

INTUITIVE SURGICAL INC
Form 10-Q
November 08, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004

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

(State or Other Jurisdiction of Incorporation or Organization)

77-0416458

(I.R.S. Employer Identification Number)

950 Kifer Road
Sunnyvale, California 94086

(Address of Principal Executive Offices including Zip Code)

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(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

x NO o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES

x NO o

The Registrant had 33,990,854 shares of Common Stock, \$0.001 par value per share, outstanding as of October 31, 2004.

Intuitive Surgical, Inc.
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PART I. FINANCIAL INFORMATION

| |
|------------------------------|
| Item 1. Financial Statements |
|------------------------------|

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

| | September 30, 2004 | December 31, 2003 |
|--|-----------------------|----------------------|
| | ----- | ----- |
| | | (See Note 1) |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents..... | \$ 11,268 | \$ 11,335 |
| Short-term investments..... | 109,947 | 101,614 |
| Accounts receivable, net..... | 26,361 | 26,820 |
| Inventory..... | 6,596 | 8,788 |
| Prepays and other current assets..... | 3,688 | 3,203 |
| Restricted cash equivalents..... | 204 | 188 |
| | ----- | ----- |
| Total current assets..... | 158,064 | 151,948 |
| Property and equipment, net..... | 27,779 | 10,288 |
| Restricted cash equivalents..... | 319 | 642 |
| Intangible assets, net..... | 6,688 | 8,089 |
| Goodwill..... | 143,332 | 143,106 |
| Other assets..... | 641 | 921 |
| | ----- | ----- |
| Total assets..... | 336,823 | 314,994 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable..... | \$ 5,214 | \$ 5,894 |
| Accrued compensation and employee benefits..... | 7,450 | 5,267 |
| Restructuring accrual..... | 806 | 971 |
| Other accrued liabilities..... | 7,488 | 9,134 |
| Deferred revenue..... | 14,092 | 11,345 |
| Current portion of notes payable..... | 813 | 1,030 |
| | ----- | ----- |
| Total current liabilities..... | 35,863 | 33,641 |
| Long-term notes payable..... | 52 | 695 |
| Deferred revenue..... | 1,077 | 1,148 |
| Other accrued liabilities..... | 57 | 553 |
| | ----- | ----- |
| Total non-current liabilities..... | 1,186 | 2,396 |
| Commitments and contingencies (Note 11)..... | -- | -- |
| Stockholders' equity: | | |
| Preferred stock, 2,500,000 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of September 30, 2004 and and December 31, 2003, respectively..... | -- | -- |
| Common stock, 100,000,000 shares authorized, \$0.001 par value, 33,977,398 and 33,051,631 shares issued and outstanding as of September 30, 2004 and December 31, 2003, respectively..... | 34 | 33 |
| Additional paid-in capital..... | 426,390 | 416,559 |
| Deferred compensation..... | -- | (99) |
| Accumulated deficit..... | (126,618) | (138,414) |

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| | | |
|--|------------|------------|
| Accumulated other comprehensive income (loss)..... | (32) | 878 |
| | ----- | ----- |
| Total stockholders' equity..... | 299,774 | 278,957 |
| | ----- | ----- |
| Total liabilities and stockholders' equity..... | \$ 336,823 | \$ 314,994 |
| | ===== | ===== |

See accompanying notes to consolidated financial statements.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|------------|------------------------------------|------------|
| | 2004 | 2003 | 2004 | 2003 |
| Sales: | | | | |
| Products..... | \$ 29,262 | \$ 20,515 | \$ 77,583 | \$ 56,958 |
| Services..... | 6,231 | 2,878 | 16,026 | 7,123 |
| Total sales..... | 35,493 | 23,393 | 93,609 | 64,081 |
| Cost of sales: | | | | |
| Products..... | 9,798 | 9,397 | 27,871 | 24,075 |
| Services..... | 2,973 | 1,932 | 7,552 | 5,513 |
| Total cost of sales..... | 12,771 | 11,329 | 35,423 | 29,588 |
| Gross profit..... | 22,722 | 12,064 | 58,186 | 34,493 |
| Operating costs and expenses: | | | | |
| Selling, general, and administrative..... | 12,600 | 11,320 | 34,378 | 29,303 |
| Research and development..... | 4,635 | 4,407 | 13,571 | 11,457 |
| Total operating costs and expenses..... | 17,235 | 15,727 | 47,949 | 40,760 |
| Income (loss) from operations..... | 5,487 | (3,663) | 10,237 | (6,267) |
| Other income, net | 692 | 310 | 1,924 | 1,499 |
| Income (loss) before taxes..... | 6,179 | (3,353) | 12,161 | (4,768) |
| Income tax expense..... | 66 | -- | 365 | -- |
| Net income (loss)..... | \$ 6,113 | \$ (3,353) | \$ 11,796 | \$ (4,768) |
| Net income (loss) per share: | | | | |
| Basic..... | \$ 0.18 | \$ (0.12) | \$ 0.35 | \$ (0.22) |
| Diluted | \$ 0.17 | \$ (0.12) | \$ 0.34 | \$ (0.22) |
| Shares used in computing net income (loss) per share: | | | | |
| Basic..... | 33,823 | 26,878 | 33,556 | 21,296 |
| Diluted..... | 35,305 | 26,878 | 34,534 | 21,296 |

See accompanying notes to consolidated financial statements.

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

| | For the Nine Months Ended September 30, | |
|---|--|------------|
| | 2004 | 2003 |
| OPERATING ACTIVITIES: | | |
| Net income (loss)..... | \$ 11,796 | \$ (4,768) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Depreciation..... | 3,859 | 3,021 |
| Provision for doubtful accounts..... | (320) | 707 |
| Loss on disposition of property and equipment..... | 270 | 5 |
| Amortization of deferred compensation and stock compensation..... | 99 | 379 |
| Amortization of intangible assets..... | 1,401 | 1,350 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable..... | 779 | (3,000) |
| Prepays and other current assets..... | (590) | (314) |
| Inventory..... | 2,192 | 664 |
| Other assets..... | 280 | (1,087) |
| Accounts payable..... | (688) | (5,021) |
| Accrued compensation and employee benefits..... | 2,149 | (841) |
| Restructuring accrual..... | (312) | (2,112) |
| Other accrued liabilities..... | (1,762) | (4,660) |
| Deferred revenue..... | 2,676 | 2,987 |
| Net cash provided by (used in) operating activities.... | 21,829 | (12,690) |
| INVESTING ACTIVITIES: | | |
| Acquisition of property and equipment..... | (21,960) | (1,914) |
| Disposition of property and equipment..... | 26 | 192 |
| Acquisition of business, net of cash acquired..... | -- | (4,088) |
| Release of restricted cash equivalents..... | 307 | 70 |
| Purchase of short-term investments..... | (77,441) | (10,866) |
| Proceeds from sales of short-term investments..... | 46,257 | 21,224 |
| Proceeds from maturities of short-term investments..... | 21,986 | 4,899 |
| Net cash (used in) provided by investing activities.... | (30,825) | 9,517 |
| FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock..... | 9,832 | 5,181 |
| Repurchase of common stock..... | -- | (6) |
| Repayment of notes payable..... | (860) | (1,243) |
| Net cash provided by financing activities..... | 8,972 | 3,932 |
| Effect of exchange rate changes on cash..... | (43) | (168) |
| Net (decrease) increase in cash and cash equivalents... | (67) | 591 |
| Cash and cash equivalents, beginning of period..... | 11,335 | 8,052 |

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| | | | | |
|---|----|--------|----|-------|
| Cash and cash equivalents, end of period..... | \$ | 11,268 | \$ | 8,643 |
| | | ===== | | ===== |

See accompanying notes to consolidated financial statements.

INTUITIVE SURGICAL, INC.
NOTES TO 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, 2003 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, 2003. The financial statements included in this report should be read in conjunction with the audited financial statements for the year ended December 31, 2003 included in the Annual Report. The results for the interim period ended September 30, 2004 are not necessarily indicative of the results to be expected for the full year ending December 31, 2004 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. Certain reclassifications have been made to prior year balances in order to conform to the current year presentation. These reclassifications had no impact on previously reported net income or stockholders' equity.

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 generated from 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 or return rights.

Revenue from sales of instruments and accessories is recognized upon shipment. 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 in June 2003. As required under Statement of Financial Accounting Standards Board ("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 (amounts in thousands, except per share amounts):

Three Months Ended Nine Months Ended

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| | September 30, | | September 30, | |
|--|---------------|------------|---------------|-------------|
| | 2004 | 2003 | 2004 | 2003 |
| Net income (loss), as reported..... | \$ 6,113 | \$ (3,353) | \$ 11,796 | \$ (4,768) |
| Add: Total stock-based employee compensation expense included in reported net income (loss), net of \$0 related tax effect.. | -- | 83 | 99 | 379 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of \$0 related tax effect..... | (2,429) | (2,123) | (7,546) | (6,107) |
| Pro forma net income (loss)..... | \$ 3,684 | \$ (5,393) | \$ 4,349 | \$ (10,496) |
| | ===== | ===== | ===== | ===== |
| Net income (loss) per share: | | | | |
| Basic - as reported..... | \$ 0.18 | \$ (0.12) | \$ 0.35 | \$ (0.22) |
| Basic - pro forma..... | \$ 0.11 | \$ (0.20) | \$ 0.13 | \$ (0.49) |
| Diluted - as reported..... | \$ 0.17 | \$ (0.12) | \$ 0.34 | \$ (0.22) |
| Diluted - pro forma..... | \$ 0.10 | \$ (0.20) | \$ 0.13 | \$ (0.49) |

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 September 30, | | Nine Months Ended September 30, | |
|----------------------------------|-------------------------------------|--------|------------------------------------|--------|
| | 2004 | 2003 | 2004 | 2003 |
| Stock Option Plans: | | | | |
| Average risk free interest rate. | 3.24 % | 2.52 % | 3.10 % | 2.51 % |
| Average expected life (years)... | 4.0 | 4.0 | 4.0 | 4.0 |
| Volatility..... | 68 % | 80 % | 70 % | 80 % |
| Stock Purchase Plan: | | | | |
| Average risk free interest rate. | 1.47 % | 1.21 % | 1.34 % | 1.48 % |
| Average expected life (years)... | 1.4 | 0.5 | 1.2 | 0.5 |
| Volatility..... | 62 % | 48 % | 62 % | 48 % |

Recent Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 46R, ("FIN 46R"), (revised December 2003), "Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51," which addresses how a business enterprise should evaluate whether it has a controlling interest in an entity through means other than voting rights and accordingly should consolidate the entity. FIN 46R replaces FASB Interpretation FIN 46, which was issued in January 2003. As of the effective date of FIN 46R, an enterprise must evaluate its involvement with all entities or legal structures created before February 1, 2003, to determine whether consolidation requirements of FIN No. 46R apply to those entities. There is no grandfathering of existing entities. The adoption of FIN No. 46R did not have a significant impact on the Company's consolidated financial position, results of operations or cash flow.

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In December 2003, the SEC issued Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition." SAB No. 104 revised and rescinded portions of the interpretative guidance included in Topic 13 of the codification of staff accounting bulletins in order to make that interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The adoption of SAB No. 104 did not have a significant impact on the Company's consolidated financial position, results of operations or cash flow.

In March 2004, the EITF reached a consensus on recognition and measurement guidance previously discussed under EITF 03-01. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under SFAS 115, "Accounting for Certain Investments in Debt and Equity Securities," and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached is to be applied to other-than-temporary impairment evaluations. In September 2004, FASB issued a final FASB Staff Position, FSP EITF Issue 03-01-1, that delays the effective date for the measurement and recognition guidance of EITF 03-01. The Company is currently evaluating the impact of adopting EITF 03-01.

On October 13, 2004, the FASB concluded that Statement 123R, "Share-Based Payment," which would require all companies to measure compensation cost for all share-based payments, including employee stock options, at fair value, would be effective for public companies, except small business issuer as defined in SEC Regulation S-B, for interim or annual periods beginning after June 15, 2005. The Company is currently evaluating the impact of the adopting Statement 123R.

NOTE 2. CONCENTRATIONS OF RISK

Financial instruments that subject the Company to potential risk consist of its cash equivalents, short-term investments, accounts receivable, and foreign exchange contracts. The counterparties to the agreements relating to the Company's investment securities and foreign exchange contracts 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 and nine months ended September 30, 2004 and 2003, no customer accounted for more than 10% of total sales. The Company extends reasonably short collection terms but does not require collateral. The Company provides reserves for potential credit losses.

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 and nine months ended September 30, 2004 and 2003. 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 September 30, | | Nine Months Ended September 30, | |
|--------------------|-------------------------------------|-----------|------------------------------------|-----------|
| | 2004 | 2003 | 2004 | 2003 |
| Domestic..... | \$ 27,819 | \$ 19,962 | \$ 72,999 | \$ 50,759 |
| International..... | 7,674 | 3,431 | 20,610 | 13,322 |
| Total sales..... | \$ 35,493 | \$ 23,393 | \$ 93,609 | \$ 64,081 |
| | ===== | ===== | ===== | ===== |

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 September 30, 2004 and December 31, 2003. Approximately \$4.0 million and \$4.8 million of money market instruments were included in cash and cash equivalents at September 30, 2004 and December 31, 2003, 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):

| | September 30, 2004 | December 31, 2004 |
|-----------------------------|--------------------|-------------------|
| | ----- | ----- |
| U.S. corporate debt..... \$ | 48,773 | \$ 44,904 |
| U.S. government debt..... | 31,924 | 28,210 |
| Municipal debt..... | 17,450 | 11,950 |
| Commercial paper..... | 11,800 | 16,550 |
| | ----- | ----- |
| Total..... \$ | 109,947 | \$ 101,614 |
| | ===== | ===== |

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):

| | September 30, 2004 | December 31, 2003 |
|-----------------------|-----------------------|----------------------|
| | ----- | ----- |
| Raw materials..... \$ | 1,753 | \$ 1,247 |
| Work-in-process..... | 1,235 | 1,797 |
| Finished goods..... | 3,608 | 5,744 |
| | ----- | ----- |
| Total..... \$ | 6,596 | \$ 8,788 |
| | ===== | ===== |

NOTE 6. GOODWILL AND INTANGIBLE ASSETS

Goodwill and Intangible Assets

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Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. 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 once each fiscal year (more frequently if certain indicators are present), which the Company will do in the fourth quarter. 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 incur 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):

| | September 30, 2004 | | | |
|-----------------------------------|--------------------|-----------------------------|------------|----------|
| | Gross | Accumulated Amortization | Impairment | Net |
| Developed technology..... | \$ 3,500 | \$ 250 | \$ 3,250 | \$ -- |
| Core technology..... | 3,300 | 589 | -- | 2,711 |
| Customer relationships..... | 1,300 | 433 | -- | 867 |
| Patents..... | 7,310 | 4,340 | -- | 2,970 |
| Other intangible assets..... | 500 | 69 | 291 | 140 |
| Total intangible assets, net..... | \$ 15,910 | \$ 5,681 | \$ 3,541 | \$ 6,688 |
| | ===== | ===== | ===== | ===== |
| | December 31, 2003 | | | |
| | Gross | Accumulated Amortization | Impairment | Net |
| Developed technology..... | \$ 3,500 | \$ 250 | \$ 3,250 | \$ -- |
| Core technology..... | 3,300 | 236 | -- | 3,064 |
| Customer relationships..... | 1,300 | 233 | -- | 1,067 |
| Patents..... | 7,310 | 3,511 | -- | 3,799 |
| Other intangible assets..... | 500 | 50 | 291 | 159 |
| Total intangible assets, net..... | \$ 15,910 | \$ 4,280 | \$ 3,541 | \$ 8,089 |
| | ===== | ===== | ===== | ===== |

Amortization expense related to intangible assets was \$0.5 million and \$0.6 million for the three months ended September 30, 2004 and 2003, respectively. Amortization expense related to intangible assets was \$1.4 million and \$1.4 million for the nine months ended September 30, 2004 and 2003, respectively.

Estimated future amortization expense related to intangible assets at September 30, 2004 is as follows (in thousands):

| Fiscal Year | |
|------------------------------|--------|
| 2004 (remaining 3 months)... | \$ 467 |
| 2005..... | 1,868 |

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| | |
|-----------------|----------|
| 2006..... | 1,275 |
| 2007..... | 1,077 |
| 2008..... | 811 |
| Thereafter..... | 1,190 |
| | ----- |
| Total..... | \$ 6,688 |
| | ===== |

Impairment of Goodwill

The Company has elected to perform an annual analysis of goodwill during the fourth quarter of each year. Based on our 2003 impairment analysis, no impairments were identified, and no indicators of impairment were identified during the nine months ended September 30, 2004.

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 nine months ended September 30, 2004 and 2003.

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. Effective July 1, 2003, the Company adopted the provisions of EITF No. 00-21 on a prospective basis. Under EITF No. 00-21, for certain arrangements, a portion of the overall system price attributable to the first year service is deferred and recognized as revenue over the service period. As such, the Company recognizes warranty and related service costs as incurred for these arrangements. The warranty provision resulting from transactions prior to July 1, 2003 will be reduced in future periods for material and labor costs incurred as related product is returned during the warranty period or when the warranty period elapses. 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 for the period indicated (in thousands):

| | Balance at Beginning of Period | Warranty Usage | Warranty Accrued | Balance at End of Period |
|---------------------------------------|--------------------------------------|-------------------|---------------------|--------------------------------|
| | ----- | ----- | ----- | ----- |
| Nine months ended September 30, 2004. | \$ 702 | \$ (703) | \$ 149 | \$ 148 |

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 September 30, 2004 or December 31, 2003.

NOTE 8. RESTRUCTURING CHARGES

In connection with the acquisition of Computer Motion in June 2003, the Company recorded an accrual for acquisition integration liabilities, which includes the incremental costs to exit and consolidate activities at Computer Motion locations, termination of certain Computer Motion employees, and for other costs to integrate operating locations and other activities of Computer Motion. The accrual was recorded using the guidance provided by EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination," which requires that these acquisition integration expenses, which are not associated with the generation of future revenues and have no future economic benefit, be reflected as assumed liabilities in the allocation of the purchase price to the net assets acquired. During 2003, the Company recorded a \$3.4 million accrual in accordance with EITF 95-3. The accrual was comprised of \$2.6 million for employee severance costs and \$0.8 million for estimated losses to be incurred to sublet vacated facilities. During the nine months ended September 30, 2004, the Company increased the accrual for the estimated losses to be incurred to sublet vacated facilities by \$0.2 million due to the change in estimates on assumptions used to calculate the losses on subleasing the vacated facilities.

During the three months ended December 31, 2003, based on the Company's cost structure and future development plans, the Company planned to completely shut down the Goleta research and development facility. In accordance with SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," the Company recorded restructuring charges of \$0.2 million, which are related to the costs of one-time employee terminations. SFAS No. 146 requires that a liability for costs associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. As employees are generally required to render service beyond the minimum retention period or 60 days, the severance payments are recognized ratably over the service periods. During the nine months ended September 30, 2004, the Company completed the shutdown of the Goleta research and development facilities and accrued \$0.2 million of employee severance costs and \$0.5 million of lease commitment costs to exit the leased facility. The charges incurred in the nine months ended September 30, 2004 were recorded in research and development expenses on the income statement. 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 nine months ended September 30, 2004 (in thousands):

| | EITF No. 95-3 | | SFAS No. 146 | | |
|---|-----------------------|----------------------|-----------------------|----------------------|----------|
| | Employee Severance | Lease Commitments | Employee Severance | Lease Commitments | Total |
| Cost accrued..... | \$ 2,628 | \$ 816 | \$ 186 | \$ -- | \$ 3,630 |
| Cash payments, net of subleasing proceeds.. | (2,310) | (303) | -- | -- | (2,613) |
| Currency impact..... | (23) | (23) | -- | -- | (46) |
| Balance at December 31, 2003..... | 295 | 490 | 186 | -- | 971 |
| Cost accrued..... | -- | 226 | 224 | 525 | 975 |
| Cash payments, net of subleasing proceeds.. | (291) | (268) | (410) | (177) | (1,146) |
| Currency impact..... | -- | 6 | -- | -- | 6 |
| Balance at September 30, 2004..... | \$ 4 | \$ 454 | \$ -- | \$ 348 | \$ 806 |

NOTE 9. COMPREHENSIVE INCOME (LOSS)

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Comprehensive income (loss) includes net income (loss) 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 (loss) consist of the following (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|------------------------------------|-------------------------------------|------------|------------------------------------|------------|
| | 2004 | 2003 | 2004 | 2003 |
| Net income (loss)..... | \$ 6,113 | \$ (3,353) | \$ 11,796 | \$ (4,768) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation | | | | |
| adjustments..... | 11 | (13) | (46) | (168) |
| Change in unrealized gain (loss) | | | | |
| on available-for-sale securities.. | 243 | (198) | (864) | (654) |
| Comprehensive income (loss)..... | \$ 6,367 | \$ (3,564) | \$ 10,886 | \$ (5,590) |
| | ===== | ===== | ===== | ===== |

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

| | September 30, 2004 | December 31, 2003 |
|---------------------------------------|-----------------------|----------------------|
| Accumulated net unrealized gain on | | |
| available-for-sales securities..... | \$ 76 | \$ 940 |
| Foreign currency translation | | |
| adjustments..... | (108) | (62) |
| Total accumulated other comprehensive | | |
| (loss) income..... | \$ (32) | \$ 878 |
| | ===== | ===== |

NOTE 10. NET INCOME (LOSS) PER SHARE

The following table presents the computation of basic and diluted net income (loss) per share (in thousands, except per share data). Basic net income (loss) per share is computed using the weighted-average number of common shares outstanding. Diluted net income (loss) per share is computed using the weighted-average number of common shares outstanding and potential dilutive common shares from the assumed exercise of options and warrants outstanding during the period, if any, using the treasury method.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--------------------------------|-------------------------------------|------------|------------------------------------|------------|
| | 2004 | 2003 | 2004 | 2003 |
| Numerator used for basic and | | | | |
| diluted net income (loss) per | | | | |
| common share..... | \$ 6,113 | \$ (3,353) | \$ 11,796 | \$ (4,768) |
| | ===== | ===== | ===== | ===== |
| Denominator used for basic and | | | | |

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| | | | | |
|---|---------|-----------|---------|-----------|
| diluted net income (loss) per common share: | | | | |
| Weighted-average shares | | | | |
| outstanding..... | 33,823 | 26,881 | 33,556 | 21,301 |
| Less weighted-average shares subject to repurchase..... | -- | (3) | -- | (5) |
| | ----- | ----- | ----- | ----- |
| Weighted-average shares used in computing basic net income (loss) per common share..... | 33,823 | 26,878 | 33,556 | 21,296 |
| | ===== | ===== | ===== | ===== |
| Add common stock equivalents..... | 1,482 | -- | 978 | -- |
| Weighted-average shares used in computing diluted net income (loss) per common share..... | 35,305 | 26,878 | 34,534 | 21,296 |
| | ===== | ===== | ===== | ===== |
| Net income (loss) per common share: | | | | |
| Basic..... | \$ 0.18 | \$ (0.12) | \$ 0.35 | \$ (0.22) |
| | ===== | ===== | ===== | ===== |
| Diluted..... | \$ 0.17 | \$ (0.12) | \$ 0.34 | \$ (0.22) |
| | ===== | ===== | ===== | ===== |

Potential weighted-average common shares excluded from the computation of diluted net income per share as their effect would be antidilutive were 193,000 shares and 359,000 shares, respectively, for the three months and nine months ended September 30, 2004. The exercise price of these options exceeded the average market price during the three-month and nine-month periods mentioned above. These shares could, however, potentially dilute basic income per share in the future. For the three months and nine months ended September 30, 2003, the Company did not include options outstanding to purchase 4,977,000 and 3,803,000 shares, respectively, of common stock in the diluted net loss per share since their effect was antidilutive due to the reported loss.

NOTE 11. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company entered into a lease arrangement of office and manufacturing space in Sunnyvale, California effective January 2002 (the "Sunnyvale Lease"). Under the Sunnyvale Lease, the Company was required to lease additional space in the same building starting in January 2004. The Sunnyvale Lease was scheduled to expire on April 30, 2007. On April 30, 2004, the Company purchased the property for approximately \$20.0 million and canceled the Sunnyvale Lease. In addition, 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 September 30, 2004, the Company sublet approximately 90% of its office space in Goleta.

Future minimum lease commitments, net of sublease income of \$1.4 million throughout the next 4 years, under the Company's operating leases as of September 30, 2004 are as follows (in thousands):

| | |
|--------------------------------|--------|
| 2004 (remaining 3 months)..... | \$ 112 |
| 2005..... | 408 |
| 2006..... | 399 |
| 2007..... | 236 |
| 2008..... | 36 |
| Thereafter..... | 34 |

| | | |
|------------|----|-------|
| Total..... | \$ | 1,225 |
| | | ===== |

Rent expense was approximately \$0.1 million and \$0.9 million for the three months ended September 30, 2004 and 2003, respectively. Rent expense was approximately \$1.0 million and \$2.4 million for the nine months ended September 30, 2004 and 2003, respectively.

CONTINGENCIES

The discussion of the Company's legal proceedings is incorporated by reference from Part II, 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," "Company," "we," "us," and "our" refer to Intuitive Surgical, Inc.

This management's discussion and analysis of financial condition as of September 30, 2004 and results of operations for the three months and nine months ended September 30, 2004 and September 30, 2003 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.

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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.

RESULTS OF OPERATIONS

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Product Sales (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % Change |
|-------------------------|-----------------------|-----------------------|---------|-------------|
| Three months ended..... | \$ 29.3 | \$ 20.5 | \$ 8.8 | 43 % |
| Nine months ended..... | \$ 77.6 | \$ 57.0 | \$ 20.6 | 36 % |

Product sales increased to \$29.3 million for the three months ended September 30, 2004 from \$20.5 million for the three months ended September 30, 2003. This 43% increase in product sales resulted primarily from higher *da Vinci* Surgical System unit sales and higher recurring instrument and accessory revenue.

Total third quarter 2004 system revenue was \$19.0 million compared to \$15.5 million during the third quarter of 2003. We shipped 18 *da Vinci* Surgical Systems during the third quarter of 2004: 13 in North America, 1 in Europe, and 4 in the rest of the world. The 18 total units shipped represented a 3 unit increase compared to 15 units shipped during the third quarter of 2003. As of September 30, 2004 we have shipped a total of 261 *da Vinci* Surgical Systems: 184 in North America, 52 in Europe, and 25 in the rest of the world. We shipped 15 *da Vinci* Surgical System fourth arms during the third quarter of 2004, compared to 16 during the third quarter of 2003. We shipped 8 *Aesop* systems during the third quarter of 2004, compared to 5 during the third quarter of 2003.

Third quarter 2004 instrument and accessory revenue increased to \$10.3 million from \$5.0 million for the third quarter of 2003, reflecting a growing number of surgical procedures performed by our customers, such as those for radical prostatectomy procedures. This growth resulted from a larger base of installed *da Vinci* Surgical Systems and improved system utilization per site.

Product sales increased to \$77.6 million for the nine months ended September 30, 2004 from \$57.0 million for the nine months ended September 30, 2003. This 36% increase in product sales resulted primarily from higher recurring instrument and accessory revenue, higher *da Vinci* Surgical System unit sales, and higher fourth arm unit sales.

Total system revenue for the nine months ended September 30, 2004 was \$51.7 million compared to \$44.3 million for the nine months ended September 30, 2003. We shipped 51 *da Vinci* Surgical Systems during the first nine months of 2004, compared to 43 units shipped during the first nine months of 2003. We shipped 17 *Aesop* systems during the first nine months of 2004, compared to 5 for the first nine months of 2003.

Instrument and accessory revenue for the nine months ended September 30, 2004 increased to \$25.9 million from \$12.7 million for the nine months ended September 30, 2003, reflecting a growing number of surgical procedures performed by our customers, such as those for radical prostatectomy procedures. This growth resulted in large part from a larger base of installed *da Vinci* Surgical Systems and improved system utilization per site.

Service Sales (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % Change |
|-------------------------|-----------------------|-----------------------|--------|-------------|
| Three months ended..... | \$ 6.2 | \$ 2.9 | \$ 3.3 | 114 % |
| Nine months ended..... | \$ 16.0 | \$ 7.1 | \$ 8.9 | 125 % |

Service sales, comprised of system service, installation and customer training, increased to \$6.2 million for the three months ended September 30, 2004 from \$2.9 million for the three months ended September 30, 2003. The increase

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was primarily due to a larger base of *da Vinci* Surgical Systems generating service revenue. The base of systems generating service revenue grew by 125 systems entering the third quarter of 2004 compared to the third quarter of 2003. The increase of 125 was comprised of 59 systems sold between the third quarter of 2002 and the second quarter of 2003 coming out of the warranty period onto service contracts and 66 systems sold between the third quarter of 2003 and the second quarter of 2004, with first year service deferred according to EITF 00-21, which was adopted prospectively effective July 1, 2003. In addition, the average service revenue per active system under a service contract increased in 2004 due to higher rates charged for four-arm systems.

Service sales increased to \$16.0 million for the nine months ended September 30, 2004 from \$7.1 million for the nine months ended September 30, 2003. The increase was primarily due to a larger base of *da Vinci* Surgical Systems generating service revenue.

Product Sales Gross Profit (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % Change |
|----------------------------------|-----------------------|-----------------------|---------|-------------|
| Three months ended..... | \$ 19.5 | \$ 11.1 | \$ 8.4 | 76 % |
| Percentage of product sales..... | 66.5 % | 54.2 % | | |
| Nine months ended..... | \$ 49.7 | \$ 32.9 | \$ 16.8 | 51 % |
| Percentage of product sales..... | 64.1 % | 57.7 % | | |

Product sales gross profit for the three months ended September 30, 2004 was \$19.5 million, or 66.5% of product sales, compared to \$11.1 million, or 54.2% of product sales for the three months ended September 30, 2003. The \$8.4 million increase in product gross profit was driven by \$8.8 million higher product sales during the third quarter of 2004, as described previously, in combination with a higher third quarter 2004 gross profit percentage. Our increased third quarter 2004 gross profit percentage was driven by maintaining product pricing, leveraging fixed manufacturing costs across higher product sales volume, and reducing system and instrument material costs. In addition, third quarter 2003 product margin was negatively impacted by approximately \$1.0 million, or 4.9 margin points, due to integration costs incurred associated with the Computer Motion entity acquired on June 30, 2003.

Product sales gross profit for the nine months ended September 30, 2004 was \$49.7 million, or 64.1% of product sales, compared to \$32.9 million, or 57.7% of product sales for the nine months ended September 30, 2003. The increase was driven by maintaining product pricing, leveraging fixed manufacturing costs across higher product sales volume, and reducing system and instrument material costs.

Service Sales Gross Profit (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % Change |
|----------------------------------|-----------------------|-----------------------|--------|-------------|
| Three months ended..... | \$ 3.3 | \$ 0.9 | \$ 2.4 | 267 % |
| Percentage of service sales..... | 52.3 % | 32.9 % | | |
| Nine months ended..... | \$ 8.5 | \$ 1.6 | \$ 6.9 | 431 % |
| Percentage of product sales..... | 52.9 % | 22.6 % | | |

Service sales gross profit for the three months ended September 30, 2004 was \$3.3 million, or 52.3% of service sales, compared to \$0.9 million, or 32.9% of service sales for the three months ended September 30, 2003. Service sales

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gross profit for the nine months ended September 30, 2004 was \$8.5 million, or 52.9% of service sales, compared to \$1.6 million, or 22.6% of service sales, for the nine months ended September 30, 2003. Higher 2004 service sales gross profit was driven by increased service revenue, as described above, in combination with increased leverage of the mostly fixed service and training organization expenses across a larger base of installed systems.

Selling, General and Administrative Expenses (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % |
|-------------------------|-----------------------|-----------------------|--------|-------|
| | ----- | ----- | ----- | ----- |
| Three months ended..... | \$ 12.6 | \$ 11.3 | \$ 1.3 | 12 % |
| Nine months ended..... | \$ 34.4 | \$ 29.3 | \$ 5.1 | 17 % |

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 three months ended September 30, 2004 were \$12.6 million, up 12% from \$11.3 million for the three months ended September 30, 2003. Selling, general and administrative expenses for the nine months ended September 30, 2004 were \$34.4 million, up 17% from \$29.3 million for the nine months ended September 30, 2003. The year over year increases were primarily due to higher incentive compensation and other variable costs associated with achieving higher revenues, incremental patent costs associated with maintaining the Computer Motion patent portfolio, and additional accounting personnel, consulting, and auditing resources added to support compliance with the Sarbanes Oxley Act of 2002. These items were partially offset by the elimination of Computer Motion integration costs incurred during the third quarter of 2003.

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

Research and Development Expenses (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % |
|-------------------------|-----------------------|-----------------------|--------|-------|
| | ----- | ----- | ----- | ----- |
| Three months ended..... | \$ 4.6 | \$ 4.4 | \$ 0.2 | 5 % |
| Nine months ended..... | \$ 13.6 | \$ 11.5 | \$ 2.1 | 18 % |

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 three months ended September 30, 2004 were \$4.6 million, up 5% compared to \$4.4 million for the three months ended September 30, 2003. The increase was primarily due to higher third quarter 2004 incentive compensation and product development project costs, partially offset by the elimination of the Computer Motion integration and operating costs incurred during the third quarter of 2003.

Research and development expenses for the nine months ended September 30, 2004 were \$13.6 million, up 18% compared to \$11.5 million for the nine months ended September 30, 2003. The increase during the nine months ended September 30, 2004 was due in large part to expenses incurred in the first quarter of 2004 to close the former Computer Motion facilities located in Goleta, California. In accordance with our restructuring plan, we completely shut down the Goleta site on March 31, 2004 and terminated all remaining Goleta-based employees, resulting in a

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\$0.8 million restructuring expense recorded in the first quarter of 2004. The remainder of the increase for the nine months ended September 30, 2004 was primarily due to higher incentive compensation and product development costs.

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 increase in the future.

Other Income, Net, and Income Tax Expense (dollars in millions)

| | September 30, 2004 | September 30, 2003 | Change | % |
|-------------------------|-----------------------|-----------------------|--------|-------|
| | ----- | ----- | ----- | ----- |
| Three months ended..... | \$ 0.6 | \$ 0.3 | \$ 0.3 | 100 % |
| Nine months ended..... | \$ 1.6 | \$ 1.5 | \$ 0.1 | 7 % |

Other income, comprised mostly of interest income, increased to \$0.7 million for the three months ended September 30, 2004 from \$0.3 million for the three months ended September 30, 2003. The increase resulted primarily from higher interest income earned on a larger cash balance position during the third quarter of 2004 resulting from the proceeds of our public offering of common stock in the fourth quarter of 2003.

Other income for the nine months ended September 30, 2004 was \$1.9 million, compared to \$1.5 million for the nine months ended September 30, 2003. First quarter 2003 other income included \$0.5 million of gains realized on sales of securities. Excluding these first quarter 2003 capital gains, other income for the nine months ended September 30, 2004, comprised mostly of interest income, increased \$0.9 million primarily due to higher interest income earned on a larger cash balance position during the period resulting from the proceeds of the fourth quarter of 2003 public offering of our common stock.

Income tax expense was \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2004, respectively. This expense represents estimated income tax based on our profitability for the periods presented.

LIQUIDITY AND CAPITAL RESOURCES

Our operations have been financed primarily through the sale of our equity securities. 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. At September 30, 2004 we had total stockholders equity of \$299.8 million and outstanding equipment financing debt of \$0.9 million. As of September 30, 2004, we had cash, cash equivalents and short-term investments of \$121.2 million, compared to \$112.9 million at December 31, 2003. Working capital as of September 30, 2004 was \$122.2 million, compared to \$118.3 million as of December 31, 2003. The increase in cash, cash equivalents and short-term investments and in working capital resulted primarily from our 2004 year-to-date net income of \$11.8 million, non-cash operating expenses of \$5.3 million, and net proceeds of \$9.8 million realized from stock option exercises and our employee stock purchase plan, partially offset by the purchase of our Sunnyvale, California facility during the second quarter of 2004 for approximately \$20.0 million in cash and the purchase of other property and equipment for approximately \$2.0 million in cash.

Net cash provided by operating activities was \$21.8 million for the nine months ended September 30, 2004, compared to \$12.7 million of cash used in operating activities for the nine months ended September 30, 2003. The \$21.8 million of cash provided by operations during the nine months ended September 30, 2004 resulted from net income of \$11.8 million, non-cash expenses of \$5.3 million and net working capital generated of \$4.7 million. The \$12.7 million of cash used in operating activities during the nine months ended September 30, 2003 was comprised primarily of

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working capital consumed of \$13.4 million and our net loss of \$4.8 million, partially offset by non-cash expenses of \$5.5 million. The \$13.4 million of working capital consumed during the nine months ended September 30, 2003 was driven by the payment of net liabilities acquired in the Computer Motion acquisition which closed on June 30, 2003.

Net cash used in investing activities was \$30.8 million for the nine months ended September 30, 2004, compared to net cash provided by investing activities of \$9.5 million for the nine months ended September 30, 2003. Net cash used in investing activities during the nine months ended September 30, 2004 resulted mainly from investments in fixed assets of \$22.0 million, comprised mostly of our purchase of our Sunnyvale, California facility (\$20.0 million) during the second quarter of 2004, and the net conversion of cash into short-term investments of \$8.9 million. Net cash provided by investing activities during the nine months ended September 30, 2003 resulted primarily from the net conversion of short-term investments into cash of \$15.3 million, partially offset by \$4.1 million of cash used to acquire Computer Motion and \$1.7 million of cash related to the purchase and disposition of fixed assets.

Net cash provided by financing activities was \$9.0 million for the nine months ended September 30, 2004, compared to \$3.9 million for the nine months ended September 30, 2003. Net cash provided by financing activities for the nine months ended September 30, 2004 resulted primarily from net proceeds realized from stock option exercises and our employee stock purchase plan of \$9.8 million, partially offset by repayments of long-term debt of \$0.9 million. Net cash provided by financing activities for the nine months ended September 30, 2003 resulted primarily from net proceeds realized from stock option exercises and our employee stock purchase plan of \$5.2 million, partially offset by repayments of long-term debt of \$1.2 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 \$1.4 million throughout the next 4 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 |
|--------------------------------|--------|---------------------|--------------|--------------|----------------------|
| Long-term debt | \$ 0.9 | \$ 0.8 | \$ 0.1 | \$ 0.0 | \$ 0.0 |
| Building lease | 1.2 | 0.4 | 0.7 | 0.1 | 0.0 |
| P u r c h a s e commitments | 0.3 | 0.3 | 0.0 | 0.0 | 0.0 |
| Total | \$ 2.4 | \$ 1.5 | \$ 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 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.

Because of our limited operating history, 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 uncertain, and we may be unable to generate significant revenues. In addition, our costs may be higher than we, securities analysts or investors expect. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. 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:

- 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 extent to which our products gain market acceptance;
- third-party payor reimbursement policies;
- 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;
- actions relating to regulatory matters;
- 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 September 30, 2004 and 2003, approximately 52% and 65%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems, which are high revenue dollar items. During the nine months ended September 30, 2004 and 2003, approximately 54% and 69%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems. During the three-month and nine-month periods ended September 30, 2004 and 2003, 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.

Our 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.

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.

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.

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 will 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 intend to sell our products and these efforts are expected to continue.

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 and computer software, either 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.

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 ("GMP") requirements contained in the FDA's Quality System Regulations, or QSR. We are also required to comply with the Medical Device Directive ("MDD") and International Organization for Standardization ("ISO"), quality system standards in order to produce products for sale in Europe. If we fail to continue to comply with GMP requirements, the MDD, 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 inspections at any time, and we are subject to MDD and ISO audits on an annual basis to maintain our certifications. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with GMP requirements, the MDD, or ISO standards in future inspections and audits by regulatory authorities.

The state of California also requires that we maintain a license 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.

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.

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.

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 scientific 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.

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:

- 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.

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.

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

Our integration strategy related to our acquisition of Computer Motion may involve the termination of Computer Motion's relationships with a number of companies that served as Computer Motion's distributors prior to the acquisition. Several of these former distributors have informed us that they believe that they are entitled to compensation in connection with such termination. We may be unable to resolve these claims without litigation. 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. If we sue or are sued by any of Computer Motion's former distributors, these proceedings may be expensive to litigate, may be protracted, and Computer Motion's 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.

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., and SRI International. 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.

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 22% of our sales for the three months ended September 30, 2004 and 14% for the three months ended September 30, 2003. Sales to markets outside of the United States accounted for approximately 22% of our sales for the nine months ended September 30, 2004 and 21% for the nine months ended September 30, 2003.

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.

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.

INVESTOR CONFIDENCE AND SHARE VALUE MAY BE ADVERSELY IMPACTED IF WE OR OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ARE UNABLE TO PROVIDE AN UNQUALIFIED ATTESTATION OF THE ADEQUACY OF OUR INTERNAL CONTROLS OVER FINANCIAL REPORTING AS OF DECEMBER 31, 2004, AS REQUIRED BY SECTION 404 OF THE SARBANES- OXLEY ACT OF 2002.

The Securities and Exchange Commission, as directed by Section 404 of the Sarbanes-Oxley Act of 2002, adopted rules requiring public companies to include a report of management on the company's internal controls over financial reporting in its annual reports on Form 10-K that contain an assessment by management of the effectiveness of the company's internal controls over financial reporting. In addition, the company's independent registered public accounting firm must attest to and report on management's assessment of the effectiveness of the company's internal controls over financial reporting. This requirement will first apply to our Annual Report on Form 10-K for the fiscal year ending December 31, 2004. Although we intend to diligently and vigorously review our internal controls over financial reporting in order to ensure compliance with the Section 404 requirements, if we or our independent registered public accounting firm are not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, reviewed or tested, or if our independent registered public accounting firm interprets the requirements, rules or regulations differently from us, then we or they may decline to attest to management's assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares.

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.

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 principal amount 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 money market accounts. The average time to maturity of all of our investments as of September 30, 2004 was approximately 1.04 years. At September 30, 2004 and December 31, 2003, approximately 48% and 37%, respectively, of our investment portfolio was composed of investments with original 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. On a limited basis, we have used forward foreign exchange contracts to reduce a portion of our exposure to foreign currency risk from operational and balance sheet exposures resulting from changes in foreign currency exchange rates. Such exposures result from sales denominated in foreign currencies. These contracts were typically short-term in nature (i.e., less than 6 months).

For the three months ended September 30, 2004 and 2003, sales denominated in foreign currencies were 7% and 10%, respectively, of total sales. For the nine months ended September 30, 2004 and 2003, sales denominated in foreign currencies were 7% and 11%, respectively, of total sales. We did not enter into forward foreign exchange contracts during the three months and nine months ended September 30, 2004 and 2003.

We do not use derivative financial instruments for speculative trading purposes, nor do we hold or issue leveraged derivative financial instruments. We have not entered into any forward contracts since July 2002, and as of September 30, 2004 and December 31, 2003, we had no outstanding derivative instruments.

Foreign currency fluctuations resulted in \$23,000 of foreign exchange gain for the three months ended September 30, 2004 and \$50,000 of foreign exchange loss for the three months ended September 30, 2003. Foreign currency fluctuations resulted in \$65,000 of foreign exchange loss for the nine months ended September 30, 2004 and \$68,000 of foreign exchange gain for the nine months ended September 30, 2003.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures 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.

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, a former customer of Computer Motion filed a lawsuit against our company. We received the complaint on April 23, 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 believe the allegation is baseless and intend to vigorously defend this suit. To date, we have filed a motion to dismiss the fraud-based complaints and an answer defending the breach of contract claim. The litigation continues to be in discovery.

In November 2003, an Israeli company filed suit against our company and Computer Motion in Israel alleging breach of a distribution contract and seeking damages. We received the complaint on April 27, 2004. Following the acquisition of Computer Motion, we withdrew Computer Motion's distributorship offer to this Israeli company. We believe the allegation is baseless and intend to vigorously defend the suit. We have filed a motion to have the case dismissed on jurisdictional grounds. The court has not yet ruled on the motion as the parties are still submitting briefs on the motion.

In October 2003, SIC System, S.R.L. ("SIC System") a former Italian distributor for Computer Motion, filed suit against our company and Computer Motion seeking damages in the Civil Court of Rome, Italy (the "Italian Action"). In the Italian Action, 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 Italian Action on both jurisdictional grounds and on the merits. To date, the Court in the Italian Action has ruled that SIC System's service process in filing its complaint is defective and has ordered SIC System to re-file its complaint on or about October 6, 2004. The court in the Italian Action has not ruled on jurisdiction or other pending issues pertaining to the applicable law or appropriate forum.

On November 11, 2003, we filed a lawsuit in the United States District Court for the Central District of California captioned *Intuitive Surgical, Inc., et. al v. SIC System Srl*, Case Number CV-03-08220 for declaratory relief, breach of contract and preliminary and permanent injunction (the "Federal Action"). The Federal Action 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. The complaint in the Federal Action was served on SIC System on November 28, 2003, and the Court entered Default against SIC Systems on March 31, 2004. On August 16, 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 and awarded taxable costs to us.

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 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. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of these matters at this time and, therefore, cannot estimate the range of possible loss.

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

| Exhibit Number | Description |
|-------------------|-------------|
|-------------------|-------------|

31

Certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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Certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 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: November 8, 2004

EXHIBIT INDEX

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