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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 MARCH 31, 2001

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)  
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DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

77-0416458  
(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

1340 W. 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 35,789,067 shares of Common Stock, \$0.001 par value per  
share, outstanding as of April 17, 2001.  
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## 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)

## ASSETS

	MARCH 31, 2001	DECEMBER 31, 2000
	----- (UNAUDITED)	----- (SEE NOTE 1)
Current assets:		
Cash and cash equivalents.....	\$ 13,670	\$ 22,657
Short-term investments.....	63,246	66,784
Accounts receivable.....	10,266	6,444
Inventory, net.....	6,523	6,076
Prepaid expenses.....	1,606	1,705
	-----	-----
Total current assets.....	95,311	103,666
Property and equipment, net.....	5,803	4,669
Intangible and other assets.....	3,892	4,086
	-----	-----
Total assets.....	\$105,006 =====	\$112,421 =====

## LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable.....	\$ 5,540	\$ 7,128
Accrued compensation and employee benefits.....	1,452	2,609
Warranty accrual.....	1,543	1,494
Accrued royalty expense.....	--	1,000
Other accrued liabilities.....	1,699	2,028
Deferred revenue.....	2,340	3,552
Current portion of notes payable.....	2,072	2,019
	-----	-----
Total current liabilities.....	14,646	19,830
Long-term notes payable.....	1,473	1,861
Stockholders' equity		
Preferred stock, 5,000,000 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of March 31, 2001 and December 31, 2000.....	--	--
Common stock, 200,000,000 shares authorized, \$0.001 par value, 35,828,944 and 35,675,822 shares issued and outstanding as of March 31, 2001 and December 31, 2000, respectively.....	36	36
Additional paid-in capital.....	187,407	186,713
Deferred compensation.....	(1,866)	(2,483)
Accumulated deficit.....	(97,077)	(93,670)
Accumulated other comprehensive income (loss).....	387	134
	-----	-----
Total Stockholders' equity.....	88,887	90,730
	-----	-----
Total liabilities and stockholders' equity.....	\$105,006 =====	\$112,421 =====

See accompanying notes to consolidated financial statements.

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

	THREE MONTHS ENDED	
	MARCH 31, 2001	MARCH 31, 2000
Sales.....	\$12,079	\$ 2,933
Cost of sales.....	6,563	2,532
	-----	-----
Gross profit.....	5,516	401
Operating costs and expenses:		
Research and development.....	3,231	2,631
Selling, general and administrative.....	6,835	3,138
	-----	-----
Total operating costs and expenses.....	10,066	5,769
Loss from operations.....	(4,550)	(5,368)
Other income (expense).....	1,143	336
	-----	-----
Net loss.....	\$(3,407)	\$(5,032)
	=====	=====
Basic and diluted net loss per common share.....	\$ (0.10)	\$ (0.90)
	=====	=====
Shares used in computing net loss per common share.....	35,401	5,574

See accompanying notes to consolidated financial statements.

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

	THREE MONTHS ENDED	
	MARCH 31, 2001	MARCH 31, 2000
	-----	-----
<b>OPERATING ACTIVITIES:</b>		
Net loss.....	\$ (3,407)	\$(5,032)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation.....	428	385
Amortization of deferred compensation.....	617	346
Amortization of intangible and other assets.....	194	--
Changes in operating assets and liabilities:		
Accounts receivable.....	(3,822)	(736)
Prepaid expenses.....	99	(437)
Inventory.....	(447)	(712)
Accounts payable.....	(1,588)	733
Accrued compensation and employee benefits.....	(1,157)	(428)
Warranty accrual.....	49	(25)
Other accrued liabilities.....	(329)	138
Accrued royalty expense.....	(1,000)	--
Deferred revenue.....	(1,212)	(28)
	-----	-----
Net cash used in operating activities.....	(11,575)	(5,796)
<b>INVESTING ACTIVITIES:</b>		
Acquisition of property and equipment.....	(1,562)	(755)
Purchase of short-term investments.....	(10,434)	--
Proceeds from sales of short-term investments.....	479	2,000
Proceeds from maturities of short-term investments.....	13,746	4,562
	-----	-----
Net cash provided by investing activities.....	2,229	5,807
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuance of preferred stock.....	--	34,756
Proceeds from issuance of common stock.....	755	69
Repurchase of common stock.....	(61)	(9)
Proceeds from notes payable.....	--	500
Repayment of notes payable.....	(335)	(387)
	-----	-----
Net cash provided by financing activities.....	359	34,929
	-----	-----
Net increase (decrease) in cash and cash equivalents.....	(8,987)	34,940
Cash and cash equivalents, beginning of period.....	22,657	4,106
	-----	-----
Cash and cash equivalents, end of period.....	13,670	39,046
	=====	=====

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, 2000, included in the Annual Report on Form 10-K of Intuitive Surgical, Inc, filed with the Securities and Exchange Commission. The results for the interim period ended March 31, 2001 are not necessarily indicative of the results to be expected for the full year ending December 31, 2001 or future operating periods.

## NOTE 2. CONCENTRATIONS OF RISK

For the three months ended March 31, 2001, two customers, A and B, accounted for 21% and 14%, respectively, of total sales. For the three months ended March 31, 2000, four customers A, B, C and D, accounted for 30%, 28%, 22%, and 14%, respectively, of total sales. The Company extends reasonably short collection terms but does not require collateral. The Company provides reserves for potential credit losses but has not experienced significant losses to date.

The Company's da Vinci Surgical System, related instruments and accessories and service have accounted for all of the Company's sales for the three months ended March 31, 2001 and 2000. Purchases of key parts and components used to manufacture our products are from limited supply sources. The inability of any of these suppliers to fulfill our supply requirements may negatively impact future operating results.

## NOTE 3. 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 March 31, 2001 and December 31, 2000.

## NOTE 4. 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, 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 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 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.

## INTUITIVE SURGICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(UNAUDITED)

## NOTE 5. INVENTORY, NET

Inventory, net consists of the following (in thousands):

	MARCH 31, 2001	DECEMBER 31, 2000
	-----	-----
Raw materials.....	\$2,667	\$2,650
Work-in-process.....	1,415	1,130
Finished goods.....	2,441	2,296
	-----	-----
	\$6,523	\$6,076
	=====	=====

## NOTE 6. INTANGIBLE AND OTHER ASSETS

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 years. At March 31, 2001 gross intangible assets totaled \$4.7 million and related accumulated amortization was \$779,000.

## NOTE 7. COMPREHENSIVE LOSS

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

	THREE MONTHS ENDED MARCH 31,	
	-----	-----
	2001	2000
	-----	-----
Net loss.....	\$(3,407)	\$(5,032)
Other comprehensive income (loss):		
Change in unrealized gain on forward exchange		
contracts.....	(67)	--
Change in unrealized gain (loss) on available-for-sale		
securities.....	320	(7)
	-----	-----
Comprehensive loss.....	\$(3,154)	\$(5,039)
	=====	=====

## NOTE 8. NET LOSS PER SHARE

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

	THREE MONTHS ENDED MARCH 31,	
	-----	-----
	2001	2000
	-----	-----
Numerator used for basic and diluted net loss per common share.....	\$ (3,407)	\$ (5,032)
Denominator used for basic and diluted net loss per common share:		
Weighted-average shares outstanding.....	35,743,685	6,691,431
Less weighted-average shares subject to repurchase.....	(342,658)	(1,116,936)
	-----	-----
Weighted-average shares used in computing basic and diluted net loss per common share:.....	35,401,027	5,574,495
	=====	=====

Basic and diluted net loss per common share.....	\$	(0.10)	\$	(0.90)
		=====		=====



NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(UNAUDITED)

## NOTE 9. REVENUE RECOGNITION

Revenue from system sales is recognized upon installation for direct sales and upon shipment for sales to our distributors. If substantial contractual obligations exist after system installation, revenue is recognized after such obligations are fulfilled. Our distributors do not have price protection rights. Revenue from instruments and accessories is recognized upon shipment. Service revenue is billed in advance and recognized over the service period. Amounts are billed in accordance with the terms of the underlying sales agreement.

We apply the provisions of SAB 101 when recognizing revenue. SAB 101 states that revenue generally is realized or realizable and earned when all of the following criteria are met: a) persuasive evidence of an arrangement exists, b) delivery has occurred or services have been rendered, c) the seller's price to the buyer is fixed or determinable, and d) collectibility is reasonably assured. Accordingly, amounts billed in excess of revenue recognized are included as deferred revenue in the accompanying consolidated balance sheets.

## NOTE 10. OTHER FINANCIAL INSTRUMENTS

We did not hold any forward exchange contracts at March 31, 2001. At December 31, 2000, we had forward foreign exchange contracts of approximately 2 months duration, to exchange euro and Belgian Francs for U.S. dollars in the total gross notional amount of \$781,000. The net effect on settlement of these contracts during the three months ended March 31, 2001 was not material to our financial position or our results of operations and is included in other income (expense) in the accompanying consolidated statements of operations.

## NOTE 11. RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). We adopted SFAS 133 effective January 1, 2001. This statement establishes accounting and reporting standards requiring that every derivative instrument, including certain derivative instruments embedded in other contracts, be recorded in the balance sheet as either an asset or liability measured at its fair value. The statement also requires that changes in the derivative's fair value be recognized in earnings unless specific hedge accounting criteria are met. The adoption of SFAS 133, as amended, has not had a significant impact on our financial position or results of operations.

## 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 March 31, 2001 and for the three-month periods ended March 31, 2001 and March 31, 2000 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in Intuitive Surgical's Annual Report on Form 10-K for the year ended December 31, 2000.

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)(R), da Vinci(TM), EndoWrist(TM), InSite(TM) and Navigator(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 Surgical System consists of a surgeon's console, a patient-side cart, a high performance vision system and proprietary 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 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 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 March 2001, we received clearance from the FDA for use of our da Vinci Surgical System in non-cardiac thoracoscopic surgical procedures.

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. A small percentage of revenue also comes from ongoing service of installed da Vinci Surgical Systems. 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 and service 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 and ongoing service.

### RESULTS OF OPERATIONS

Sales. Sales for the three months ended March 31, 2001 were \$12.1 million, up 312% from \$2.9 million for the three months ended March 31, 2000. The sales increase was primarily due to an increase in the number of da Vinci Surgical Systems sold to 12 in the first quarter of 2001 from 3 in the first quarter of 2000.

**Gross Profit.** Gross profit for the three months ended March 31, 2001 was \$5.5 million, or 46% of sales, compared with \$0.4 million, or 14% of sales in the same period last year. The improvement in gross profit resulted from sales growth and increased manufacturing efficiencies.

**Research and Development Expenses.** Research and development expenses for the three months ended March 31, 2001 were \$3.2 million, up 23% from \$2.6 million for the same period last year. The increase resulted primarily from headcount additions to support product development and enhancements.

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 March 31, 2001 were \$6.8 million, up 118% from \$3.1 million in the same period last year. The increase 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.

**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 expense and selling, general and administrative expenses. Non-cash deferred compensation expense included in research and development expenses was \$0.4 million and \$0.3 million for the three months ended March 31, 2001 and 2000, respectively. Non-cash deferred compensation expense included in selling, general and administrative expenses was \$0.2 million and \$0.1 million for the three months ended March 31, 2001 and 2000, respectively. The remaining \$1.9 million of deferred compensation 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.

**Other Income (Expense).** Other income (expense) for the three months ended March 31, 2001 was \$1.1 million, up 240% from \$0.3 million in the same period last year. The increase resulted from higher cash and short-term investment 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 \$46.8 million.

#### LIQUIDITY AND CAPITAL RESOURCES

Prior to our initial public offering, operations were financed primarily through sales of our preferred stock, yielding net proceeds of approximately \$127.3 million, and equipment financing arrangements yielding approximately \$7.5 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 completed the initial public offering of 5,750,000 shares of our common stock and realized net proceeds of approximately \$46.8 million.

As of March 31, 2001, we had working capital of \$80.7 million, compared to \$83.8 million as of December 31, 2000. The decrease in working capital during the first quarter of 2001 approximated the net loss of \$3.4 million.

As of March 31, 2001, we had cash, cash equivalents and short-term investments of \$76.9 million, compared to \$89.4 million as of December 31, 2000, a decrease of \$12.5 million. In addition to our net loss of \$3.4 million, our decrease in cash was primarily due to an increase in accounts receivable of \$3.8 million. The increased accounts receivable balance reflects a return to a more typical average days sales outstanding for our business of 76 days compared to the 54 days at the end of the fourth quarter of 2000. Since our average selling price is nearly \$1.0 million per system, the timing of collection on only a few systems can cause dramatic swings in our accounts receivable balances. Other uses of cash include the payment of the \$1.0 million IBM royalty accrued last year, \$1.6 million for fixed asset additions, and general working capital requirements.

Net cash provided by financing activities was \$359,000 for the three months ended March 31, 2001, compared to \$34.9 million provided during the same period in 2000. The primary reason for the decreased cash provided by financing activities in the first quarter of 2001 versus 2000 relates to proceeds received from the issuance of preferred stock of \$34.8 million during the first quarter of last year.

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 and short-term investment balances, together with revenue to be derived from the sale of our products, will be sufficient to fund our operations at least through 2002. 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 this quarter was \$3.4 million compared to a net loss of \$5.0 million for the same period last year. As of March 31, 2001, we had an accumulated deficit of \$97.1 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. For the three months ended March 31, 2001, AB Medica SRL, our Italian distributor, accounted for 21% of total sales and Marubeni America Corporation, our Japanese distributor, accounted for 14% of our total sales. For the year ended December 31, 2000, none of our customers accounted for 10% or more of total sales. For the three months ended March 31, 2000, four customers, Henrico Doctors' Hospital, located in Virginia, AB Medica SRL, Marubeni America Corporation and Pitt County Memorial Hospital, located in North Carolina, accounted for 30%, 28%, 22% and 14% of total sales, respectively.

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 and operations 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 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 ("FDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another legally marketed device. If we modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or 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 legally marketed device, we will be required to obtain FDA approval by submitting a premarket approval application ("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, require us to conduct further testing, or compile more data, including clinical data, 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 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, rather than substantially equivalent to another legally marketed device. 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 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. 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. For additional information concerning regulatory approvals of our products, see "Item 1: Business -- Government Regulation," included in the Annual Report on Form 10-K of Intuitive Surgical, Inc., filed with the Securities and Exchange Commission or SEC.

In March 2001, we received a warning letter from the FDA concerning our marketing of the da Vinci Surgical System for cardiac and radical prostatectomy procedures on our company web site. The warning letter indicated, among other things, that we have no specific clearance for these procedures in the United States, and therefore should not be promoting them. We have already taken specific steps that we believe fully rectify the concerns expressed by the FDA. In addition, prior to receiving the aforementioned warning letter, the FDA informed us in February 2001 of its concern that radical prostatectomy was not within the scope of procedures encompassed in the FDA's clearance of the da Vinci Surgical System for laparoscopic surgical procedures which we received in July 2000. This was an advisory, or guidance, letter. Although we disagree with the agency's interpretation regarding the scope of the cleared intended use, we have ceased marketing the product for this indication and have submitted a 510(k) application to the FDA seeking clearance for a radical prostatectomy indication for the da Vinci Surgical System. We have received a 510(k) document control number from the FDA and expect a response to this filing by approximately the end of the second quarter.

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 "Item 1: Business -- Third-Party Reimbursement," included in the Annual Report on Form 10-K of Intuitive Surgical, Inc., filed with the SEC.

WE ARE INVOLVED IN INTELLECTUAL PROPERTY LITIGATION WITH COMPUTER MOTION AND BROOKHILL-WILK 1, LLC 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. On December 7 and 8, 2000, the U.S. Patent and Trademark Office ("PTO") declared three interferences between a single SRI patent application exclusively licensed to us and three of Computer Motion's patents, Numbers 5,878,193, 5,907,664 and 5,855,583. In light of those declarations of interference, the District Court on February 5, 2001 stayed -- put on hold -- all proceedings in the litigation for one year while the PTO conducts the interference proceedings.

If the litigation proceeds after the PTO has resolved the interferences, and 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.

On September 1, 2000, Brookhill-Wilk 1, LLC ("Wilk") filed a lawsuit in the United States District Court for the Southern District of New York (Case No. 00 Civ. 6599 (NRB)) alleging that by making, using, selling or offering for sale our da Vinci Surgical System, we are infringing U.S. Patent Nos. 5,217,003 and 5,368,015 in willful disregard of Wilk's patent rights. These patents concern methods and devices for "remote" surgery. In March 2001, Wilk withdrew its assertion of the '015 patent against Intuitive. If we lose Wilk'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 may need to obtain from Wilk a license to this technology if we are to continue to market our products that have been found to infringe Wilk's patents. This license could be expensive, which could seriously harm our business. We believe that we have multiple meritorious defenses in this action. However, litigation is unpredictable and we may not prevail with any of these defenses. If Wilk is successful in its suit against us and is unwilling to grant us a license, we may be required to stop selling our products that are found to infringe Wilk's patents unless we can redesign them so they do not infringe Wilk's patents, which we may be unable to do. In addition, if we lose the patent suit, we could be required to pay Wilk damages, including treble damages, which could be substantial and harm our financial position.

These claims will be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in these lawsuits, this litigation could consume substantial amounts of our financial and managerial resources. At any time Computer Motion or Wilk may file additional claims against Intuitive Surgical, or we may file claims against Computer Motion or Wilk, which could increase the risk, expense and duration of the litigations. 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 "Item 1: Business -- Legal Proceedings," included in the Annual Report on Form 10-K of Intuitive Surgical, Inc., filed with the SEC.

#### PUBLIC ANNOUNCEMENTS OF LITIGATION EVENTS MAY HURT OUR STOCK PRICE.

During the course of our administrative proceedings and/or lawsuits with Computer Motion and Brookhill-Wilk 1, LLC, 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 and Brookhill-Wilk 1, LLC have 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 "Item 1: Business -- Intellectual Property," included in the Annual Report on Form 10-K of Intuitive Surgical, Inc., 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 "Item 1: Business -- Intellectual Property," included in the Annual Report on Form 10-K of Intuitive Surgical, Inc., filed with the SEC.

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 contained in the FDA's Quality System Regulations (QSR). 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 satisfactorily resolved with the FDA. 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 32% of our sales for the year ended December 31, 2000, 52% for the three months ended March 31, 2001 and 56% for the three months ended March 31, 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 2002. 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.

SALES BY CURRENT STOCKHOLDERS COULD CAUSE OUR COMMON STOCK PRICE TO DECLINE.

The market price of our common stock could decline as a result of sales of a large number of shares in the market. These sales may also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate to raise funds through future offerings of common stock. As of March 31, 2001, several entities beneficially owned more than 5% of the outstanding shares of our common stock, including Mayfield Fund, Investor Guernsey Ltd. and PatMark Company, Inc. On May 8, 2001, Mayfield Fund distributed 1,734,176 shares of Intuitive common stock to its members.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 June 2000 initial public offering.

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 March 2001 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. Each of these nine patents concerns methods and devices for conducting various aspects of robotic surgery. Until February 2001, the litigation was proceeding in the early stages of discovery, with no trial date set. In February 2001, in response to Intuitive's request, the District Court stayed -- put on hold -- all proceedings in the litigation because of the declaration by the U.S. Patent and Trademark Office ("PTO") of three interferences between a single SRI patent application exclusively licensed to us and three of Computer Motion's patents (see next paragraph). A status report is due to the Court in one year, or earlier if the interferences are resolved before then. 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. While we continue to believe we have multiple meritorious defenses to this action, we cannot assure you that we ultimately will prevail on any issue in the litigation or that we will be able to successfully defend Computer Motion's charges, 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 and as recently as January 2001, we requested that the PTO declare interferences between some of our exclusively licensed SRI patent applications and six of Computer Motion's U.S. patents. An interference is a proceeding within the U.S. Patent Office to resolve questions regarding the patentability of inventions and who first invented subject matter claimed by two or more patents or patent applications. On December 7 and 8, 2000, the PTO formally declared three interference proceedings between a single SRI patent application licensed to us and three of Computer Motion's patents: Nos. 5,878,193, 5,907,664 and 5,855,583. Several of our requests for other interferences are still pending. Because the SRI patent application licensed to Intuitive was filed in January 1992 and Computer Motion's three patents were filed no earlier than August 1992 and as late as February 1996, SRI/Intuitive will be the "Senior Party" in each interference. As "Junior Party," Computer Motion will bear the burden of proving that it is entitled to keep its patents. Each party filed its preliminary motions in the three interferences on March 7, 2001. A hearing on those motions is expected sometime in late summer or early autumn of 2001, with decisions expected before year-end.

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 proceedings. An Opposition proceeding allows the EPO to determine whether the challenged patent should be revoked in its entirety, should be amended, or should remain unaltered. In its Notice of Opposition, Intuitive cited numerous prior art references not cited to the EPO during the '922 patent's original prosecution.

On March 30, 2001, Intuitive and International Business Machines Corporation ("IBM") jointly filed suit against Computer Motion, Inc. ("CMI") in the U.S. District Court for the District of Delaware. The complaint alleges that by continuing to make, use, sell, and offer for sale its AESOP and ZEUS voice-controlled products, CMI willfully infringes U.S. Patent No. 6,201,984. The '984 patent issued to IBM on March 13, 2001, and is exclusively licensed to us under the terms of our 1997 License Agreement with IBM. The '984 patent concerns various aspects of controlling movement of surgical instruments with voice

commands and predates by several years CMI's development of voice-controlled surgical robots. Because CMI's voice-controlled HERMES product interfaces with the AESOP and ZEUS products, HERMES is also implicated in the patent infringement complaint.

On September 1, 2000, Brookhill-Wilk 1, LLC ("Wilk") filed a lawsuit in the United States District Court for the Southern District of New York (Case No. 00 Civ. 6599 (NRB)) alleging that by making, using, selling or offering for sale our da Vinci Surgical System, we are infringing U.S. Patent Nos. 5,217,003 and 5,368,015 in willful disregard of Wilk's patent rights. These patents concern methods and devices for "remote" surgery. In March 2001, Wilk withdrew its assertion of the '015 patent against Intuitive. If we lose Wilk'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 may need to obtain from Wilk a license to this technology if we are to continue to market our products that have been found to infringe Wilk's patents. This license could be expensive, which could seriously harm our business. We believe that we have multiple meritorious defenses in this action. However, litigation is unpredictable and we may not prevail with any of these defenses. If Wilk is successful in its suit against us and is unwilling to grant us a license, we may be required to stop selling our products that are found to infringe Wilk's patents unless we can redesign them so they do not infringe Wilk's patents, which we may be unable to do. In addition, if we lose the patent suit, we could be required to pay Wilk damages, including treble damages, which could be substantial and harm our financial position.

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

### RECENT SALES OF UNREGISTERED SECURITIES

Since January 1, 2001, we have sold and issued the following unregistered securities:

(1) From January 1, 2001 through March 31, 2001, we granted stock options to purchase 1,523,450 shares of our common stock, at prices ranging from \$5.38 to \$8.44 per share, to employees pursuant to our 2000 Equity Incentive Plan.

(2) From January 1, 2001 through March 31, 2001, we granted stock options to purchase 40,000 shares of common stock, at \$8.63 per share, to directors pursuant to our 2000 Non-Employee Directors' Stock Option Plan.

(3) On January 31, 2001, we issued 102,629 shares at an exercise price of \$7.12 per share, to employees pursuant to our 2000 Employee Stock Purchase Plan.

The sales and issuance of securities described in paragraphs (1), (2) and (3) 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.

## 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.
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(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 March 31, 2001.

SIGNATURES

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

INTUITIVE SURGICAL, INC.

By: /s/ SUSAN K. BARNES

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Susan K. Barnes  
Vice President, Finance, Chief  
Financial  
Officer and Assistant Secretary

Date: May 14, 2001

## EXHIBIT INDEX

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