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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 10-Q  
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QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2000

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 NO.)

1340 WEST MIDDLEFIELD ROAD  
MOUNTAIN VIEW, CALIFORNIA 94043-3061  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (650) 237-7000

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 periods that the  
Registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days. Yes  No

The Registrant had 35,684,462 shares of Common Stock, \$0.001 par value per  
share, outstanding as of November 13, 2000.

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## INTUITIVE SURGICAL, INC.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## INTUITIVE SURGICAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS  
 (UNAUDITED)  
 (IN THOUSANDS, EXCEPT PER SHARE DATA)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999
Sales.....	\$ 7,859	\$ 3,280	\$ 15,918	\$ 6,914
Cost of sales.....	4,708	2,928	10,743	6,170
Gross profit.....	3,151	352	5,175	744
Operating costs and expenses:				
Research and development.....	3,172	2,372	8,624	8,142
Selling, general and administrative.....	5,395	2,648	12,510	6,663
Total operating costs and expenses.....	8,567	5,020	21,134	14,805
Loss from operations.....	(5,416)	(4,668)	(15,959)	(14,061)
Interest income.....	1,489	413	2,730	1,151
Interest expense.....	(93)	(113)	(313)	(294)
Interest income, net.....	1,396	300	2,417	857
Net loss.....	\$(4,020)	\$(4,368)	\$(13,542)	\$(13,204)
Basic and diluted net loss per common share.....	\$ (.12)	\$ (.87)	\$ (.68)	\$ (2.83)
Shares used in computing net loss per common share.....	34,665	4,997	20,016	4,672

See accompanying notes to consolidated financial statements.

INTUITIVE SURGICAL, INC.  
CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS)

ASSETS

	SEPTEMBER 30, 2000	DECEMBER 31, 1999
	----- (UNAUDITED)	----- (SEE NOTE 1)
Current assets:		
Cash and cash equivalents.....	\$ 25,965	\$ 4,106
Short-term investments.....	61,718	22,154
Accounts receivable.....	8,373	2,044
Inventories.....	5,256	2,861
Prepaid expenses.....	1,635	581
	-----	-----
Total current assets.....	102,947	31,746
Property and equipment, net.....	3,839	2,709
Other assets.....	4,281	--
	-----	-----
Total assets.....	\$111,067	\$ 34,455
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 5,225	\$ 2,722
Accrued compensation and employee benefits.....	1,990	1,325
Warranty provision.....	1,171	812
Accrued liabilities.....	1,299	1,116
Deferred revenue.....	3,727	2,130
Current portion of notes payable.....	1,941	1,618
	-----	-----
Total current liabilities.....	15,353	9,723
Notes payable.....	1,241	2,521
Stockholders' equity		
Preferred stock, 5,000,000 shares authorized, \$0.001 par value, issuable in series: no shares and 19,134,375 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively.....	--	19
Common stock, 200,000,000 shares authorized, \$0.001 par value, 35,679,783 and 6,681,848 shares issued and outstanding as of September 30, 2000 and December 31, 1999, respectively.....	36	7
Additional paid-in capital.....	186,450	98,508
Deferred compensation.....	(3,203)	(943)
Accumulated deficit.....	(88,689)	(75,147)
Accumulated other comprehensive income.....	(121)	(233)
	-----	-----
Total stockholders' equity.....	94,473	22,211
	-----	-----
Total liabilities and stockholders' equity.....	\$111,067	\$ 34,455
	=====	=====

See accompanying notes to consolidated financial statements.

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

	NINE MONTHS ENDED	
	SEPTEMBER 30, 2000	SEPTEMBER 30, 1999
<b>OPERATING ACTIVITIES</b>		
Net loss.....	\$(13,542)	\$(13,204)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation.....	1,147	1,069
Amortization of deferred compensation.....	1,803	617
Amortization of other assets.....	389	--
Changes in operating assets and liabilities:		
Accounts receivable.....	(6,329)	(2,644)
Inventories.....	(2,395)	(1,889)
Prepaid expenses.....	(1,054)	58
Accounts payable.....	2,503	139
Accrued compensation and employee benefits.....	665	198
Warranty provision.....	359	512
Accrued liabilities.....	183	425
Deferred revenue.....	1,597	314
Net cash used in operating activities.....	(14,674)	(14,405)
<b>INVESTING ACTIVITIES</b>		
Capital expenditures.....	(2,277)	(705)
Acquisition of patents.....	(3,000)	--
Purchase of short-term investments.....	(55,628)	(27,260)
Proceeds from sales and maturities of short-term investments.....	16,176	17,323
Net cash used in investing activities.....	(44,729)	(10,642)
<b>FINANCING ACTIVITIES</b>		
Proceeds from issuance of convertible preferred stock.....	34,756	19,284
Proceeds from issuance of common stock.....	47,478	8
Repurchase of common stock.....	(15)	(38)
Proceeds from notes payable.....	500	2,000
Repayment of notes payable.....	(1,457)	(803)
Net cash provided by financing activities.....	81,262	20,451
Net increase (decrease) in cash and cash equivalents.....	21,859	(4,596)
Cash and cash equivalents at beginning of period.....	4,106	10,169
Cash and cash equivalents at end of period.....	\$ 25,965	\$ 5,573
	=====	=====

See accompanying notes to consolidated financial statements.

## INTUITIVE SURGICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

## NOTE 1. BASIS OF PRESENTATION

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

The accompanying unaudited 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 footnotes 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 financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 1999, included in the Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the Securities and Exchange Commission. The results for the interim period ended September 30, 2000 are not necessarily indicative of the results to be expected for the full year ending December 31, 2000 or future operating periods.

## NOTE 2. CASH AND CASH EQUIVALENTS

Intuitive Surgical considers all highly liquid investments with an original maturity from date of purchase of three months 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 December 31, 1999 and September 30, 2000.

## NOTE 3. SHORT-TERM INVESTMENTS

All short-term investments are classified as available-for-sale and therefore carried at fair value. We view our available-for-sale portfolio as available for use in our current operations. Accordingly, we have classified all investments 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 value based upon quoted market prices of the securities. Unrealized gains and losses on such securities, when material, are reported as a separate component of stockholders' equity. Realized gains and losses, net, 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.

## NOTE 4. INVENTORIES

Inventories consist of the following (in thousands):

	SEPTEMBER 30, 2000	DECEMBER 31, 1999
	-----	-----
Raw materials.....	\$1,698	\$1,147
Work-in-process.....	1,140	619
Finished goods.....	2,418	1,095
	-----	-----
	\$5,256	\$2,861
	=====	=====

## NOTE 5. OTHER ASSETS

In April 2000, we entered into an agreement with Heartport, Inc. to exclusively license a number of Heartport's patents in exchange for cash of \$3.0 million and a warrant to purchase 200,000 shares of our common stock at an exercise price of \$3.00 per share. In accordance with EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," we valued the warrant to be approximately \$1.7 million using the Black-Scholes option

## INTUITIVE SURGICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(UNAUDITED)

pricing model. As a result of this agreement, we capitalized approximately \$4.7 million as other assets, which will be amortized over the estimated useful life of the patents. The estimated life of the patents is approximately six years.

## NOTE 6. COMPREHENSIVE LOSS

The components of comprehensive loss consist of the following (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2000	1999	2000	1999
Net loss.....	\$(4,020)	\$(4,368)	\$(13,542)	\$(13,204)
Other comprehensive income (loss):				
Foreign currency translation adjustments.....	14	(15)	(77)	4
Change in unrealized gain (loss) on available-for-sale securities.....	169	(14)	112	(196)
Comprehensive loss.....	\$(3,837)	\$(4,397)	\$(13,507)	\$(13,396)

## NOTE 7. NET LOSS PER SHARE

Statement of Financial Accounting Standard No. 128, "Earnings Per Share," requires presentation of both basic and diluted net loss per share in the financial statements. Intuitive Surgical's basic net loss per share is the same as its diluted net loss per share because inclusion of outstanding stock options and warrants in the calculation is antidilutive. Net loss per share is calculated using the weighted average number of common shares outstanding during the period.

## NOTE 8. REVENUE RECOGNITION

We recognize system revenue upon installation for direct sales and upon shipment for sales to its distributors. If substantial contractual obligations exist after system installation, revenue is recognized after such obligations are fulfilled. Distributors do not have price protection or return rights. We recognize revenue for instruments and accessories upon shipment. Amounts are billed in accordance with the terms of the underlying sales agreement, and amounts billed in excess of revenue recognized are included as deferred revenue in the accompanying consolidated balance sheets.

## NOTE 9. STOCKHOLDERS' EQUITY

On June 13, 2000, as part of the initial public offering of our common stock, we issued 5,000,000 shares of our common stock at an offering price of \$9.00 per share and all of Intuitive Surgical's convertible preferred stock automatically converted into 22,813,173 shares of common stock. On July 13, 2000, the underwriters exercised in full their over-allotment option to purchase an additional 750,000 shares at \$9.00 per share. Cash proceeds from the sale of the 5,750,000 shares of common stock, net of underwriters' discount and offering expenses, totaled approximately \$46.5 million.

In April 2000, we issued a warrant to purchase 200,000 shares of our common stock in connection with a patent licensing agreement. (See Note 5.)

## NOTE 10. RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities ("SFAS 133"), which, as amended, is required to be adopted

## INTUITIVE SURGICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(UNAUDITED)

in years beginning after June 15, 2000. Because we do not use derivatives, management does not anticipate that the adoption of SFAS 133 will have a significant effect on our results of operations, financial position or cash flows.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 summarizes some areas of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We believe that our current revenue recognition principles comply with SAB 101.

On March 31, 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation," ("FIN 44") which provides guidance on several implementation issues related to Accounting Principles Board Opinion No. 25 ("APB 25"). The most significant topics discussed in FIN 44 are the clarification of the definition of employee for purposes of applying Opinion No. 25 and the accounting for stock options that have been repriced and the classification of accounting for modification made to stock awards. FIN 44 is effective for the most significant topics discussed beginning July 15, 2000. The impact of the interpretation on Intuitive Surgical's financial position and results of operations is not material.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations as of September 30, 2000 and for the three and nine-month periods ended September 30, 2000 and September 30, 1999 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in Intuitive Surgical's Registration Statement on Form S-1 for the year ended December 31, 1999.

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.

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

Intuitive(TM), da Vinci(TM) and EndoWrist(TM) are trademarks of Intuitive Surgical, Inc.

### OVERVIEW

We design, manufacture, and market the da Vinci Surgical System, an advanced surgical system that we believe represents a new generation of surgery. The da Vinci System consists of a surgeon's console, a patient-side cart, a high performance vision system and proprietary instruments. The da Vinci 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 surgeon 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 System enables surgeons to perform better surgery while giving patients the benefits of MIS surgery, including decreased trauma and postoperative pain, reduced surgical complications, shorter hospital stays and lower total treatment costs.

In early 1999, we obtained permission from the European Union to affix the CE Mark to the da Vinci Surgical System and EndoWrist instruments for general surgical and cardiac surgical use. Based on this approval, we recognized revenue for the first time in the second quarter of 1999 for the sale of our products. In July 2000, we received clearance from the U.S. Food and Drug Administration, the FDA, to begin commercialization of our da Vinci Surgical System in the United States for use in laparoscopic surgical procedures. In June and July 2000, we raised net proceeds of approximately \$46.5 million through the initial public offering of our common stock.

To date, the majority of our revenues have come from the sales of the da Vinci Surgical System, which are high revenue dollar items. A smaller percentage of revenues have come from sales of EndoWrist instruments and accessories, which are lower revenue dollar items. Although we expect the majority of our revenues to continue to come from the sale of da Vinci Surgical Systems over the next few years, the percentage of revenue from our EndoWrist instruments should continue to increase. Due to the high dollar revenue per system sold, small variations in system unit sales may cause revenue to vary significantly from quarter to quarter. During the useful life of each installed da Vinci Surgical System, we expect to generate recurring revenue through sales of the EndoWrist instruments and accessories.

### RESULTS OF OPERATIONS

Sales. Sales for the three months ended September 30, 2000 were \$7.9 million, up 140% from \$3.3 million for the three months ended September 30, 1999. The sales increase was primarily due to an increase in the number of da Vinci Surgical Systems sold to eight in 2000 from four in 1999. Sales for the nine months ended September 30, 2000 were \$15.9 million, up 130% from \$6.9 million for the nine months ended

September 30, 1999. The sales increase was primarily due to an increase in the number of da Vinci Surgical Systems sold to seventeen in 2000 from eight in 1999.

**Gross Profit.** Gross profit for the three months ended September 30, 2000 was \$3.2 million, or 40% of sales, compared with \$0.4 million, or 11% of sales in the same period last year. Gross profit for the nine months ended September 30, 2000 was \$5.2 million, or 33% of sales, compared to \$0.7 million, or 11% of sales in the same period last year. The improvement in gross profit for the three and nine months periods from the same periods last year resulted from sales growth and increased manufacturing efficiencies.

**Research and Development Expenses.** Research and development expenses for the three months ended September 30, 2000 were \$3.2 million, up 34% from \$2.4 million for the same period last year. The increase resulted primarily from headcount additions to support product development and enhancements. R&D expenses for the nine months ended September 30, 2000 were \$8.6 million, up 6% from \$8.1 million for the same period last year. The net increase was due to headcount increases, offset by a decrease caused by classifying manufacturing costs as cost of sales instead of R&D beginning in the second quarter of 1999 as sales were recorded for the first time.

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

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended September 30, 2000 were \$5.4 million, up 104% from \$2.6 million in the same period last year. Selling, general and administrative expenses for the nine months ended September 30, 2000 were \$12.5 million, up 88% from \$6.7 million in the same period last year. The year over year increases during these periods was due in large part to increases in headcount in the sales and marketing areas to support increased revenue.

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 are expected to increase in the future to support expanding business activities and the additional administrative costs related to being a public company.

**Deferred Compensation.** We record deferred compensation as the difference between the exercise price of options granted and the fair value of our common stock at the time of grant for financial reporting purposes. Deferred compensation is amortized to research and development expenses and selling, general and administrative expenses. Deferred compensation recorded through September 30, 2000 was \$8.8 million with accumulated amortization of \$5.6 million. The remaining \$3.2 million will be amortized over the remaining vesting periods of the options, generally four years from the date of grant, using a graded-vesting method. The amount of deferred compensation expense to be recorded in future periods may decrease if unvested options for which deferred compensation has been recorded are subsequently canceled.

**Interest Income (Expense), Net.** Net interest income increased 365% to \$1.4 million for the three months ended September 30, 2000 from \$0.3 million for the three months ended September 30, 1999. Net interest income increased 182% to \$2.4 million for the nine months ended September 30, 2000 from \$0.9 million for the same period last year. These year over year increases resulted from higher cash balances, driven by the exercise of warrants to purchase preferred stock in March 2000, yielding approximately \$34.8 million in net proceeds, and our initial public offering in June and July 2000, which raised net proceeds of approximately \$46.5 million.

#### LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have financed our operations primarily through sales of our preferred stock, yielding net proceeds of approximately \$127.3 million, and equipment financing arrangements yielding approximately \$6.5 million. The equipment arrangements provide financing at specific interest rates for

periods of up to 48 months, by which time the principal is repaid to the lessors. As collateral for the equipment financing, we have granted the lessors a security interest in equipment specified under each arrangement. In June and July 2000, we sold and issued 5,750,000 shares of common stock in our initial public offering, yielding net proceeds of approximately \$46.5 million.

As of September 30, 2000, we had cash, cash equivalents and short-term investments of \$87.7 million. Working capital at September 30, 2000 was approximately \$87.6 million, compared to approximately \$22.0 million at December 31, 1999. The increase in working capital was primarily attributable to the exercise of warrants to purchase preferred stock in March 2000, yielding approximately \$34.8 million in net proceeds, and our initial public offering in June and July 2000, raising net proceeds of approximately \$46.5 million.

Net cash used in operating activities was \$14.7 million for the nine months ended September 30, 2000, compared to \$14.4 million for the nine months ended September 30, 1999. Differences between the periods related to higher accounts payable and accruals to support expanding business activities and higher deferred revenue, which was offset by higher inventory and accounts receivable levels to support increased sales activity.

Net cash used in investing activities was \$44.7 million for the nine months ended September 30, 2000, compared to \$10.6 million for the nine months ended September 30, 1999. Differences between the periods related to the investment of the net proceeds of \$46.5 million from our initial public offering in June and July 2000 and the net proceeds of \$34.8 million from the exercise of warrants to purchase preferred stock in March 2000.

Net cash provided by financing activities was \$81.3 million for the nine months ended September 30, 2000, compared to \$20.5 million for the nine months ended September 30, 1999. The primary difference between the nine months ended September 30, 2000 and the nine months ended September 30, 1999 relates to our initial public offering in June and July 2000, yielding net proceeds of \$46.5 million, and the exercise of warrants to purchase preferred stock in March 2000, yielding net proceeds of \$34.8 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 support and product development activities and for other general corporate activities. We believe that our current cash balances, together with revenue to be derived from the sale of our products, will be sufficient to fund our operations at least through 2001. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain additional credit arrangements. Additional financing may not be available on terms acceptable to us or at all. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders.

#### 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 unproven, and we may be unable to generate significant commercial 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, if any, will be difficult to forecast because the market for new surgical technologies is still evolving. Our results of operations will depend upon numerous factors, including:

- the progress and results of clinical trials;
- actions relating to regulatory matters;
- the extent to which our products gain market acceptance;
- our timing and ability to develop our manufacturing and sales and marketing capabilities;
- demand for our products;

- 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;
- product quality problems;
- our ability to protect our proprietary rights;
- our ability to license additional intellectual property rights; and
- third-party payor reimbursement policies.

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 HAVE A LARGE ACCUMULATED DEFICIT, WE EXPECT FUTURE LOSSES, AND WE MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY.

We have incurred substantial losses since inception and we expect to incur substantial additional operating losses for at least the next two years, primarily as a result of expected increases in expenses for our manufacturing and sales and marketing capabilities, research and development activities, clinical trials and regulatory approval applications. The extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If the time required to generate significant revenues and achieve profitability is longer than anticipated, we may not be able to continue our operations. Our net loss for the year ended December 31, 1999 was \$18.4 million and was \$13.5 million for the nine months ended September 30, 2000. As of September 30, 2000, we had an accumulated deficit of \$88.7 million.

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. We do not plan to maintain an inventory of assembled da Vinci Surgical Systems, but rather plan to manufacture our products only after receiving customer orders. 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 could 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 ORDER.

A relatively small number of customers account for a significant portion of our total revenues. In 1999 and for the nine months ended September 30, 2000, the majority of our revenues came from the sales of da Vinci Surgical Systems, which are high revenue dollar items. Due to the high dollar revenue per system sold, small variations in system unit sales may cause revenue to vary significantly from quarter to quarter. For the year ended December 31, 1999, two customers, AB Medica SRL, located in Italy, and Marubeni America Corporation, located in New York, each accounted for 16% of our total sales. AB Medica SRL and Marubeni America Corporation are our Italian and Japanese distributors, respectively. For the nine months ended September 30, 2000, AB Medica SRL accounted for 11% of total sales.

We expect that revenues from a limited number of new customers will account for a large percentage of total revenues in future quarters. Our ability to attract new customers will depend on a variety of factors, including the capability, safety, efficacy, ease of use, price, quality and reliability of our products and effective sales, support, training and service. The loss or delay of individual orders could have a significant impact on

revenues and operating results. Our failure to add new customers that make significant purchases of our products would reduce our future revenues.

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 so 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. Although we are in the process of developing training programs for surgical teams, 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 are subject to extensive regulation in the United States by the U.S. Food and Drug Administration, or FDA. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution and production of medical devices in the United States. In November 1999, we submitted a premarket approval, or PMA, application requesting permission to market our da Vinci Surgical System and EndoWrist instruments for laparoscopic surgical procedures, which the FDA accepted for review in December 1999. In July 2000, we received clearance from the FDA for the commercialization of our da Vinci Surgical System in the United States for use in laparoscopic surgical procedures. In addition, the FDA determined through review of Intuitive's PMA application that this and future submissions for Intuitive's devices, including new clinical indications, could be more appropriately reviewed through the Premarket Notification or 510(k) process and as such, the FDA reclassified Intuitive's devices from Class III to Class II, thus requiring a premarket notification rather than a premarket approval. In August 2000, we submitted a 510(k) application to the FDA requesting clearance to expand the labeling of the da Vinci Surgical System and EndoWrist instruments to include thoracoscopic procedures such as internal mammary artery mobilization. A 510(k) application must be supported by valid scientific evidence, which typically includes extensive preclinical and clinical trials and other data, to demonstrate the safety and effectiveness of the device. Data obtained from clinical trials are subject to varying interpretations that could delay, limit or prevent us from obtaining FDA clearance. We cannot assure you that we will successfully obtain FDA clearance for the use of our products in other surgical procedures on a timely basis or at all. Even if our products are cleared by the FDA, if we modify them, the FDA may require us to obtain clearance of the modified products before we are permitted to market and sell them. We anticipate that the FDA will require a new 510(k) clearance for additional types of surgical procedures for which we propose to market our products. Any delay in receiving clearance, failure to receive clearance or failure to comply with existing or future regulatory requirements would harm our ability to market and sell our products. For additional information concerning regulatory approval of our products, see "Business -- Government Regulation," included in the

Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the Securities and Exchange Commission or SEC.

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 for general surgical use. We received additional CE approvals for use of our da Vinci Surgical System and EndoWrist instruments in cardiac surgery in September 1999 and February 2000.

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

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

Domestic institutions 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. In such circumstances, we may have to apply to the American Medical Association for a unique Current Procedural Terminology code covering computer-enhanced surgery. If an application for a unique code is required, reimbursement for any use of our products may be unavailable until an appropriate code is granted. The application process, from filing until adoption of a new code, can take two or more years.

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. For further information on third-party reimbursement policies, see

"Business -- Third-Party Reimbursement," included in the Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the SEC.

WE ARE INVOLVED IN INTELLECTUAL PROPERTY LITIGATION WITH COMPUTER MOTION THAT MAY HURT OUR COMPETITIVE POSITION, MAY BE COSTLY TO US AND MAY PREVENT US FROM SELLING OUR PRODUCTS.

On May 10, 2000, Computer Motion, Inc. filed a lawsuit in United States District Court for the Central District of California (Case No. CV00-4988 CBM) alleging that by making, using, selling or offering for sale our da Vinci Surgical System, we are infringing United States Patent Numbers 5,524,180, 5,878,193, 5,762,458, 6,001,108, 5,815,640, 5,907,664 and 5,855,583 in willful disregard of Computer Motion's patent rights. On June 1, 2000, Computer Motion amended its lawsuit to allege that we also infringe U.S. Patent Number 6,063,095. On October 30, 2000, Computer Motion filed a motion seeking to add U.S. Patent Number 6,102,850 to the litigation. These patents concern methods and devices for conducting various aspects of robotic surgery. Beginning in May 1999, we requested that the U.S. Patent and Trademark Office declare interferences between some of our exclusively licensed patent applications and five of Computer Motion's U.S. patents, each of which is included in Computer Motion's suit. An interference is a proceeding within the U.S. Patent and Trademark Office to resolve questions regarding who was the first to invent the subject matter of a patent and/or a patent application.

If we lose Computer Motion's suit against us, it will hurt our competitive position, may be costly to us and may prevent us from selling our products. In addition, if we lose the patent suit, we will need to obtain from Computer Motion a license to this technology if we are to continue to market our products that have been found to infringe Computer Motion's patents. This license could be expensive, or could require us to license to Computer Motion some of our technology which would result in a partial loss of our competitive advantage in the marketplace, each of which could seriously harm our business. We believe that we have meritorious defenses in this action. However, litigation is unpredictable and we may not prevail with any of these defenses. If Computer Motion is successful in its suit against us and is unwilling to grant us a license, we will be required to stop selling our products that are found to infringe Computer Motion's patents unless we can redesign them so they do not infringe Computer Motion's patents, which we may be unable to do. In addition, if we lose the patent suit, we could be required to pay Computer Motion damages, including treble damages, which could be substantial and harm our financial position.

This litigation will be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in this lawsuit, this litigation could consume substantial amounts of our financial and managerial resources. At any time Computer Motion may file additional claims against Intuitive Surgical, or we may file claims against Computer Motion, which could increase the risk, expense and duration of the litigation. Further, because of the substantial amount of discovery often involved in connection with this type of litigation, there is a risk that some of our confidential information could be compromised by disclosure. For more information on our litigation with Computer Motion, see "Business -- Legal Proceedings," included in the Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the SEC.

PUBLIC ANNOUNCEMENTS OF LITIGATION EVENTS WITH COMPUTER MOTION MAY HURT OUR STOCK PRICE.

During the course of our lawsuit with Computer Motion, 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.

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 and evolving legal and factual questions. We cannot assure you that 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 cannot assure you that 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. Given the early priority dates of some of our licensed patents, we believe one or more patent proceedings may be in our best interests. 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.

We are aware of both United States and foreign patents issued to third parties that relate to computer-assisted surgery and minimally invasive surgery. Some of these patents on their face appear 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 because of one or more of these third parties, regardless of the merits or likely outcome of such suit or proceeding. We cannot assure you 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 assure you 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 as Computer Motion has done, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending ourselves. 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. For further information on our intellectual property and the difficulties in protecting it, see "Business -- Intellectual Property," included in the Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the SEC.

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 SRI International, IBM, MIT and Heartport. Any of these agreements may be terminated for breach, including the failure to make required payments under the IBM license and the failure to commercialize our products under the SRI International license. 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. See "Business -- Intellectual Property," included in the Registration Statement on Form S-1 of Intuitive Surgical, Inc., as amended, filed with the SEC, for further information on our license agreements.

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 must compete with established minimally invasive surgery and open surgery. These procedures are widely accepted in the medical community and in many cases have a long history of use. We also face competition from several companies that are developing new approaches and products for the minimally invasive surgery market. In addition, we presently face increasing competition from companies who are developing robotic and computer-assisted surgical systems. 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.

In many cases, the medical conditions that can be treated using our products can also be treated by pharmaceuticals or other medical devices and procedures. Many of these alternative treatments are also widely accepted in the medical community and have a long history of use. In addition, 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.

IF SOFTWARE 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 sophisticated computer software. Complex software frequently contains 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 software defects. We cannot assure you that our software will not experience errors or performance problems in the future. If we experience software errors 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;
- increased service or warranty costs; or
- product liability claims.

WE HAVE LIMITED EXPERIENCE IN MANUFACTURING OUR PRODUCTS AND MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE.

We have manufactured a limited number of our products for prototypes and sales to customers. We may be unable to establish or maintain reliable, high-volume manufacturing capacity. Even if this capacity can be established and 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. We plan to manufacture products to fill purchase orders rather than to maintain inventories of our assembled products. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to establish and maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace would 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 WOULD RESULT IN PRODUCT DELIVERY DELAYS AND LOST REVENUE.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Good Manufacturing Practice requirements. We are also required to comply with the ISO 9000 series standards in order to produce products for sale in Europe. If we fail to continue to comply with Good Manufacturing Practice requirements or ISO 9000 series standards, we may be required to cease all or part of our operations until we comply with these regulations. We are currently in compliance with ISO 9000 series standards. In March 2000, the FDA inspected our Mountain View facility and the Good Manufacturing Practice issues raised during the inspection have been resolved. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or the ISO 9000 series standards in future audits by regulatory authorities.

The state of California also requires that we maintain a license to manufacture medical devices. Our facilities and manufacturing processes were inspected in February 1998. In March 1998, we passed the inspection and received a device manufacturing license from the California Department of Health Services. We will be 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 any 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 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.

OUR GROWTH WILL PLACE A SIGNIFICANT STRAIN ON OUR MANAGEMENT SYSTEMS AND RESOURCES AND, IF WE FAIL TO MANAGE OUR GROWTH, OUR ABILITY TO MARKET, SELL AND DEVELOP OUR PRODUCTS MAY BE HARMED.

In order to complete clinical trials, scale-up manufacturing, expand marketing and distribution capabilities and develop future products, we must expand our operations. We expect that future expansion will occur particularly in the areas of sales and marketing, manufacturing and research and development. This expansion will likely result in new and increased responsibilities for management personnel and place significant strain upon our management, operating and financial systems and resources. We plan to sell our products primarily through direct sales, and we currently have a small sales organization. Our products require a complex marketing and sales effort targeted at several levels within a prospective customer's organization. We will need to expand our sales team significantly over the next 12 months to achieve our sales growth goals. We will face significant challenges and risks in building and managing our sales team, including managing geographically dispersed sales efforts and adequately training our sales people in the use and benefits of our products. To accommodate our growth and compete effectively, we will be required to improve our information systems, create additional procedures and controls and expand, train, motivate and manage our work force. Our future success will depend in part on the ability of current and future management personnel to operate effectively, both independently and as a group. We cannot be certain that our personnel, systems, procedures and controls will be adequate to support our future operations.

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, in particular Lonnie M. Smith, our President and Chief Executive Officer, Frederic H. Moll, M.D., our Vice President and Medical Director and Robert G. Younge, our Vice President and Chief Technology Officer. In order to pursue our product development, marketing and commercialization plans, we will need to hire additional qualified personnel with expertise in research and development, clinical testing, government regulation, manufacturing,

sales and marketing, and finance. Our product development plans depend in part on our ability to attract and retain engineers with experience in mechanics, software and optics. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense, particularly in Silicon Valley. 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.

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 a component of our growth strategy is to expand our presence into additional foreign markets. Sales to markets outside of the United States accounted for approximately 91% of our sales for the year ended December 31, 1999 and 41% for the nine months ended September 30, 2000. We will be 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 U.S. dollars. As a result, an increase in the value of the U.S. 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.

FAILURE TO RAISE ADDITIONAL CAPITAL OR GENERATE THE SIGNIFICANT CAPITAL NECESSARY TO EXPAND OUR OPERATIONS AND INVEST IN NEW PRODUCTS COULD REDUCE OUR ABILITY TO COMPETE, RESULT IN LOWER REVENUES AND MAY PREVENT US FROM TAKING ADVANTAGE OF MARKET OPPORTUNITIES.

We expect that our existing capital resources and the revenue to be derived from the sale of our products will be sufficient to meet our working capital and capital expenditure needs at least through 2001. After that, we may need to raise additional funds and we cannot be certain that we will be able to obtain additional financing on favorable terms, or at all. If we need additional capital and cannot raise it on acceptable terms, we may not be able to, among other things:

- develop or enhance our products and services;
- acquire technologies, products or businesses;
- expand operations in the United States or internationally;
- hire, train and retain employees; or
- respond to competitive pressures or unanticipated capital requirements.

Our failure to do any of these things could result in lower revenues and could harm our business.

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

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, including commercial paper, money market funds and government and non-government debt securities. The average duration of all of our investments as of September 2000 was less than one year. Due to the short term nature of these investments, we believe that we have no material exposure to interest rate risk arising from our investments. Therefore, no quantitative tabular disclosure is required.

## PART II. OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

On May 10, 2000, Computer Motion, Inc. filed a lawsuit in United States District Court for the Central District of California (Case No. CV00-4988 CBM) alleging that by making, using, selling or offering for sale our da Vinci Surgical System, we are infringing United States Patent Numbers 5,524,180, 5,878,193, 5,762,458, 6,001,108, 5,815,640, 5,907,664 and 5,855,583 in willful disregard of Computer Motion's patent rights. On June 1, 2000, Computer Motion amended its lawsuit to allege that we also infringe U.S. Patent Number 6,063,095. On October 30, 2000, Computer Motion filed a motion seeking to add U.S. Patent Number 6,102,850 to the litigation. These patents concern methods and devices for conducting various aspects of robotic surgery. The Computer Motion action seeks damages based upon the making, using, selling and offering for sale of our products and processes, and seeks to enjoin our continued activities relating to these products. This action subjects us to potential liability for damages, including treble damages, and could require us to cease making, using or selling the affected products, or to obtain a license in order to continue to manufacture, use or sell the affected products. The litigation is still in the early stages of discovery. While we continue to believe we have meritorious defenses to this action, we cannot provide assurance that we will prevail in this action, nor can we provide assurance that any license required would be made available on commercially acceptable terms, if at all. Failure to successfully defend against the Computer Motion action could harm our business, financial condition and operating results. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss.

Beginning in May 1999, we requested that the U.S. Patent and Trademark Office declare interferences between some of our exclusively licensed patent applications and five of Computer Motion's U.S. patents. An interference is a proceeding within the U.S. Patent and Trademark Office to resolve questions regarding who was the first to invent the subject matter of a patent and/or a patent application. All five of Computer Motion's patents were issued by the U.S. Patent and Trademark Office without consideration of the exclusively-licensed and earlier-filed patent applications on which we now rely to request the interferences. All five of Computer Motion's patents subject to our requests for interference are included in Computer Motion's May 2000 suit for patent infringement.

In September 2000, we filed a Notice of Opposition in the European Patent Office ("EPO") challenging European Patent No. 653,922, which was issued to Computer Motion in 1999 and is related to several of the patents now involved in the U.S. litigation and the interference process.

## ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

## RECENT SALES OF UNREGISTERED SECURITIES

Since April 1, 2000, we have sold and issued the following unregistered securities:

(1) From April 1, 2000 through June 30, 2000, we granted stock options to purchase 232,150 shares of our common stock at an exercise price of \$3.00 per share, to employees pursuant to our 2000 Equity Incentive Plan.

(2) From April 1, 2000 through June 30, 2000, we issued 415,022 shares of our common stock, at prices ranging from \$0.05 to \$3.00 per share, to employees, consultants and directors pursuant to outstanding stock options to purchase shares of our common stock.

(3) In April 2000, we issued a warrant to purchase 200,000 shares of our common stock at an exercise price of \$3.00 per share to Heartport, Inc., in connection with a license agreement, with an aggregate value of \$600,000.

(4) In June 2000, we issued a warrant to purchase 5,081 shares of our common stock, at an exercise price of \$9.00 per share, to one company for services rendered to Intuitive Surgical, with an aggregate value of \$45,729.

(5) From July 1, 2000 through September 30, 2000, we granted stock options to purchase 137,900 shares of common stock, at prices ranging from \$9.50 to \$16.12 per share, to employees pursuant to our 2000 Equity Incentive Plan.

The sales and issuance of securities described in paragraphs (1), (2), and (5) above were deemed to be exempt from registration under the Securities Act by virtue of Rule 701 promulgated thereunder in that they were offered and sold either pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation, as provided by Rule 701. The sale and issuance of securities described in paragraph (3) and (4) above were deemed to be exempt from registration under the Securities Act by virtue of Section 4(2).

USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-33016) that was declared effective by the SEC on June 13, 2000, and pursuant to which we sold 5,750,000 shares of common stock that had been registered

Our initial public offering was completed after the shares of common stock that were registered were sold. The managing underwriters in the offering were Lehman Brothers Inc., Bear, Stearns & Co., Inc., FleetBoston Robertson Stephens Inc. and UBS Warburg LLC. The aggregate offering price of the 5,750,000 shares registered and sold was \$51.8 million. Of this amount, \$3.6 million was paid in underwriting discounts and commissions, and an additional \$1.7 million of expenses was incurred through September 30, 2000. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10 percent or more of our common stock, or to our affiliates. As of September 30, 2000, we had applied the estimated aggregated net proceeds of \$46.5 million from our initial public offering as follows:

Temporary investments \$46.5 million

The foregoing amounts represent our best estimate of our use of proceeds for the period indicated. No such payments were made to our directors or officers or their associates, holders of 10% or more of any class of our equity securities or to our affiliates, other than payments to officers for salaries in the ordinary course of business.

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 AND REPORTS ON FORM 8-K

(a) Exhibits.

EXHIBIT NUMBER -----	DESCRIPTION -----
3.1(1)	Amended and Restated Certificate of Incorporation of Intuitive Surgical.
3.2(2)	Bylaws of Intuitive Surgical.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2(3)	Specimen Stock Certificate.
27.1	Financial Data Schedule.

- - - - -

- (1) Previously filed as Exhibit 3.2 to our Registration Statement on Form S-1, Registration No. 333-33016.
- (2) Previously filed as Exhibit 3.3 to our Registration Statement on Form S-1, Registration No. 333-33016.
- (3) Previously filed as like-numbered Exhibit to our Registration Statement on Form S-1, Registration No. 333-33016.
  - (b) Current Reports on Form 8-K. We did not file a Current Report on Form 8-K during the three month period ending September 30, 2000.

## 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.

By: /s/ SUSAN K. BARNES

-----  
Susan K. Barnes,  
Vice President, Finance, Chief  
Financial Officer  
and Assistant Secretary  
(Principal Financial and Accounting  
Officer)

Date: November 13, 2000

## EXHIBIT INDEX

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9-MOS

DEC-31-2000  
JAN-01-2000  
SEP-30-2000  
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