and capital purchasing activities are transacted in U.S. dollars. However, since a portion of our operations consists of sales activities outside of the United States, we have entered into transactions in other currencies, primarily the euro.

For the three months ended March 31, 2005 and 2004, sales denominated in foreign currencies were 5% and 12%, respectively, of total sales.

Foreign currency fluctuations resulted in approximately \$0.3 million and \$0.1 million of foreign exchange loss for the three months ended March 31, 2005 and 2004, respectively.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as such term is defined in SEC Rule 13a-15(e) that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’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 for 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 provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In February 2004, the University of Miami, a former customer of Computer Motion, filed a lawsuit against our company in the U.S. District Court, Southern District of Florida. We received the complaint in April 2004. The customer alleges that it relied to its detriment on representations made by Computer Motion in connection with Computer Motion’s sale of products to the customer, which representations the customer believes were not fulfilled. The customer is seeking damages. We filed a motion to dismiss the fraud-based complaints and an answer defending the breach of contract claim. After discovery was completed, we filed a motion for summary judgment to dismiss the entire case. In January 2005, the Court granted our motion for summary judgment and dismissed the case against us in its entirety. In February 2005, the customer filed a notice of appeal. We intend to respond to such appeal.

In November 2003, Tzamal Jacobson, Ltd., an Israeli company, filed suit against our company and Computer Motion in the District Court in Tel-Aviv – Jaffa, Israel, Civil File 2293/03, alleging breach of a distribution contract and seeking damages. We received the complaint in April 2004. Following the acquisition of Computer Motion, we withdrew Computer Motion’s distributorship offer to this Israeli company. We intend to vigorously defend the suit, and have filed a motion to have the case dismissed on jurisdictional grounds. The court has not yet ruled on the

motion. Tzamal's request for access to a Company's witness for discovery has been granted by the court.

In October 2003, SIC System, S.R.L., a former Italian distributor for Computer Motion, filed suit against our company and Computer Motion seeking damages in the Civil Court of Rome, Italy. In the complaint, SIC System alleges that we breached the distribution agreement between SIC System and Computer Motion when, following our acquisition of Computer Motion, we deleted two products previously covered under the distribution agreement. The distribution agreement provides, among other things, that (1) it shall be governed and construed under the laws of the State of California and (2) in the event of any dispute or controversy arising under the distribution agreement or the transactions contemplated thereunder, the parties mutually consent to the exclusive jurisdiction of a court of competent jurisdiction within Santa Barbara County, California. We are defending the lawsuit on both jurisdictional grounds and on the merits. The Italian court has ruled that SIC System's service of process in filing its complaint was defective and has ordered SIC System to re-file its complaint on or about October 6, 2004, which service our company did not receive. The parties continue to dispute the service of process issue. The Italian court has not ruled on jurisdiction or other pending issues pertaining to the applicable law or appropriate forum.

In November 2003, we filed a lawsuit against SIC System, S.R.L. in the United States District Court for the Central District of California for declaratory relief, breach of contract and preliminary and permanent injunction. In particular, we sought a judicial declaration of the rights and obligations of the parties under a distribution agreement, specifically that our company effectively deleted the products from the distribution agreement, and a preliminary and permanent injunction prohibiting SIC System from proceeding with the Italian action described above. The complaint was served on SIC System in November 2003, and the Court entered default against SIC Systems in March 2004. In August 2004, the Court entered a judgment in favor of our company in the amount of \$195,155 for breach of contract. The Court also awarded judgment in favor of our company as to its claim for declaratory relief. The Court awarded judgment in favor of SIC Systems as to our company's claim for preliminary and permanent injunction. The Court found our company as the prevailing party. We intend to enforce this judgment against SIC System in the Italian portion of the lawsuit.

The foregoing proceedings could be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in these lawsuits, these proceedings could consume substantial amounts of our financial and managerial resources. At any time, the other parties may file additional claims against us, or we may file claims against them, which could increase the risk, expense and duration of the litigations.

We are subject to legal proceedings and claims, including those discussed above, that arise in the normal course of our business. We do not know whether we will prevail in these matters, nor can we assure that any remedy could be reached on commercially viable terms, if at all. In accordance with Statement of Financial Accounting Standards, or SFAS, No. 5, "Accounting for Contingencies," we record a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impacts of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to a particular case.

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

None.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

## **ITEM 5. OTHER INFORMATION**

None.

## **ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
31	Certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

---

**SIGNATURE**

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

INTUITIVE SURGICAL, INC.

*(Registrant)*

By: /s/ SUSAN K. BARNES

Susan K. Barnes

*Senior Vice President, Chief Financial Officer and Assistant Secretary*

Date: May 10, 2005

<b>Exhibit Number</b>	<b>Description</b>
31	Certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

---