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

FORM 10-KSB

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission file number 1-12471

INTEGRATED SURGICAL SYSTEMS, INC.

(Name of small business issuer in its charter)

Delaware 68-0232575

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

(530) 792-2600

(Issuer's telephone number)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Title of each Class

Common Stock, \$0.01 Par Value Common Stock Purchase Warrants

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period 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 [X]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. []

State issuer's revenues for its most recent fiscal year: \$2,359,839

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the closing price of the common stock on April 11, 2005 was \$871,948.

As of April 11, 2005, the issuer had 45,084,089 shares of common stock, \$0.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Integrated Surgical Systems, Inc.
Form 10-KSB
For the fiscal year ended December 31, 2004
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## Item 1. Description of Business

Integrated Surgical Systems, Inc. (the "Company") designs, manufactures, sells and services image-directed, computer-controlled robotic software and hardware products for use in orthopaedic and neurosurgical procedures. The Company was incorporated in Delaware in 1990.

In 1997, the Company acquired 100% interest in a French company, Innovative Machines International, S.A., involved in the manufacturing and servicing of neurosurgical products and changed the name to Integrated Surgical Systems, S.A. ("ISS-SA"). Under French law, a company whose net assets are less than 50% of its capital stock may come under the supervision and control of a regional administrative tribunal. On September 30, 2003, the Tribunal de Commerce (the "Tribunal") in Lyon, France appointed an administrator to manage the Company's operations and the administrator exercised control over all aspects of ISS-SA's operations including employee retention, purchasing, sales and inventory management. Effective with the administrator's appointment, the Company no longer had access to the assets, personnel or records of ISS-SA. As a result, in the fourth quarter of 2003, the Company recorded a loss of \$1,516,519 in connection with the liquidation of its investment in ISS-SA and closure of the Company's European operation.

# Orthopaedic Applications

The Company's principal orthopaedic product, the ROBODOC(R) Surgical Assistant System ("ROBODOC"), integrates the ORTHODOC(R) Presurgical Planner ("ORTHODOC") with a computer-controlled robot for use in joint replacement surgeries. The surgeon uses ORTHODOC, a computer workstation with the Company's proprietary software, for preoperative surgical planning. ORTHODOC converts a computerized tomography ("CT") scan data of the patient's joint into three-dimensional bone images. The surgeon selects a prosthesis from the ORTHODOC prosthesis software library, and manipulates the three-dimensional prosthesis models against the bone image. The ORTHODOC then allows the surgeon to preoperatively visualize the possible results of the surgical outcome. The Company offers software for several lines of prostheses in its software library. Implant manufacturers contract with the Company for the development of prosthesis software. After the surgeon selects the optimal bone cuts and a prosthesis, ORTHODOC creates a surgical plan, which is then up-loaded to the surgical robot. The surgical plan quides the robot as it mills the bone in the operating room. Both hip and knee replacement surgeries involve removing a portion of the bone at the joint, referred to as "milling," to properly replace it with a prosthesis. For hip replacement surgery, a cavity is milled by the robot into which the selected prosthesis is inserted. In the case of knee replacement surgery, ROBODOC mills both the upper and lower leg bone ends for precise and accurate prosthesis placement according to the plan.

# Neurosurgical Applications

The Company entered the neurosurgical equipment sector with the acquisition of Innovative Medical Machines International, S.A., of Lyon, France, in September 1997. This wholly-owned subsidiary, which was renamed Integrated Surgical Systems, S.A. ("ISS-SA"), designed, manufactured, sold and serviced the NeuroMate(TM) System ("NeuroMate"). The Company continues to market NeuroMate, although no sales have occurred since the end of the second quarter of 2003. Based on its experience of over five years in commercializing the NeuroMate System on a worldwide basis, the Company has developed a new strategy for the neurosurgery market. It consists of consolidating different robotic platforms to increase overall functionality while lowering the costs. The Company is planning to offer a new proprietary product to the neurosurgical market on a worldwide basis

# Specialized Product Development

The Company develops specialized presurgical planning software for several major implant manufacturing companies. These implant manufacturers contract with the Company for the development of software for particular lines of new prostheses to be used with the ROBODOC system.

Utilizing its many years of experience in presurgical planning in the 3D mode, the Company has entered the presurgical planning software market for orthopaedics on an OEM basis. The Company offers presurgical planning software for use in stand-alone systems, as well as an integral part of PACS (Picture, Archiving and Communication Systems) commercialized worldwide by all major imaging corporations.

#### Marketing, Sales and Distribution

As further discussed in "Government Regulations," ROBODOC cannot be marketed in the United States until it has been cleared by the U.S. Food and Drug Administration (the "FDA"). Accordingly, substantially all of the Company's sales are made to customers located in foreign countries. The Company markets the ROBODOC system to orthopaedic and trauma surgeons and hospitals in Europe through direct sales and through distributors in Japan, Korea and India.

The Company promotes the ROBODOC system through presentations at trade shows, advertisements in professional journals and technical and clinical publications, and direct mail campaigns. Presentations to potential customers focus on the clinical benefits to the patient and the potential financial and marketing benefits to hospitals and surgeons.

#### Manufacturing

The Company's manufacturing process primarily consists of the assembly of purchased components, integration of proprietary software, product testing and packaging. The Company's manufacturing facility is located in Davis, California. The surgical components of the ROBODOC consist of readily available commercial parts, a customized robot arm, a robot base and a control cabinet. Upon receipt, these and other components are tested and assembled into a complete system. The final assembled product is tested once again before shipment to a customer.

One of the key components of the ROBDOC system, a customized Robotic arm, has been manufactured by a Japanese manufacturer, Sankyo Seiki, per ISS specifications. The specifications for this component are the proprietary property of the Company and cannot be used by anyone else to build or supply robot arms. The manufacturer has discontinued their medical robot business, and will not manufacture new robot arms for the Company. This situation does not create immediate risk as the Company has supplies in inventory to meet anticipated demand through December 31, 2005, the Company is redesigning the robot arm and is securing a new vendor for alternative vendor manufacture. Any significant delay in securing a new vendor for this component could have a material adverse effect on the financial condition, results of operations, or cash flow of the Company.

ORTHODOC consists of a pre-surgical planning computer workstation and associated data peripherals incorporating the Company's proprietary software.

Surgical supplies, including sterile drapes and cutters, are manufactured to the Company's specification by outside vendors. These vendors are inspected periodically by the Company and samples are evaluated to ensure that these specifications are consistently met. The Company and the Company's authorized distributors purchase these items in quantity and distribute them to customers as needed.

The Company's production facilities are subject to periodic inspection by the FDA for compliance with Good Manufacturing Practices. The Company is also subject to European manufacturing standards for European sales, and is routinely audited to ensure compliance to the EC Medical Device Directives. All products are shipped bearing the CE Mark, certifying that they meet the European Union's marketing requirement.

# Research and Development

Since inception, the Company's engineering activities have focused on the development of innovative image-directed, pre-surgical planning and computer-controlled robotic products for surgical applications, along with specialized operating software and hardware systems to support these products. The Company incurred research and development expenses of approximately \$994,000 during the year ended December 31, 2004, and \$1,664,000 in the year ended December 31, 2003.

#### Competition

The principal competition for ROBODOC comes from manual surgery performed by orthopaedic surgeons using surgical power tools, navigated instrumentation and manual devices. These tools and devices are manufactured and/or distributed by major orthopaedic companies, including Striker/Howmedica Osteonics (a division of Stryker Corporation), Zimmer, Inc., DePuy, Inc. (a subsidiary of Johnson & Johnson), Smith and Nephew, and Biomet, Inc.

Navigational instrumentation systems, offered by the major manufacturers of orthopaedic devices, are an intermediate step between unaided free hand and robotic surgery. Navigational systems use a tracking device affixed to the end of traditional cutting tools to assist the surgeon in visualizing tool positions for bone preparation and implant placement.

Since URS GmbH, a German medical robotics company, ceased its operations in 2002, there is no direct competition to the Company's product.

# Warranty and Service

The Company offers a one-year warranty for parts and labor on all ROBODOC systems commencing upon the completion of training and installation, except when the sales contract requires formal customer acceptance. In most cases, the Company's customers purchase service contracts, which include extended warranty coverage (parts and labor), unspecified product maintenance updates, customer support services and various consumables required during surgical procedures. Customers not covered by warranties or service contracts are billed on a time and materials basis for service, and on a per unit basis for consumable products.

The Company's technical staff trains medical professionals in its use of the product and provides field service. Additional technical support is provided by the Company's engineering department. In Europe, the Company has entered into an arrangement with a third party under which it provides warranty and extended warranty services to the Company's customers. For these customers, the Company may receive a royalty payment if the cost of providing such service meets certain threshold levels.

# Patents and Proprietary Rights

The Company relies on a combination of patent, trade secret, copyright and trademark laws and contractual restrictions to establish and protect the Company's proprietary rights in its products and to maintain a competitive position.

ROBODOC and ORTHODOC are registered trademarks of the Company. The Company has been issued five U.S. patents, has four U.S. patents pending, and has filed additional patent applications covering various aspects of the technology in Europe and in the United States. U.S. issued patents include:

- o Computer aided system for revision total hip replacement surgery;
- o Computer system and method for finish cutting bone cavities;
- o Computer system and method for positioning a surgical robot;
- o Computer system and method for cavity generation for surgical planning and initial placement of a bone prosthesis; and
- O Computer system and method for performing image directed robotic orthopaedic procedures without a fiducial reference system.

Significant portions of ORTHODOC and ROBODOC software are protected by copyrights. IBM has granted the Company a perpetual royalty-free license for the underlying software code utilized in ROBODOC. In addition, IBM has agreed not to assert infringement claims against the Company with respect to an IBM patent relating to robotic medical technology, to the extent that this technology is used in its products. The Company has registered the marks ROBODOC and ORTHODOC.

The Company cannot guarantee that it will have the necessary working capital to enforce and/or defend its patents, copyrights or trademarks if challenged.

#### Government Regulations

The medical devices the Company manufactures and markets are subject to extensive regulation by the FDA and other federal and foreign governmental authorities.

The ROBODOC system is approved for use in Europe and carries the European Union's CE Mark. The ORTHODOC is cleared by the FDA for marketing in the United States of America. While ROBODOC has not yet been approved for use by the Japanese regulatory agency, the Ministry of Health, Labor and Welfare ("MHLW"), Japanese hospitals and surgeons are able to purchase and use the systems while approval is pending. The Company completed clinical trials in Japan and submitted a petition for approval in 2002. Although no assurance can be offered, the Company believes the approval can reasonably be expected in late 2005. However, there can be no assurance that the determination will be favorable, or that any determination will not include unfavorable limitations or restrictions.

U.S. clinical trials designed to secure FDA clearance to market the ROBODOC system in the U.S. began in December 2000. This trial strategy calls for performing pinless hip (latest version) replacement surgeries on up to 181 subjects. Upon completion, the Company will submit the application to the FDA for clearance to market this ROBODOC product in the United States. At December 31, 2004, a total of 111 patients have been enrolled in this study. In 2003, the Company added a third clinical study site in Buffalo, N.Y., and, with this additional study site, the Company anticipates the completion of clinical trials by the end of 2005, although no assurances can be given.

In the fourth quarter of 2004, the principal investigator at the University of Arkansas Medical Science Department in Little Rock, Arkansas passed away. The ROBODOC system has been removed from this clinical site and final preparations are being made to relocate this system to a new clinical site.

Products manufactured or distributed pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including quality system requirements, documentation and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their facilities and list their devices with the FDA and with certain state agencies and are subject to periodic compliance inspections by the FDA and others.

Labeling and promotion activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The Company is also subject to a variety of state laws and regulations in those states or localities where the products are or will be marketed. As is the case with other manufacturers, the Company is subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

Although the Company has not been cleared to market the ROBODOC System in the U.S., the Company is permitted to export the system provided certain requirements are met. Products approved for use by European Union member countries, as well as Australia, Canada, India, Israel, Japan, Korea, New Zealand, Switzerland and South Africa, do not require FDA export approval. FDA export approval, when it is required, is granted when certain requirements are met including documentation demonstrating that the product is approved for import into the country to which it is to be exported and, in some instances, safety data from animal or human studies.

The introduction of products in foreign markets has subjected the Company, and will continue to subject the Company, to foreign regulatory clearances that vary from country to country. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties and tax requirements.

ROBODOC satisfies international electromedical standard IEC 601-1 and the protection requirements of the Electromagnetic Compatibility Directive (89/336/EEC). The Company has also received ISO 9001 registration, EN 46001 certification, and ED Directive 93/42/EEC Annex II, Article 3 approval. Meeting these standards and requirements, and receiving these certifications and approvals, allows the Company to apply the CE Mark to its products. ROBODOC meets the relevant provisions of the Medical Device Directive for Class IIb Medical Devices.

# Product Liability

Prior to June 2004, the Company maintained product liability insurance in the amount of \$10 million per occurrence and \$10 million in aggregate. This coverage was cancelled by the insurance carrier in June 2004, due to the Company's financial inability to pay the requisite insurance premiums. Effective March 4, 2005, the Company secured a new product liability insurance policy in the amount of \$2 million per occurrence and \$2 million in aggregate.

The Company is subject to legal proceedings and claims that arise in the normal course of business as is discussed in Item 3 "Legal Proceedings" in this report.

#### Major Customers

The Company sells its robotic systems to international distributors, who in turn resell the product to specific international hospitals and clinics. The Company's international distributors are Imatron (KTEC) in Japan, ROCOM Frontier in Korea and Paramount Impex in India.

A significant portion of the Company's sales are to a limited number of customers located in foreign countries. Three major foreign customers of the Company accounted for 45%, 24% and 22% of the Company's revenue during the year ended December 31, 2004, and three major foreign customers accounted for 22%, 14% and 13% for the year ended December 31, 2003. At December 31, 2004, two foreign customers accounted for 98% of accounts receivable, and at December 31, 2003, two customers accounted for 100% of accounts receivable.

During the first nine months of 2003, the Company sold its products in Europe through its wholly owned subsidiary, ISS-SA. In the fourth quarter of 2003, the Company recorded a loss of \$1,516,519 in connection with the liquidation of the Company's European operation. Since December 23, 2003, the Company's Davis, California headquarters office has assumed the sales responsibility for its products in Europe.

The Company also develops specialized pre-surgical planning software for several major customers, including DePuy International Limited, Fujifilm Medical Systems USA, Inc, Stryker and Zimmer Inc.

# Employees

On December 31, 2004, the Company had a total of 15 employees: 10 in engineering, 2 in manufacturing and 3 in sales and administration. None of the employees is covered by a collective bargaining agreement and the Company believes that the relationship with its employees is satisfactory.

# Item 2. Description of Property

The Company's executive offices and production facility are located in Davis, California. The Company occupies the facility in Davis under a lease that expires in June 2005, which is currently being renegotiated. The Company can

give no assurance that the lease will be extended. If the lease were not extended, the Company would be unable to conduct business until another facility was leased, and there is no assurance That the company will be able to obtain a lease extension or a new lease on terms as favorable to the Company as are provided in the current lease. The Company's failure to secure a lease could have material effect on the business, financial condition, cash flows and results of operations.

During the third quarter of 2004, the Company renegotiated this lease to reduce the square footage from approximately 30,500 square feet to approximately 16,000 square feet, with a corresponding per month reduction in monthly rent expense from approximately \$32,500 per month to approximately \$18,000 per month. Prior to the renegotiations of the lease, the Company paid utilities and maintenance fees directly to the providers of these services. These utility and maintenance fees are now paid by the lessor and billed back to the Company, along with property taxes, on a pro-rated percentage based on the Company's occupancy.

### Item 3. Legal Proceedings

The Company is subject to legal proceedings and claims that arise in the normal course of business. The Company cannot assure that it would prevail in such matters nor can it assure that any remedy could be reached on mutually agreeable terms, if at all. Due to the inherent uncertainties of litigation, the Company would not be able to accurately predict their ultimate outcome.

On December 17, 2004, the Company was served with a summons and complaint commenced in Yolo County (California) Superior Court, styled Bischoff, et al. vs. Integrated Surgical Systems, Inc. et al. The plaintiffs' in the litigation, all from Germany, and all of whom were subject to medical treatment which utilized the ROBODOC System, allege that the Company's ROBODOC System is defective and dangerous, both in its manufacture and design and, as a result of such defect and dangerous condition, the plaintiffs sustained injury. The plaintiffs are seeking class status for this matter.

The Company believes the plaintiff's allegations are without merit. The Company intends to conduct a vigorous defense against the allegations contained in the complaint. However, the Company did not have any product liability insurance from June 2004 through March 3, 2005, due to its financial inability to pay the requisite insurance premiums. Effective March 4, 2005 the Company secured a new product liability insurance policy in the amount of \$2 million per occurrence and \$2 million in aggregate.

This case is at its incipient stages. The Company has retained competent counsel to represent it in this matter. The amount of damages, if any, are indeterminable at this juncture.

Defending against a product liability action can be expensive and time consuming to management personnel. The Company currently does not have the funds, which may be necessary to defend against the plaintiffs' allegations. The failure to properly defend the Company against the allegations could result in a material judgement against the Company, which could adversely affect our financial condition, results of operation and cash flows. The Company may also currently not have the funds necessary to satisfy any judgement rendered against it. The Company's failure to successfully defend against the allegations could result in our seeking protection under the United States Bankruptcy Code. Such action could have a material adverse effect on the market price of the Company's common stock, business, financial condition, cash flow and results of operations.

Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Market for Common Equity and Related Stockholder Matters and Small Business Issuers Purchase of Equity

#### Market Information for Common Stock

On May 24, 2004, the OTC Bulletin Board discontinued the quotation of the Company's stock on its system due to our failure to file our annual report on a timely basis. The Company's stock then began to be quoted, and continues to be quoted on the pink sheets, under the trading symbol "RDOC." The following table sets forth the high and low sales prices, as reported on the by the NASDAQ on-line web site www.NASDAQ. com, for shares of the Company's common stock for the periods indicated. Such prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	Common Stock (RDOC)		
Fiscal Year Ended December 31, 2004	High 	Low	
First Quarter Second Quarter Third Quarter Fourth Quarter	\$0.130 \$0.115 \$0.080 \$0.070	\$0.060 \$0.050 \$0.050 \$0.035	
Fiscal Year Ended December 31, 2003			
First Quarter Second Quarter Third Quarter Fourth Quarter	\$0.055 \$0.044 \$0.055 \$0.190	\$0.022 \$0.025 \$0.038 \$0.040	

As of April 11, 2005 there were 268 holders of record of the common stock.

### Dividends

The Company has never paid dividends on its common stock and its present policy is to retain anticipated future earnings for use in its business.

# Recent Sale of Unregistered Securities

During the twelve-month period ended December 31, 2004, the Company issued 300,000 warrants, which have been valued at \$12,000, to outside legal counsel for such firm foregoing demand for immediate payment to said firm. The Company believes that the issuance of such warrants was exempt from the registration requirements of the Securities Act pursuant to the provisions of Section 4(2) of the Securities Act.

# Equity Compensation Plans

The following table provides information as of the fiscal year ended December 31, 2004 with respect to the Company's compensation plans (including individual compensation arrangements).

(a) (b) (c) Number of securities to be Number of securities Plan Category Weighted-average exercise issued upon exercise of price of outstanding remaining available for outstanding options, options, warrants and future issuance under warrants and rights equity compensation plans rights (excluding securities reflected in column (a)) Equity compensation plans 2,203,192 (1) \$0.83 438,953 approved by security holders Equity compensation plans not 1,360,000 (2) approved by security holders \$0.06 1.040.000

\$0.54

1,478,953

(1) Includes the Company's 1995 and 1998 Stock Option Plans and its 2000 Stock Award Plan and 2004 Long-Term Performance Plan.

3,563,192

(2) Consists of: (i) 100,000 warrants issued for consulting services which expire in May 2007 and have an exercise price of \$0.06 per share; (ii) 300,000 warrants for consulting which expire in July 2014 and have an exercise price of \$0.0625 per share; (iii) 960,000 options to purchase shares for the Company's 2004 Long-Term Performance Plan, which has yet to be approved by the stockholders of the Corporation.

Item 6. Management's Discussion and Analysis or Plan of Operation

The following discussion and analysis relates to the consolidated operations of the Company and should be read in conjunction with the consolidated financial statements of the Company, including the notes thereto, appearing elsewhere in this report.

Results of Operations (2004 vs. 2003)

Total

Revenue of \$2.4 million for the year ended December 31, 2004 was down 60% when compared to \$5.8 million for the year ended December 31, 2003 primarily due to the decrease in product sales. Cost of revenue of \$0.9 million for the year ended December 31, 2004 was down \$3.1 million when compared to \$4.0 million for the year ended December 31, 2003, primarily due to the decreased level of product sales. Operating expenses of \$2.1 million for the year ended December 31, 2004 decreased by \$3.5 million when compared to the year ended December 31, 2003. This decrease of \$3.5 million in operating expenses was comprised of \$1.3 million decrease in selling, general and administrative expense, \$0.7 million decrease in research and development expense, and a \$1.5 million decrease in non-recurring charges. The \$1.5 million decrease in non-recurring charges was related to the one-time loss on disposal of subsidiary resulting from the liquidation of the Company's investment in ISS-SA and closure of its European operations in the fourth quarter 2003. Other income, net for the year ended December 31, 2004, decreased by \$0.4 million when compared to \$0.5 million for the year ended December 31, 2003, primarily due to non-recurring events, including the forgiveness of a \$0.1 million loan and a gain of \$0.2 million for the reversal of a reserve for clinical robots. These changes in revenue and expenses resulted in a net loss of \$0.6 million for the period ended December 31, 2004 as compared to a loss of \$3.3 million in the prior year. The decrease in revenue of approximately \$3,471,000 in 2004 from 2003 is presented in the following table:

		2004	2003		Increase (Decrease)	
	Units Sold	Revenues	Units Sold	Revenues	Units Sold	Revenues
ROBODOC System ROBODOC Modules NeuroMate Systems	2 3	\$ 793,000 262,000 	4  4	\$ 2,547,000  827,000	(2) 3 (4)	\$(1,754,000) 262,000 (827,000)
Total Systems and Modules	5	1,055,000	8	3,374,000	(3)	(2,319,000)
Service contracts, parts and consumables		547,000		1,907,000		(1,360,000)
Development revenues		758,000		550,000		208,000
Total Revenues		\$ 2,360,000		\$ 5,831,000 ======		\$(3,471,000) =======

The decrease in ROBODOC systems of two units in 2004, compared to four units in 2003, and the decrease in revenues from service contracts and consumables of approximately \$1,360,000 in 2004 when compared to 2003 is directly related to the negative publicity in Germany concerning routine surgical complications in which the ROBODOC was used starting in late 2002, 2003 and 2004, that lead to the current law suit. Although no NeuroMate units have been sold since the second quarter of 2003, the Company continues to market this product. Development revenue of approximately \$758,000 for the year ended December 31, 2004 was up 38% when compared to approximately \$550,000 for the year ended December 31, 2003, due to completion of a greater number of projects.

The FDA allows the Company to market NeuroMate as described in the Company's 510(k) pre-market notification.

The gross margin for 2004 was 62% compared to 32% in 2003. The increase was primarily due to a reduction in manufacturing costs and overhead charged to cost of revenue, an increase in revenue from higher margin development projects, the sale of two refurbished ROBODOC Systems. The Company charges its manufacturing expense and overhead directly to cost of revenue due to its low manufacturing volume. During 2004, the Company reduced its work force and operating costs and, as a result, manufacturing expenses and overhead were reduced. The cost to manufacture a refurbished system is considerably less than the cost to manufacture a new system. For the year ended December 31, 2004, ROBODOC and NeoroMate systems generated 45% of revenues compared to 58% for the year ended December 31, 2003. Service contracts, parts, consumables and development revenues were 55% for the year ended December 31, 2004 as compared to 42% for the year ended December 31, 2003. The Company's margins for its service contracts, parts, consumables and development projects are substantially higher than margins on ROBODOC and NeuroMate systems.

Selling and general and administrative expenses are comprised of salaries, commissions, travel expenses and costs associated with trade shows as well as its finance, legal and human resources functions. Selling and general administrative expenses for the year ended December 31, 2004 decreased 53% to \$1,140,000 from \$2,439,000 for the year ended December 31, 2003. The decrease in selling, general and administrative expenses was primarily due to a decrease in average staffing levels in the year ended December 31, 2004 due to attrition and the inability to replace employees due to the lack of working capital.

Research and development expenses are comprised of the engineering and related costs associated with the development of innovative image-directed computer-controlled robotic products for surgical applications, along with specialized operating software and hardware systems to support these products, quality assurance and testing. Research and development expenses decreased 40% to \$994,000 during the year ended December 31, 2004 as compared to \$1,664,000 for the year ended December 31, 2003. The decrease in the year ended December 31, 2004 is due to decreased staffing and staffing related expenses due to attrition and the inability to replace employees due to the lack of working capital.

# Restatement of Interim Financial Information

In conjunction with the audit of its financial statements for the year ended December 31, 2004, the Company determined that it had overstated accounts receivable and unearned income as of September 30, 2004 due to prematurely or incorrectly recording certain service contracts with its customers. Accounts

receivable and unearned income as of September 30, 2004 were overstated by \$287,897 and \$253,933, respectively. In the third quarter of 2004, net revenue was overstated by \$33,964 and net loss understated by a similar amount, as a result of the amortization related to these service contracts. There was no impact on the reported amount of basic or diluted net loss per common share as a result of the correction. (See Note. 13. Unaudited Interim Financial Information (Restated) in Notes to Consolidated Financial Statements)

### Liquidity

The reports of the Company's Independent Registered Public Accounting Firm on the 2004 and 2003 consolidated financial statements included explanatory paragraphs stating that there is substantial doubt with respect to the Company's ability to continue as a going concern. The Company believes that it has a plan to address these issues which will enable the Company to continue to operate through December 31, 2005. This plan includes obtaining additional equity or debt financing, increasing sales of the products in existing markets, increasing sales of system upgrades, and reducing operating expenses as necessary. Although the Company believes that the plan will be realized, there is no assurance that these events will occur. In the event that the Company is unsuccessful, it is possible that it will cease operations or seek bankruptcy protection. The consolidated financial statements do not include any adjustments to reflect the uncertainties related to the recoverability and classification of assets or the amounts and classification of liabilities that may result from an inability on the Company's part to continue as a going concern.

Through December 31, 2004, the Company has been funded through cash from operations and sales of equity securities (see, "Capital Resources"). At December 31, 2004, the "quick ratio" (cash and accounts receivable divided by current liabilities), a conservative liquidity measure designed to predict the Company's ability to pay bills, was only .18. It has been difficult for the Company to meet financial obligations, including payroll, as they come due, and the Company expects this situation to continue through 2005.

Net cash provided by operating activities was \$1,079,000 for the year ended December 31, 2004. This resulted from the net loss of \$556,000, adjusted for non cash transactions of \$21,000 for depreciation and \$21,000 for stock compensation for non-employees. The primary changes in operating assets and liabilities were decreases in accounts receivable and other current assets of \$133,000, increases in accounts payable of \$211,000, accrued payroll and related expenses of \$425,000 and other income of \$1,074,000 offset by an increase in inventory of \$159,000 and a decrease in accrued liabilities of \$95,000.

The increase in unearned income was primarily due to a December 2004 software license agreement with a customer. The increase in inventory was due to the capitalization of development project costs and the increase in accounts payable and accrued payroll and related expense is directly related to the lack of cash. Accrued liabilities decreased primarily as the result of accrued expenses transitioning to accounts payable.

The increase in cash from financing activities of \$96,000 was primarily due to the receipt of \$150,000 received per a securities agreement (as defined in Item 6. Capital Resources) offset by repayment of loans which had been advanced by the officers of \$56,000. The Company also received \$3,000 from the exercising of stock options by former employees.

The cash balance of \$1,324,000 at December 31, 2004 was the result of a late December 2004 cash receipt for software development and licensing, and was mostly disbursed during the first quarter of 2005 to pay down existing liabilities. The Company expects to derive most of the cash required to support operations through sales of ROBODDC systems, continued conversion of the inventory balance into cash, collection of accounts receivable and through additional financing. It is critical for the Company to obtain cash from these sources. There can be no assurance given that the Company can continue to convert inventory, collect receivables or raise additional funds on acceptable terms or at all.

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The Company has the following contractual obligations and commercial commitments at December 31, 2004:

	Total	less than 1 year	1-3 years	greater than 3 years
Facility operating leases	\$90,017	\$90,017	\$0	\$0

The Company will require substantial funds for operating activities, further product development, future clinical trials, regulatory approvals, litigation expenses and marketing of its products. The Company's future capital requirements will depend upon the progress of its research and development programs; the time and costs involved in securing regulatory approvals; the cost of filing, defending and enforcing intellectual property rights; and competing technology and market developments. Future expenditures for product development and clinical trials are discretionary and, accordingly, can be adjusted, as can certain selling, general and administrative expenses, based on the availability of cash.

At December 31, 2004, the Company had an aggregate amount due to executive officers of approximately \$1,013,000. These amounts due are in the form of deferred salaries and unreimbursed travel expenses. Of such amounts, \$460,000 and \$276,000 are included in accrued payroll and related expense and accounts payable and accrued liabilities, respectively, and are due to Ramesh C. Trivedi, president and chief executive officer of the Company; \$141,000 and \$27,000 are included in accrued payroll and related expense and accounts payable, respectively, and are due to Leland Witherspoon, vice president of engineering of the Company; and \$109,000 is included in accrued payroll and related expense and is due to Charles J. Novak, chief financial officer of the Company. At December 31, 2004, the Company had accrued payroll and accrued payroll taxes of \$479,000 for all other employees.

# Capital Resources

On April 11, 2005, there were 45.1 million shares of the Company's common stock outstanding, and is listed on the pink sheets at \$0.02 a share, giving the Company a market capitalization of \$0.9 million. In the first quarter of 2001, the Company's common stock and warrants were delisted by the Nasdaq because the stock did not maintain the market's minimum bid price of \$1.00 per share. On May 24, 2004, the OTC Bulletin Board ceased quoting the Company's stock due to the failure of the Company to file its annual report on Form 10-KSB on a timely basis. Securities traded at less than \$5.00 and not traded on a national securities exchange or quoted on the Nasdaq are called "penny stocks". The Securities and Exchange Commission rules require brokers to provide specified information to purchasers of penny stocks, and these disclosure requirements and the requirement that brokers must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction in advance may have the effect of reducing trading activity in the common stock and making it more difficult for investors to sell the shares of the Company's stock.

To obtain funding for the Company's ongoing operations, the Company entered into a securities purchase agreement (the "Agreement") with an accredited investor on June 15, 2004 with respect to the sale by the Company for aggregate consideration of \$150,000 of (i) a convertible debenture in the principal amount of \$150,000 and (ii) warrants to purchase 1,500,000 shares of Company common stock. The Agreement contemplates the sale of additional convertible debentures and warrants upon the occurrence of specific events. The Company is obligated to register under the Securities Act for resale by the investor the common stock underlying the debenture and warrants issued pursuant to the Agreement.

In connection with the sale of the original \$150,000 convertible debenture and 1.5 million warrants the investor provided the Company with funds as follows:

- o \$100,000 was disbursed to the Company on June 15, 2004;
- o \$50,000 was disbursed to the Company on October 19, 2004; and
- o \$50,000 has been retained by the investor for disbursement to various professionals in payment for services to be provided to the Company.

The convertible debenture bears interest at 6 3/4%, matures two years from the date of issuance, and is convertible into, at the investor's option, into the number of shares of Company common stock equal to the principal amount of the debenture being converted multiplied by 11, less the product of the conversion factor multiplied by ten times the dollar principal amount of the debenture being converted. The conversion factor for the convertible debenture is the lesser of (i) \$0.25 or (ii) eighty percent of the average of the five lowest volume weighted average prices during the twenty (20) trading days prior to the conversion. Accordingly, there is no limit on the number of shares into which the debenture may be converted. In addition, the investor is obligated to proportionately exercise, concurrently with the submission of a conversion notice by the selling stockholder, the warrants. The warrants are at an exercise price of \$1.00 per share.

The investor has contractually agreed to restrict its ability to convert or exercise its warrants and receive shares of Company common stock such that the number of shares of common stock held by it and its affiliates after such conversion and exercise does not exceed 4.9% of the then issued and outstanding shares of Company common stock.

The issuance of more than 51.5 million shares of common stock upon conversion of the convertible debenture and exercise of the warrants issued pursuant to the Agreement would require the Company to issue shares of common stock in excess of the Company's currently authorized shares of its common stock. The Company intends to seek stockholder approval to amend the Company's certificate of incorporation to increase the Company's authorized common stock from 100,000,000 to 300,000,000 shares. Such solicitation will be made pursuant to a proxy statement conforming to the rules and regulations of the Securities and Exchange Commission. This Annual Report on Form 10-KSB should not be considered, in any manner, a solicitation for voting in favor of such an increase in the Company's authorized common stock.

The issuance of the convertible debenture and warrants to the investor is contingent upon stockholder approval of the increase in the Company's authorized common stock. If such approval is not received, the Agreement will terminate and the Company will be obligated to repay the proceeds received to date and other funds disbursed by the investor to professionals in payment of services rendered on behalf of the Company. As a result, the Company recorded such proceeds in other current liabilities.

On December 14, 2004, the Company entered into a \$2.5 million agreement with Fujifilm Medical Systems, USA ("Fuji") under which Fuji will license the Company's orthopedic surgical planning technology for its use solely in the Picture Archiving and Communications Systems ("PACS") market. Under the terms of the license agreement the Company received \$2.1 million in December 2004. Additional milestone payments totaling \$0.4 million will be paid to the Company over a two-year period, assuming all such milestones are met.

At December 31, 2004, the Company had 168 shares of convertible preferred stock outstanding. Each share of preferred stock has a stated value of \$1,000 and is convertible into common stock at a conversion price equal to 80% of the lowest sale price of the common stock over the five trading days preceding the date of conversion. Because there is no minimum conversion price, there is no limit on the number of shares of common stock that holders of preferred stock may acquire upon conversion.

The holders of the preferred stock could also engage in short sales of the common stock after delivering a conversion notice to the Company, which could contribute to a decline in the market price of the Company's common stock and give them the opportunity to profit from that decrease by covering their short position with the converted shares acquired at a 20% discount to the prevailing market price. This activity, or the possibility of such activity, could exacerbate any decline or impede any increase in the market price of the Company's common stock.

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The Company's discussion and analysis of the financial condition and results of operations are based upon the Company's audited consolidated financial statements included elsewhere in this Form 10-KSB and have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of such audited consolidated financial statements requires the Company to make estimates and judgments that affect the reported amounts of the Company's assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates the estimates, including those related to bad debts, inventories, impairment of assets, warranties, contingencies and litigation. The Company bases these estimates on historical experience and on other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. The Company has discussed its critical accounting policies with the audit committee of the Company. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policies affect the Company's more significant judgments and estimates used in the preparation of the consolidated financial statements:

The Company recognizes revenue from sales of its products upon the completion of equipment installation and training at the end-user's site, except when the sales contract requires formal customer acceptance. Equipment sales with contractual customer acceptance provisions are recognized as revenue upon written notification of customer acceptance, which generally occurs after the completion of installation and training. Furthermore, due to business customs in Japan and the interpretation of Japanese law, all equipment sales to Japan are recognized after customer acceptance, which generally occurs after the completion of installation and training. Revenue related to maintenance and service contracts is recognized ratably over the duration of the contracts. Development projects are accounted for under the provisions of Statement of Position ("SOP") 81-1, "Accounting for Performance of Construction-Type and Certain Production-Type Contracts," using the completed contract and percentage of completion method of accounting.

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of the Company's customers to make required payments. If the financial condition of the customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Where the Company's products are not covered by separate service agreements, the Company reserves against the estimated cost of product warranties at the time revenue is recognized. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required.

The Company writes down the inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those the Company projected, additional inventory write-downs may be required.

Property, plant and equipment are amortized over their useful lives. Useful lives are based on estimates of the period that the assets will generate revenue. Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 151, "Inventory Costs--An Amendment of ARB No. 43, Chapter 4". SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, excessive spoilage, double freight, and re-handling costs be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005. The Company is currently evaluating the effect that the adoption of SFAS No. 151 will have on its consolidated results of operations and financial condition but does not expect SFAS No. 151 to have a material impact.

In December 2004, the FASB issued SFAS No. 123R (revised 2004), "Share-Based Payment," which replaces SFAS No. 123, "Accounting for Stock-Based Compensation," and supercedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period that begins after December 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R beginning January 1, 2006. As of the effective date, the Company will be required to expense all awards granted, modified, cancelled or repurchased as well as the portion of prior awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards as calculated for pro forma disclosures under SFAS No. 123. The Company will apply SFAS No. 123R using a modified version of prospective application. Under this method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under SFAS No. 123 for either recognition or pro forma disclosures.

Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based method to be used at date of adoption. The Company is evaluating the requirements of SFAS No. 123R and expects that the adoption of SFAS No. 123R will have a material impact on the Company's consolidated results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

Risk Factors and Cautionary Statement Regarding Forward-Looking Information

The Company cautions that this Form 10-KSB contains "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. The Company's plans, strategies, objectives, expectations and intentions are subject to change at any time at the discretion of management and the board of directors. The plans and results of operations will be affected by the Company's ability to manage any growth and working capital and the ability to finance future operations, none of which is assured. In addition, the risk factors that follow may affect the actual results and may cause actual results to differ materially from those expressed in or implied by any forward-looking statement. These risk factors are not an exhaustive list. Additional factors are discussed elsewhere in this Form 10-KSB and also from time to time in the Company's filings with the Securities and Exchange Commission. The Company undertakes no obligation to update such factors in the future.

The reports of the Company's Independent Registered Public Accounting Firm on the 2004 and 2003 consolidated financial statements included explanatory paragraphs stating that there is substantial doubt with respect to the Company's ability to continue as a going concern. The Company has a plan to address these issues which it believes will enable the Company to continue to operate through December 31, 2005. This plan includes obtaining additional equity or debt financing, increasing sales of the products in existing markets, increasing sales of system upgrades, and reducing operating expenses as necessary. Although the Company believes that the plan will be realized, there is no assurance that these events will occur. In the event that the Company is unsuccessful, it is possible that the Company will cease operations or seek bankruptcy protection.

The consolidated financial statements do not include any adjustments to reflect the uncertainties related to the recoverability and classification of assets or the amounts and classification of liabilities that may result from an inability on the Company's part to continue as a going concern.

The Company's facility lease expires on June 2, 2005. The Company's seven-year lease, of its executive offices and production facility located in Davis, California, will expire on June 2, 2005. The Company is currently negotiating with the lessor of the facility to extend the lease beyond June 2, 2005. The Company can give no assurance that the lease will be extended. If the lease were not extended, the Company would be unable to conduct business until another facility was leased, and there is no assurance That the company will be able to obtain a lease extension or a new lease on terms as favorable to the Company as are provided in the current lease. The Company's failure to secure a lease could have material effect on the business, financial condition, cash flows and results of operations.

The Company's future financial performance will depend almost entirely on sales of the ROBODOC system. The Company expects to derive most of its near-term revenue from sales of the ROBODOC System. Having recognized revenue on two ROBODOC systems in 2004 and four ROBODOC systems in 2003, the Company must develop an effective sales and marketing organization and expend sufficient funds to inform potential customers of the distinctive characteristics and advantages of using the system instead of traditional surgical tools and procedures.

Because the ROBODOC system employs innovative technology rather than an improvement of existing technology, and because it represents a substantial capital expenditure, the Company expects to encounter resistance to change, which it must overcome if the system is to achieve significant market acceptance.

Furthermore, the Company's ability to market the ROBODOC System in the U.S. is dependent upon clearance by the FDA. The Company can give no assurance that it will receive FDA clearance, or that the ROBODOC System will achieve the market acceptance in the U.S. and foreign markets to generate sufficient revenue to secure profitability.

The Company is dependent on foreign sales. Most of the sales have been to customers in Europe and Asia. Until such time, if ever, as the Company receives clearance from the FDA to market the ROBODOC System in the U.S., it will continue to be subject to the risks of foreign sales. These risks include economic or political instability, shipping delays, fluctuations in foreign currency exchange rates, changes in regulatory requirements, customs duties and export quotas and other trade restrictions. Any of these risks could have a material adverse effect on the Company's business.

The Company's quarterly revenue and results of operations may fluctuate and may not be indicative of expected revenue and results of operations for the full year. The level of revenue and results of operations fluctuate with the number of ROBODOC Systems sold and development project revenue recognition. The number and timing of the systems sold may cause revenue and earnings to vary significantly on a quarterly basis and a quarter's results may not be indicative of revenue and earnings for the full year.

The Company may not be able to secure the regulatory approvals needed to expand the sales of the products to new foreign markets. The introduction of the products in foreign markets has subjected and will continue to subject the Company to foreign regulatory approvals. These approvals may be unpredictable and uncertain and may impose substantial additional costs and burdens. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on medical devices. The Company can give no assurance that any of the products will receive further approvals.

The Company needs, but has not yet secured, clearance from the FDA under 510(k) petition to market the ROBODOC System in the U.S. In December 2000, the Company began U.S. clinical trials designed to demonstrate that the ROBODOC System is safe and effective for its intended use as an alternative to other surgical power tools and manual devices used in hip replacement surgery. The trials anticipate the completion of hip replacement surgeries in a total of up to 181

subjects performed at up to four clinical trial sites. The Company has established three sites, Sutter General Hospital in Sacramento, California, the University of Arkansas in Little Rock, Arkansas and Buffalo General Hospital in Buffalo, New York. In the fourth quarter of 2004, the principal investigator at the University of Arkansas Medical Science Department in Little Rock, Arkansas passed away. The ROBODOC system has been removed from this clinical site and final preparations are being made to relocate this system to a new clinical site. As of December 31, 2004, approximately 61% of the mandated total surgeries have been performed.

The Company can provide no assurance that, at the completion of the clinical trials, the FDA will grant clearance to market the system in the U.S. and that such clearance will not include unfavorable limitations or restrictions. In addition, FDA clearance gives no assurance of market acceptance or that the Company will generate gross margins to obtain profitability.

Even after receipt of any FDA clearance to market, the Company expects that the FDA may consider any new ROBODOC surgical applications to be new indications for use, which generally require FDA clearance prior to marketing. The FDA may require additional trials before allowing the Company to incorporate new imaging modalities (such as ultrasound and MRI) or other different technologies in the ROBODOC System. The FDA may require new clinical data to support new indications and may require new clinical data for clearance of enhanced technological characteristics.

The Company may not be able to comply with quality system and other FDA reporting and inspection requirements. Although the Company believes it is in full compliance with the regulatory requirements in the markets in which it participates, there can be no assurance that the Company will be able to continue to comply with these requirements. Assuming that the Company secures the necessary FDA clearances for the products, in order to maintain these clearances the Company must, among other things, register its establishment and list the devices with the FDA and with certain state agencies. The Company must maintain extensive records, report any adverse experiences on the use of the products and submit to periodic inspections by the FDA and state agencies. The Food, Drug and Cosmetic Act also requires devices to be manufactured in accordance with the quality system regulation, which sets forth good manufacturing practices requirements with respect to manufacturing and quality assurance activities.

Noncompliance with FDA requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device the Company manufactures or distributes.

The manufacture and sale of medical products exposes the Company to the risk of significant damages from product liability claims. On December 17, 2004, the Company was served with a summons and complaint commenced in Yolo County (California) Superior Court, styled Bischoff, et al. vs. Integrated Surgical Systems, Inc. et al. The plaintiffs, in the litigation, all from Germany, allege that the Company's ROBODOC System is defective and dangerous, both in its manufacture and design and, as a result of such defect and dangerous condition, the plaintiff, all of whom were subject to medical treatment utilized the ROBODOC System, sustained injury. The plaintiffs are seeking class status for this matter.

The Company believes the plaintiff's allegations are without merit. The Company intends to conduct a vigorous defense against the allegations contained in the complaint. However, the Company did not have any product liability insurance from June 2004 through March 3, 2005, due to its financial inability to pay the requisite insured premiums. Effective March 4, 2005, the Company secured a new product liability insurance policy in the amount of \$2 million per occurrence and \$2 million in aggregate.

This case is at its incipient stages. The Company has retained counsel to represent it in this matter. The amount of damages, if any, are indeterminable at this juncture.

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Defending against a product liability action can be expensive and time consuming to management personnel. The Company currently does not have the funds which may be necessary to defend against the plaintiffs' allegations. The failure to properly defend the Company against the allegations could result in a material judgement against the Company which could adversely affect our financial condition and results of operation. The Company also may currently not have the funds necessary to satisfy any judgement rendered against it. The Company's failure to successfully defend against the allegations could result in our seeking protection under the United States Bankruptcy Code. Such action could have a material adverse effect on the market price of the Company's Common Stock.

The Company has produced a limited number of commercial ROBODOC Systems and may not be able to manufacture the systems at a cost or in such quantity as will be necessary for profitable operation. Manufacturers often encounter difficulties in scaling up for manufacturing new products, including problems involving product yields, quality control and assurance, component and service availability, adequacy of control policies and procedures, lack of qualified personnel, compliance with FDA regulations, and the need for further FDA approval of new manufacturing processes and facilities. The Company can give no assurance that production yields, costs or quality will not be adversely affected as the Company seeks to increase production, and any such adverse effect could have a material adverse effect on the business, financial condition, cash flows and results of operations.

The Company is dependent on the suppliers of robots. Although the Company has multiple sources for most of the components, parts and assemblies used in the systems, one of the key components of the ROBDOC system has been manufactured by a Japanese manufacturer, Sankyo Seiki, per ISS specification. The specifications, for this component, are the proprietary property of the Company and can not be used by anyone else to build or supply robot arms. The manufacturer has discontinued their medical robot business, and will not manufacture new robot arms for the Company. This situation does not create immediate risk as the Company has supplies in inventory to meet anticipated demand through December 31, 2005 and, the Company is redesigning the robot arm and is securing a new vendor for alternative vendor manufacture. Any significant delay in securing a new vendor for this component could have a material adverse effect on the financial condition, results of operations, or cash flow of the Company.

The Company depends heavily on the principal members of its management team and engineers. The Company's growth and future success will depend in large part on the continued contributions of key technical and senior management personnel. Dr. Ramesh Trivedi, the Company's President and Chief Executive Officer, Charles J. Novak, the Company's Chief Financial Officer and Leland Witherspoon, the Company's Vice President, Engineering, are employed pursuant to employment agreements terminable by the Company or by such officer at any time. None of the executives or technical personnel, other than Dr. Trivedi, Mr. Novak and Mr. Witherspoon are employed pursuant to an employment agreement. The loss of the services of Dr. Trivedi, Mr. Novak, Mr. Witherspoon or other senior management or key technical personnel could have a material adverse effect on the business, financial condition, cash flows and results of the Company's operations.

The Company's success may depend, in part, on its ability to defend its intellectual property. The Company has secured patent and other proprietary right protection for the technologies and relies on trade secrets, proprietary know-how and continuing technological innovation to develop the products. Any defense of the intellectual property could be costly and require significant time and the attention of the management and technical personnel.

Purchases of the Company's shares are subject to the SEC's penny stock rules. Securities traded at less than \$5.00 and not traded on a national securities exchange or quoted on the Nasdaq are called penny stocks. The Securities and Exchange Commission rules require brokers to provide information to purchasers of penny stocks, and these disclosure requirements and the requirement that brokers must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written

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agreement to the transaction in advance may have the effect of reducing trading activity in the common stock and make it more difficult for investors to sell. On May 24, 2004, the OTC Bulletin Board ceased quoting the Company's stock due to the Company's failure to file its annual report on a timely basis. Since that time, the Company's common stock has traded on the pink sheets (symbol "RDOC"). As a result, the market liquidity for the Company's securities is severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Impact of issuing additional shares. The Company is seeking additional financing that may require issuing additional common or preferred shares of the Company. Although the dilution factor cannot be determined until the amount of shares are known, there will be a dilution of some unknown magnitude. Additional financing also could result in a change of control of the Company.

To obtain funding for the Company's ongoing operations, the Company entered into a securities purchase agreement (the "Agreement") with an accredited investor on June 15, 2004 with respect to the sale by the Company for aggregate consideration of \$150,000 of (i) a convertible debenture in the principal amount of \$150,000 and (ii) warrants to purchase 1,500,000 shares of Company common stock. The Agreement contemplates the sale of additional convertible debentures and warrants upon the occurrence of specific events. The Company is obligated to register under the Securities Act for resale by the investor the common stock underlying the debenture and warrants issued pursuant to the Agreement.

In connection with the sale of the original \$150,000 convertible debenture and 1.5 million warrants the investor provided the Company with funds as follows:

- o \$100,000 was disbursed to the Company on June 15, 2004;
- o \$50,000 was disbursed to the Company on October 19, 2004; and
- o \$50,000 has been retained by the investor for disbursement to various professionals in payment for services to be provided to the Company.

The convertible debenture bears interest at 6 3/4%, matures two years from the date of issuance, and is convertible, at the investor's option, into the number of shares of Company common stock equal to the principal amount of the debenture being converted multiplied by 11, less the product of the conversion factor multiplied by ten times the dollar principal amount of the debenture being converted. The conversion factor for the convertible debenture is the lesser of (i) \$0.25 or (ii) eighty percent of the average of the five lowest volume weighted average prices during the twenty (20) trading days prior to the conversion. Accordingly, there is no limit on the number of shares into which the debenture may be converted. In addition, the investor is obligated to proportionately exercise, concurrently with the submission of a conversion notice by the selling stockholder, the warrants. The warrants are at an exercise price of \$1.00 per share.

The investor has contractually agreed to restrict its ability to convert or exercise its warrants and receive shares of Company common stock such that the number of shares of common stock held by it and its affiliates after such conversion and exercise does not exceed 4.9% of the then issued and outstanding shares of Company common stock.

The issuance of more than 51.5 million shares of common stock upon conversion of the convertible debenture and exercise of the warrants issued pursuant to the Agreement would require the Company to issue shares of common stock in excess of the Company's currently authorized shares of its common stock. The Company intends to seek stockholder approval to amend the Company's certificate of incorporation to increase the Company's authorized common stock from 100,000,000 to 300,000,000 shares. Such solicitation will be made pursuant to a proxy statement conforming to the rules and regulations of the Securities and Exchange Commission. This Annual Report on Form 10-KSB should not be considered, in any manner, a solicitation for voting in favor of such an increase in the Company's authorized common stock.

The issuance of the convertible debenture and warrants to the investor is contingent upon stockholder approval of the increase in the Company's authorized common stock. If such approval is not received, the Agreement will terminate and the Company will be obligated to repay the proceeds received to date and other funds disbursed by the investor to professionals in payment of services rendered on behalf of the Company. As a result, the Company recorded such proceeds in other current liabilities.

#### Item 7. Financial Statements

The financial statements follow Item 14 of this report.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

The Company did not have any changes in or disagreements with the accountants on accounting and financial disclosure.

#### Item 8A. Controls and Procedures

An evaluation was performed, as of December 31, 2004, under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on such evaluation, the Company's management has concluded that its disclosure controls and procedures were effective as of December 31, 2004, except as described in the following paragraph.

In connection with the audit of the Company's financial statements for the fiscal year ended December 31, 2004, the Company's independent registered public accounting firm identified weakness relating to the Company's documentation of its sales contracts with some of its customers. The Company has encountered difficulties in some instances in dealing with the cultural nuances involved in conducting business with some foreign customers. The Company will endeavor to resolve this issue by December 31, 2005. We expect that these efforts will, over time, positively address the weakness noted by our independent auditors.

There have been no significant changes in the Company's internal controls or in other factors that could significantly affect the Company's internal controls subsequent to December 31, 2004.

Item 8B. Other Information

None

# Part III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act

The Company's executive officers and directors are listed below:

Name	Age	Position with the Company
Ramesh C. Trivedi Charles J. Novak Leland Witherspoon Falah Al-Kadi Jack W. Moorman Paul A.H. Pankow	65 57 52 54 57 74	President, Chief Executive Officer, Director Chief Financial Officer, Treasurer, Secretary Vice President Chairman of the Board of Directors Director Director

The directors hold office until the next annual meeting of shareholders and until their successors have been duly elected and qualified. The Board of Directors elects the officers at its annual meeting immediately following the shareholders annual meeting and hold office until they resign or are removed from office. There are no family relationships that exist between any director, executive officer, significant employee or person nominated or chosen by the Company to become a director or executive officer. The Company has established audit and incentive compensation committees, consisting of the independent directors.

Biographical Information on Officers, Directors and Control Persons

Ramesh C. Trivedi has been president, chief executive officer and a director of Integrated Surgical Systems since 1995. Prior to that time, Dr. Trivedi was a principal of California Biomedical Consultants, an international consulting firm, and he served as the president and chief executive officer of DigiRad Corporation, a medical imaging company. Dr. Trivedi received his Ph.D. in chemical engineering from Lehigh University, and holds an MBA from Pepperdine University.

Charles J. Novak has been the chief financial officer since joining Integrated Surgical Systems in July 2002. From September 2001 to December 2001, Mr. Novak was the vice president of finance and administration and CFO for Realty Plus Online, a real estate software transaction system company. From January 2001 to September 2001, he was the vice president of finance and administration and CFO for WebRaiser Technologies, Inc., an integration and professional services firm. From February 1999 to January 2001, Mr. Novak was the director of operations for MRI Sierra International Group, Inc., an executive search firm. From September 1995 to February 1999, he was the assistant corporate controller for USCS International, Inc., a supplier of customer management software and open billing solutions. Prior to that, Mr. Novak served in executive management positions for Describe, Inc. and HealthTek, Inc. and he served in various management positions with the Hewlett-Packard Company. Mr. Novak earned his BS in Accounting from Lewis University in Lockport, Illinois.

Leland Witherspoon has been vice president of engineering since joining ISS in late 1997. From 1992 to 1997, Mr. Witherspoon was director of product research and development for Sorin Biomedicals, Inc., a developer and manufacturer of cardiopulmonary and cardiovascular hardware and software products. Prior to that time, he served in various technical and management positions for Pfizer/Shiley, Xerox Medical Systems and IBM. Mr. Witherspoon received his Bachelor of Science from Rensselaer Polytechnic Institute.

Falah Al-Kadi has been chairman of the board of directors since January 2000 and a director since December 1999. Mr. Al-Kadi is vice chairman of International Licensing Holding sal ("ILTAG"), a position he has held since 1994. ILTAG is a Lebanese holding company.

Jack W. Moorman has been a director of the Company since October 2002. Since February 2004 Mr. Moorman has been a consultant and advisor to various companies in the medical device, biotech instrumentation and semiconductor equipment businesses. In February 2005 he was named Senior Director of Donations and Facilities for The Enterprise Network of Silicon Valley, a nonprofit organization. From August 2002 to February 2004, Mr. Moorman was president and chief executive officer of Microbar Inc., a capital equipment manufacturer of advanced chemical management systems, and acted as interim president of Microbar Inc., from December 2001 to August 2002. From December 2000 to December 2001,

Mr. Moorman was a self-employed start-up consultant to various companies. From July 1999 to December 2000, Mr. Moorman served as President of Vivant Medical Incorporated, an early stage, venture capital funded, medical device company, which merged with MCT Medical Inc., a liver tumor ablation medical device company founded by Mr. Moorman in November 1998. From June 1999 to July 1999, Mr. Moorman provided business and consulting services to the Company. From December 1997 to July 1999, Mr. Moorman was self-employed as a business and technical consultant in parallel with MCT Medical Inc. Mr. Moorman received his BS in Ceramic Engineering from the University of Illinois and his MS in Management from Stanford Graduate School of Business.

Paul A. H. Pankow has been a director of the Company since January 2003. Mr. Pankow previously served as a director of the Company from May 1995 through December 1999. Since March 1995, Mr. Pankow has been president of PAP Consulting, a business and technical consulting firm. From September 1959 to February 1995, he held various positions with 3M Corporation, most recently as a vice president of its Imaging Systems Division, staff vice president of Digital Imaging Application Center and staff vice president of special programs. He currently serves as a member of several private boards. Mr. Pankow received his B.S. in mechanical engineering and business administration from the University of Minnesota.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers, directors, and persons who own more than ten percent of a registered class of the Company's equity securities within specified time periods to file certain reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and ten- percent stockholders are required by regulation to furnish the Company with copies of all Section 16(a) forms they file. Based solely on a review of copies of the reports the Company received and written representations from persons concerning the necessity to file these reports, the Company is not aware of any failure to file reports or report transactions in a timely manner during the fiscal year ended December 31, 2004, except that Mr. Al-Kadi failed to timely file a report on form 3 disclosing his election to the board of directors and reports on Form 4 disclosing the acquisition of 100,000 stock options in September 2001, and 100,000 stock of options in July 2004. These events will be updated no later than April 30, 2005.

Committees of the Board Of Directors

The Company has an Audit Committee and a Compensation Committee.

The Company's Audit Committee is composed of Mr. Jack Moorman (Director) and Mr. Paul Pankow (Director). The duties of the Audit Committee are to review and evaluate the scope of the quarterly reviews, to be performed, the adequacy of services performed by, and the fees and compensation of the independent auditors. The Audit Committee also reviews the Company's audited financial statements with management and with the Company's independent auditors and recommends approval of the audited financial statements to the Board of Directors before publication in the Annual Report on Form 10-KSB; reviews and considers matters which may have a bearing upon continuing auditor independence; considers and recommends to the Board of Directors the selection of the independent auditors to examine the Company's consolidated financial statements for the next year; reviews and evaluates the scope and appropriateness of the Company's system of internal control; reviews and evaluates the appropriateness of the Company's accounting principles and practices and financial reporting matters.

The Board of Directors has determined that under the rules of the SEC and within the Nasdaq director independence standards, all members of the Audit Committee are independent. The Board of Directors has also determined that Mr. Jack Moorman meets the criteria for "audit committee financial expert" as defined by the rules promulgated by the SEC."

The Company's Compensation Committee is composed of Mr. Jack Moorman (Director) and Mr. Falah Al-Kadi, Chairman. The duties of the Compensation Committee are to recommend to the Board of Directors remuneration for the Company's officers, to determine the number and issuance of options pursuant to the Company's stock option plans and to recommend the establishment of and to monitor a compensation and incentive program for all Company executives.

### Terms of Office

The directors of the Company are appointed for a one-year term to hold office until the next annual general meeting of the holders of the Company's common stock or until removed from office in accordance with the Company's by-laws. The officers of the Company are appointed by the Company's board of directors and hold office until removed by the board of directors.

### Code Of Ethics

A Code of Ethics that applies to our executive officers as well as to all employees was approved and adopted by the Board of Directors on April 8, 2004 and it is attached to the Company's 10-KSB for the fiscal year ended December 31, 2003. Copies of the Code of Ethics may be obtained free of charge by written request to Integrated Surgical Systems, Inc. attention Chief Financial Officer, 1850 Research Park Drive, Suite 300, Davis California, 95616.

### Item 10. Executive Compensation

The following table sets forth, for the fiscal years ended December 31, 2004, 2003 and 2002, the compensation awarded to, earned by or paid to the Company's Chief Executive Officer and each of the other executive officers whose total salary and bonus exceeded \$100,000 for the year ended December 31, 2004 (collectively, the "Named Executive Officers").

# Summary Compensation Table

		Annual Compen	sation		Long-Term Compensation
Name and Principal Position	Year 	Salary (1)	Cash Bonus	Other (2)	Securities Underlying Options
Ramesh C. Trivedi President and Chief Executive Officer	2004 2003 2002	\$302,226 302,226 302,215	\$0 0 0	\$13,862 25,139 16,752	100,000 300,000 -0-
Leland Witherspoon Vice President, Engineering	2004 2003 2002	142,600 142,600 142,600	0 0 0	0 0 0	100,000 125,000 -0-
Charles J. Novak Chief Financial Officer	2004 2003 2002	120,000 120,000 55,000	0 0 0	0 0 0	100,000 80,000 30,000

<sup>(1)</sup> The 2002 salary information for Charles J. Novak represents a partial year as his start date with the Company was in July 2002.(2) Represents expense allowances under the terms of Dr. Trivedi's employment

<sup>(2)</sup> Represents expense allowances under the terms of Dr. Trivedi's employment agreement.

The following table discloses the salaries not paid, but owed to the officers of the Company due to lack of working capital.

# Compensation Owed to Officers As of December 31.

	Balance 2003	Paid	Accrued	Balance 2004
Ramesh C. Trivedi				
2001		\$	\$	
2002	24,494			24,494
2003	120,234	(27,672)	3,414	95,976
2004			283,241	283,241
Total Trivedi	201,053	(27,672)	286,655	460,036
Leland Witherspoon				
2001				
2002	11,417			11,417
2003	42,187	(42,187)		
2004			129,528	129,528
Total Witherspoon	53,604	(42,187)	129,528	140,945
Charles J. Novak				
2001				
2002				
2003	37,639	(37,639)		
2004			109,000	109,000
Total Novak	37,639	(37,639)	109,000	109,000
Tatal Dafaward	Ф 202 202	Φ(407, 400)	ф гог 400	Ф 700 004
Total Deferred	\$ 292,296 ======	\$(107,498) ======	\$ 525,183 ======	\$ 709,981 ======

### **Employment Agreements**

Dr. Ramesh C. Trivedi serves as President and Chief Executive Officer of the Company pursuant to an employment agreement with the Company dated December 8, 1995, as amended on March 31, 1998 and January 1, 2000, terminable at will by either party. Pursuant to such employment agreement, as amended, Dr. Trivedi is to receive a base salary of \$25,186 per month and incentive compensation. Pursuant to such employment agreement, Dr. Trivedi received a 10-year option to purchase an aggregate of 100,000 shares of common stock of the Company at a purchase price of \$4.75 per share, the closing price of the Company's common stock on February 19, 1998, all such shares being currently exercisable. Dr. Trivedi's employment with the Company is for no specified period and constitutes at-will employment. However, it is provided in the employment agreement that in the event that Dr. Trivedi is terminated by the Company for reasons other than for Cause (as defined in his employment agreement), he will be entitled to receive severance pay of his base salary for a period of 18 months from the date of termination.

On February 14, 2003, the Company entered into substantially similar employment agreements with Charles J. Novak and Leland Witherspoon (individually, the "Executive") to serve as Chief Financial Officer and Vice President, Engineering, respectively, of the Company. The employment agreements provide for an annual base salary of \$10,000 and \$11,883 per month to Mr. Novak and Mr. Witherspoon, respectively, and such incentive compensation as shall be determined from time to time by the Board of Directors of the Company. The Executives' employment with the Company is for no specified period and constitutes at-will employment. However, it is provided in each of the employment agreements that in the event that the Executive is terminated by the Company for reasons other than for Cause (as defined in his employment

agreement), the Executive will be entitled to receive severance pay of his base salary for a period of three months from the date of termination; and if the Company is a party to any consolidation or merger with or into another entity, or the sale of all or substantially all of the assets of the Company to another entity, the Executive is unable to reach a reasonable agreement of employment with such entity, he will be entitled to receive severance pay of his base salary for a period of six months from the date of termination, provided, however, the Executive agrees to make reasonable efforts to assist such entity in its transition for a reasonable period of time.

## Stock Options

The following table contains information concerning the grant of stock options under any of the Company stock option plans to the Named Executive Officers during the fiscal year ended December 31, 2004.

# Stock Option Grants in Last Fiscal Year

(Individual Grants)

	Number of Shares Underlying Options	% of Total Options Granted to Employees in Fiscal	Exercise Price per		Potential Realizable Annual Rates of Appreciation for	Stock Price
Name	Granted (1)	Year	Share	Expiration Date	5%	10%
Ramesh C. Trivedi	100,000	10.13%	\$0.0625	July 22, 2008	\$1,727	\$3,816
Leland Witherspoon	100,000	10.13%	\$0.0625	July 22, 2013	3,930	9,961
Charles J. Novak	100,000	10.13%	\$0.0625	July 22, 2013	3,930	9,961

- (1) All options have an exercise price per share equal to 100% of the fair market value of the Company's common stock on the grant date. Stock options have a 10-year term, except for Dr. Trivedi which have a 5-year term, and vest periodically over a period not to exceed five years.
- (2) As required by SEC rules, these columns show the potential gains that may exist for respective options, assuming that the market price for Integrated Surgical Systems, Inc.'s common stock appreciates from the date of grant to the end of the option terms at the annual rates of 5% and 10%, respectively. These numbers are not estimates of the Company's future stock price performance and are not necessarily indicative of the Company's future stock price performance. If the price of the Company's common stock does not increase above the exercise price, no value will be realizable from these options.

The following table summarizes, for each of the Named Executive Officers, the total number of unexercised options held at December 31, 2004, and the aggregate dollar value of in-the-money, unexercised options, held at December 31, 2004. The value of the unexercised in-the-money options at December 31, 2004, is the difference between their exercise or base price and the value of the underlying common stock on December 31, 2004. The closing sale price of the common stock on December 31, 2004 was \$0.035 per share.

### Aggregated Option Exercises in the Last Fiscal Year and Fiscal Year End Option Values

Shares Acquired Value of Unexercised Number of Securities Upon Exercise Underlying In-The-Money Of Options Unexercised Options During Fiscal Options at December 31, 2004 2004 At December 31, 2004 Value Number Realized Exercisable Unexercisable Exercisable Unexercisable Name --------------------1,147,417 300,000 Ramesh C. Trivedi 0 \$10,500 0 Leland Witherspoon 300,000 198,125 4,375 2,800 Charles J. Novak 11.875

### Director Compensation

The Company currently does not have in effect a policy regarding compensation for serving on the Company's board of directors. However, the Company does reimburse its directors for their reasonable expenses incurred in attending meetings of the Company's board and its non-employee directors are periodically granted options to purchase shares of the Company's common stock.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information concerning the beneficial ownership of the Company's common stock as of April 15, 2005 by (i) each person known by the Company to be the owner of more than 5% of the outstanding common stock, (ii) each director, (iii) each executive officer named in the Summary Compensation Table above and (iv) all directors and officers as a group.

Name	Amount and Nature of Beneficial Ownership (1)	Percentage of Common Stock Beneficially Owned (2)
Ramesh C. Trivedi (3)	1,161,417 (4)	2.51%
Leland Witherspoon (3)	311,484 (5)	*
Charles J. Novak (3)	198,125 (6)	*
Falah Al-Kadi (7)	1,647,136 (8)	3.65%
Jack W. Moorman (9)	160,938 (10)	*
Paul A.H. Pankow (3)	160,938 (11)	*
All directors and officers as a group (6 persons)	3,640,038	7.74%

- Less than one percent.
- (1) Unless otherwise indicated, each person has sole investment and voting power with respect to the shares indicated, subject to community property laws, where applicable. Includes any securities that such person has the right to acquire within 60 days pursuant to options, warrants, conversion privileges or other rights.
- (2) Based on 45,084,089 shares of common stock outstanding as of April 11, 2005.
- (3) Address is c/o Integrated Surgical Systems, Inc., 1850 Research Park Drive, Suite 300, Davis, California 95616.
   (4) Includes 1,147,417 shares that Dr. Trivedi may acquire upon exercise of
- (4) Includes 1,147,417 shares that Dr. Trivedi may acquire upon exercise of stock options exercisable within the next 60 days 316,907 shares at an exercise price of \$0.07 per share, 120,000 shares at an exercise price of \$3.00 per share, 304,300 shares at an exercise price of \$1.81 per share, 6,210 shares at an exercise price of \$0.10 per share, 300,000 shares at an exercise price of \$0.025 per share and 100,000 shares at an exercise price of \$0.0625 per share.

- (5) Includes 300,000 shares that Mr. Witherspoon may acquire upon exercise of stock options exercisable within the next 60 days - 45,000 shares at an exercise price of \$3.00 per share, 30,000 shares at an exercise price of \$1.81 per share, 125,000 shares at an exercise price of \$0.025 per share and 100,000 shares at an exercise price of \$0.0625 per share.
- (6) Includes 198,125 shares that Mr. Novak may acquire upon exercise of stock options exercisable within the next 60 days 20,000 shares at an exercise price of \$0.055 per share, 80,000 shares at an exercise price of \$0.025 per share and 100,000 shares at an exercise price of \$0.0625 per share. Does not include options to purchase 10,000 shares at an exercise price of \$0.055 per share, none of which are currently exercisable.
- (7) Address is c/o Dogmoch Group of Companies, Adnan Al Hakim St., Assaf Bldg., P.O. Box 135660, Beirut, Lebanon.
- (8) Includes 1,461,198 shares of the Company's common stock, all of which are owned by ILTAG, an affiliate of Dogmoch, of which Mr. Al-Kadi is Vice-Chairman, and 190,625 shares that Mr. Al-Kadi may acquire upon exercise of stock options exercisable within the next 60 days 90,625 shares at an exercise price of \$0.06 per share and 100,000 shares at an exercise price of \$0.0625. Does not include options to purchase 9,375 shares at an exercise price of \$0.060 per share, none of which are currently exercisable.
- (9) Address is c/o Microbar Inc. 136 Pinta court, Los Gatos, CA 95030.
- (10) Includes 165,625 shares that Mr. Moorman may acquire upon exercise of stock options exercisable within 60 days 65,625 shares at an exercise price of \$0.035 per share and 100,000 shares at an exercise price of \$0.0625 per share. Does not include options to purchase 34,375 shares at an exercise price of \$0.055 per share, none of which are currently exercisable.
- price of \$0.035 per share, none of which are currently exercisable.

  (11) Includes 160,938 shares that Mr. Pankow may acquire upon exercise of stock options exercisable within the next 60 days 65,625 shares at an exercise price of \$0.035 per share and 100,000 shares at an exercise price of \$0.0625 per share. Does not include options to purchase 34,375 shares at an exercise price of \$0.035 per share, none of which are currently exercisable.

Securities Authorized for Issuance Under Equity Incentive Plans

The Company has provided in the "Equity Compensation Plans" section of Item 5 of this Annual Report on Form 10-KSB certain information with respect to securities authorized for issuance under The Company's equity plans.

Item 12. Certain Relationships and Related Transactions

At December 31, 2004, the Company had an aggregate amount due to executive officers of approximately \$1,013,000. These amounts due are in the form of deferred salaries and unreimbursed travel expenses. Of such amounts, \$460,000 and \$276,000 are included in accrued payroll and related expense and accounts payable and accrued liabilities, respectively, and are due to Ramesh C. Trivedi, president and chief executive officer of the Company; \$141,000 and \$27,000 are included in accrued payroll and related expense and accounts payable, respectively, and are due to Leland Witherspoon, vice president of engineering of the Company; and \$109,000 is included in accrued payroll and related expense and is due to Charles J. Novak, chief financial officer of the Company. At December 31, 2004, the Company had accrued payroll and accrued payroll taxes of \$479,000 for all other employees.

See also "Item 5 - Market for Common Equity and Related Stockholder Matters - Recent Sale of Unregistered Securities" and "Item 10 - Executive Compensation - Employment Agreements."

# Exhibit Description

- Composite of Restated Certificate of Incorporation of the Registrant, 3.1 as amended. (14)
- By-laws of the Registrant, as amended. (1) 3.2
- Certificate of Designations for Series F Convertible Preferred Stock. 3.3 (4)
- 3.4 Certificate of Designations for Series G Convertible Preferred Stock. (11)
- 3.5 Certificate of Designations for Series H Convertible Preferred Stock. (12)
- Form of warrant issued to the underwriters for the Registrant's 4.1 initial public offering in November 1996. (2)
- Form of Warrant Agreement relating to the Registrant's Redeemable 4.2 Common Stock Purchase Warrants. (2)
- Specimen Common Stock Certificate. (2) 4.3
- Specimen Warrant Certificate (included as Exhibit A to Exhibit 4.2 4.4 herein). (2)
- 4.5 1998 Stock Option Plan. (5)
- 4.6
- Employee Stock Purchase Plan. (5)
  Common Stock Purchase Warrant issued by the Registrant to 4.7 International Business Machines Corporation ("IBM"), dated February 6, 1991, as amended (included as Exhibit J to Exhibit 10.5 herein). (2)
- 4.8 Stockholders' Agreement between the Founders of the Registrant and IBM, dated February 6, 1991 as amended. (2) Common Stock Purchase Warrant issued by the Registrant to IBM, dated
- 4.9 December 21, 1995 (included as Exhibit I to Exhibit 10.5 herein). (2)
- Series D Preferred Stock Purchase Warrant issued by the Company to 4.10 IBM, dated December 21, 1995 (included as Exhibit H to Exhibit 10.5
- herein). (2) Warrant issued by the Registrant to Sutter Health, Sutter Health 4.11 Venture Partners ("Sutter Health VP") and Keystone Financial Corporation ("Keystone"), dated December 21, 1995 (included as
- Exhibits K, L and M, respectively, to Exhibit 10.5 herein). (2)
  Registration Rights Agreement among the Registrant, IBM, John N,
  Kapoor Trust ("Kapoor"), EJ Financial Investments V, L.P. ("EJ
  Financial"), Keystone, Sutter Health and Sutter Health VP, dated as of 4.12 December 21, 1995 (included as Exhibit G to Exhibit 10.5 herein). (2) 1995 Stock Option Plan, as amended. (2)
- 4.13
- Series D Preferred Stock Purchase Warrant issued by the Registrant to 4.14 IBM, dated February 29, 1996 (together with the warrant referred to in Exhibit 4.10, the "Series D Warrants"). (2)
- Letter Agreement between the Registrant and IBM dated October 29, 4.15 1997, amending the Series D Preferred Stock and Warrant Purchase Agreement among the Registrant, IBM and EJ Financial, dated December 21, 1995. (6)
- Form of warrant issued to CA IB Investmentbank Aktiengesellschaft and 4.16 Value Management & Research GmbH. (6)
- Form of warrant issued to purchasers of Series A Convertible Preferred 4.17 Stock. (7)
- Form of warrant issued to purchasers of Series B Convertible Preferred 4.18 Stock. (8)
- 4.19 Form of warrant issued to purchasers of Series C Convertible Preferred Stock, (3)
- Form of warrant issued to purchasers of Series D Convertible Preferred 4.20 Stock. (3)
- Form of warrant issued to purchasers of Series E Convertible Preferred 4.21 Stock, (9)
- Form of warrant issued to purchasers of Series F Convertible Preferred 4.22 Stock, (4)
- Form of warrant issued to purchasers of Series G Convertible Preferred 4.23 Stock. (11)
- Form of warrant issued to purchasers of Series H Convertible Preferred 4.24 Stock. (12)
- Form of Registration Rights Agreement for Series A Convertible 4.25
- Preferred Stock financing. (7)
- 4.26 Form of Registration Rights Agreement for Series B Convertible Preferred Stock financing. (8)
  Form of Registration Rights Agreement for Series C Convertible
- 4.27 Preferred Stock financing. (3)
  Form of Registration Rights Agreement for Series D Convertible
- 4.28 Preferred Stock financing. (3)

- Form of Registration Rights Agreement for Series E Convertible 4.29
- Preferred Stock financing. (9) Form of Registration Rights Agreement for Series F Convertible 4.30 Preferred Stock financing. (4)
- Form of Registration Rights  $\dot{\text{Agreement}}$  for Series G Convertible 4.31 Preferred Stock financing. (11)
- Form of Registration Rights Agreement for Series H Convertible 4.32 Preferred Stock financing. (12)
- 4.33
- Form of warrant dated December 14, 1999 issued to ILTAG International Licensing Holding S.A.L., Bernd Herrmann and Urs Wettstein. (10) Form of Registration Rights Agreement dated December 14, 1999 among 4.34 the Registrant, ILTAG International Licensing Holding S.A.L., Bernd
- Herrmann and Urs Wettstein. (10) Registration Rights Agreement for the purchasers of Stock under the 4.35 Equity Line of Credit Agreement (included as Exhibit C to Exhibit
- 10.26). 4.36 Form of warrant issued under the Equity Line of Credit Agreement
- (included as Exhibit D to Exhibit 10.26).
- 4.37 2000 Stock Award Plan
- 2000 Long Term Performance Plan. 4.38
- 4.39 Change in Auditing Firm
- Loan and Warrant Purchase Agreement between the Registrant and IBM, 10.1 dated as of February 6, 1991. (2) License Agreement between the Registrant and IBM, dated February 4,
- 10.2 1991. (2)
- Series B Preferred Stock Purchase Agreement among the Registrant, 10.3
- Sutter Health and Kapoor, dated as of April 10, 1992. (2) Series C Preferred Stock Purchase Agreement among the Registrant, 10.4 Sutter Health and Keystone, dated as of November 13, 1992, as amended
- December 13, 1995. (2) Series D Preferred Stock and Warrant Purchase Agreement among the 10.5
- Registrant, IBM and EJ Financial, dated December 21, 1995. (2) Investors Agreement among the Registrant, IBM, Wendy Shelton-Paul Trust, William Bargar, Brent Mittelstadt, Peter Kazanzides, Kapoor, Sutter Health, Sutter Health VP, and EJ Financial, dated as of 10.6 December 21, 1995, (2)
- Employment Agreement between the Registrant and Ramesh Trivedi, dated 10.7 December 8, 1995, (2)
- License Agreement between the Registrant and IBM, dated February 4, 10.8 1991. (2)
- Stock Purchase Agreement dated as of September 5, 1997 between the 10.9 Registrant and the holders of the outstanding capital stock of Innovative Medical Machines International, S.A. (6)
- 10.10 Registration Rights Agreement dated September 5, 1997 by and among the Registrant and the holders of the outstanding capital stock of Innovative Medical Machines International, S.A. (6)
- Preferred Stock Purchase Agreement for Series A Convertible Preferred 10.11 Stock, (7)
- 10.12 Preferred Stock Purchase Agreement for Series B Convertible Preferred Stock. (8)
- Preferred Stock Purchase Agreement for Series C Convertible Preferred 10.13 Stock, (3)
- Preferred Stock Purchase Agreement for Series D Convertible Preferred 10.14 Stock. (3)
- Preferred Stock Purchase Agreement for Series E Convertible Preferred 10.15 Stock. (9)
- Preferred Stock Purchase Agreement for Series F Convertible Preferred 10.16 Stock, (4)
- Preferred Stock Purchase Agreement for Series G Convertible Preferred 10.17 Stock. (11)
- 10.18 Preferred Stock Purchase Agreement for Series H Convertible Preferred Stock. (12)
- 10.19 Stock and Warrant Purchase Agreement dated as of October 1, 1999 among the Registrant, ILTAG International Licensing Holding S.A.L., Bernd Herrmann and Urs Wettstein. (10)
- Distribution Agreement dated November 12, 1999 between the Registrant 10.20 and Spark 1st Vision GmbH & Co. KG. (14)
- Mutual Termination Agreement dated May 9, 2000 between the Registrant 10.21
- and Spark 1st Vision GmbH & Co. KG. (14)
- Personal Undertaking dated May 30, 2000 by ILTAG International 10.22
  - Licensing Holding S.A.L. towards the Registrant. (14)
- Personal Undertaking dated May 21, 2000 of Urs Wettstein. (14) 10.23
- 10.24 Personal Undertaking dated May 16, 2000 of Bernd Herrmann. (14)

- Private Equity Line of Credit Agreement dated September 15, 2000 with 10.25
- Triton West Group, Inc. (14) Escrow Agreement dated September 15, 2000 for the Equity Line of Credit Agreement (included as Exhibit A to Exhibit 10.26). (14) 10.26
- Letter Agreement dated October 6, 2000 amending the Private Equity Line of Credit Agreement dated September 15, 2000. (14) 10.27
- Addendum One dated March 31, 1998 to Employment Agreement between Registrant and Ramesh Trivedi dated December 8, 1995. (14) 10.28
- Employment Agreement dated February 14, 2003, between Integrated Surgical Systems, Inc. and Charles J. Novak. (14) 10.29
- Employment Agreement dated February 14, 2003, between Integrated 10.30 Surgical Systems, Inc. and Leland Witherspoon. (14)
- Code of ethics (15) 14.1
- 21.1 List of Subsidiaries
- Consent of Macias Gini and Company LLP, Independent Registered Public 23.0 Accounting Firm
- Consent of Ernst & Young LLP, Independent Registered Public Accounting 23.1 Firm '
- Certification Pursuant to Exchange Act Rule 13a-14(a) of Ramesh 31.1 Trivedi
- 31.2 Certification Pursuant to Exchange Act Rule 13a-14(a) of Charles Novak\*
- Certification Pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 of Ramesh Trivedi\* 32.1
- 32.2 Certification Pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 of Charles Novak

# \* Filed Herewith

- (1) Incorporated by reference to the Registrant's Registration Statement on Form SB-2 (Registration No. 333-48040) declared effective on October 31, 2000.
- Incorporated by reference to the Registrant's Registration Statement on (2) Form SB-2 (Registration No. 333-9207), declared effective on November 20, 1996.
- Incorporated by reference to the Registrant's Registration Statement on (3) Form S-3 (Registration No. 333-83067), declared effective on October 14, 1999.
- Incorporated by reference to the Registrant's Registration Statement on (4) Form S-3 (Registration No. 333-30422), declared effective on February 22, 2000.
- Incorporated by reference to the Registrant's Annual Report on Form 10- KSB for the fiscal year ended December 31, 1997.
- Incorporated by reference to the Registrant's Registration Statement on Form SB-2 (Registration No. 333-31481), declared effective on November 14, 1997.
- Incorporated by reference to the Registrant's Registration Statement on Form S-3 (Registration No. 333-66133), declared effective on January 14, 1999.
- Incorporated by reference to the Registrant's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 1999.
- Incorporated by reference to the Registrant's Quarterly Report on Form 10-QSB for the fiscal quarter ended June 30, 1999.
- (10) Incorporated by reference to the Registrant's proxy statement dated October 5, 1999.
- (11) Incorporated by reference to the Registrant's Registration Statement on Form S-3 (Registration No. 333-40710), declared effective on July 28, 2000.
- (12) Incorporated by reference to the Registrant's Registration Statement on Form S-3 (Registration No. 333-45706), declared effective on September 28, 2000.
- (13) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999.
- (14) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002.
- (15) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003.

### Item 14. Principal Accountant Fees and Services

#### Audit Fees

All audit related fees are approved by the Audit Committee. The Audit Committee has considered whether the provisions of such services, including non-audit services, by the Company's Independent Registered Public Accounting Firm is compatible with maintaining their independence and has concluded that it is.

The following table sets forth the Company's aggregate fees billed by its Independent Registered Public Accounting Firm for each of the last two fiscal years for the categories of services indicated.

Category	2004	2003
Audit fees (1)	\$ 120,000	\$ 75,000
Audit Related Fees	- 0 -	-0-
Tax fees (2)	20,000	20,000
All Other Fees	-0-	- 0 -
Total	\$ 140,000	\$ 95,000
	=======	=======

- (1) Consists of the Company estimates of the aggregate fees billed by its Independent Registered Public Accounting Firm for professional services rendered in connection with the audit of the Company's annual financial statements on Form10-KSB and the review of the Company's quarterly financial statements on Form 10-QSB and services that are normally provided by the Independent Registered Public Accounting Firm in connection with the statutory and regulatory filings or engagements.
- (2) Consists of professional services rendered for tax compliance, tax advice, and tax planning.

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# REPORT OF MACIAS GINI & COMPANY LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders Integrated Surgical Systems, Inc.

We have audited the accompanying consolidated balance sheet of Integrated Surgical Systems, Inc. as of December 31, 2004, and the related consolidated statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for the years ended December 31, 2004 and 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Integrated Surgical Systems, Inc. as of December 31, 2004, and the results of its operations and its cash flows for the years ended December 31, 2004 and 2003 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Integrated Surgical Systems, Inc. will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses, has a working capital deficit of \$5,749,062 and an accumulated deficit of \$68,287,471 as of December 31, 2004. In addition, as more fully described in Note 11, the Company is a defendant in a product liability lawsuit. The amount of damages, if any, related to the lawsuit is indeterminable. The Company may not be covered by insurance for legal fees, and damages, if any, related to this lawsuit. The Company does not have the funds, which may be necessary to defend itself against the plaintiffs claim, or satisfy any judgment against it. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

/s/ MACIAS GINI & COMPANY LLP

Sacramento, California April 15, 2005

# Integrated Surgical Systems, Inc.

# Consolidated Balance Sheet December 31, 2004

Assets Current assets:     Cash     Accounts receivable less allowance     for doubtful accounts of \$0     Inventory	\$ 1,324,403 58,569 646,210
Other current assets Total current assets	31,903  2,061,085
TOTAL CUITCHE ASSETS	2,001,003
Property and equipment, net	5,414
	\$ 2,066,499
Liabilities and stockholders' deficit Current liabilities:    Accounts payable    Accrued payroll and related expense    Accrued liabilities    Unearned income    Other current liabilities	\$ 2,173,941 1,306,729 260,151 3,917,827 151,499
Total current liabilities	7,810,147
Convertible preferred stock, \$0.01 par value, 1,000,000 shares authorized; 168 shares issued and outstanding (\$168,496 aggregate liquidation value)	168,496
Stockholders' deficit: Common stock, \$0.01 par value, 100,000,000 shares authorized; 45,084,089 shares issued and outstanding Additional paid-in capital Accumulated deficit	450,841 61,924,486 (68,287,471)
Total stockholders' deficit	(5,912,144)
	\$ 2,066,499
	, ,

See accompanying notes to the consolidated financial statements.

# Integrated Surgical Systems, Inc.

# Consolidated Statements of Operations

	Years ended	December 31,
	2004	
Net revenue Cost of revenue	\$ 2,359,839 893,682 	3,990,140
Operating expenses: Selling, general and administrative Research and development Loss on disposal of subsidiary	1,139,569 994,030 	2,439,172 1,664,160 1,516,519  5,619,851
Operating loss	(667,442)	(3,778,509)
Other income (expense):    Foreign currency exchange gain    Loan forgiveness    Other, net	111,180	143,321 109,000 275,969 528,290
Net loss available to common stockholders	\$ (556,262) =======	\$ (3,250,219) =======
Basic and diluted net loss per common share	\$ (0.01) ======	\$ (0.08) ======
Shares used in computing basic and diluted net loss per share	44,961,384 ======	43,015,760

See accompanying notes to the consolidated financial statements.

## Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

		Convertible Preferred Stock					Stockholders' Deficit			
					 Additional Paid-in			Common	Sto	ck
	Shares	Amou	nt 		Capital		Total	Shares		Amount
Balance at December 31, 2002 Conversions of preferred stock Comprehensive loss: Net loss	250 (82)	\$	2	\$	250,494 (82,000)	\$	250,496 (82,000)	41,978,469 2,888,889	\$	419,785 28,889
Foreign currency translation adjustments Foreign currency translation										
adjustment related to disposal of subsidiary Comprehensive loss										
Balance at December 31, 2003 Stock compensation, non-employees Employee stock options exercised Comprehensive loss: Net loss	168  	\$	2	\$	168,494  	\$	168,496  	44,867,358 130,000 86,731	\$	448,674 1,300 867
Comprehensive loss										
Balance at December 31, 2004	168 =======	\$ :======	2	\$ ====	168,494 =======	\$	168,496	45,084,089 ========	\$	450,841

# Integrated Surgical Systems, Inc.

# Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (Continued)

#### Stockholders' Deficit Accumulated Additional 0ther Total Paid-in Capital Comprehensive Loss Accumulated Stockholders' Deficit Deficit -----Balance at December 31, 2002 \$ 61,849,581 \$(64,480,990) \$ (1,217,907) \$ (3,429,531) Conversions of preferred stock Comprehensive loss: 53,111 82,000 Net loss (3,250,219)(3,250,219) Foreign currency translation adjustments (66,862) (66,862) Foreign currency translation adjustment related to disposal of subsidiary 1,284,769 1,284,769 (2,032,312) Comprehensive loss Balance at December 31, 2003 Stock compensation, non-employees Employee stock options exercised \$ 61,902,692 \$ -- \$(67,731,209) \$ (5,379,843) 21,200 19,900 1,894 2,761 Comprehensive loss: Net loss (556, 262)(556, 262) Comprehensive loss (556, 262) Balance at December 31, 2004 \$ 61,924,486 \$ \$(68,287,471) \$ (5,912,144)

See accompanying notes to the consolidated financial statements.

# Consolidated Statements of Cash Flows

	Years ended December 31,		
	2004	2003	
Cash flows from operating activities: Net loss	\$ (556,262)		
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		,	
Loss on disposal of subsidiary		1,446,597	
Loss on write-down of fixed assets	2,296		
Depreciation	21,086	236,992	
Forgiveness of note payable		(109,262)	
Stock compensation, non-employees	21,200		
Changes in operating assets and liabilities:			
Accounts receivable	52,187	1,115,890	
Inventory	(159, 254)	663,301	
Other current assets	81,006	46,310	
Accounts payable	211,092	72,244	
Accrued payroll and related expenses	425, 282	585,779	
Accrued liabilities	(94,764)	70,376	
Unearned income	1,073,654	(434,892)	
Other current liabilities	1,499	(257,468)	
Net cash provided by operating activities	1,079,022	185,648	
Cash flows from investing activities:			
Purchases of property and equipment		(20,174)	
Disposal of property and equipment		9,343	
Proceeds from sale of property and equipment	6,200		
Troceds from sale of property and equipment			
Net cash provided by (used in) investing activities	6,200	(10,831)	
Cash flows from financing activities:			
Proceeds from Financing Agreement	150,000		
Proceeds from exercise of stock options	2,761		
Proceeds from officers advances	210,846	70,099	
Payments on officers advances	(267, 335)	(66, 286)	
Net cash provided by financing activities	96,272	3,813	
Effect of exchange rate changes on cash		(117,790)	
Net decrease de cont	4 404 404		
Net increase in cash	1,181,494	60,840	
Cash at beginning of year	142,909	82,069	
Cash at end of year	\$ 1,324,403 ========	\$ 142,909 =======	
Supplemental disclosure of non-cash activity: Supplemental disclosure of non-cash financing activities: Conversion of preferred stock	\$	\$ 82,000	
conversion or breferren stock	Ф	⊅ 8∠,000	

See accompanying notes to the consolidated financial statements.

#### Notes to Consolidated Financial Statements

# Note 1. Description of Business and Basis of Presentation

Integrated Surgical Systems, Inc. ("the Company") designs, manufactures, sells and services image-directed, pre-surgical planning computer-controlled robotic software and hardware products for use in orthopaedic and neurosurgical procedures. The Company was incorporated in Delaware in 1990.

In 1997, the Company acquired 100% interest in a French company, Innovative Machines International, S.A., involved in the manufacturing and servicing of neurosurgical products and changed the name to Integrated Surgical Systems, S.A. ("ISS-SA"). Under French law, a company whose net assets are less than 50% of its capital stock may come under the supervision and control of a regional administrative tribunal. On September 30, 2003, the Tribunal de Commerce (the "Tribunal") in Lyon, France appointed an administrator to manage the Company's operations and the administrator exercised control over all aspects of ISS-SA's operations including employee retention, purchasing, sales and inventory management. Effective with the administrator's appointment, the Company no longer had access to the assets, personnel or records of ISS-SA. As a result, in the fourth quarter of 2003, the Company recorded a loss of \$1,516,519 in connection with the liquidation of its investment in ISS-SA and closure of the Company's European operation. The results of operations of ISS-SA are only included for the nine-months ended September 30, 2003, reflecting the Company's liquidation of its operations concurrent with the assumption of the Tribunal.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary Integrated Surgical Systems, BV ("ISS-BV") for the years ended December 31, 2004 and 2003. All significant intercompany balances and transactions have been eliminated.

#### Note 2. Results of Operations and Management's Plans

The Company had net losses of \$556,262 and \$3,250,219 for the years ended December 31, 2004 and 2003, respectively. In addition, the Company had a working capital deficit of \$5,749,062 and an accumulated deficit of \$68,287,471 at December 31, 2004. In addition, as more fully described in Note 11, the Company is a defendant in a product liability lawsuit. The report of Independent Registered Public Accounting Firm on the Company's December 31, 2004 and December 31, 2003 consolidated financial statements includes an explanatory paragraph indicating there is substantial doubt about the Company's ability to continue as a going concern.

The Company believes that it has a plan to address these issues and enable the Company to continue operating through December 31, 2005. This plan includes effecting the issuance of additional convertible debentures and warrants as described in Note 5, seeking additional sources of equity or debt financing, generating cash flows through product, system upgrade and technology sales and continued limitation of discretionary expenditures. Although the Company believes that the plan will be realized, there is no assurance that these events will occur, or that the plan will generate the necessary funds to allow the Company to defend itself against, or satisfy any judgment resulting from the product liability lawsuit (see Note 11). In the event that the Company is unsuccessful, it is possible that it will cease operations or seek bankruptcy protection. The consolidated financial statements do not include any adjustments to reflect the uncertainties related to the recoverability and classification of assets or the amounts and classification of liabilities that may result from an inability on the Company's part to continue as a going concern.

# Note 3. Significant Accounting Policies

# Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

#### Notes to Consolidated Financial Statements

Revenue for product sales is generally recognized upon completion of training and installation of the equipment at the end-user's site, except when the sales contract requires formal customer acceptance. Equipment sales with contractual customer acceptance provisions are recognized as revenue upon written notification of customer acceptance, which generally occurs after the completion of training and installation. Furthermore, due to business customs in Japan and the Company's interpretation of Japanese law, all equipment sales to Japan are recognized after customer acceptance, which generally occurs after the completion of training and installation. Revenue related to maintenance and service contracts is recognized ratably over the duration of the contracts.

Effective with its adoption of Emerging Issues Task Force ("EITF") 00-21, "Multiple Deliverable Revenue Arrangements," when elements such as products and services or other elements are combined in a single arrangement, or in related arrangements with same customer, the Company allocates revenue to each element based on its relative fair value, provided that such element meets the criteria for treatment as a separate unit of accounting. The price charged when the element is sold separately generally determines fair value. In the absence of fair value for an undelivered element, the arrangement is accounted for as a single unit of accounting, resulting in a delay of revenue recognition for the delivered elements until the undelivered elements are fulfilled.

The Company develops specialized operating software for several implant manufacturing companies. These implant manufacturers contract with the Company for the development of particular lines of new prosthesis software to be used with the ROBODOC system. These contracts are accounted for under the provisions of Statement of Position ("SOP") 81-1, "Accounting for Performance of Construction-Type and Certain Production-Type Contracts," using the completed contract and percentage of completion method of accounting. Product development revenue for contracts recorded using the completed contract method is recognized when development is complete under the terms of the contract, and the customer has accepted the product. The direct cost, primarily labor, of product development contracts is deferred until the development revenue is recognized. Losses on contracts are accrued in the period that such losses are determined under the percentage of completion method. Under the percentage of completion method, revenue is recognized as work is performed, based on the relationship between actual costs incurred and total estimated costs at completion. Revenues are adjusted prospectively for revisions in estimated total contract costs when identified. Losses, if any, are recognized in full when identified.

The Company has not leased any equipment to customers since liquidating its ISS-SA European operation in the fourth quarter of 2003. Prior to the fourth quarter of 2003, the Company, through its ISS-SA subsidiary, recognized revenue from leasing activities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 13, "Accounting for Leases." Accordingly, leases that, transfer substantially all the benefits and risks of ownership are accounted for as sales-type leases. All other leases are accounted for as operating leases. Under the sales-type method, profit is recognized at lease inception by recording revenue and cost. Revenue consists of the present value of the future minimum lease payments discounted at the rate implicit in the lease. Cost consists of the equipment's book value. The present value of the estimated value of the equipment at lease termination (the residual value), which is generally not material, and the present value of the future minimum lease payments are recorded as assets. In each period, interest income is recognized as a percentage return on asset carrying values. The cost of equipment subject to operating leases is recorded as leased equipment and is depreciated on a

# Notes to Consolidated Financial Statements

straight-line basis over the estimated service life of the equipment. Operating lease revenue is recognized as earned over the term of the underlying lease. All such leasing activity was performed by, and recorded on the books of, ISS-SA. As a result, at December 31, 2003, the Company held no such leases. During the year ended December 31, 2004 and the year ended December 31, 2003, the Company recorded \$0 and \$238,000, respectively, in revenues from cancelable operating leases.

# Foreign Currency Translation

The financial position and results of ISS-SA and ISS-BV are measured in Euros. Balance sheet accounts are translated into dollars at the year-end exchange rate and statement of operations amounts are translated at the average exchange rate for the period. The resulting translation adjustments are recorded in the other comprehensive income section of stockholders' deficit. The Company's foreign currency transactions are usually recorded and settled in the same foreign currency, without foreign exchange transaction gains or losses. Foreign exchange transaction gains or losses are, however, recognized when translating inter-company receivables and payables. Primarily due to the liquidation of ISS-SA and the closure of its European operations, the Company reversed its existing accumulated foreign exchange translation adjustment balance of \$1,284,769 in December 2003.

# Research and Development

Research and development costs are expensed as incurred. Grants received from third parties for research and development activities are recorded as reductions of research and development expense over the term of the agreement as the related activities are conducted.

#### Shipping and Handling Costs

Costs related to shipping and handling are included in costs of revenues for all periods presented.

## Certain Risks and Uncertainties

The Company uses financial instruments that potentially subject it to concentrations of credit risk. Such instruments consist primarily of cash and accounts receivable. The Company's cash is invested in cash deposits, substantially all with one financial institution. The Company sells its products to companies in the healthcare industry, most of which are located in foreign countries. The Company requires a down payment when an order is received, with a progress payment upon shipment, and final payment upon completion of training and installation or customer acceptance. The Company believes that adequate provisions for uncollectable accounts receivable has been made in the accompanying consolidated financial statements.

A significant portion of the Company's sales are to a limited number of customers located in foreign countries. Three major foreign customers of the Company accounted for 45%, 24% and 22% of the Company's revenue during the year ended December 31, 2004, and three major foreign customers accounted for 22%, 14% and 13% for the year ended December 31, 2003. At December 31, 2004, two foreign customers accounted for 98% of accounts receivable, and at December 31, 2003, two customers accounted for 100% of accounts receivable.

#### Notes to Consolidated Financial Statements

Foreign revenue, substantially all from Western European countries, Japan, India and Korea was approximately \$2,360,000 and \$5,225,000 for the years ended December 31, 2004 and December 31, 2003, respectively.

One of the key components of the ROBDOC system, a customized Robotic arm, has been manufactured by a Japanese manufacturer, Sankyo Seiki, per ISS specifications. The specifications, for this component, are the proprietary property of the Company and can not be used by anyone else to build or supply robot arms. The manufacturer has discontinued their medical robot business, and will not manufacture new robot arms for the Company. This situation does not create immediate risk as the Company has supplies in inventory to meet anticipated demand through December 31, 2005 and, the Company is redesigning the robot arm and is securing a new vendor for alternative vendor manufacture. Any significant delay in securing a new vendor for this component could have a material adverse effect on the financial condition, results of operations, or cash flow of the Company.

## Financial Statement Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Cash

Cash includes cash deposited in bank accounts.

# Property and Equipment

Property and equipment are stated at cost. Depreciation is calculated using the straight-line method over estimated useful lives of 3 to 5 years or the lease term, whichever is shorter.

# Inventory

Inventory is recorded at the lower of cost (first-in, first-out method) or market and consists of materials and supplies used in the manufacture and service support of the Company's products, and deferred costs associated with certain of the Company's development contracts.

Inventory consisted of the following at December 31, 2004:

Raw materials Work-in-process Finished goods	\$125,790 219,669 94,181
Deferred product development contract costs	206,570
	\$646,210
	=======

#### Notes to Consolidated Financial Statements

#### Warranty

The Company offers a one-year warranty for parts and labor on all ROBODOC systems commencing upon the completion of training and installation, except when the sales contract requires formal customer acceptance. In most cases, the Company's customers purchase a service contract, which includes warranty coverage (parts and labor), unspecified product maintenance updates, customer support services and various consumables required during surgical procedures. Revenue from service contracts is initially deferred and then recognized ratably over the term of the agreements. Service contracts can be renewed at the customers' option, annually thereafter. Where the Company's products are not covered by separate service agreements, the Company provides for the estimated cost of product warranties at the time revenue is recognized, based on historical results. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. The Company has no recorded warranty liability for the periods ending December 31, 2004 and December 31, 2003, as all systems within the one-year warranty periods were covered by service contracts.

# Stock-Based Compensation

As permitted under the provisions of SFAS No. 123 "Accounting for Stock-Based Compensation," the Company has elected to account for stock-based compensation using the intrinsic value method prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees." Under the intrinsic value method, compensation cost is the excess, if any, of the quoted market price or fair value of the stock at the grant date or other measurement date over the amount an employee must pay to acquire the stock.

Pro forma information regarding net income (loss) and earnings (loss) per share is required by SFAS No. 123, which also requires that the information be determined as if the Company had accounted for the employee stock options granted subsequent to December 31, 1994 under the fair value method of that statement. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2004 and 2003, respectively: risk-free interest rates of 3.4% and 3.0%; dividend yield of 0%; volatility factors of the expected market price of the common stock of 101% and 107%; and an expected life of the option of 4 years.

The weighted average grant date fair value of these options was \$0.08 in 2004 and \$0.03 in 2003. No options with option prices less than the fair market value of the Company's stock on the date of grant were granted to employees in 2004 or 2003. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, it is the Company's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the employee stock options. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period.

#### Notes to Consolidated Financial Statements

		Year Ended 2004	December 31, 2003	
Net loss, as reported Less: stock-based employee compensation	\$	(556, 262)	\$(3,	,250,219)
cost included in net loss, as reported Stock-based employee compensation expense, determined under fair				
value method for all awards		(11,104)	(	(112,444)
Pro forma net loss		\$ (567,366) \$(3,362, ====================================		,362,663) ======
Loss per share:				
Basic and diluted net loss per share	\$ ==	(0.01)		(0.08)
Pro forma basic and diluted net loss per share	\$	(0.01)	\$ ====	(0.08)

# Income Taxes

The liability method is used to account for income taxes. Under this method, deferred income tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are scheduled to be in effect when the differences are expected to reverse.

# Recent Accounting Pronouncements

In May 2003, FASB issued Statement of Financial Accounting Standards No. (SFAS No. 150), "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 requires certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity to be classified as liabilities. Many of these instruments previously were classified as equity or temporary equity and, as such, SFAS No. 150 represents a significant change in practice in the accounting for a number of mandatorily redeemable equity instruments and certain equity derivatives that frequently are used in connection with share repurchase programs. SFAS No. 150 is effective for all financial instruments created or modified after May 31, 2003, and to other instruments at the beginning of the first interim period beginning after June 15, 2003.

The adoption of SFAS No. 150 did not have a material impact on the Company's consolidated financial position, cash flows or results of operations.

In November 2002, the EITF reached a consensus on Issue 00-21, "Multiple Deliverable Revenue Arrangements" (EITF 00-21). EITF 00-21 addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The consensus mandates how to identify whether goods or services, or both, are to be delivered separately in a bundled sales arrangement should be accounted for separately because they are "separate units of accounting." The guidance can affect the timing of revenue recognition for such arrangements, even though it does not change rules governing the timing or pattern of revenue recognition of individual items accounted for separately. The final consensus is applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies will be permitted

#### Notes to Consolidated Financial Statements

to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, "Accounting Changes." The adoption of EITF 00-21 did not have a material impact on the Company's consolidated financial position, cash flows or results of operations.

# Note 4. Property and Equipment

Property and equipment consists of the following at December 31, 2004:

Computer hardware and purchased software	\$ 206,166
Machinery and equipment	242,210
ROBODOC and NeuroMate System equipment	687,082
Furniture and fixtures	85,997
Leasehold improvements	10,383
Less accumulated depreciation	1,231,838 1,226,424
	\$ 5,414 =======

## Note 5. Financing Agreement

To obtain funding for the Company's ongoing operations, the Company entered into a securities purchase agreement (the "Agreement") with an accredited investor on June 15, 2004 with respect to the sale by the Company for aggregate consideration of \$150,000 of (i) a convertible debenture in the principal amount of \$150,000 and (ii) warrants to purchase 1,500,000 shares of Company common stock. The Agreement contemplates the sale of additional convertible debentures and warrants upon the occurrence of specific events. The Company is obligated to register under the Securities Act for resale by the investor the common stock underlying the debenture and warrants issued pursuant to the Agreement. In connection with the sale of the original \$150,000 convertible debenture and 1.5 million warrants the investor provided the Company with funds as follows:

- o \$100,000 was disbursed to the Company on June 15, 2004;
- o \$50,000 was disbursed to the Company on October 19, 2004; and
- o \$50,000 has been retained by the investor for disbursement to various professionals in payment for services to be provided to the Company.

The convertible debenture bears interest at 6 3/4%, matures two years from the date of issuance, and is convertible into, at the investor's option, into the number of shares of Company common stock equal to the principal amount of the debenture being converted multiplied by 11, less the product of the conversion factor multiplied by ten times the dollar principal amount of the debenture being converted. The conversion factor for the convertible debenture is the lesser of (i) \$0.25 or (ii) eighty percent of the average of the five lowest volume weighted average prices during the twenty (20) trading days prior to the conversion. Accordingly, there is no limit on the number of shares into which the debenture may be converted. In addition, the investor is obligated to proportionately exercise, concurrently with the submission of a conversion notice by the selling stockholder, the warrants. The warrants are at an exercise price of \$1.00 per share.

#### Notes to Consolidated Financial Statements

The investor has contractually agreed to restrict its ability to convert or exercise its warrants and receive shares of Company common stock such that the number of shares of common stock held by it and its affiliates after such conversion and exercise does not exceed 4.9% of the then issued and outstanding shares of Company common stock.

The issuance of more than 51.5 million shares of common stock upon conversion of the convertible debenture and exercise of the warrants issued pursuant to the Agreement would require the Company to issue shares of common stock in excess of the Company's currently authorized shares of its common stock. The Company intends to seek stockholder approval to amend the Company's certificate of incorporation to increase the Company's authorized common stock from 100,000,000 to 300,000,000 shares. Such solicitation will be made pursuant to a proxy statement conforming to the rules and regulations of the Securities and Exchange Commission. This Annual Report on Form 10-KSB should not be considered, in any manner, a solicitation for voting in favor of such an increase in the Company's authorized common stock.

The issuance of the convertible debenture and warrants to the investor is contingent upon stockholder approval of the increase in the Company's authorized common stock. If such approval is not received, the Agreement will terminate and the Company will be obligated to repay the proceeds received to date and other funds disbursed by the investor to professionals in payment of services rendered on behalf of the Company. As a result, the Company recorded such proceeds in other current liabilities.

## Note 6. Note Payable

The Company received a \$143,403 interest-free loan in 1997 from ANVAR, a French agency established to aid research and development projects. The loan provided funding for the first phase of the development of NeuroMate applications for spinal surgery. Under the terms of the loan, 50% of the revenues generated from the sale or licensing of the related technology, prototype, or articles manufactured specifically for the research project, were to be paid to ANVAR in the subsequent year, up to the balance of the loan amount outstanding. No such revenues were recorded during the years ending December 31, 2004 and 2003.

The loan also provided for the forgiveness of the loan under certain conditions, including a review by ANVAR. In August 2003, ANVAR completed a review of the loan balance and determined that the remaining balance of approximately \$109,000 was forgiven. The Company has recorded the forgiveness of the loan in other income, net in August 2003.

# Note 7. Stockholders' Deficit

# Common Stock

At December 31, 2004 the Company has reserved a total of 6,017,714 shares of common stock for future issuance pursuant to Series G Convertible Preferred Stock, warrants and options outstanding.

The Company established an Employee Stock Purchase Plan ("ESPP") in 1998. The ESPP plan provides all eligible employees an opportunity to acquire an ownership interest in Integrated Surgical Systems, Inc. on a payroll deduction or other compensation basis at a 15% discount. The plan is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code. The plan covers an aggregate of 300,000 shares of the Company's common stock. At December 31, 2004, no offerings have been made to employees under the ESPP plan.

#### Notes to Consolidated Financial Statements

## Warrants

The following table summarizes information about common stock warrants outstanding at December 31, 2004 and 2003:

	Tanua	Funimation		Evenedes	Outstand	
	Issue	Expiration		Exercise	Decembe	er 31,
Warrants issued	Year	Date	Issued	Range	2004	2003
Pursuant to stock purchase agreement (2)	1997	December 2006	2,274,066	\$0.01	2,206,479	2,206,479
With Series F preferred stock (1)	2000	February 2004	125,000	2.38	-	125,000
With Series G preferred stock (1)	2000	May 2004	63,000	1.88	-	63,000
With Series H preferred stock (1)	2000	August 2004	650,000	0.50-1.02	-	650,000
In connection with equity financing (3)	2000	September 2004	35,000	0.86	-	35,000
In connection with services (4)	2002	May 2007	100,000	0.06	100,000	100,000
In connection with services (5)	2004	July 2014	300,000	.0625	300,000	-
			3,547,066		2,606,479	3,179,479
			========		=========	=========

Unless otherwise stated below, the warrants are exercisable when granted and expire between 2004 and 2014.

- ------
- (1) Warrants are exercisable when vested, generally within one year of issue.
- (2) Number of common shares and exercise price are subject to dilution adjustment.
- (3) Aggregate estimated fair value of \$20,650, based on Black-Scholes option valuation model.
- (4) Aggregate estimated fair value of \$5,000, based on Black-Scholes option valuation model.
- (5) Aggregate estimated fair value of \$18,000, based on Black-Scholes option valuation model

# Preferred Stock

The Company's Certificates of Incorporation authorize 1,000,000 shares of undesignated, serial preferred stock. Preferred stock may be issued from time to time in one or more series. The Board of Directors is authorized to determine the rights, preferences, privileges, and restrictions granted to and imposed upon any wholly unissued series of preferred stock and designation of any such series without any further vote or action by the Company's stockholders.

# Convertible Preferred Stock

The Company's convertible preferred stock is classified as mezzanine financing, outside of permanent equity, due to its liquidation rights upon a change in control, as this condition is not solely within the Company's control. Given the liquidation rights of the Company's convertible preferred stock, these securities have been accounted for as if they were redeemable preferred stock. As such, the redemption value of the convertible preferred stock has been its liquidation preference of \$168,496, and the carrying value of the convertible preferred stock is adjusted to its redemption amount at each balance sheet date through corresponding debits and credits to accumulated deficit and convertible preferred stock respectively, up to the liquidation preference.

#### Notes to Consolidated Financial Statements

Since September 1998, the Company has received aggregate net proceeds of \$14,084,995 from the sale of eight series of convertible preferred stock. Information concerning these convertible preferred stock financing is set forth below:

Series	Date of Sale	Shares Sold		Net Proceeds
Α	September 10, 1998	3,520	\$	3,300,447
В	March 26, 1999	1,000	Ψ	916,918
	•	,		,
С	June 10, 1999	750		658,190
D	June 30, 1999	2,000		1,861,549
E	July 30, 1999	3,000		2,819,484
F	February 8, 2000	2,000		1,850,861
G	May 30, 2000	1,800		1,610,555
Н	August 17, 2000	1.200		1.066.991

Each series of convertible preferred stock has a stated value of \$1,000 per share and is convertible into common stock at conversion prices equal to 80% or 85% of the lowest sale price of the common stock on its listed market over the five trading days preceding the date of conversion ("Beneficial Conversion Feature") subject to a maximum conversion price. The number of shares of common stock that may be acquired upon conversion is determined by dividing the stated value of the number of shares of convertible preferred stock to be converted by the conversion price.

The value assigned to the Beneficial Conversion feature of each class of preferred stock was based upon the difference between the maximum conversion price and the quoted market price of the common stock on the date the convertible preferred stock was sold (the "Discount"). The Discount was accreted using the straight-line method over the conversion period. No series of convertible preferred stock entitles holders to dividends or voting rights, unless required by law or with respect to certain matters relating to a particular series of convertible preferred stock.

During the year ended December 31, 2003, 82 shares of Series G convertible preferred stock were converted into 2,888,889 shares of common stock. At December 31, 2004 and 2003, 168 shares of Series G convertible preferred stock were outstanding. At December 31, 2004, the series G shares would have converted into a minimum of 103,371 shares of common stock based upon its maximum conversion price of \$1.63. No other series of preferred stock were outstanding. The number of shares of common stock issued upon conversion and the average actual conversion price for each series of convertible preferred stock converted into shares of common stock through December 31, 2004 was as follows:

#### Notes to Consolidated Financial Statements

Series	Common Shares	Price
Α	2,867,135	\$2.23
В	459,831	2.17
С	563,497	1.33
D	1,605,203	1.25
E	1,490,101	1.22
F	2,143,242	0.93
G	9,887,747	0.17
Н	10,921,902	0.11

Stock Option and Long-Term Performance Plans

The Company has established four specific stock option plans in which officers, employees, directors and consultants may participate. Options granted under the plans may be incentive stock options or non-incentive stock options and generally have a term of ten years from the date of grant. The exercise price of incentive stock options granted under the plans may not be less than 100% of the fair market value of the common stock on the date of the grant. The exercise price of non-statutory stock options granted under the plans may not be less than 85% of the fair market value of the common stock on the date of the grant. For a person who, at the time of the grant, owns stock representing 10% of the voting power of all classes of the Company's stock, the exercise price of the incentive stock options or the non-statutory stock options granted under the plans may not be less than 110% of the fair market value of the common stock on the date of the grant.

Each plan is administered by the Company's board of directors, as the board of directors may be composed from time to time. Certain officers and directors may be deemed to be "affiliates" as that term is defined under the Securities Act. The common stock acquired under the Plans by an affiliate may be re-offered or resold only pursuant to an effective registration statement or pursuant to Rule 144 under the Securities Act or another exemption from the registration requirements of the Securities Act.

The 1995 Stock Option Plan: The 1995 Plan was approved by the Company's board of directors on December 22, 1995. The purpose of the 1995 Plan is to attract, motivate and retain selected employees and other individuals providing services to us. The options in this plan were not intended to qualify as incentive stock options. The options vest over a four-year period and must be exercised within three months of termination.

The 1998 Stock Option Plan: The 1998 Plan was approved by the Company's board of directors on May 13, 1998. The purpose of the 1998 Plan is to attract, motivate and retain selected employees and other individuals providing services to the Company. The options in this plan were not intended to qualify as incentive stock options. The options vest over a four-year period and must be exercised within three months of termination.

The 2000 Stock Award Plan: The 2000 Plan was approved by the Company's board of directors on December 12, 2000. The purpose of the 2000 Plan is to attract, motivate and retain selected employees and other individuals providing services to the Company. The 2000 Plan is a long-term performance plan and the options are intended to qualify as incentive stock options. The options vest over a four-year period and must be exercised within 30 days of termination.

The 2004 Long-Term Performance and Incentive Plan: The 2004 Plan was approved by the Company's board of directors on July 22, 2004. The purpose of the 2004 Plan is to attract, motivate and retain selected employees of, and other individuals

# Notes to Consolidated Financial Statements

providing services to the Company. The 2004 plan is a long-term performance and incentive plan. The options in this plan were not intended to qualify as incentive stock options. The options vest over a four-year period and must be exercised within three month of termination. This plan has not yet been approved by the stockholders and will be presented for approval at a future date.

The following table summarizes activity under the plans for the years ended December 31, 2004 and 2003:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2002 (at \$.03 to \$8.50 per share)	1,608,971	\$1.28
Granted (at \$0.03 to \$0.06 per share)	1,130,100	0.03
Cancelled (at \$0.03 to \$3.94 per share)	(260,429)	0.67
Exercised	-	-
Outstanding at December 31, 2003 (at \$.03 to \$8.50 per share)	2,478,642	\$0.77
Granted (at \$0.06 to \$0.08 per share)	27,500	0.08
Cancelled (at \$0.03 to \$5.69 per share)	(216,219)	0.47
Exercised (at \$0.03 to \$0.06 per share)	(86,731)	0.05
Outstanding at December 31, 2004 (at \$.03 to \$8.50 per share)	2,023,192	\$0.82
outstanding at becomber 31, 2004 (at \$.03 to \$0.30 per share)	========	Ψ0.02

The weighted average exercise price of options granted in 2004 and 2003 with option prices equal to the fair market value of the stock on the grant date was \$0.08 and \$0.06, respectively. At December 31, 2004 there were 438,951 shares of common stock reserved for future grants under the Stock Option Plan.

The following table summarizes information related to options outstanding and options exercisable at December 31, 2004:

Exercise Price	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Options Exercisable	Weighted Average Exercise Price
\$0.00 -\$ .49	858,000	\$0.03	8.1	776,855	\$0.03
0.50 - 0.99	668,652	0.08	3.9	585,805	0.08
1.00 - 1.99	384, 263	1.78	5.1	384, 263	1.78
2.00 - 3.99	233,000	3.08	3.8	233,000	3.08
4.00 - 8.50	59,277	5.97	2.1	59,277	5.97
	2,203,192	\$0.82	5.7	2,039,200	\$0.89
	========			========	

# Notes to Consolidated Financial Statements

#### Note 8. Income Taxes

Deferred taxes result from temporary differences in the recognition of certain revenue and expense items for income tax and financial reporting purposes. The significant components of the Company's deferred taxes as of December 31, 2004 and 2003 are as follows:

	2004	2003
Deferred tax assets:		
Net operating loss carryover	\$19,249,000	\$19,882,000
Research and development credit Research and development	2,301,000 228,000	2,212,000 305,000
Accrued product retrofit costs		
Inventory	268,000	303,000
Depreciation Stock compensation	77,000 289,000	154,000 289,000
Loss on investment	126,000	126,000
Deferred income Other	1,565,000 199,000	1,130,000 227,000
	24,302,000	24,628,000
Less valuation allowance	24,302,000	24,628,000
Net deferred taxes	\$	\$
	==========	:=========

The Company expects the carryforward amounts will not be used prior to the expiration of the carryforward periods. The principal reasons for the difference between the effective income tax rate and the federal statutory income tax rate as of December 31, 2004 and 2003 are as follows:

	==	=======	=========
	\$		\$
Other non-deductible items			2,361
Other taxes		1,590	(3,814,892)
Net effect of foreign operations			(70,744)
Domestic net operating loss with no current benefit		187,539	5,019,945
Federal benefit expected at statutory rates	\$	(189,129)	\$(1,136,670)
		2004	2003

As a result of stock sales through December 31, 1995, a change of ownership (as defined in Section 382 of the Internal Revenue Code of 1986, as amended) has occurred. As a result of this change, the federal and state net operating loss carryforwards from these years will be subject to a total annual limitation in the amount of approximately \$400,000.

The Company had at December 31, 2004 a net operating loss carryover of approximately \$42,055,000 for federal income tax purposes which expires between 2005 and 2023, a net operating loss carryforward of approximately \$11,204,000 for state income tax purposes which expires between 2005 and 2013, and a net capital loss carryover for federal income tax purposes of \$12,640,000 which will expire in 2008.

#### Notes to Consolidated Financial Statements

The Company had at December 31, 2004 research and development credit carryovers of approximately \$1,446,000 and \$1,295,000 for federal and state income tax purposes, respectively. The Company paid \$800 for income and franchise taxes during each of the two years ended December 31, 2004 and 2003. The valuation allowance decreased by \$326,000 in 2004 and increased by \$5,855,000 in 2003.

# Note 9. Net Loss Per Share Information

At December 31, 2004, outstanding options to purchase 2,203,192 shares of common stock (with exercise prices ranging from \$0.025 to \$8.50), 2,606,479 outstanding warrants to purchase 2,606,479 shares of common stock (with exercise prices from \$0.01 to \$0.0625), and 6,017,714 shares of common stock issuable upon conversion of Series G Preferred Stock could potentially dilute basic earnings per share in the future and have not been included in the computation of diluted net loss per share because to do so would have been antidilutive for the periods presented. The exercise price and the ultimate number of shares of common stock issuable upon conversion of the warrants are subject to adjustments based upon the occurrence of certain future events.

#### Note 10. Commitments

The Company's executive offices and production facility are located in Davis, California. The Company occupies the facility in Davis under a lease that expires in June 2005, which is currently being renegotiated. During the third quarter of 2004, the Company renegotiated this lease to reduce the square footage from approximately 30,500 square feet to approximately 16,000 square feet, with a corresponding per month reduction in monthly rent expense from approximately \$32,500 per month to approximately \$18,000 per month. Prior to the renegotiations of the lease, the Company paid utilities and maintenance fees directly to the providers of these services. These utility and maintenance fees are now paid to the providers directly by the lessor and billed back to the Company, along with property taxes, on a pro-rated percentage based on the Company's percentage of occupancy.

Future payments under the non-cancelable facility operating lease is approximately \$90,000 for the year ending December 31, 2005. Aggregate rental expense under this lease and the Company's lease for ISS-SA's facility in France amounted to approximately \$321,000 and \$438,000 during the years ended December 31, 2004 and 2003, respectively. Effective October 1, 2003, the lease in France was terminated by the Tribunal and no further expenses were recorded.

# Note 11. Contingencies

The Company is subject to legal proceedings and claims that arise in the normal course of business. The Company cannot assure that it would prevail in such matters nor can it assure that any remedy could be reached on mutually agreeable terms, if at all. Due to the inherent uncertainties of litigation, the Company would not be able to accurately predict their ultimate outcome.

On December 17, 2004, the Company was served with a summons and complaint commenced in Yolo County (California) Superior Court, styled Bischoff, et al. vs. Integrated Surgical Systems, Inc. et al. The plaintiffs, in the litigation,

#### Notes to Consolidated Financial Statements

all from Germany, allege that the Company's ROBODOC System is defective and dangerous, both in its manufacture and design and, as a result of such defect and dangerous condition, the plaintiff, all of whom were subject to medical treatment utilized the ROBODOC System, sustained injury. The plaintiffs are seeking class status for this matter.

The Company believes the plaintiff's allegations are without merit. The Company intends to conduct a vigorous defense against the allegations contained in the complaint. However, the Company did not have any product liability insurance from June 2004 through March 3, 2005, due to its financial inability to pay the requisite insured premiums. Effective March 4, 2005 the Company secured a new product liability insurance policy in the amount of \$2 million per occurrence and \$2 million in aggregate.

This case is at its incipient stages. The Company has retained competent counsel to represent it in this matter. The amount of damages, if any, are indeterminable at this juncture.

Defending against a product liability action can be expensive and time consuming to management personnel. The Company currently does not have the funds, which may be necessary to defend against the plaintiffs' allegations. The failure to properly defend the Company against the allegations could result in a material judgement against the Company, which could adversely affect our financial condition, results of operations and cash flow. The Company may also currently not have the funds necessary to satisfy any judgement rendered against it. The Company's failure to successfully defend against the allegations could result in our seeking protection under the United States Bankruptcy Code. Such action could have a material adverse effect on the market price of the Company's common stock, business, financial condition, cash flow and results of operations.

In accordance with SFAS No. 5. "Accounting for Contingencies," the Company has reviewed the facts related to the liquidation of its investment in ISS-SA and closure of its European operations (see Note 1) and has determined that no provision for loss is required related to this action. Were a claim to be filed the Company would not be able to accurately predict its ultimate outcome.

# Note 12. Related Party Transactions

At December 31, 2004, the Company had an aggregate amount due to executive officers of approximately \$1,013,000. These amounts due are in the form of an interest bearing advance, deferred salaries and unreimbursed travel expenses. Of such amounts, \$460,000 and \$276,000 are included in accrued payroll and related expense and accounts payable and accrued liabilities, respectively, and are due to Ramesh C. Trivedi, president and chief executive officer of the Company; \$141,000 and \$27,000 are included in accrued payroll and related expense and accounts payable, respectively, and are due to Leland Witherspoon, vice president of engineering of the Company; and \$109,000 is included in accrued payroll and related expense and is due to Charles J. Novak, chief financial officer of the Company. At December 31, 2004, the Company had accrued payroll and accrued payroll taxes of \$479,000 for all other employees.

# Note 13. Restatement of Unaudited Interim Financial Information

In conjunction with the audit of its financial statements for the year ended December 31, 2004, the Company determined that it had overstated accounts receivable and unearned income as of September 30, 2004 due to prematurely or incorrectly recording certain service contracts with its customers. Accounts receivable and unearned income as of September 30, 2004 were overstated by \$287,897 and \$253,933, respectively. In the third quarter of 2004, net revenue

# Notes to Consolidated Financial Statements

was overstated by \$33,964 and net loss understated by a similar amount, as a result of the amortization related to these service contracts. There was no impact on the reported amount of basic or diluted net loss per common share as a result of the correction.

A summary of the Company's interim financial information as of, and for the three month period ended, September 30, 2004, as reported and as restated is provided below:

	As Reported	As Restated
Accounts Receivable	\$ 329,948	\$ 42,051
Unearned Income	\$ 2,714,991	\$ 2,461,058
Net Revenue	\$ 139,140	\$ 105,176
Net Loss	\$ (332,861)	\$ (366,825)
Basis and Diluted Net Loss Per Common Share	\$ (.01)	\$ (.01)

# Signatures

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Integrated Surgical Systems, Inc.

By: /s/ RAMESH C. TRIVEDI

Ramesh C. Trivedi, President (Principal Executive Officer)

By: /s/ CHARLES J. NOVAK

Charles J. Novak

(Principal Financial and Accounting Officer)

Dated: April 15, 2005

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant on April 15, 2004 in the capacities indicated.

Signature Title

Chief Executive Officer, President and a Director (Principal Executive Officer) /s/ RAMESH C. TRIVEDI

Ramesh C. Trivedi

/s/ CHARLES J. NOVAK Chief Financial Officer (Principal Financial and Accounting Officer)

Charles J. Novak

Chairman of the Board /s/ FALAH AL-KADI

Falah Al-Kadi

/s/ JACK W. MOORMAN Director

Jack W. Moorman

/s/ PAUL A.H. PANKOW Director

Paul A.H. Pankow

# CONSENT OF MACIAS GINI & COMPANY LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 Nos. 333-44093, 333-70779, 333-53188 and 333-53190 pertaining to the 1995 Stock Option Plan, as amended, the 1998 Stock Option Plan and Employee Stock Purchase Plan and the 2000 Stock Award Plan, of Integrated Surgical Systems, Inc. of our report dated April 15, 2005, with respect to the consolidated financial statements of Integrated Surgical Systems, Inc. included in the Annual Report on Form 10-KSB for the year ended December 31, 2004.

MACIAS GINI & COMPANY LLP

Sacramento, California April 15, 2005

# CERTIFICATION

I, Ramesh C. Trivedi, Chief Executive Officer of Integrated Surgical Systems, Inc., certify that:

- I have reviewed this annual report on Form 10-KSB for the year ended December 31, 2004 of Integrated Surgical Systems, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
- The small business issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) (language intentionally omitted pursuant to SEC Release No 5 33-8238 and 34-47986) for the small business issue and have:
  - Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (Language intentionally omitted pursuant to SEC Release No 5 33-8238 and 34-47986);
  - (c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusion about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
- The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
  - All significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2005 By: /s/ RAMESH C. TRIVEDI

Ramesh C. Trivedi

Chief Executive Officer

# CERTIFICATION

I, Charles J. Novak, Chief Financial Officer of Integrated Surgical Systems, Inc., certify that:

- I have reviewed this annual report on Form 10-KSB for the year ended December 31, 2004 of Integrated Surgical Systems, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
- The small business issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) (language intentionally omitted pursuant to SEC Release No 5 33-8238 and 34-47986) for the small business issue and have:
  - Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (Language intentionally omitted pursuant to SEC Release No 5 33-8238 and 34-47986);
  - (c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusion about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
- The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
  - All significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2005 By: /s/ CHARLES J. NOVAK Charles J. Novak

Chief Financial Officer

Exhibit 32.1

# CERTIFICATION

I, Ramesh C. Trivedi, Chief Executive Officer of Integrated Surgical Systems, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Annual Report on Form 10-KSB of the Company for the year ended December 31, 2004, which this certification accompanies (the "Periodic Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 15, 2005 /s/ Ramesh C. Trivedi
Ramesh C. Trivedi

Chief Executive Officer

# CERTIFICATION

I, Charles J. Novak, Chief Financial Officer of Integrated Surgical Systems, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Annual Report on Form 10-KSB of the Company for the year ended December 31, 2004, which this certification accompanies (the "Periodic Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 15, 2005 /s/ Charles J. Novak
Charles J. Novak

Chief Financial Officer