

INTUITIVE SURGICAL INC
Form 424B5
December 11, 2003
Table of Contents

PROSPECTUS

Filed Pursuant to Rule 424(b)(5)

Registration Nos. 333-110229 and 333-110972

Up to 726,842 Shares

Intuitive Surgical, Inc.

COMMON STOCK

This prospectus relates to the offer and sale from time to time by the selling stockholders named in this prospectus of up to 726,842 shares of our common stock, par value \$0.001 per share, issuable upon the exercise of warrants assumed by us in connection with our acquisition of Computer Motion, Inc. We will not receive any proceeds from the sale of the shares, but we could receive up to approximately \$14.9 million in proceeds from the exercise of the warrants prior to those sales, which proceeds would be used for general corporate purposes. Please see Selling Stockholders and Plan of Distribution for information about the selling stockholders and the manner of offering of the common stock.

Our common stock is traded on the Nasdaq National Market under the symbol ISRG. On December 10, 2003, the last reported sale price for our common stock on the Nasdaq National Market was \$15.44 per share.

See Risk Factors beginning on page 4 to read about the risks you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

The date of this prospectus is December 11, 2003.

Table of Contents

TABLE OF CONTENTS

	Page
<u>Where You Can Find More Information</u>	ii
<u>Disclosure Regarding Forward-Looking Statements</u>	iv
<u>About Intuitive Surgical</u>	1
<u>Risk Factors</u>	4
<u>Use of Proceeds</u>	15
<u>Price Range of Common Stock</u>	15
<u>Selected Consolidated Financial Data</u>	16
<u>Description of Capital Stock</u>	18
<u>Selling Stockholders</u>	19
<u>Plan of Distribution</u>	22
<u>Legal Matters</u>	23
<u>Experts</u>	23

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of any offer to buy common stock, nor does this prospectus constitute an offer to sell or the solicitation of any offer to buy common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date of this prospectus or that any information we have incorporated by reference in this prospectus is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or common stock sold on a later date.

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission, which we refer to as the Commission or the SEC. You can inspect and copy these reports, proxy statements and other information at the public reference facility of the Commission, in Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. You can also obtain copies of these materials from the public reference section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. The Commission also maintains a web site at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants such as Intuitive Surgical that file electronically with the Commission.

We have filed registration statements and related exhibits with the Commission under the Securities Act of 1933, as amended, or Securities Act. The registration statements contain additional information about us and our common stock. You may inspect the registration statements and exhibits without charge at the office of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, and you may obtain copies from the Commission at prescribed rates.

The Commission allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the Commission will automatically update, modify and supersede this information. The following documents, which Intuitive Surgical has filed with the Commission, are incorporated by reference into this prospectus:

Annual Report of Intuitive Surgical on Form 10-K/A for the fiscal year ended December 31, 2002;

Proxy Statement included in registration statement on Form S-4 for Intuitive Surgical's annual meeting of stockholders held June 30, 2003;

Quarterly Report of Intuitive Surgical on Form 10-Q for the quarter ended September 30, 2003;

Quarterly Report of Intuitive Surgical on Form 10-Q for the quarter ended June 30, 2003;

Quarterly Report of Intuitive Surgical on Form 10-Q for the quarter ended March 31, 2003;

Report of Intuitive Surgical on Form 8-K filed November 3, 2003;

Item 5 of Report of Intuitive Surgical on Form 8-K filed October 27, 2003;

Report of Intuitive Surgical on Form 8-K filed July 15, 2003;

Item 5 of Report of Intuitive Surgical on Form 8-K filed April 24, 2003;

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

Report of Intuitive Surgical on Form 8-K filed March 7, 2003;

Description of Intuitive Surgical's common stock contained in our registration statement on Form 8-A dated May 26, 2000; and

All documents filed by us with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, after the date of this prospectus and before the selling stockholders stop offering common stock under this prospectus (other than those portions of such documents described in paragraphs (i), (k), and (l) of Item 402 of Regulation S-K promulgated by the Commission).

In addition, the following documents, which Computer Motion has filed with the Commission, are incorporated by reference into this prospectus:

Annual Report of Computer Motion on Form 10-K/A for the fiscal year ended December 31, 2002;

Quarterly Report of Computer Motion on Form 10-Q for the quarter ended March 31, 2003;

Table of Contents

Report of Computer Motion on Form 8-K filed March 11, 2003;

Report of Computer Motion on Form 8-K filed February 24, 2003; and

Report of Computer Motion on Form 8-K filed February 7, 2003.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address:

Investor Relations
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, California 94086
(408) 523-2100

Table of Contents

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results of operations, business strategies, operating efficiencies or synergies, competitive position, growth opportunities for existing products, plans and objectives of management, markets for our common stock and other matters. Statements in this prospectus and the documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements, including, without limitation, those relating to the future business prospects, revenues and income wherever they occur in this prospectus or the documents incorporated herein or therein by reference, are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including those set forth in and incorporated by reference in this prospectus. In addition to the risk factors identified elsewhere, important factors that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to the following:

timing and success of product development and market acceptance of developed products;

regulatory approvals, clearances and restrictions;

guidelines and recommendations in the health care and patient communities;

intellectual property positions and litigation;

competition in the medical device industry and in the specific markets of surgery in which Intuitive Surgical operates;

our ability to integrate the operations of Computer Motion with our operations, including the respective research and development operations, personnel, product lines and technology, and the rate at which the operations of the two companies are integrated;

our ability to achieve anticipated synergies and cost savings of our acquisition of Computer Motion and the rate at which these anticipated synergies and costs savings are achieved; and

unanticipated manufacturing disruptions, delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products.

Words such as estimate, project, plan, intend, expect, anticipate, believe and similar expressions are intended to identify forward-looking statements. These forward-looking statements are found at various places throughout this prospectus and the documents incorporated by reference. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus, or in the case of documents incorporated by reference, as of the date of those documents. We undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as required by law.

Table of Contents

ABOUT INTUITIVE SURGICAL

We encourage you to read carefully this entire prospectus. In addition, we encourage you to read the information incorporated by reference into this prospectus, which includes important information about our company that we have filed with the SEC. You may obtain the information incorporated by reference in this prospectus without charge by following the instructions in the section entitled "Where You Can Find More Information." Unless the context otherwise requires, references in this prospectus to Intuitive Surgical, Intuitive, we, us, and our refer to Intuitive Surgical, Inc. and its subsidiaries.

Our Business

We design, manufacture and market the *da Vinci* Surgical System, an advanced surgical system that we believe represents a new generation of surgery – the third generation. We believe that this new generation of surgery, which we call *Intuitive* surgery, is a revolutionary advance similar in scope to the previous two generations of surgery – open surgery and minimally invasive surgery, or MIS. Our *da Vinci* Surgical System consists of a surgeon's console, a patient-side cart, a high performance vision system and proprietary wristed instruments. By placing computer-enhanced technology between the surgeon and patient, we believe that our system enables surgeons to perform better surgery in a manner never before experienced. 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. Our *da Vinci* Surgical System provides 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 MIS. As of September 30, 2003, we had sold 192 *da Vinci* Surgical Systems and we believe surgeons using our technology have successfully completed thousands of surgical procedures of various types in major hospitals throughout the United States as well as in Europe and Asia.

Although open surgery is still the predominant form of surgery, the large incisions required create significant trauma to the patient, often contributing to long hospitalization and recovery times and high hospitalization costs, as well as significant pain and suffering. Over the past several decades, physicians have made progress in reducing surgery-related trauma by developing MIS techniques. These techniques allow surgery to be performed through ports rather than large incisions, resulting in shorter recovery times and reduced hospitalization costs. MIS techniques have been widely adopted for certain surgical procedures, such as gall bladder removal, but have not been widely adopted for most complex surgical procedures. We believe surgeons have been slow to adopt conventional MIS tools and techniques for complex surgical procedures due to the limitations of conventional MIS, including backward instrument movements, restricted range of motion, magnified hand tremor, lack of precision, difficulty in performing fine tissue manipulations, exaggerated instrument movements and poor visibility.

Our Solution

We believe that our technology overcomes many of the limitations of existing MIS tools and techniques in the following ways:

Natural Instrument Movements. Our technology is designed to directly transform the surgeon's natural hand movements outside the body into corresponding micro-movements inside the patient's body. Our technology eliminates the backward instrument movements of conventional MIS.

EndoWrist Instruments Provide Natural Dexterity and Range of Motion. Our technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions of a human hand and wrist. Our proprietary instruments incorporate wrist

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

joints that enable surgeons to reach behind tissues and suture with precision, just as they can in open surgery.

Table of Contents

More Precise Movements and Reduced Tremor. With our technology, the surgeon can also use motion scaling, a feature that translates, for example, a three millimeter hand movement outside the patient's body into a one millimeter instrument movement in the surgical field inside the patient's body. Motion scaling is designed to allow greater precision than is normally achievable in both open surgery and MIS.

Immersive 3-D Visualization. Our vision system is designed to give surgeons the perception that their hands are immersed in the surgical field even though they are outside the patient's body. We believe our vision system, which incorporates our proprietary technology that allows the surgeon to easily change, move, zoom and rotate his or her field of vision, provides a much brighter and sharper image than any other 3-D endoscope vision system.

Easy to Learn, Easy to Master. We have designed our products to make them as simple as possible to use, even though the underlying technology is inherently complex.

Multi-Specialty Surgical Platform. The *da Vinci* Surgical System is designed to enable surgeons to perform surgery in virtually any part of the body.

We believe that these advantages give the patient the benefits of less traumatic MIS while restoring to the surgeon the range of motion and fine tissue control possible with open surgery, along with further enhancements such as tremor reduction, motion scaling and superior visualization.

Our Products

Our products include our *da Vinci* Surgical System consisting of a surgeon's console, a patient-side cart, a high performance vision system and a variety of smart disposable *EndoWrist* instruments that incorporate our flexible wrist joint technology. We recently introduced a fourth robotic arm and three-channel vision system, which are available as options on new *da Vinci* Surgical Systems or as upgrades to existing *da Vinci* Surgical Systems. Our product revenues are generated primarily from the sale of our *da Vinci* Surgical Systems and our *EndoWrist* instruments, which include scissors, forceps, scalpels and a variety of other tools. Our *EndoWrist* instruments are resterilizable and reusable for a defined number of procedures. The *da Vinci* Surgical System will not allow an *EndoWrist* instrument to be used for more than its prescribed number of procedures to ensure that it performs up to its specifications. Accordingly, we expect to generate recurring revenues from sales of our *EndoWrist* instruments to be used with our installed base of *da Vinci* Surgical Systems. We also expect that as we increase the installed base of our *da Vinci* Surgical Systems and as the number of procedures performed with those installed systems also increases, recurring revenues from sales of our *EndoWrist* instruments will account for an increasing percentage of our total revenues.

Our Strategy

Our goal is to establish *Intuitive* surgery as the standard for complex surgical procedures and many other procedures currently performed using either open surgery or MIS. We intend to accomplish this objective both by pioneering new types of endoscopic surgery and by making existing MIS procedures easier, safer and more cost effective. Over time, our strategy is to broaden the number of procedures performed using the *da Vinci* Surgical System and to educate surgeons and hospitals as to the benefits of *Intuitive* surgery. Key elements of our strategy include the following:

Focus on Key Institutions. Our marketing efforts are focused on both academic and community hospitals in order to increase the prestige associated with use of the *da Vinci* Surgical System and drive system and procedure volume.

Focus on Key Procedures. Our procedure marketing efforts are primarily focused within urologic surgery, cardiothoracic surgery and general surgery.

Table of Contents

Focus on Leading Surgeons to Drive Rapid and Broad Adoption. We place significant emphasis on marketing the *da Vinci* Surgical System to leading surgeons who are considered to be the thought leaders in their institutions and fields.

Develop Protocols for New Surgical Procedures. We intend to leverage our relationships with key institutions and surgical thought leaders to develop protocols for new surgical procedures.

Maintain Market Leadership. We intend to maintain our leadership advantage by continuing to develop and enhance our technology and to communicate the benefits of our *da Vinci* Surgical System to surgeons, hospitals and patients.

Develop Industry Alliances. We intend to continue to establish strategic alliances with leading medical device companies. We have formed alliances with, among other companies, Ethicon Endo-Surgery, Inc., Olympus Corporation and Medtronic, Inc.

Our Acquisition of Computer Motion

In June 2003, we acquired Computer Motion, Inc. in a stock transaction pursuant to which a wholly owned subsidiary of our company merged with and into Computer Motion. Computer Motion developed and marketed robotic and computerized surgical systems. In connection with the merger, each outstanding share of Computer Motion common stock was converted into the right to receive a fraction of one share of our common stock. In addition, we assumed all of Computer Motion's outstanding options and warrants. The total purchase price was approximately \$148.6 million. In connection with our acquisition of Computer Motion, all pending patent litigation between the companies was dismissed and Robert Duggan, the Chief Executive Officer and Chairman of the Board of Directors of Computer Motion, and Eric Halvorson, a director of Computer Motion, were appointed to our board of directors.

Our acquisition of Computer Motion is intended to enhance the competitive position of the combined company and to enable us to better capitalize on the market opportunity for the application of robotics to MIS. In addition, the acquisition is intended to strengthen our workforce, to enable us to better focus on strategic products and customers and to achieve significant cost synergies and economies of scale. The acquisition also eliminated ongoing intellectual property litigation between the two companies.

Recent Developments

In October 2003, we sold 5,000,000 shares of common stock in an underwritten public offering at a price of \$14.50 per share. In November 2003, we sold an additional 750,000 shares of common stock at a price of \$14.50 per share in connection with the exercise of the underwriters over-allotment option. We estimate that our net proceeds from the offering will be approximately \$77.9 million, after deducting the underwriting discount and the estimated offering expenses payable by us.

Our company was founded in 1995. Our executive offices are located at 950 Kifer Road, Sunnyvale, California 94086, our telephone number is (408) 523-2100 and our website address is www.intuitivesurgical.com. Information contained on our website is not incorporated by reference into and does not form any part of this prospectus. Intuitive®, *da Vinci*®, ZEUS®, AESOP®, HERMES®, *EndoWrist*®, InSite® and Navigator are trademarks of Intuitive Surgical, Inc. or its subsidiaries.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. In addition to the other information included in this prospectus, including the matters addressed in Disclosure Regarding Forward-Looking Statements. You should carefully consider the following risks before purchasing our common stock. Additional risks and uncertainties not presently known to us or that are not currently believed to be important to you also may adversely affect our company.

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 revenues. In addition, our costs may be higher than we, securities analysts or investors expect. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. Further, future revenue from sales of our products is difficult to forecast because the market for new surgical technologies is still evolving. Our results of operations will depend upon numerous factors, including:

the extent to which our products gain market acceptance;

actions relating to regulatory matters;

our timing and ability to develop our manufacturing and sales and marketing capabilities;

demand for our products;

the 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 and defend against third party challenges;

our ability to license additional intellectual property rights;

the integration of Computer Motion with our company;

the progress and results of clinical trials; 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 experience long and variable sales cycles, which could have a negative impact on our results of operations for any given quarter.

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

Table of Contents

Because a small number of customers have and are likely to continue to account for a substantial portion of our revenues, our revenues could decline due to the loss or delay of a single customer.

A relatively small number of customers account for a significant portion of our total revenues. During the three months ended September 30, 2003 and 2002, approximately 65% and 77%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems, which are high revenue dollar items. During the nine months ended September 30, 2003 and 2002, approximately 69% and 80%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems. During the three and nine month periods ended September 30, 2003 and 2002, no customer accounted for more than 10% of total sales. However, due to the high average selling price of the *da Vinci* Surgical System, our failure to add new customers that make significant purchases of our products could reduce our future revenues. The loss or delay of individual orders could have a significant impact on revenues and operating results.

If our products do not achieve market acceptance, we will not be able to generate the revenue necessary to support our business.

Our products represent a fundamentally new way of performing surgery. Achieving physician, patient and third-party payor acceptance of *Intuitive* surgery as a preferred method of performing surgery will be crucial to our success. If our products fail to achieve market acceptance, hospitals will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that physicians and third-party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing surgical techniques. Even if we can prove the effectiveness of our products through clinical trials, surgeons may elect not to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional open-heart surgery simply because such surgery is already widely accepted. In addition, surgeons may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third-party payors.

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

We are involved in intellectual property litigation with Brookhill-Wilk 1, LLC that may hurt our competitive position, may be costly to us and may prevent us from selling our products.

In September 2000 Brookhill-Wilk 1, LLC, or Wilk, filed a lawsuit against our company 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 United States 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 our company. In November 2001, in response to a motion on one of Intuitive Surgical's noninfringement defenses, the District Court granted summary judgment of noninfringement of the 003 patent in our favor and dismissed Wilk's complaint in its entirety without prejudice. Wilk appealed the summary judgment ruling to the United States Court of Appeals for the Federal Circuit. In April 2003, the Court of Appeals reversed the District Court's judgment and remanded the case for further proceedings. This reversal is based on the Court of Appeals' determination that the particular claim limitation at issue should be interpreted differently than as construed by the District Court.

Table of Contents

Upon remand, we intend to continue to vigorously defend our rights and, if necessary, are prepared to conduct discovery and file further motions on whether the patent is infringed, valid and/or enforceable. We believe that we have multiple meritorious defenses to Wilk's allegations. However, litigation is unpredictable and we may not prevail. Both parties have expressed a desire to engage in non-binding mediation before engaging in further proceedings in the District Court. The District Court has not yet set a schedule for further proceedings if mediation is unsuccessful.

In July 2003, Wilk filed a new lawsuit against three of our customers: Mt. Sinai Hospital, Lenox Hill Hospital and the New York and Presbyterian Hospital. Pursuant to agreements with those customers, we are defending the lawsuit on behalf of our customers. We do not expect this lawsuit to significantly impact the scope of the existing litigation with Wilk since any resolution of the existing Wilk litigation, whether on the merits or by settlement, will likely resolve this new lawsuit at the same time.

In September 2003, Wilk amended its complaint against our company to include Computer Motion within the lawsuit and to allege that Computer Motion's Zeus product also infringes Wilk's 003 patent. Prior to our acquisition of Computer Motion, Wilk sued Computer Motion but dismissed that lawsuit voluntarily in order to await the outcome of the appeal proceedings in Wilk's litigation with our company. We believe that we have multiple meritorious defenses to Wilk's allegations against Computer Motion, including many of the same defenses that apply to Wilk's allegations against our company. However, litigation is unpredictable and we may not prevail. Wilk's allegations against Computer Motion are directed only to Computer Motion products.

If we lose Wilk's lawsuits against us and the three hospital customers, it will hurt our competitive position, may be costly to us and may prevent us from selling our products. 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. 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, we could be required to pay Wilk damages, including treble damages, which could be substantial and harm our financial position. Due to the inherent uncertainties of litigation, however, we cannot accurately predict the ultimate outcome of the Wilk litigation at this time and, therefore, cannot estimate the range of possible loss.

The foregoing proceeding could be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in this lawsuit, the proceeding could consume substantial amounts of our financial and managerial resources. At any time, Wilk may file additional claims against our company, or we may file claims against Wilk, which could increase the risk, expense and duration of the litigations.

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 do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. We also do not know whether we will be able to develop additional patentable proprietary technologies. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or reexaminations.

Table of Contents

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, remote 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 with, one or more of these third parties. 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 Brookhill-Wilk 1, LLC has, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages, including treble damages, and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our patents from infringement or claims of invalidity or unenforceability, or to defend against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could cause our stock price to decline.

The rights and measures we rely on to protect the intellectual property underlying our products may not be adequate to prevent third parties from using our technology, which could harm our ability to compete in the market.

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

Table of Contents

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 Corporation, MIT, Olympus Optical Co., Ltd. and Heartport, Inc., now part of Johnson & Johnson. Any of these agreements may be terminated for breach. If any of these agreements is terminated, we may be unable to reacquire the necessary license on satisfactory terms, or at all. The loss or failure to maintain these licenses could prevent or delay further development or commercialization of our products.

Public announcements of litigation events may cause our stock price to decline.

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

Our products are subject to a lengthy and uncertain domestic regulatory process. If we do not obtain and maintain the necessary domestic regulatory approvals, we will not be able to market and sell our products in the United States.

Our products and operations are subject to extensive regulation in the United States by the United States 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, or FDCA. Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfather status. If we significantly modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or premarket approval application, or PMA, for the modified product before we are permitted to market the products in the United States. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfather status, we will be required to obtain FDA approval by submitting a PMA.

The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions, or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, all of which could delay or preclude sale of new products in the United States. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies, in support of a 510(k) submission. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex and burdensome application than a 510(k). To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, or the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products we develop, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition and results of operations.

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

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

Table of Contents

Review Board, or 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, or IDE application. Most of our products to date have been considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices we intend to market in the United States in the future. If we obtain such approvals, we may not be able to comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

Complying with FDA regulations is an expensive and time-consuming process, and our failure to comply fully could subject us to significant enforcement sanctions.

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

Quality System Regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations;

the FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or off-label uses;

the Reports of Corrections and Removals regulation, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA that may pose a risk to health; and

the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

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

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

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

In December 2002, the FDA inspected our Sunnyvale manufacturing facility and issued a Form FDA 483 setting forth three observed compliance deficiencies relating to the QSR and two observed deficiencies relating

Table of Contents

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

We recently acquired Computer Motion and are working to integrate its FDA compliance system with our own. Our review is not complete, but we believe that Computer Motion likely has had deficiencies in QSR compliance, complaint handling, MDR reporting and Corrections and Removals reporting in the last several years that will require submission of retroactive reports to the FDA. We are also reviewing whether Computer Motion responded to complaints with appropriate follow up. We cannot assure you that the FDA will not seek to impose enforcement sanctions on us for Computer Motion violations preceding our acquisition of Computer Motion, that the FDA will agree that since the acquisition we have corrected all regulatory problems, or that our review of Computer Motion's complaint handling will not lead us to initiate recalls or field actions to remedy problems with Computer Motion products already in the field.

Our products are subject to various international regulatory processes and approval requirements. If we do not obtain and maintain the necessary international regulatory approvals, we will not be able to market and sell our products in foreign countries.

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

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

If we modify existing products or develop new products in the future, including new instruments, we may need to apply for permission to affix the CE mark to those 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.

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

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

Table of Contents

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

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

In many cases, the medical conditions that can be treated using our products can also be treated by drugs 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 defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer.

Our products incorporate mechanical parts and computer software, either of which can contain errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. We cannot assure you that our products will not experience errors or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

delays in product shipments;

loss of revenue;

delay in market acceptance;

diversion of our resources;

damage to our reputation;

increased service or warranty costs; or

product liability claims.

Table of Contents

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 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. 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 could result in product delivery delays and lost revenue.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities, and our operations will continue to be regulated by the FDA for compliance with Good Manufacturing Practice requirements contained in the FDA's Quality System Regulations, or QSR. We are also required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe. If we fail to continue to comply with Good Manufacturing Practice requirements or ISO standards, we may be required to cease all or part of our operations until we comply with these regulations. We are currently in compliance with ISO standards. The FDA inspected our Mountain View and Sunnyvale facilities in March 2000 and December 2002, respectively. The Good Manufacturing Practice issues raised by the FDA during the inspections either were satisfactorily resolved with the FDA or we believe can be resolved by us to the FDA's satisfaction, although we cannot assure you that we will be able to do so. We continue to be subject to FDA inspections at any time. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards in future inspections and audits by regulatory authorities.

The FDA inspected the Goleta facilities of Computer Motion in 1998 and noted deficiencies in Computer Motion's systems for reviewing and reporting product-related complaints and defect information. We have determined that these deficiencies may not have been addressed. While the Goleta manufacturing facility has been closed and production of certain products has been transferred to our Sunnyvale facility, these issues raised by the FDA must nonetheless be resolved. We are presently addressing the situation to resolve all the issues to our own and the FDA's satisfaction, although we cannot assure you that we will be able to do so, nor can we assess what regulatory impact, if any, this may have on our company.

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. In March 2002, our facilities and manufacturing processes in our Sunnyvale facility were re-inspected by the Food and Drug Branch, or FDB, and we were issued an updated device manufacturing license for our Sunnyvale facility. We are

Table of Contents

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

During the second quarter 2003, two former patients of The Valley Hospital in New Jersey filed suit against The Valley Hospital, their surgeons and our company alleging various harms caused during their surgeries. We were named because the *da Vinci* Surgical System was utilized for a portion of the surgeries and the detachable tip of an *EndoWrist* instrument is alleged to have remained in each patient after each surgery. Each suit alleges, among others, negligence, carelessness and/or recklessness by each defendant, that the *da Vinci* Surgical System was defectively designed and manufactured, that we failed to properly instruct and train the surgeon in its use, and that the defendants failed to properly apprise the patients of the risks involved. Each suit seeks an unspecified amount of general, special and punitive damages from the defendants, in addition to a request to recover the costs of suit and attorney fees. As each suit was just recently filed, both are in very early stages and discovery has recently commenced.

If we lose our key personnel or are unable to attract and retain additional personnel, our ability to compete will be harmed.

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

inability to attract and retain qualified personnel could harm our business and our ability to compete.

Table of Contents

International sales of our products account for a significant portion of our revenues, which exposes us to risks inherent in international operations. Our growth may be limited if we are unable to successfully manage our international activities.

Our business currently depends in large part on our activities in Europe and other foreign markets. Sales to markets outside of the United States accounted for approximately 14% of our sales for the three months ended September 30, 2003 and 10% for the three months ended September 30, 2002. Sales to markets outside of the United States accounted for approximately 21% of our sales for the nine months ended September 30, 2003 and 15% for the nine months ended September 30, 2002. For 2002, 2001 and 2000, sales to markets outside the United States accounted for approximately 18%, 34% and 39%, respectively, of our net sales.

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

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

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

Termination of relationships with former distributors of Computer Motion could result in litigation.

Our integration strategy related to our acquisition of Computer Motion provides that we terminate Computer Motion's relationships with a number of companies that served as Computer Motion's distributors prior to the acquisition. Several of these former distributors have informed us that they believe that they are entitled to compensation in connection with such termination. We may be unable to resolve these claims without litigation. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such litigation at this time and, therefore, cannot estimate the range of possible loss. If we sue or are sued by any of Computer Motion's former distributors, these proceedings could be expensive to litigate, may be protracted and Computer Motion's confidential information may be compromised. Whether or not we are successful in these lawsuits, these proceedings could consume substantial amounts of our financial and managerial resources.

The conviction of Arthur Andersen LLP on obstruction of justice charges may adversely affect Arthur Andersen's ability to satisfy claims arising from the provision of auditing services to Computer Motion.

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

Arthur Andersen LLP audited Computer Motion's financial statements for the years ended December 31, 2001 and December 31, 2000. On March 14, 2002, an indictment was unsealed charging Arthur Andersen with federal obstruction of justice arising from the government's investigation of Enron Corp. On June 15, 2002, Arthur Andersen was convicted of these charges. The impact of this conviction on Arthur Andersen's financial condition may adversely affect the ability of Arthur Andersen to satisfy any claims arising from its provision of auditing services to Computer Motion.

Table of Contents**USE OF PROCEEDS**

We will not receive any of the proceeds from the selling stockholders' sales of our common stock. We could receive up to approximately \$14.9 million in proceeds from the exercise of the warrants by the selling stockholders, which proceeds would be used for general corporate purposes.

PRICE RANGE OF COMMON STOCK

Our common stock has been traded on The Nasdaq Stock Market under the symbol "ISRG" since June 13, 2000. The following table sets forth the high and low closing prices of our common stock for the periods indicated and are as reported by Nasdaq.

Quarter	High	Low
Year Ended December 31, 2003		
First Quarter	\$ 13.50	\$ 7.52
Second Quarter	18.20	10.96
Third Quarter	18.08	12.08
Fourth Quarter (through December 9, 2003)	17.89	13.93
Year Ended December 31, 2002		
First Quarter	\$ 20.30	\$ 16.78
Second Quarter	21.80	15.84
Third Quarter	16.62	11.54
Fourth Quarter	16.26	12.16
Year Ended December 31, 2001		
First Quarter	\$ 18.13	\$ 9.75
Second Quarter	27.02	6.70
Third Quarter	27.90	10.78
Fourth Quarter	20.30	12.90

As of October 1, 2003, there were approximately 553 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

Table of Contents**SELECTED CONSOLIDATED FINANCIAL DATA**

The tables below present our selected consolidated statements of operations and balance sheet data. We derived the selected consolidated financial data from our audited financial statements for the three years ended December 31, 2002. We derived the selected consolidated financial data for the nine months ended September 30, 2003 and 2002 from our unaudited condensed consolidated financial statements. The unaudited condensed consolidated financial statement data includes, in our opinion, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation. Operating results for the nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003 or any other future period. On June 30, 2003, we completed our acquisition of Computer Motion. The operations of Computer Motion have been included in the unaudited consolidated statement of operations data for the nine months ended September 30, 2003 from the date of acquisition. You should read this information together with our consolidated financial statements and related notes contained in our annual and quarterly reports and other information that we have filed with the SEC and incorporated by reference in this prospectus. Please see [Where You Can Find More Information](#).

(in thousands, except per share amounts)

	Fiscal Year Ended December 31,					Nine Months Ended September 30,	
	2002	2001	2000	1999	1998	2003	2002
							(Unaudited)
Consolidated Statements of Operations Data:							
Sales	\$ 72,022	\$ 51,673	\$ 26,624	\$ 10,192	\$	\$ 64,081	\$ 50,877
Cost of sales	34,584	28,218	18,031	9,273		27,051	25,072
Gross profit	37,438	23,455	8,593	919		37,030	25,805
Operating costs and expenses:							
Selling, general and administrative	40,864	29,987	19,136	9,338	7,565	31,840	30,262
Research and development	16,793	13,851	11,734	11,130	23,208	11,457	12,767
Total operating costs and expenses	57,657	43,838	30,870	20,468	30,773	43,297	43,029
Loss from operations	(20,219)	(20,383)	(22,277)	(19,549)	(30,773)	(6,267)	(17,224)
Interest income, net	1,841	3,641	3,862	1,134	1,330	1,436	1,476
Other income (expense)	(43)	42	(108)			63	(73)
Net loss	\$ (18,421)	\$ (16,700)	\$ (18,523)	\$ (18,415)	\$ (29,443)	\$ (4,768)	\$ (15,821)
Basic and diluted net loss per common share	\$ (1.01)	\$ (0.93)	\$ (1.56)	\$ (7.61)	\$ (16.27)	\$ (0.22)	\$ (0.87)
Shares used in computing basic and diluted net loss per common share	18,229	17,908	11,898	2,419	1,810	21,296	18,199

Table of Contents

	As of December 31,					As of
	2002	2001	2000	1999	1998	September 30, 2003
						(Unaudited)
Consolidated Balance Sheet Data:						
Cash, cash equivalents and short-term investments	\$ 50,839	\$ 66,661	\$ 89,441	\$ 26,260	\$ 23,220	\$ 35,449
Working capital	52,562	67,922	83,836	22,023	19,817	42,894
Total assets	91,581	100,361	112,421	34,455	28,167	238,764
Notes payable, less current portion	1,838	771	1,861	2,521	2,438	950
Deferred compensation	(223)	(886)	(2,483)	(943)	(1,128)	(375)
Accumulated deficit	(128,791)	(110,370)	(93,670)	(75,147)	(56,732)	(133,559)
Total stockholders' equity	63,680	78,293	90,730	22,211	20,596	204,647

Table of Contents

DESCRIPTION OF CAPITAL STOCK

Holders of common stock are entitled to receive such dividends, if any, as may from time to time be declared by our Board of Directors out of funds legally available therefor. Pursuant to our Amended and Restated Certificate of Incorporation, as amended, holders of common stock are entitled to one vote per share on all matters on which the holders of common stock are entitled to vote and do not have cumulative voting rights. Holders of common stock have no preemptive, conversion, redemption or sinking fund rights. In the event of a liquidation, dissolution or winding-up of our company, holders of common stock are entitled to share equally and ratably in the assets of our company, if any, remaining after the payment of all debts and liabilities of our company and the liquidation preference of any outstanding preferred stock. The outstanding shares of common stock are, and the shares of common stock offered hereby when issued will be, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock which we may issue in the future.

Our Board of Directors may issue up to 2,500,000 shares of preferred stock in one or more series and, subject to the provisions of the Delaware General Corporation Law, may fix the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions, if any), the redemption price or prices, the liquidation preferences, any other designations, preferences and relative, participating, optional or other special rights and any qualifications, limitations or restrictions thereof and the number of shares constituting any series and the designation thereof. In addition, our Board of Directors may increase or decrease the number of shares of any series subsequent to the issue of shares of that series, but not below the number of shares of such series then outstanding. Our Board of Directors has the power to issue our preferred stock with voting and conversion rights that could negatively affect the voting or other rights of our common stockholders, and our Board of Directors could take that action without stockholder approval. The issuance of our preferred stock could delay or prevent a change of control in our company.

Table of Contents**SELLING STOCKHOLDERS**

In connection with the completion of our acquisition of Computer Motion, Inc. on June 30, 2003, we assumed warrants previously issued by Computer Motion, which warrants became exercisable for shares of our common stock in connection with that transaction. Pursuant to the registration statements of which this prospectus is a part, we have registered the resale of up to 726,842 shares of our common stock issuable upon exercise of these warrants.

We have filed with the Commission, under the Securities Act, registration statements on Form S-3, of which this prospectus forms a part, with respect to the resale of the shares issuable upon exercise of the warrants from time to time on the Nasdaq National Market, in privately-negotiated transactions, or otherwise. We intend to prepare and file such amendments and supplements to the registration statements as may be necessary to keep the registration statements effective until all shares covered by the registration statements have been sold or may be resold in a 90-day period under Rule 144 of the Securities Act without volume limitation or reliance on Rule 144(k).

The following table sets forth the name of each selling stockholder, the number of shares of our common stock known by us to be beneficially owned by each selling stockholder as of November 18, 2003, the number of shares of our common stock that may be offered for resale for the account of each selling stockholder pursuant to this prospectus and the number of shares of our common stock to be held by each selling stockholder after the sale of all of the shares covered by this prospectus by that selling stockholder. Percentage ownership is based on 32,962,144 shares of common stock outstanding as of November 18, 2003. The selling stockholders may sell all, some or none of the common stock being offered. This information is based upon our review of public filings, our stockholder and optionholder registers and information furnished by certain of the selling stockholders.

Name of Selling Stockholder	Shares Beneficially Owned Prior to the Offering (1)		Shares Offered by This Prospectus	Shares Beneficially Owned Subsequent to the Offering (1)(2)	
	Shares	Percent		Shares	Percent
Harold Wayne Andrews Jr.	1,833	*	1,333	500	*
Brian and Renee Arington	32	*	16	16	*
Marita Arington	500	*	500	0	*
Michael Arington, as custodian for Alyssa Arington	32	*	16	16	*
Richard and Marita Arington	1,166	*	1,166	0	*
Shanna Assiter	316	*	316	0	*
Matthew Balk	10,085	*	10,085	0	*
Stephen Barrett	6,405	*	2,692	3,713	*
Baystar	14,521	*	14,521	0	*
Bedford Oak Partners, L.P.	12,856	*	12,856	0	*
Christopher A. Ben	332	*	166	166	*
Mike S. Ben	166	*	166	0	*
Jeffrey C. Bermant	1,667	*	1,667	0	*
Laura Burnam Braswell and Ann Bennett Braswell	833	*	833	0	*
Mark Alan Buntz	833	*	833	0	*
California Central Trust Bank TTEE Craig Carlson #1050184743	270	*	270	0	*
California Central Trust Bank TTEE Lawrence Cohn #1050184761	270	*	270	0	*
California Central Trust Bank TTEE Bruce Feuchter #1050184789	148	*	148	0	*
California Central Trust Bank TTEE Ben Frydman #1050184798	270	*	270	0	*
California Central Trust Bank TTEE John Ireland #1050184565	83	*	83	0	*
California Central Trust Bank TTEE John Murphy #1050184912	148	*	148	0	*
California Central Trust Bank TTEE William R. Rauth #1050185387	270	*	270	0	*
California Central Trust Bank TTEE K.C. Schaaf #1050184958	148	*	148	0	*
California Central Trust Bank TTEE Bruce Stuart #1050184994	270	*	270	0	*

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

California Central Trust Bank TTEE Robert Whalen #1050185029	270	*	270	0	*
California Central Trust Bank TTEE Nick E. Yocca #105018047	270	*	270	0	*
Peter A. Cannon	500	*	500	0	*
Castle Creek Healthcare Partners LLC	12,545	*	12,545	0	*
CC Life Sciences, Ltd.	25,087	*	25,087	0	*

Table of Contents

Name of Selling Stockholder	Shares Beneficially Owned Prior to the Offering (1)		Shares Offered by This Prospectus	Shares Beneficially Owned Subsequent to the Offering (1)(2)	
	Shares	Percent		Shares	Percent
CD Capital Management, LLC	2,571	*	2,571	0	*
Michael Chan	1,667	*	1,667	0	*
Greg J. Chavarria	1,166	*	1,166	0	*
Bradley and Kathleen Chewakin	106	*	106	0	*
Kathleen Chewakin, as custodian for Eric Lee Chewakin	32	*	32	0	*
Clarion Capital Corporation	15,679	*	15,679	0	*
Clarion Offshore Fund Ltd.	7,839	*	7,839	0	*
Clarion Partners L.P.	7,839	*	7,839	0	*
Cleveland Overseas Ltd.	31,357	*	31,357	0	*
Community Investment Partners II, L.P.	5,839	*	4,167	1,672	*
Cranshire Capital, L.P.	31,499	*	31,499	0	*
Daniel R. and Pamela G. Doiron, as joint tenants	11,232	*	7,565	3,667	*
Doiron Family Trust	3,733	*	733	3,000	*
Paul R. and Peggy Doiron	3,334	*	1,667	1,667	*
Frederick Charles Dorr and Emily Jean Hass Revocable Trust	1,667	*	1,667	0	*
Turtle Dorr Trust #2	2,316	*	2,316	0	*
Robert Duggan (3)	1,081,578	3.3%	63,330	1,018,248	3.1%
Caren L. Dunne	1,166	*	1,166	0	*
James D. Dunne	3,334	*	1,667	1,667	*
Donald and Diana Evans	332	*	166	166	*
Ken Flood	74,423	*	43,569	30,854	*
Paul F. Glenn Revocable Trust	5,167	*	1,833	3,334	*
Ralph Goodson	4,114	*	4,114	0	*
Ron Goodson	4,114	*	4,114	0	*
Gryphon Master Fund, L.P.	7,842	*	7,842	0	*
H.C. Wainwright & Co., Inc.	3,673	*	3,673	0	*
Cecil Heftel	13,336	*	6,668	6,668	*
Richard Heftel Living Trust dated Jan 9, 1996	3,334	*	3,334	0	*
Jeff Henley	21,664	*	7,261	14,403	*
Thomas R. Hower	1,250	*	1,250	0	*
Robert Hussey	928	*	928	0	*
Joseph P. Ilvento, M.D., Judy C. Dean, M.D., Inc. Money Purchase Pension Plan	2,316	*	2,316	0	*
Jordan M. Laby & Sandra Laby Trustees of the Laby Family Trust Dated November 10, 1997	3,334	*	3,334	0	*
Todd Mitchell Laby	2,567	*	333	2,234	*
Bryan A. Lamey	1,366	*	1,366	0	*
George S Mauerman	2,083	*	2,083	0	*
George S. Mauerman, Trustee for Adrien M. Mauerman Testamentary Trust	3,750	*	3,750	0	*
Frank Louis Mitchell	833	*	833	0	*
MRT, L.P.	15,679	*	15,679	0	*
Pei Jin Ruan	1,928	*	1,928	0	*
Pequot Navigator Offshore Fund, Inc.	12,535	*	12,535	0	*
Pequot Scout Fund, LP	25,070	*	25,070	0	*
Roberto J. and Danna Perez	333	*	333	0	*
Knowland James Plucknett Revocable Trust, Knowland James Plucknett Trustee	6,668	*	6,668	0	*
Quantico Partners L.P.	7,839	*	7,839	0	*
Radyr Investments Limited	7,843	*	7,843	0	*
Redpoint Partners L.P.	20,382	*	20,382	0	*
Redwood Partners LLC	9,385	*	9,385	0	*
RGRJ Venture Fund II LLC	15,138	*	6,715	8,423	*
Jeff Barbaro and Brenda Gail Sanders	463	*	463	0	*
SDS Merchant Fund L.P.	514,536	1.6	23,527	491,009	1.5
SF Capital Partners Ltd.	47,042	*	47,042	0	*
Eric Singer	928	*	928	0	*
Reed Slatkin	8,335	*	8,335	0	*

Table of Contents

Name of Selling Stockholder	Shares Beneficially Owned Prior to the Offering (1)		Shares Offered by This Prospectus	Shares Beneficially Owned Subsequent to the Offering (1)(2)	
	Shares	Percent		Shares	Percent
Societe Generale	58,091	*	58,091	0	*
Stradling, Yocca, Carlson & Rauth Investment Partnership of 1982	3,334	*	1,667	1,667	*
The Larry Haimovitch 2000 Separate Property Revocable Trust	3,921	*	3,921	0	*
The Tamkin Living Trust for Trust dated 10/7/96	128	*	128	0	*
Triton West Group, Inc.	10,928	*	10,928	0	*
Vertical Ventures Investments, LLC	15,678	*	15,678	0	*
Victus Capital Management	25,713	*	25,713	0	*
Gene and Leslie Wang	7,848	*	4,632	3,216	*
Yulan and Susan Wang	555	*	555	0	*
Scott Weisman	9,063	*	9,063	0	*
Stephen Wiggins	24,466	*	24,466	0	*
Stephen Wilson	4,584	*	4,584	0	*
Xue Li Qian	1,881	*	1,881	0	*
Maky Zanganeh	50,871	*	348	50,523	*
Total	2,373,671		726,842	1,646,849	

* Represents less than 1% of the issued and outstanding shares.

- (1) Beneficial ownership is determined in accordance with the rules of the Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options and warrants which are currently exercisable, or will become exercisable within 60 days of November 18, 2003, are deemed outstanding for computing the percentage of the person or entity holding such securities but are not deemed outstanding for computing the percentage of any other person or entity. Subject to community property laws, to our knowledge the persons named in the table above have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.
- (2) Assumes for each stockholder the exercise in full of the warrant held by such stockholder and the sale of all shares offered hereby.
- (3) Mr. Dugan, the former Chief Executive Officer and Chairman of the Board of Directors of Computer Motion, became a member of our board of directors on June 30, 2003 in connection with our acquisition of Computer Motion.

Table of Contents

PLAN OF DISTRIBUTION

The selling stockholders, or, subject to applicable law, their pledgees, donees, distributees, transferees or other successors in interest, may sell shares from time to time in public transactions, on or off the Nasdaq National Market, or in private transactions, at prevailing market prices or at privately negotiated prices, including but not limited to, one or any combination of the following types of transactions

ordinary brokers transactions;

transactions involving cross or block trades or otherwise on the Nasdaq National Market;

purchases by brokers, dealers or underwriters as principal and resale by these purchasers for their own accounts pursuant to this prospectus;

at the market, to or through market makers, or into an existing market for our common stock;

in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;

through transactions in options, swaps or other derivatives (whether exchange-listed or otherwise);

in privately negotiated transactions; or

to cover short sales.

In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate in the resales. The selling stockholders may enter into hedging transactions with broker-dealers, and in connection with those transactions, broker-dealers may engage in short sales of the shares. The selling stockholders also may sell shares short and deliver the shares to close out such short positions. The selling stockholders also may enter into option or other transactions with broker-dealers that require the delivery to the broker-dealer of the shares, which the broker-dealer may resell pursuant to this prospectus. The selling stockholders also may pledge the shares to a broker or dealer. Upon a default, the broker or dealer may effect sales of the pledged shares pursuant to this prospectus.

Brokers, dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholders in amounts to be negotiated in connection with the sale. The selling stockholders and any participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commission, discount or concession these underwriters receive may be deemed to be underwriting compensation.

To the extent required, the following information will be set forth in a supplement to this prospectus:

Edgar Filing: INTUITIVE SURGICAL INC - Form 424B5

information as to whether underwriters who the selling stockholders may select, or any other broker-dealer, is acting as principal or agent for the selling stockholders;

the compensation to be received by underwriters that the selling stockholders may select or by any broker-dealer acting as principal or agent for the selling stockholders; and

the compensation to be paid to other broker-dealers, in the event the compensation of such other broker-dealers is in excess of usual and customary commissions.

Any dealer or broker participating in any distribution of the shares may be required to deliver a copy of this prospectus, including a prospectus supplement, if any, to any person who purchases any of the shares from or through this dealer or broker.

We have advised the selling stockholders that they are required to comply with Regulation M promulgated under the Securities Exchange Act during such time as they may be engaged in a distribution of the shares. With some exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers and any broker-dealer or other person who participates in such distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security that is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the common stock.

Table of Contents

LEGAL MATTERS

The validity of the shares being offered hereby has been passed upon for us by Latham & Watkins LLP, Menlo Park, California.

EXPERTS

The consolidated financial statements and schedule of Intuitive Surgical, Inc. appearing in Intuitive Surgical's Annual Report on Form 10-K/A for the year ended December 31, 2002 have been audited by Ernst & Young LLP, independent auditors, as set forth in their report included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Computer Motion, Inc. at December 31, 2002, and for the year then ended, appearing in Computer Motion, Inc.'s Annual Report on Form 10-K/A have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference, (which contain an explanatory paragraph describing conditions that raise substantial doubt about Computer Motion Inc.'s ability to continue as a going concern as described in Note 1 to the consolidated financial statements). Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

After reasonable efforts, Computer Motion has been unable to obtain the consent of Arthur Andersen LLP to the incorporation into the registration statement, of which this prospectus is a part, of their report with respect to the consolidated financial statements of Computer Motion which appear in its Annual Report on Form 10-K for the year ended December 31, 2001 and December 31, 2000. Under these circumstances, Rule 437(a) under the Securities Act permits the registration statement to be filed without a written consent from Arthur Andersen. The absence of such consent may limit your recovery on certain claims. In particular, and without limitation, you will not be able to assert claims against Arthur Andersen under Section 11 of the Securities Act for any untrue statement of a material fact contained in Computer Motion's financial statements which appear in its Annual Report on Form 10-K for the year ended December 31, 2001 and December 31, 2000 or any omission to state a material fact required to be stated therein.