

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-QSB

Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 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.

(Exact name of small business issuer as specified in its charter)

Delaware

68-0232575

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

1850 Research Park Drive, Davis, California 95616-4884

(Address of principal executive offices)

(530) 792-2600
(Issuer's telephone number)

N/A

(Former name, former address and formal fiscal year, if changed since last report)

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

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: The number of shares of the issuer's common stock outstanding as of December 10, 2004 was 45,084,089.

Transitional Small Business Disclosure Format: Yes No

Integrated Surgical Systems, Inc. and Subsidiaries
Form 10-QSB
For the quarter ended September 30, 2004

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Part I. Financial Information
Item 1. Financial Statements (unaudited)

Integrated Surgical Systems, Inc. and Subsidiaries
Condensed Consolidated Balance Sheet
September 30, 2004
(Unaudited)

Assets	
Current assets:	
Cash	\$ 24,661
Accounts receivable	329,948
Inventories	608,591
Other current assets	31,962

Total current assets	995,162
Property and equipment, net	7,528

	\$ 1,002,690
	=====
Liabilities and stockholders' deficit	
Current liabilities:	
Accounts payable	\$ 2,351,630
Accrued payroll and related expense	1,558,027
Accrued liabilities	334,733
Unearned income	2,714,991
Other current liabilities	276,636

Total current liabilities	7,236,017
Commitments and contingencies	
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; 45,058,945 shares issued and outstanding	450,589
Additional paid-in capital	61,923,930
Accumulated deficit	(68,776,342)

Total stockholders' deficit	(6,401,823)

	\$ 1,002,690
	=====

See accompanying notes.

Integrated Surgical Systems, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,	
	2004	2003
Net revenue	\$ 139,140	\$ 539,406
Cost of revenue	135,501	704,710
	3,639	(165,304)
Operating expenses:		
Selling, general and administrative	235,744	571,132
Research and development	92,741	454,650
	328,485	1,025,782
Operating loss	(324,846)	(1,191,086)
Other income (expense), net:	(8,015)	134,779
Net loss	\$ (332,861)	\$ (1,056,307)
	=====	=====
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.02)
	=====	=====
Shares used in computing basic and diluted net loss per share	44,955,408	43,478,469
	=====	=====

See accompanying notes.

Integrated Surgical Systems, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

	Nine months ended September 30,	
	2004	2003
Net revenue	\$ 1,389,013	\$ 5,501,202
Cost of revenue	693,931	3,840,847
	-----	-----
	695,082	1,660,355
Operating expenses:		
Selling, general and administrative	918,888	1,942,115
Research and development	811,224	1,191,062
	-----	-----
	1,730,112	3,133,177
	-----	-----
Operating loss	(1,035,030)	(1,472,822)
Other income (expense), net:	(10,103)	231,669
	-----	-----
Net loss	\$ (1,045,133)	\$ (1,241,153)
	=====	=====
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.03)
	=====	=====
Shares used in computing basic and diluted net loss per share	44,924,130	42,681,766
	=====	=====

See accompanying notes.

Integrated Surgical Systems, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	\$(1,045,133)	\$(1,241,153)
Adjustments to reconcile net loss to net cash provided by (used in)		
Operating activities:		
Depreciation	18,039	218,944
Release of note payable related to loan	--	(109,262)
Non-cash compensation charge	21,200	--
Loss on disposal of fixed assets	4,829	--
Changes in operating assets and liabilities:		
Accounts receivable	(219,192)	912,800
Inventories	(121,636)	477,130
Other current assets	80,948	89,533
Accounts payable	388,781	20,520
Accrued payroll and related expenses	676,580	244,309
Accrued liabilities	(20,181)	102,909
Unearned income	(129,182)	(820,690)
Other current liabilities	99,546	31,414
Net cash used in operating activities	(245,401)	(73,546)
Cash flows from investing activities:		
Purchases of property and equipment	--	(17,708)
Proceeds on disposals of property and equipment	4,600	--
Net cash provided by (used in) investing activities	4,600	(17,708)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,954	--
Proceeds from officer advances and deferrals of salaries and unreimbursed travel expenses	180,799	483,825
Payments on officer advances, deferred salaries and unreimbursed travel expenses	(60,200)	(295,514)
Net cash provided by financing activities	122,553	188,311
Effect of exchange rate changes on cash	--	(103,348)
Net decrease in cash	(118,248)	(6,291)
Cash at beginning of period	142,909	82,069
Cash at end of period	\$ 24,661	\$ 75,778
	=====	=====
Supplemental disclosure of non-cash investing activity:		
Conversion of preferred stock:	\$ --	\$ 32,000

See accompanying notes.

Integrated Surgical Systems, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements (unaudited)
September 30, 2004

1. Basis of Presentation

The condensed consolidated financial statements have been prepared by Integrated Surgical Systems, Inc. (the "Company") pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted as permitted by such rules and regulations. While the interim financial information contained in this filing is unaudited, such financial statements reflect all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation. The results for interim periods are not necessarily indicative of the results to be expected for the entire fiscal year. These financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-KSB for the fiscal period ended December 31, 2003.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures. Actual results could differ from those estimates.

2. Results of Operations and Management's Plan

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying condensed consolidated financial statements for the nine-month period ended September 30, 2004, the Company incurred a net loss for such nine-month period of \$1,045,133 and had an accumulated deficit as of September 30, 2004 of \$68,776,342. For the year ended December 31, 2003, the Company incurred a net loss of \$3,250,219 and had an accumulated deficit at December 31, 2003 of \$67,731,209. The report of independent auditors on the Company's 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 September 30, 2005. This plan includes obtaining additional equity or debt financing, increasing product sales in existing markets, increasing sales of system upgrades, and further reductions in operating expenses as necessary (see notes 5 and 11). 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 in realizing the benefits of such plan, it is possible that the Company will cease operations and/or seek bankruptcy protection. The September 30, 2004 condensed 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 of the Company to continue as a going concern.

3. Inventories

At September 30, 2004, the components of inventories were:

Raw materials	\$123,031
Work-in-process	218,731
Finished goods	137,465
Deferred product development contract costs	129,364

	\$608,591
	=====

4. Warranty and Service Contracts

The Company offers a one-year warranty for parts and labor on all ROBODOC(R) systems. These warranties generally commence upon the completion of training and installation. In most cases, the Company's customers purchase a service contract, which includes 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 products. At September 30, 2004, the Company had no recorded warranty liability as all systems within the one-year warranty period were covered by service contracts. Revenue related to maintenance and service contracts is recognized ratably over the duration of the contract.

5. Securities Purchase 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 Company common stock at the investor's option. The convertible debenture is convertible 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 Quarterly Report on Form 10-QSB 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.

6. Stockholders' Equity

During the nine-month period ended September 30, 2004, 61,587 shares of common stock were issued as a result of employees exercising stock options at exercise prices ranging from \$0.025 to \$0.06 per share. The Company also issued 40,000 and 90,000 shares of its common stock, at \$ 0.095 and \$0.06 per share, respectively, as payment for services rendered.

7. Stock-Based Compensation

The Company uses the intrinsic value method in accounting for its employee stock options in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Under the intrinsic value method, when the exercise price of employee stock option equals or exceeds the market price of the underlying stock on the date of grant, no compensation expense is recognized. Stock option awards which are granted at less than fair market value result in the recognition of deferred compensation. Deferred compensation is shown as a reduction of stockholders' equity and is amortized to operating expenses over the vesting period of the stock award. The Company had no deferred compensation at September 30, 2004.

Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure of an Amendment of SFAS No. 123" and Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation," require the disclosure of certain information as if the Company had adopted the fair value provisions of SFAS No. 123. The table below illustrates the effect on net loss and net loss per share had the Company adopted the fair value provisions of SFAS No. 123 using the following assumptions: risk-free interest rates of 3.4% for the three-months and nine-month periods ended September 30, 2004 and 3.0% for the three-months and nine-month periods ended September 30, 2003; volatility factors of the expected market price of the common stock of 1.006 for the three-months and nine-month periods ended September 30, 2004 and 1.004 for the three-months and nine-month periods ended September 30, 2003 and an expected life of the option of 4 years.

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net loss	\$ (320,861)	\$(1,056,307)	\$(1,033,133)	\$(1,241,153)
Add: stock-based employee compensation included in reported net loss	--	--	--	--

Less: stock-based employee compensation expense, determined under fair value methods for all awards	(1,307)	(28,700)	(9,156)	(90,056)
	-----	-----	-----	-----
Pro forma net loss	<u>\$ (322,168)</u>	<u>\$(1,085,007)</u>	<u>\$(1,042,289)</u>	<u>\$ (1,331,209)</u>
Loss per share:				
Basic and diluted loss per share	\$ (0.01)	\$ (0.02)	\$ (0.02)	\$ (0.03)

8. Net Loss Per Share

Basic net loss per share is computed by dividing the net loss available to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and potential common shares outstanding during the period if their effect is dilutive. Potential common shares are comprised of shares issuable upon exercise or conversion of outstanding employee stock options, warrants and convertible preferred stock. The potential common shares issuable under stock options, warrants and preferred stock to purchase common shares have been excluded for the three and nine-month periods ending September 30, 2004 and 2003 from the diluted calculation because the effect of such shares would have been anti-dilutive.

At September 30, 2004, the Company had outstanding options to purchase an aggregate of 2,332,734 shares of common stock (with exercise prices ranging from \$0.025 to \$8.50 per share), warrants to purchase an aggregate 2,606,479 shares of common stock (with exercise prices from \$0.01 to \$0.0625 per share), and of Series G convertible preferred stock convertible into 3,150,333 shares of common stock. The exercise price and the ultimate number of shares of common stock issuable upon exercise of outstanding options and warrants and conversion of the Series G convertible preferred stock are subject to adjustments based upon the occurrence of certain future events.

9. Accumulated Other Comprehensive Loss

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	-----	-----	-----	-----
Net loss	\$ (332,861)	\$(1,056,307)	\$(1,045,133)	\$(1,241,153)
Other comprehensive income (loss):				
Foreign currency translation	--	(8,587)	--	(66,862)
	-----	-----	-----	-----
Comprehensive loss	<u>\$ (332,861)</u>	<u>\$(1,064,894)</u>	<u>\$(1,045,133)</u>	<u>\$(1,308,015)</u>
	=====	=====	=====	=====

10. 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 the Company would have sufficient funds available to satisfy any adverse judgement. Due to the inherent uncertainties of litigation, were there any such matters, the Company may not be in the position at any specific time to accurately predict a litigation's ultimate outcome. As of September 30, 2004, there were no current proceedings or litigation involving the Company that the Company believes, if judgement were rendered against the Company, would have a material adverse impact on its financial position, results of operations or cash flows

11. Subsequent Events

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 \$0.5 million in conjunction with the

signing of the agreement. Additional milestone payments totaling \$2.0 million will be paid to the Company over a two year period, assuming all such milestones are met.

Item 2. Management's Discussion and Analysis or Plan of Operation

Overview

The Company designs, manufactures, sells and services image-directed, computer-controlled robotic software and hardware products for use in orthopedic and neurosurgical procedures.

In 1997, the Company acquired a 100% interest in a French company, Innovative Medical Machines International. S. A. ("ISS-SA"), involved in the manufacturing and servicing of neurosurgical products. In the fourth quarter of 2003, the Company recorded a loss of \$1,516,519 in connection with the liquidation of the Company's investment in ISS-SA and closure of the Company's European operation.

The Company's revenue consists of product revenue, product development revenue, parts and consumables and service revenue.

Product revenue consists of the Company's principal orthopaedic product, the ROBODOC(R) Surgical Assistant System ("ROBODOC"), which integrates the ORTHODOC(R) Presurgical Planner ("ORTHODOC") with a computer-controlled robot for use in joint replacement surgeries. Also included in product revenue for the first and second quarters of 2003 are sales of the NeuroMate(TM) System ("NeuroMate"), which consists of a computer-controlled robotic arm, head stabilizer, presurgical planning workstation and proprietary software used to position and precisely hold critical tools during stereotactic brain surgery. The Company continues to market NeuroMate, although no sales have occurred since the end of the second quarter of 2003. 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. Fees for these services are recorded as product development revenue as earned.

The Company offers a one-year warranty for parts and labor on all ROBODOC systems. These warranties generally commence upon the completion of training and installation. In most cases, the Company's customers purchase a service contract, which includes 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 products. Revenue related to maintenance and service contracts is recognized ratably over the duration of the contract.

Results of Operations

For the three-month period ending September 30, 2004, net revenue decreased approximately 74% or \$0.4 million when compared to the three-month period ended September 30, 2003. Cost of revenue for the same three-month comparative periods decreased 81% or \$0.6 million which resulted in an increase in the gross margin of 102% or \$0.2 million. Operating expenses decreased during the three-month period ending September 30, 2004 compared to the same three-month period of 2003 by 61% or \$0.3 million, with an operating loss of approximately \$325,000 and net loss of approximately \$332,000 for the three-month period ended September 30, 2004 as compared to an operating loss of \$1,191,000 and net loss of \$1,056,000, respectively, for the same three-month comparative period in 2003. For the nine-month period ending September 30, 2004, net revenue decreased 75% or \$4.1 million when compared to the nine-month period ended September 30, 2003. Cost of revenue decreased 82% or \$3.2 million between the nine-month periods ended September 30, 2004 and 2003, which resulted in a decrease in the gross margin of 58% or \$1.0 million between the comparison periods. Operating expenses decreased during the nine-month period ending September 30, 2004 compared to the same nine-month period of 2003 by 53% or \$1.0 million, with an operating loss of approximately \$1,035,000 and net loss of approximately \$1,045,000 in the current nine-month period as compared to an operating loss of approximately \$1,473,000 and net loss of approximately \$1,241,000 for the 2003 nine-month comparative period.

Net Revenue

Net revenue of \$0.5 million for the third quarter of 2003 decreased to \$0.1 million for the third quarter of 2004. This 74% decrease for comparative quarters is due to the loss of almost \$0.4 million in net revenue generated by the Company's European operations, that were liquidated during the fourth quarter of 2003. The Company recorded no systems sales in the third quarter of 2003 or the third quarter of 2004. The only revenue derived during the third quarter of 2003 and the third quarter of 2004 was from development projects and servicing contracts. The revenues generated by service contracts, for the Company's non-European operations, for the third quarters of 2004 and 2003 was relatively flat.

Net revenue decreased 75% from \$5.5 million during the first nine-months of 2003 to \$1.4 million during the first nine months of 2004. The decrease in net revenue was primarily due to the elimination of \$3.0 million in net revenue generated by the Company's European operations, which were liquidated in December 2003. The remaining reduction of \$1.1 million in revenue in the first nine months of 2004, when compared to the first nine months of 2003, was primarily due to a decrease in product development revenue as a result of decreases in the number of projects and development activity that the Company's non-European operations were involved in. During the nine-month period ended September 30, 2003, the Company had recognized revenue on four ROBODOC systems and four NeuroMate systems while only two ROBODOC systems were sold for the same nine-month period of 2004. Both of the ROBODOC systems in 2004 were previously returned units, which were recorded in inventory at a zero dollar value, and have a lower average selling price when resold.

Cost of revenue

Cost of revenue decreased 81% from \$0.7 million during the third quarter of 2003 to \$0.1 million during the third quarter of 2004. The decrease in cost of revenue was primarily due to the elimination of \$0.3 million in cost of revenue generated by the Company's European operations, which were liquidated during the fourth quarter of 2003. The remaining reduction of \$0.3 million in the cost of revenue in the third quarter of 2004, when compared to the third quarter of 2003, primarily was the result of decreases in headcount and lease facility expenses allocated to manufacturing.

Cost of revenue for the nine-month period ended September 30, 2004 decreased 82% to \$0.7 million from \$3.8 million for the nine-month period ended September 30, 2003. The decrease in the cost of revenue was primarily due to the elimination of \$2.2 million in cost of revenue attributable to the Company's European operations. The remaining reduction in cost of revenue during the nine-month period ending September 30, 2004, when compared to the cost of revenue for the same period of the prior year, primarily was due to the decreases in the number of units shipped and cost reduction measures initiated during fiscal 2004 which included reductions in headcount and related expenses.

Gross margin, as a percentage of net revenue, increased from an approximate negative 31% for the three-month period ending September 30, 2003 to a positive 3% for the three-month period ending September 30, 2004 and increased from a positive 30% for the nine-month period ending September 30, 2003 to a positive 50% for the nine-month period ending September 30, 2004. The increase for the three and nine-month periods in 2004 was primarily due to the higher margins the Company enjoyed on the sale of refurbished units as well as cost reductions related to reduced headcount and manufacturing overhead costs.

Operating expenses

Total operating expenses have continued to decline as a result of the Company's cost reduction program and the liquidation of its European operations. Selling and general administrative expenses are comprised of salaries, commissions, travel expenses and costs associated with trade shows as well as the finance, legal and human resources departments and professional support fees for these functions. Selling and general administrative expenses for the three-month period ending September 30, 2004 decreased approximately 61% to \$0.2 million from \$0.6 million for the three-month period ending September 30, 2003. Selling and general administrative expenses for the nine-month period ending September 30, 2004 decreased 53% to \$1.0 million from \$1.9 million for the nine-month period ending September 30, 2003. The primary factor causing such decreases in

selling, general and administrative expense is the liquidation of the Company's European operation, which accounted for \$0.2 million and \$0.6 million of the decrease for the three and nine-month periods ended September 30, 2003, respectively. The remaining decrease in selling and general administrative expense for the three-month period ending September 30, 2004 is due to a reduction in staffing expense and rent expense. During the third quarter of 2004, the Company renegotiated the lease on its corporate headquarters and manufacturing facilities to reduce the size of the leased premises and the leased facilities expense by approximately 50%. In addition to the reduction of occupancy expense, selling and general administrative expense decreased in the nine-month period as a result of reduced headcount and commission expense resulting from lower sales volume.

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 approximately 80% from \$0.5 million to \$0.1 million for the three-month periods ending September 30, 2003 and 2004 respectively. The primary reason for this decrease was the reduction of the Company's direct and allocated research and development expenses through downsizing, and an increase in development projects performed for third-parties whose costs are deferred until the corresponding revenue is recognized.

Research and development expenses for the nine-month period ended September 30, 2004 decreased approximately 31% from the expenses for the 2003 nine-month period, after giving effect to \$125,000 in grant funding recorded by the Company as a reduction of research and development expense. The \$125,000, which was received in April 2003, was the final payment under a grant from the National Institute for Standards and Technology of the United States Department of Commerce ("NIST"). Under the terms of the NIST grant, the Company was entitled to reimbursement for certain of the expenses incurred in connection with the development of its revision hip surgery product. As of December 31, 2003, the Company had received a cumulative total of approximately \$1,221,000 in funding from NIST since 1995. The Company has recorded the proceeds from the NIST grant as a reduction of its research and development expenses.

During the three month period ended September 30, 2003, the Company recorded \$135,000 of other income (expense), net, of which \$109,000 resulted from a loan by the French national agency being forgiven. The French agency initially granted the loan in 1997. Under the terms of the loan, which was established for the development of a new neurological system, the balance could be forgiven upon review by the French agency. The remaining income for the three-month period ended September 30, 2003 resulted from favorable foreign currency exchange rates. For the nine-month period ending September 30, 2003, other income (expense), net was approximately \$232,000 as compared to (\$10,000) for the nine-month period ending September 30, 2004. The income for the first nine months of 2003 resulted from the loan forgiven by the French national agency and favorable currency exchange rate for the Euro related to the Company's business in Europe. The company was not effected by foreign currency exchange rates during the three-month and nine-month periods ending September 30, 2004.

Critical Accounting Policies and Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires the Company to make estimates and judgments that affect the reported amounts of 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's management has discussed these 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 condensed 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 Japanese customers 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.

The Company periodically evaluates the need for 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 its 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 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.

Liquidity and Capital Resources

The cash position of the Company is inadequate, and although the Company has identified potential sources of cash for future operations, there cannot be any assurance given that the Company will receive these cash amounts, or that these cash amounts will be sufficient to assure continuing operations. The report of independent auditors on the Company's 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 September 30, 2005. This plan includes obtaining additional equity or debt financing, increasing product sales in existing markets, increasing sales of system upgrades, and further reductions in operating expenses as necessary (see notes 5 and 11). 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 in realizing the benefits of such plan, it is possible that the Company will cease operations and/or seek bankruptcy protection. The September 30, 2004 condensed 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 of the Company to continue as a going concern.

At September 30, 2004 the Company's "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 5%. It has been difficult for the Company to meet obligations, including payroll, as they come due, and the Company expects this situation to continue through September 30, 2005. Net

cash used in operating activities was approximately \$245,000 for the nine-month period ended September 30, 2004. This primarily resulted from a net loss of \$1,045,000, an increase in accounts receivable of \$219,000, an increase in inventory of \$122,000, and a decrease in unearned income of \$129,000 which were partially offset by increases in accounts payable of \$389,000 and an increase in accrued payroll and related expenses of \$677,000 and \$100,000 of other current liabilities and \$81,000 decrease in other current assets. The \$100,000 in increase in other current liabilities is directly related to a financing agreement entered into by the Company on June 15, 2004. (See Note 5 of "Notes to Condensed Consolidated Financial Statements (unaudited)").

At September 30, 2004, the Company had amounts due to the executive officers of the Company of approximately \$1,146,000, in the aggregate, in the forms of, deferred salaries, unreimbursed travel expenses and noninterest bearing advance. Of the \$1,146,000, \$437,000, \$279,000 and \$94,000 are included in accrued payroll and related expense and accounts payable and accrued liabilities, respectively, due to Ramesh C. Trivedi, president and chief executive officer of the Company; \$132,000, \$25,000 and \$53,000 are included in accrued payroll and related expense and accounts payable and accrued liabilities, respectively, due to Leland Witherspoon, vice president of engineering of the Company; \$98,000 and \$28,000 are included in accrued payroll and related expense and accrued liabilities, respectively, due to Charles J. Novak, chief financial officer 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 into Company common stock at the investor's option. The convertible debenture is convertible 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 Quarterly Report on Form 10-QSB 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 \$0.5 million in conjunction with the signing of the agreement. Additional milestone payments totaling \$2.0 million will be paid to the Company over a two-year period, assuming all such milestones are met.

Item 3. Controls and Procedures

(a) Under the supervision and with the participation of management, including the Company's President and Chief Executive Officer and Chief Financial Officer, an evaluation was made of the effectiveness of the Company's disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, the President and Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of the end of the period covered by this quarterly report.

(b) There has been no change in the Company's internal control over financial reporting during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. Part II. Other Information

Item 1. 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 the Company would have sufficient funds available to satisfy any adverse judgement. Due to the inherent uncertainties of litigation, were there any such matters, the Company may not be in the position at any specific time to accurately predict a litigation's ultimate outcome. As of September 30, 2004, there were no current proceedings or litigation involving the Company that the Company believes, if judgement were rendered against the Company, would have a material adverse impact on its financial position, results of operations or cash flows.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the three-month period ended September 30, 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.

Item 3. Default Upon Senior Securities

None

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

None.

Item 5. Other Information

None.

Item 6. Exhibits

(a) Exhibits

- 10.1 Software Development Agreement dated November 17, 2003 between the Registrant and Fujifilm Medical Systems, USA
- 10.2 Software License Agreement dated July 29, 2004 between the Registrant and Fujifilm Medical Systems, USA
- 10.3 Amendment #1 to Software License Agreement dated December 14, 2004 between the Registrant and Fujifilm Medical Systems, USA
- 31.1 Certification Pursuant to Exchange Act Rule 13a-14(a) of Ramesh Trivedi
- 31.2 Certification Pursuant to Exchange Act Rule 13a-14(a) of Charles Novak
- 32.1 Certification Pursuant to 18 U.S.C. 1350 of Ramesh Trivedi
- 32.2 Certification Pursuant to 18 U.S.C. 1350 of Charles Novak

SIGNATURE

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

INTEGRATED SURGICAL SYSTEMS, INC.

By: /s/ CHARLES J. NOVAK

Charles J. Novak
(Principal Financial and
Accounting Officer)
(Duly Authorized Officer)

Dated: December 16, 2004

Software Development Agreement

Revised Nov 12, 2003

FUJIFILM Medical Systems USA (Fuji), and Integrated Surgical Systems (ISS) agree to work together on developing an integrated 2D and 3D Orthopedic pre-Surgical planning software which will be integrated in Fuji's Synapse(TM) product. The proposed approach is to base the software development on the existing Orthodoc(TM) technology and derivatives from ISS.

Since the Orthodoc(TM) product is currently based on CT scans (3D planning), it is agreed that Fuji and ISS will work together to add traditional X-ray based 2D and the required additional 3D planning features. At the end of this development both 2D and 3D Orthopedic planning features shall be available in Synapse.

The essential software development process proposed is as follows:

- o ISS shall reuse its core software libraries currently developed for Linux operating system and validate the functionality on windows platform.
- o ISS and Fuji shall work together to develop software directly for Fuji's Synapse product. This software shall provide the application level layer and will run directly in the Synapse environment. The software shall use the functionality from the core software libraries.

Since current Orthodoc technology supports driving the Robodoc(TM) system, it is agreed that all capability to control or drive the Robodoc system shall not be available in the integrated product as part of this agreement. Ability to integrate the Robodoc, if desired, shall be considered a separate project.

To accomplish this task, the following approach is proposed:

1. Clarify customer requirements for traditional 2D X-ray based planning features as well as requirements for additional 3D planning and develop requirements for the software. Included in this task is the following:
 - a. Fuji to identify customers who will be interviewed
 - b. ISS will supply two Orthodoc systems to help demonstrate the current features as well as receive comments from the customers.
 - c. ISS and Fuji will dedicate resources to accomplish this task
 - d. This activity may involve travel to Fuji's customers as well as to agreed upon tradeshows (such as RSNA and AAOS) where a larger group of Fuji's customers may be interviewed
 - e. Costs associated with trade show support shall be considered separately.
 - f. This activity is contingent upon receiving initial positive comments from Fuji customers traveling to Sacramento and meeting with Dr. Bargar.

2. Develop a technical architecture and plan (Interface Control Document)
 - a. Fuji and ISS engineering will work together to develop an architecture and a development plan for the total product which not only includes the software features for surgical planning but also an integration strategy with Fuji's Synapse product. b. This activity is contingent upon receiving positive comments from Fuji customers.
3. Develop alpha prototype using agreed upon development process
 - a. Initial software design and testing
 - b. Initial integration with Synapse
 - c. Review software with key customers
 - d. Determine finalization plan
4. Complete beta development

- a. Beta release for final customer review and final testing
 - b. Data collection for submission
5. USA Regulatory Submission
- a. Parallel to development, determine USA regulatory submission requirements
 - b. If submission is required then proceed with submission
6. International Regulatory submission
- a. Parallel to develop, determine international requirements
 - b. Prepare submission
 - c. Submission to each country is to be determined separately
7. Complete Product development
- a. Final release of system based on beta prototype for clinical use
 - b. Final product with documentation
8. Localization
- a. Fuji's Synapse product is a global product sold in international markets. The software architecture shall allow for language translation of the user interfaces such as menus, dialog boxes etc. Initial releases shall be in the following languages:
 - i. English
 - ii. Japanese
 - iii. French
 - iv. Italian
 - v. German
 - vi. Chinese
 - b. ISS and Fuji shall agree upon the proper technical approach for localization (local language requirements) of the jointly developed software

- c. ISS and Fuji shall agree upon the proper process to localize ISS developed software if a version for the requested language does not exist.
- d. Local implant manufacturer support shall be considered in the overall design.
 - i. ISS may negotiate separately to develop implant support for manufacturers not currently supported
 - ii. Fuji may request (as a separate project) that ISS develop implants for a specific manufacturer. Costs to be negotiated separately.

9. Software maintenance and updates

- a. Develop a process to allow Fuji to request changes to the software based on customer feedback b. Develop a process where ISS continues to release new capabilities c. Cost of maintenance and updates to be discussed at a later time. Fuji and ISS agree to work in good faith to keep maintaining the products to state of the art features and technology.

10. Licensing fees

- a. Licensing fees shall include all the features of the software. No segregation of 2D and 3D is being considered.
- b. Fuji and ISS shall work in good faith to determine appropriate licensing fees paid to ISS for the core libraries.

11. Cost structure

- a. ISS and Fuji shall develop a mutually acceptable cost structure and cost schedule for this project
- b. Runtime licensing and maintenance costs shall also be agreed upon.
- c. Execution of this agreement is dependent upon acceptable development costs as stated in Appendix A.

12. Exclusivity

- a. ISS agrees to offer the 2D and 3D integrated software developed for Synapse in conjunction with Fuji exclusively to Fuji to Market to Fuji's existing and future customers.
- b. ISS has the right to continue to offer its Orthodox product to any customer.
- c. ISS shall not engage in a similar development with a competitor of Fuji during the development period.
- d. ISS shall not offer the windows port of core technology to a Fuji competitor for a minimum of 18 months.
- e. Exclusivity begins from the date of this agreement

13. Cancellation

- a. Fuji reserves the right to cancel this agreement with a 30 day written notice at any time during the development.
- b. ISS reserves the right to cancel this agreement with a 30 day written notice at any time during the development.
- c. If either side cancels the agreement, the items stated in Intellectual Property shall still apply.
- d. If Fuji chooses to cancel the agreement, Fuji shall reimburse ISS for the work that is completed and not any work that is not completed
- e. If ISS chooses to cancel the agreement, Fuji shall not reimburse ISS for any completed and uncompleted work as Fuji will also incur a loss of time and resources spent.

14. Disclosure and confidentiality

- a. ISS agrees to disclose to Fuji if it is engaged in any relationship with Fuji's competitors during this agreement period.
- b. Fuji agrees to disclose to ISS if it is engaged in any relationship with ISS's competitors during this agreement period.
- c. If ISS engages in a relationship with Fuji's competitors, Fuji may decide to exercise its right to cancel this agreement
- d. If Fuji engages in a relationship with ISS's competitors, ISS may decide to exercise its right to cancel this agreement.
- e. This agreement and its contents shall be considered confidential by ISS and Fuji and not be disclosed to any other third party without consent from Fuji and ISS.
- f. In addition to this agreement, Fuji and ISS agree to sign a Non-Disclosure Agreement. Upon signing the non disclosure agreement shall be automatically extended to Fuji and ISS personnel who will be exposed to the confidential information.

15. Intellectual Property

- a. Any knowledge gained by ISS about Fuji's Synapse system shall be considered confidential and proprietary information. ISS shall not disclose such information to any organization except a direct healthcare organization without Fuji's permission.
- b. Conversely, any knowledge gained by Fuji about ISS's Orthodoc product shall be considered proprietary and shall be shared only with Fuji's customers
- c. Any current ISS software that is ported shall be the intellectual property of ISS.
- d. Software developed specifically for the Synapse application shall be the property of Fuji and ISS agrees to not disclose the details of the software to anyone without Fuji's permission.

- e. Any algorithms or high-level design performed jointly by ISS and Fuji shall be the intellectual property of both Fuji and ISS.
- f. Any algorithms or high-level design performed by ISS shall be the intellectual property of ISS
- g. Any algorithms or high-level design performed by Fuji shall be the intellectual property of Fuji.

16. Third party agreements

- a. If Fuji has prior agreements of confidentiality with suppliers of technology to Fuji, those agreements shall be agreed to by ISS. Fuji may require ISS to sign confidentiality agreements on behalf of the suppliers.
- b. If ISS has prior agreements of confidentiality with suppliers of technology (e.g with implant manufacturers) of confidentiality, those agreements shall be agreed to by Fuji. ISS may require Fuji to sign confidentiality agreements on behalf of the suppliers.

17. Escrow

- a. ISS agrees to allow Fuji to place the windows port of ISS software into Escrow if for whatever reason ISS decides to exit the business, or no longer supports the software, or another company purchases ISS and that company decides not to support this software.

18. Agreement period

- a. The period of this agreement is currently stated in Appendix A. It is to be considered as an estimate.
- b. Changes to the agreement shall be agreed to by Fuji and ISS whenever estimated schedules are delayed.

19. Payment terms

- a. Work mentioned in the agreement shall begin after the first payment is received by ISS.
- b. Standard payment terms are net 30 days after receipt of invoice.

Agreed by,

By: /s/ Clay Larsen	11/17/03	By: /s/ Ramesh Trivedi	11/17/03
-----	-----	-----	-----
Clay Larsen	Date	Ramesh Trivedi	Date
Vice President of		CEO	
Marketing and		Integrated Surgical	
Development		Systems	
FUJIFILM Medical			
Systems USA			

APPENDIX A

Payment process:

Project costs are categorized as follows:

- o Verification of Linux libraries on Windows platform. Costs include software engineering and testing resources
- o Joint development of application functionality. Costs include software engineering and testing resources.
- o Costs incurred for Market specification development
- o Assistance to Fuji for any regulatory documentation

The payments are made before the next activity starts provided that previous activity has been completed to Fuji's satisfaction. ISS shall invoice against a Fuji purchase order for each item in the purchase order as listed below.

Payment	Amount	Activity	Estimated Duration
1	\$200K	Get started with windows verification of libraries and market specification Complete market specification, develop a technical architecture,	1 Month from start for market spec. 2 months from start for technical architecture
2	\$200K	complete library verification effort and prototype	4 months from start for verification 5 months from start for prototype
3	\$240K	Complete beta software	9 months from start
4	\$150K	Deliver commercial software, necessary regulatory documentation	13 months from start
Total	\$790K		

ISS prefers a wire transfer form of payment method.

Bank of America
 555 Capitol Mall
 Sacramento, CA 95814
 Swift Code: BofAUS6S
 ABA Routing Number: 121000358
 Account Number: 14990-08126

SOFTWARE LICENSE AGREEMENT

This Software License Agreement ("Agreement") dated July 29, 2004, is by and between FUJIFILM Medical Systems U.S.A., Inc., a New York corporation ("Fuji") and Integrated Surgical Systems, Inc. a Delaware corporation ("ISS").

RECITALS

WHEREAS, ISS has developed pre-surgical planning software, using its proprietary technology, for use in surgeries involving the replacement of a knee or hip joint with a manmade metal joint and markets such software under the name Orthodoc™ ("Orthodoc");

WHEREAS, under valid licenses issued to ISS, Orthodoc incorporates data from multi-vendor prosthetic libraries for orthopedic implants (the "Third Party Content"), which ISS has converted, in order to render 3D templates for such orthopedic implants;

WHEREAS, Fuji has developed and markets a software product, Synapse(TM), which, among other things, enables the input and conversion of x-ray images into 2D digital images;

WHEREAS, Fuji and ISS, entered into a Software Development Agreement dated November 17, 2003 (the "Development Agreement"), whereby (a) ISS agreed to port Orthodoc, its existing 3D planning software technology, and all Third Party Content and core software libraries to function on a Windows(TM) platform (the "ISS Software") and (b) Fuji and ISS agreed, among other things, to work together, using the ISS Software, to develop user interfaces and features for an integrated 2D x-ray and 3D orthopedic implant pre-surgical planning system (the "Integrated Software"), to be owned and marketed by Fuji; and

WHEREAS, Fuji and ISS desire to enter into a license for the ISS Software, subject to and in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants contained herein, the parties agree as follows:

AGREEMENT

1. DEFINITIONS

In addition to any terms defined in the preamble and herein, the following is a list of defined terms used in this Agreement:

1.1 "Affiliate" means any entity that directly or indirectly, through one or more intermediaries, controls, or is controlled by or is under common control with Fuji or ISS (as the case may be).

1.2 "Documentation" means the ISS Software user guides, reference manuals, job aides, installation materials and other written or computer-generated materials.

1.3 "End User" means any entity, not an Affiliate of Fuji, that licenses the Fuji Product for internal use and not for resale.

1.4 "Fuji Product" means Synapse(TM) integrated with the Integrated Software and any other product developed by Fuji that contains, or is bundled or combined with the Integrated Software.

1.5 "Integrated Software" has the meaning set forth in the preamble hereof.

1.6 "ISS Software" has the meaning set forth in the preamble hereof and shall include all New Versions, Updates and Upgrades, in each case, all current and future foreign language versions thereof.

1.7 "License Fees" means the fees due to ISS for the ISS Software, pursuant to Section 4.1 hereof.

1.8 "Maintenance and Support Fee" means the fees due to ISS for the Maintenance, Upgrades, Updates New Versions or Third Party Content Update, pursuant to Section 4.2 hereof.

1.9 "Net Revenue" means that certain portion of the total license fee received by Fuji from an End User for a Fuji Product which Fuji, in its sole discretion, attributes to the license of the Integrated Software included therein or sold or licensed therewith.

1.10 "New Version" means any new version of the ISS Software, Orthodoc or the Third Party Content, for which the number to the left of the decimal point is increased. For example, Orthodoc 5.0 would be a New Version to Orthodoc 4.0. For purposes hereof, any release of ISS Software, Orthodoc or Third Party

Content in an additional language shall be considered a New Version whether or not released under a new number.

1.11 "Source Code" means those statements in a computer language, which, when processed by a compiler, assembler or interpreter, become executable by a computer and includes Source Code for the ISS Software, the Third Party Content and any and all software necessary for the integration and interface of the Third Party Content with and into the ISS Software.

1.12 "Third Party Content" has the meaning set forth in the preamble hereof and all other data regarding prosthetics and orthopedic implants that is now or hereafter used in or with the ISS Software and/or Orthodoc.

1.13 "Update" means a new release of the ISS Software, Orthodoc or the Third Party Content, which, for reason of additional functionality, the number to the right of the first decimal point is increased and includes Third Party Content Updates. For example, Orthodoc 4.1 would be an Update to Orthodoc 4.0.

1.14 "Upgrade" means a bug fix, workaround, or patch to correct any reproducible error in the ISS Software, Orthodoc or the Third Party Content.

2. LICENSE GRANT AND RIGHT OF USE

2.1 (a) License Grant. Subject to the terms and conditions of this Agreement, ISS grants to Fuji a perpetual, nontransferable (other than as set forth in Section 13.6 hereof) sublicensable license to use, reproduce, and/or modify the ISS Software to develop, create, manufacture, test, distribute, sell, maintain and support Fuji Products. Such license shall be exclusive to Fuji until May 16, 2005, and thereafter shall be nonexclusive. The license includes, but is not limited to, a license under any and all patents and any and all applications therefore, that have been filed or may be filed in the future with respect to the ISS Software and/or Orthodoc. ISS shall seek, obtain, and during the term hereof, maintain and enforce in its own name and at its own expense, appropriate patent, trademark and/or copyright protection for the ISS Software.

2.2 End User Licensing. Fuji agrees that each copy of a Fuji Product distributed by Fuji hereunder shall be accompanied by a copy of Fuji's standard end user software license; provided, however, that the terms of such license shall be drafted so as to apply to the ISS Software and shall be at least as protective of the ISS Software as the terms and conditions for the Fuji Product and the terms and conditions governing this Agreement.

2.3 Proprietary Notices. Fuji shall reproduce all copyright or other proprietary notices contained in the ISS Software code, as provided by ISS and ISS hereby conveys to Fuji a perpetual, nonexclusive, nontransferable license to use and reproduce such copyrights or other proprietary notices for the purposes of this Section 2.3. These notices may appear in conjunction with Fuji's notices.

2.4 Cooperation. Fuji may submit applications and information to the U.S. Food and Drug Administration and/or other governmental authorities for approvals or clearance of a Fuji Product containing, or combined or bundled with the ISS Software. At the request of Fuji, ISS shall cooperate with Fuji in submitting such applications and information, including providing such documentation as shall be necessary to obtain approval for the sale of such Fuji Product.

3. TERM

The term of this Agreement shall be five (5) years from the date hereof, unless terminated earlier as provided in this Agreement.

4. PAYMENT

4.1 License Fee. In consideration of the licenses granted in Section 2.1 hereof, Fuji shall pay ISS a License Fee equal to ten (10%) percent of the Net Revenue received by Fuji during the term of this Agreement. Notwithstanding the foregoing, ISS hereby grants to Fuji the right to distribute or sell fifteen (15) concurrent use licenses for the ISS Software without paying a License Fee.

4.2 Maintenance and Support Fee. In consideration of the Maintenance, Updates, Upgrades or New Versions to be provided to Fuji in accordance with Sections 5.1 and 5.2 hereof, Fuji shall pay ISS, in respect of each license of a Fuji Product, an annual Maintenance and Support Fee equal to fifteen (15%) percent of the License Fee payable hereunder for each year, other than the first year, during the term of such license.

4.3 Payment Terms. All fees due hereunder shall be paid quarterly on the last business day of each calendar quarter. Each such payment shall be accompanied by a written report from Fuji setting forth the nature and amount of each such payment.

5. MAINTENANCE, UPDATES, UPGRADES AND NEW VERSIONS

5.1 Maintenance. During the term of this Agreement, ISS shall correct or replace the ISS Software or provide an Upgrade necessary to remedy any programming error which is attributed to ISS. Such correction, replacement or services shall be promptly provided after Fuji has identified and notified ISS of any such error. All such corrections and replacements to be provided in accordance with this Section 5.1 shall function on a Windows(TM) platform. ISS shall assist Fuji in integrating all corrections and replacements into the Integrated Software.

5.2 Updates, Upgrades and New Versions. ISS shall promptly deliver to Fuji all Updates, Upgrades and New Versions, whichever is applicable. In no event will ISS deliver to Fuji an Update, Upgrade or New Version more than thirty (30) days following ISS's beta release and/or production release of the same. All Updates, Upgrades and New Versions shall function on a Windows(TM) platform. ISS shall assist Fuji in integrating all Updates, Upgrades and New Versions into the Integrated Software.

5.3 License of Updates, Upgrades and New Versions. Upon delivery of the foregoing items to Fuji, the licenses granted to Fuji pursuant to Section 2.1 hereof shall be deemed to include such items. Fuji acknowledges that during the term of this Agreement, in addition to delivering to Fuji the Updates, Upgrades and New Versions, ISS expects to release additional components and separate modules not described in Section 5.2 hereof for the ISS Software for which ISS may elect to require that licensees pay separate consideration and enter into separate agreements or amendments in order to have any rights to such modules or components.

6. OWNERSHIP

6.1 By ISS. Subject to the licenses granted herein, ISS retains all right, title and interest in and to the ISS Software. Fuji acknowledges that the licenses granted herein do not provide Fuji with title to or ownership of the ISS Software, but only the rights expressly set forth herein. No rights are granted other than the rights expressly set forth herein.

6.2 By Fuji. Fuji retains all right, title and interest in and to the Fuji Products. To the extent the Fuji Products contains any ISS Software, ISS retains all right, title and interest to such ISS Software as set forth in Section 6.1 hereof.

6.3 Source Code. ISS agrees to maintain the Source Code in both human and machine-readable form in escrow for the benefit of Fuji, at Fuji's sole expense, pursuant to a third-party escrow agreement in substantially the form annexed hereto as Exhibit A. To the extent that Fuji receives access to source code as set forth herein, ISS grants Fuji a non-exclusive license with the right to install and use, execute, display and modify the source code for the purposes of maintaining, operating, upgrading and enhancing the Fuji Products for use by Fuji pursuant to the license granted in Section 2.1 hereof.

7. WARRANTIES

7.1. ISS Warranties.

(a) Ownership. ISS represents and warrants to Fuji that: (i) it has the full power to enter into this Agreement, to carry out its obligations herein contained, and to grant the rights herein granted to Fuji and (ii) it is the owner of the ISS Software or otherwise has the right to grant to Fuji the license to use the same (including, without limitation all Third Party Content) as set forth in this Agreement without violating any rights of any third party, and there is currently no actual or threatened suit by any such third party based on an alleged violation of such right by ISS.

(b) Function. Subject to the limitations set forth in this Agreement, ISS warrants to Fuji that the ISS Software does not contain any virus, time bomb mechanism or other software or code that can disable or adversely affect any and all of the Integrated Software or destroy any data or other software and shall perform in conformance with the functional requirements set forth in the Documentation, in all material respects.

7.2 Fuji Warranty. Fuji represents and warrants to ISS that it has the full power to enter into this Agreement and to carry out its obligations herein contained.

8. WARRANTY DISCLAIMER

EXCEPT AS STATED IN SECTION 7 ABOVE, ISS PROVIDES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND SPECIFICALLY DISCLAIMS ANY WARRANTY OR CONDITION OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THIS AGREEMENT, INCLUDING WITHOUT LIMITATION WITH RESPECT TO THE ISS SOFTWARE, WHICH IS PROVIDED "AS IS".

9. LIMITATION OF LIABILITY

EXCEPT FOR LIABILITY UNDER SECTIONS 10 AND 12 HEREOF, IN NO EVENT SHALL ISS'S LIABILITY ARISING OUT OF THIS AGREEMENT EXCEED THE AMOUNTS RECEIVED BY ISS FROM FUJI HEREUNDER. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR LOST PROFITS OR ANY CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR INDIRECT DAMAGES, HOWEVER CAUSED OR INCURRED BY EITHER PARTY OR ANY THIRD PARTY AND ON ANY THEORY OF LIABILITY, ARISING OUT OF THIS AGREEMENT. EACH PARTY ACKNOWLEDGES AND AGREES THAT THE PRICE SET FORTH HEREIN IS BASED IN PART UPON THESE LIMITATIONS, AND FURTHER AGREES THAT THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

10. INDEMNIFICATIONS

10.1 ISS will indemnify, defend and hold harmless Fuji for any and all losses, claims, suits, proceedings, liabilities, causes of action, damages costs, expenses (including reasonable attorneys' fees and expenses) arising out of any claim, suit or proceeding brought against Fuji resulting, directly or indirectly, from a claim that the ISS Software supplied by ISS and when used as provided for by this Agreement, infringes any copyright, trade secret, trademark or patent of any third party. ISS will pay any award against Fuji, or settlement entered into on Fuji's behalf, based on such infringement only if Fuji notified ISS promptly in writing of the claim and provided reasonable assistance in connection with the defense and/or settlement thereof and permitted ISS to control the defense and/or settlement thereof; provided, however, that ISS shall not (a) have the right to control the defense if (i) Fuji shall have been advised by counsel that there are one or more legal or equitable defenses available to it which are different from or in addition to those available to ISS, and in the reasonable opinion of Fuji, ISS's counsel could not adequately represent the interests of Fuji because such interests could be in conflict with those of Fuji, (ii) such action or proceeding involves, or could have a material effect on, any material matter beyond the scope of the indemnification obligation of ISS, or (iii) ISS shall not have assumed the defense of any claim in a timely fashion, and (b) settle any claim without the prior written consent of Fuji, which consent shall not be unreasonably withheld or delayed. ISS shall have no liability to the extent the alleged infringement is caused by any unauthorized modifications or combination of the ISS Software with Fuji Products or other non-ISS equipment, programs or data, where the ISS Software alone would not have given rise to the claim.

10.2 ISS Options. In the event of an infringement action against Fuji with respect to the ISS Software, or in the event ISS believes such a claim is likely, ISS shall be entitled, at its option but without obligation to:

(a) appropriately modify the ISS Software, or substitute other ISS software product which, in ISS's good faith opinion, does not infringe any third party intellectual property rights;

(b) obtain a licensee with respect to the applicable third party intellectual property rights; or

(c) if neither (a) nor (b) is commercially practicable, terminate this Agreement and Fuji's licenses hereunder. In such case, the ISS shall refund to Fuji the entire amounts paid to ISS over the last year. This refund shall be in addition to the indemnification provided to Fuji in Section 10.1 above.

10.3 Entire Liability. Notwithstanding anything to the contrary, this Article 12 states ISS's entire liability for actual or alleged infringement of intellectual property rights.

10.4 Indemnification of ISS. Except for intellectual property infringement claims with respect to the ISS Software, Fuji agrees to indemnify and hold ISS harmless against any liability, or any litigation cost or expense (including reasonable attorneys fees), arising out of third party claims against ISS as a result of Fuji's use or distribution of the ISS Software. Fuji will pay any award against ISS, or settlement entered into on ISS's behalf, based on such infringement only if ISS notified Fuji promptly in writing of the claim and provided reasonable assistance in connection with the defense and/or settlement thereof and permitted Fuji to control the defense and/or settlement thereof; provided, however, that Fuji shall not (a) have the right to control the defense if (i) ISS shall have been advised by counsel that there are one or more legal or equitable defenses available to it which are different from or in addition to those available to Fuji, and in the reasonable opinion of ISS, Fuji's counsel could not adequately represent the interests of ISS because such interests could be in conflict with those of ISS, (ii) such action or proceeding involves, or could have a material effect on, any material matter beyond the scope of the indemnification obligation of Fuji, or (iii) Fuji shall not have assumed the defense of any claim in a timely fashion, and (b) settle any claim without the prior written consent of ISS, which consent shall not be unreasonably withheld or delayed. Fuji shall have no liability to the extent the alleged infringement is caused by any unauthorized modifications or combination of the ISS Software with the Fuji Product or other non-Fuji equipment, programs or data, where the Fuji Product alone would not have given rise to the claim.

10.5 Survival of Indemnification. The rights to indemnification provided in this Article 12 shall survive the termination of this Agreement.

11. TERMINATION

11.1 Termination for Cause. Either party may terminate this Agreement for the breach by the other party. The terminating party will first give the other party written notice of the breach and the alleged breaching party shall have fifteen (15) days in which to cure the alleged breach. If a cure is not achieved during the cure period, then the non-breaching party may terminate the Agreement upon written notice. Notwithstanding the foregoing, if, as a result of any event

regarding ISS, Fuji is unable to continue distributing, licensing or selling the ISS Software, Fuji may terminate this Agreement and ISS shall have no right to cure such breach.

11.2 Insolvency, Assignment, Bankruptcy or Nonavailability. Either party may terminate this Agreement upon written notice to the other party if the other party:

(a) becomes unable to pay debts in the ordinary course of business or as they become due, or is insolvent within the meaning of the federal bankruptcy laws;

(b) files or has filed against it a petition (or other document) under any bankruptcy law or similar law, which is unresolved within sixty days of the filing of such petition (or document);

(c) proposes any dissolution, liquidation, composition, financial reorganization or recapitalization with creditors;

(d) makes a general assignment or trust mortgage for the benefit of creditors;

(e) if a receiver, trustee, custodian or similar agent is appointed or takes possession of any of Fuji's or ISS's property or business; or

(f) is unable to perform its obligations hereunder.

11.3 Effect of Termination of Obligations. Termination of this Agreement will not affect any pre-termination obligation of either party under this Agreement, and any termination is without prejudice to the enforcement of any undischarged obligations existing at the time of termination. Regardless of any other provisions of this Agreement, neither party will by reason of the termination of this Agreement be liable for compensation, reimbursement, or damages on account of the loss of prospective profits on anticipated sales, or on account of expenditures, investments, leases or commitments in connection with either party's business or goodwill, or otherwise.

11.4 Effect of Termination of Licenses. Upon the termination or expiration of this Agreement, all of Fuji's rights and licenses with respect to the ISS Software shall survive. Notwithstanding the foregoing, unless this Agreement is terminated by ISS for Fuji's actual default by reason of non-payment of the License Fees and/or the Maintenance and Support Fees, Fuji shall be entitled to continue to distribute the ISS Software in accordance with Section 2.1 hereof, so long as Fuji continues to pay the applicable License Fees. Each End User license agreement in existence as of the effective date of termination shall survive in accordance with its terms.

12. CONFIDENTIALITY

12.1. Confidential Information. As used in this Agreement, the term "Confidential Information" shall mean any information disclosed by one party to the other pursuant to this Agreement which is in written, graphic, machine

readable or other tangible form and is contains current and future product information, research, development, trade secrets, financial and other business and/or proprietary information. Confidential Information may also include oral information disclosed by one party to the other.

12.2. Duty of Confidentiality. Each party shall treat as confidential all Confidential Information of the other party, shall not use such Confidential Information except as set forth herein, and shall use reasonable efforts not to disclose such Confidential Information to any third party. Without limiting the foregoing, each of the parties shall use at least the same degree of care that it uses to prevent the disclosure of its own Confidential Information of like importance to prevent the disclosure of Confidential Information disclosed to it by the other party under this Agreement. Each party shall promptly notify the other party of any actual or suspected misuse or unauthorized disclosure of the other party's Confidential Information.

12.3 Exceptions. Notwithstanding the above, neither party shall have liability to the other with regard to any Confidential Information of the other which the receiving party can prove:

(a) was in the public domain at the time it was disclosed or has become in the public domain through no fault of the receiving party;

(b) was known to the receiving party without restriction at the time of disclosure, as demonstrated by files in existence at the time of disclosure;

(c) is disclosed with the prior written approval of the disclosing party;

(d) was independently developed by the receiving party without any use of the Confidential Information;

(e) becomes known to the receiving party, without restriction, from a source other than the disclosing party without breach of this Agreement by the receiving party and otherwise not in violation of the disclosing party's rights;

(f) is disclosed generally to third parties by the disclosing party without restrictions similar to those contained in this Agreement; or

(g) such disclosure is required by order or requirement of a court, administrative agency, or other governmental body.

12.4 Confidentiality of Agreement. Each party shall be entitled to disclose the existence of this Agreement, but agrees that the terms and conditions of this Agreement shall be treated as Confidential Information and shall not be disclosed to any third party; provided, however, that each party may disclose the terms and conditions of this Agreement:

(a) as required by any court or other governmental body;

(b) as otherwise required by law;

(c) to legal counsel of the parties;

(d) in confidence, to accountants, banks, and financing sources and their advisors;

(e) in connection with the enforcement of this Agreement or rights under this Agreement; or

(f) in confidence, in connection with an actual or proposed merger, acquisition, or similar transaction.

12.5 Survival. Article 14 of this Agreement shall survive for one (1) year after the termination date of this Agreement.

13. GENERAL PROVISIONS

13.1 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, applicable to agreements entered into and to be performed wholly within such jurisdiction. All disputes arising out of this Agreement shall be subject to the exclusive jurisdiction of the courts of the State of New York and the parties agree and submit to the personal and exclusive jurisdiction and venue of these courts.

13.2 Partial Invalidity. If any provision in this Agreement shall be found or held to be invalid or unenforceable in any jurisdiction in which this Agreement is being performed, then the meaning of said provision shall be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement, which shall remain in full force and effect. In such event, the parties shall negotiate, in good faith, a substitute, valid and enforceable provision that most nearly effects the parties' intent in entering into this Agreement.

13.3 Independent Contractors. The parties hereto are independent contractors. Nothing contained herein or done in pursuance of this Agreement shall constitute either party becoming an agent of the other, for any purpose or in any sense whatsoever, or constitute the parties as partners or joint venturers. Fuji shall make no representations or warranties on behalf of ISS with respect to the ISS software products.

13.4 Modification. No alteration, amendment, waiver, cancellation or any other change in any term or condition of this Agreement shall be valid or binding on either party unless the same shall have been mutually assented to in writing by both parties.

13.5 Waiver. The failure of either party to enforce at any time any of the provisions of this Agreement, or the failure to require at any time performance by the other party of any of the provisions of this Agreement, shall in no way

be construed to be a present or future waiver of such provisions, nor in any affect the right of either party to enforce each and every such provision thereafter. The express waiver by either party of any provision, condition or requirement of this Agreement shall not constitute a waiver of any future obligation to comply with such provision, condition or requirement.

13.6 Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; provided, however, that neither party shall assign any of its rights, obligations, or privileges (by operation of law or otherwise) hereunder without the prior written consent of the other party; provided, further, that no such prior written consent shall be needed if Fuji assigns this Agreement to one of its Affiliates. Notwithstanding the foregoing, either party may assign this Agreement to a successor in interest (or its equivalent) of all or substantially all of its relevant assets, whether by sale, merger, or otherwise. Any attempted assignment in violation of this Section 13.6 shall be null and void.

13.7 Notices. Any notice required or permitted to be given by either party under this Agreement shall be in writing and shall be personally delivered or sent by commercial courier or by first class mail/air mail (certified or registered if available), or by telecopy confirmed by first class mail/air mail (registered or certified if available), to the other party at its address set forth below or such new address as may from time to time be supplied hereunder by the parties hereto.

If to Fuji:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT 06902
Attn: Clayton Larsen
Vice President, Marketing and Network Development
Tel: (203) 602-3678
Fax: (203) 353-0926

With a copy to:

Fuji Photo Film U.S.A., Inc.
200 Summit Lake
Valhalla, NY 10595
Attn: Jonathan File
General Counsel
Tel: (914) 789-8105
Fax: (914) 789-8514

If to ISS:

Integrated Surgical Systems, Inc.
1850 Research Park Drive
Davis, CA 95616
Attn: Ramesh Trivedi
Chief Executive Officer
Tel: (530) 792-2600
Fax: (530) 792-2690

13.8 Force Majeure. Notwithstanding anything else in this Agreement, and except for the obligation to pay money, no default, delay or failure to perform on the part of either party shall be considered a breach of this Agreement if such default, delay or failure to perform is shown to be due to causes beyond the reasonable control of the party charged with a default, including, but not limited to, strikes, lockouts or other labour disputes, riots, civil disturbances, actions or in actions of governmental authorities or suppliers, epidemics, war, embargoes, severe weather, fire, earthquakes, acts of God or the public enemy, nuclear disasters, or default of a common carrier.

13.9 No Third Party Beneficiaries. Unless otherwise expressly provided, no provisions of this Agreement shall be construed to confer upon or give to any person or entity other than ISS and Fuji any rights, remedies or other benefits under or by reason of this Agreement.

13.10 Entire Agreement. The terms and conditions herein contained, including all exhibits hereto, constitute the entire agreement between the parties and supersede all previous agreements and understandings, other than the Software Development Agreement, whether oral or written, between the parties hereto with respect to the subject-matter hereof. The terms and conditions of the Agreement shall automatically apply to each transaction between the parties contemplated by this Agreement notwithstanding any additional or different terms and conditions of the Software Development Agreement or other document.

13.11 Headings. The headings provided in this Agreement are for the convenience only and will not be used in interpreting or construing this Agreement.

[Signature page to follow]

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be signed by duly authorized officers of representatives.

FUJIFILM MEDICAL SYSTEMS U.S.A., INC.

By: /s/ Clayton Larsen

Name: Clayton Larsen

Title: Vice President, Marketing and Network Development

INTERGRATED SURGICAL SYSTEMS, INC.

By: /s/ Ramesh Trivedi

Name: Ramesh Trivedi

Title: Chief Executive Officer

Exhibit A

ESCROW AGREEMENT

14

AMENDMENT NO. 1 TO
SOFTWARE LICENSE AGREEMENT

AMENDMENT NO. 1, dated as of December 14, 2004 (this "First Amendment"), by and among FUJIFILM Medical Systems U.S.A., Inc., a New York corporation ("Fuji") and Integrated Surgical Systems, Inc. a Delaware corporation ("ISS").

WHEREAS, Fuji and ISS entered into that certain Software License Agreement dated July 29, 2004 (the "Software License Agreement"), pursuant to which ISS granted a license to Fuji for the ISS Software (as defined in the Software License Agreement) and the parties made agreements with respect to the relative rights each had with respect to the ISS Software and ISS agreed to provide certain maintenance and support for the ISS Software, Orthodoc and the Third Party Content (each as defined in the Software License Agreement);

WHEREAS, pursuant to the Software License Agreement, ISS and Fuji entered into a Preferred Escrow Agreement dated July 29, 2004 (the "Escrow Agreement"), whereby Fuji and ISS agreed that upon the occurrence of certain events, the source code for the ISS Software would be released to Fuji;

WHEREAS, Fuji desires to purchase from ISS, and ISS has agreed to sell to Fuji, a copy of the Source Code (as defined in the Software License Agreement, as amended by this First Amendment) including the Third Party Content, along with tangible and intangible assets and rights with respect to the Source Code, on the terms and conditions set forth herein; and

WHEREAS, Fuji desires to purchase from ISS, and ISS has agreed to sell to Fuji, a copy of the Third Party Content Development Process (as defined in herein), including any software development tools that are used to convert data from multi-vendor prosthetic libraries for orthopedic implants for integration into the ISS Software, along with tangible and intangible assets and rights with respect to the Third Party Content Development Process, on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Article 1 of the Software License Agreement is hereby amended as follows:

(a) Section 1.6 of the Software License Agreement is hereby amended by deleting such section and replacing such section with the following:

"1.6 "ISS Software" means Orthodoc, its existing 3D planning software technology and all Third Party Content and core software libraries ported to function on a Windows(TM) platform, and includes the Source Code for the ISS Software and the Third Party Content, as well as all New Versions, Updates and Upgrades thereto, respectively, and, in each case, all current and future foreign language versions thereof."

(b) Section 1.11 of the Software License Agreement is hereby amended by deleting such section and replacing such section with the following:

"1.11 "Source Code" means those statements in a computer language, which, when processed by a compiler, assembler or interpreter, become executable by a computer and includes Source Code for the ISS Software, the Third Party Content, as well as all New Versions, Updates and Upgrades thereto, respectively, and any and all Design Documents."

(c) Inserting after Section 1.14 the following:

"1.15 "Acceptance" means Fuji's verification that the delivered Source Code and/or Third Party Content Development Process on CD media represent the entire contents of Source Code and/or Third Party Content Development Process, respectively, that ISS possesses and, with respect to the Third Party Content Development Process, ISS uses in order to incorporate Third Party Content into the ISS Software, as of the date of the First Amendment."

"1.16 "Acceptance Notice" has the meaning set forth in Section 2.7(c) hereof."

"1.17 "Closing" has the meaning set forth in Section 2.7 hereof."

"1.18 "Design Documents" means all documentation (including all application programmer interface documentation in printed electronic format), manuals, tools, working papers and other documentation or methodologies reduced to writing and information related to the forgoing that has been reduced to writing and used by ISS to develop, enhance, modify and support the Source Code."

"1.19 "Development Agreement Completion Date" has the meaning set forth in Section 2.6(c) hereof."

"1.20 "First Amendment" means the First Amendment to this Agreement dated as of December ___, 2004, by and between Fuji and ISS."

"1.21 "License Exclusivity Period" has the meaning set forth in Section 2.1 hereof."

"1.22 "Purchase Price" has the meaning set forth in Section 2.6(b) hereof."

"1.23 "Source Code Purchase Price" has the meaning set forth in Section 2.6(b)(i) hereof."

"1.24 "Third Party Content Development Process" means the process used to develop and incorporate the Third Party Content into the ISS Software and Design Documents that relate to such process. This includes the Source Code for the Third Party Content Development Process, executable copies of the Third Party Content Development Process, and any and all software development tools that are used to convert data from multi-vendor prosthetic libraries for orthopedic implants for integration into the ISS Software, as well as all New Versions, Updates and Upgrades thereto."

"1.25 "Third Party Content Development Process Purchase Price" has the meaning set forth in Section 2.6(b)(ii) hereof."

2. Article 2 of the Software License Agreement is hereby amended as follows:

(a) Section 2.1 of the Software License Agreement is hereby amended by deleting such section in its entirety and replacing such section with the following:

"2.1 License Grant. Subject to the terms and conditions of this Agreement, ISS grants to Fuji a worldwide perpetual, irrevocable, fully-paid, royalty free, nontransferable (other than as set forth in Section 13.6 hereof) sublicensable license to use, reproduce, and/or modify the ISS Software to develop, create, manufacture, test, distribute, sell, maintain and support Fuji Products. Such license shall be exclusive to Fuji until December 31, 2005 (the "License Exclusivity Period"), and thereafter shall be nonexclusive. ISS also grants to Fuji a non-exclusive license to use, reproduce and/or modify the Third Party Content Development Process to develop, create, manufacture, test, distribute, sell, maintain and support Fuji Products. The license includes, but is not limited to, a license under any and all patents and any and all applications therefore, that have been filed or may be filed in the future with respect to the ISS Software, Orthodoc and/or Third Party Content Development Process. ISS shall seek, obtain, and during the term hereof, maintain and enforce in its own name and at its own expense, appropriate patent, trademark and/or copyright protection for the ISS Software and the Third Party Content Development Process."

(b) Inserting after Section 2.4 the following:

"2.5 Purchase of the Source Code and the Third Party Content Development Process. Subject to the terms and conditions of this Agreement, at the Closing (as defined in Section 2.7 hereof), ISS shall sell, transfer, convey and deliver to Fuji, and Fuji shall purchase, acquire and accept from ISS, a copy of the Source Code and the Third Party Content Development Process. "

"2.6 Purchase Price and Additional Payments. (a) Upon the execution of the First Amendment, Fuji shall pay \$500,000 to ISS. Notwithstanding any failure to pay the Purchase Price as set forth in Section 2.6(b) hereof, all of Fuji's rights and licenses as set forth in Section 2.1 hereof shall survive.

(b) As the purchase price for a copy of the Source Code and the Third Party Content Development Process, Fuji shall pay ISS the aggregate sum of \$1,600,000 (the "Purchase Price"), subject to Section 2.7 hereof, as follows:

(i) \$800,000 upon Fuji's receipt and acceptance of the Source Code in CD media at the Closing (the "Source Code Purchase Price"); and

(ii) \$800,000 upon Fuji's receipt and acceptance of the Third Party Content Development Process in CD media at the Closing (the "Third Party Content Development Process Purchase Price").

(c) ISS shall be entitled to an additional payment of \$400,000 from Fuji within five (5) business days after the completion of the Development Agreement (the "Development Agreement Completion Date"), as determined in the sole discretion of Fuji, and after ISS delivers to Fuji a copy of the Source Code as of the Development Agreement Completion Date.

"2.7 Closing. The closing (the "Closing") of the transaction whereby Fuji shall purchase the Source Code and the Third Party Content Development Process from ISS shall occur as follows:

(a) within ten (10) business days after the execution of the First Amendment, ISS shall deliver to Fuji a copy of the Source Code and the Third Party Content Development Process on CD media;

(b) Fuji shall have three (3) business days from the date of its receipt of the Source Code and the Third Party Content Development Process to verify the contents of the delivery; and

(c) upon Fuji's Acceptance of the Source Code and/or the Third Party Content Development Process, Fuji shall notify ISS in writing of its Acceptance (the "Acceptance Notice") of the Source Code and/or the Third Party Content Development Process, whichever is applicable, and shall, within three (3) business days of its delivery of the Acceptance Notice, deliver to ISS the Source Code Purchase Price and/or the Third Party Content Development Process Purchase Price, whichever is applicable, via wire transfer pursuant to instructions previously provided by ISS to Fuji."

"2.8 Acknowledgement of Development Agreement obligations. ISS hereby acknowledges and agrees to the following:

(a) within five (5) business days after the one year anniversary of the Development Agreement Completion Date, ISS shall deliver to Fuji all Updates, Upgrades and New Versions, if any, of the Source Code and Third Party Content Development Process;

(b) within five (5) business days after the second anniversary of the Development Agreement Completion Date, ISS shall deliver to Fuji all Updates, Upgrades and New Versions, if any, of the Source Code and the Third Party Content Development Process; and

(c) notwithstanding the foregoing, ISS shall also provide Maintenance, Update, Upgrades and New Versions to Fuji pursuant to Article 5 hereof and such obligations shall also apply to the Third Party Content Development Process."

"2.9 Bankruptcy. ISS acknowledges that if ISS as a debtor-in-possession or if a trustee in bankruptcy in a case under Title 11 of the United States Code, ss.101 et. seq. (the "Bankruptcy Code"), as the case may be, rejects this Agreement, Fuji may elect to retain its rights under this Agreement as provided in Section 365(n) of the Bankruptcy Code. Upon written request of Fuji to ISS or the bankruptcy trustee, whichever is applicable, ISS or the bankruptcy trustee shall not interfere with the rights of Fuji as provided in this Agreement."

3. Article 4 of the Software License Agreement is hereby amended by deleting such section in its entirety and replacing such section with the following:

"4. FURTHER COVENANTS"

"4.1 Non-Competition; Non-Interference. (a) ISS hereby covenants with Fuji that, until the expiration of the License Exclusivity Period, ISS shall not, either directly or indirectly, develop or assist in the development of any products that have similar functionality or are competitive with the products developed pursuant to the Development Agreement. In the event that ISS desires to create develop, co-develop or license any software for orthopedic templating or surgical planning purposes for non-PACS-related products with a company that may have PACS products that are competitive with Fuji Products, ISS shall submit an inquiry to Fuji regarding whether such company produces, distributes or markets any PACS-related product. Fuji shall, within five (5) business days, provide ISS with a written opinion regarding whether ISS's potential arrangement with such company would be in violation of this Section 4.1.

(b) Fuji hereby covenants with ISS that, until the expiration of the License Exclusivity Period, Fuji shall not, either directly or indirectly, develop or assist in the development of any products, including Third Party

Content, that have similar functionality or are competitive with the products developed pursuant to the Development Agreement, other than Fuji Products.

(c) Fuji hereby covenants with ISS that, after the expiration of the License Exclusivity Period and provided that the Development Agreement Completion Date has occurred, Fuji shall not, either directly or indirectly, create, develop or co-develop Third Party Content. In the event that Fuji desires to create, develop or co-develop any Third Party Content for orthopedic templating or surgical planning purposes, Fuji shall submit a notice to ISS requesting that ISS perform the tasks related to the Third Party Content at its then normal development rates and schedules. ISS shall thereafter have sixty (60) days from the date of such notice to negotiate and enter into a definitive agreement with Fuji and/or a third-party that provides Third Party Content, on terms reasonably agreeable to Fuji, to conduct such Third Party Content tasks for Fuji. In the event ISS, Fuji and/or such third-party are unable to reach a definitive agreement, then Fuji shall be free to enter an agreement with any third-party to perform such Third Party Content tasks or perform such Third Party Content tasks itself.

(d) ISS recognizes that these non-competition/non-interference restrictions are necessary to protect legitimate business interests, including trade secrets, confidential information, relationships with prospective and existing customers, and is provided by ISS to Fuji as further inducement for Fuji to license the ISS Software and purchase the Source Code."

"4.2 Right of First Negotiation for Co-Development Projects. (a) In the event that ISS desires to produce any new PACS-related product through a co-development project with any third-party, the following provisions shall apply. ISS shall notify Fuji in writing of its desire to produce a new PACS-related product. Fuji shall thereafter have thirty (30) days from the date of such notice to negotiate and enter into a definitive agreement to conduct the co-development project with ISS. Any such definitive agreement shall provide that ISS shall grant Fuji an exclusive license for such resulting products for a period of not less than three (3) years and contain such other terms as mutually agreed to by ISS and Fuji.

(b) If Fuji and ISS fail to enter into a definitive agreement with respect to such co-development project during the thirty-day period, then ISS shall be free to negotiate with and conclude an agreement with any third-party to conduct such co-development project on terms that are no less favorable than those last proposed by ISS to Fuji."

"4.3 Products Developed Independently By ISS. (a) In the event that ISS independently develops any new PACS-related product, ISS shall notify Fuji in writing. Fuji shall thereafter have thirty (30) days (the "License Negotiation Period") to negotiate and enter into a license with ISS with respect to such PACS-related product. Any such license with Fuji shall provide that ISS shall grant Fuji an exclusive license for a period to be mutually agreed to by Fuji and ISS and contain such other terms as mutually agreed to by ISS and Fuji.

(b) If, upon expiration of the License Negotiation Period, Fuji and ISS fail to enter into an exclusive license agreement for such PACS-related product, ISS may offer an exclusive license to any third-party on terms no more favorable than those last proposed to Fuji."

4. Officer's Certificate. In connection herewith and in order to induce Fuji to enter into this First Amendment, simultaneously with the execution of this First Amendment, ISS will deliver to Fuji a certificate of an officer of ISS certifying that all of ISS's representations and warranties contained in the Software License Agreement are true and correct and will be true and correct as of the date of this First Amendment.

5. No Other Modifications. Except as modified hereby, the Software License Agreement shall in all other respects remain in full force and effect. From and after the date first set forth above, all references in the Software License Agreement shall be deemed to be references to the Software License Agreement and this First Amendment.

6. Entire Agreement. This First Amendment, the Software License Agreement, the Development Agreement and the Escrow Agreement contain the entire agreement between the parties hereto and supersedes any and all prior agreements and understandings between the parties relating to the same subject matter.

7. Governing Law. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of New York applicable to agreements to be performed wholly within said state.

8. Successor and Assigns. This First Amendment shall be binding upon and shall inure to the benefit of the successors or assigns of the parties.

9. No Third Party Rights. This First Amendment is made solely for the benefit of the parties to this First Amendment, as well as Fuji Photo Film Co. Ltd., and their respective permitted successors and assigns, and no other person or entity shall have or acquire the right by virtue of this First Amendment unless otherwise agreed to, in writing, by the parties hereto.

10. For convenience of the parties, this First Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature page follows]

IN WITNESS WHEREOF, Fuji and ISS have caused this First Amendment to be executed as of the date first written above by their respective officers thereunto duly authorized.

FUJIFILM MEDICAL SYSTEMS U.S.A., INC.

By: /s/ Takushi Nasu

Name: Takushi Nasu
Title: President

INTEGRATED SURGICAL SYSTEMS, INC.

By: /s/ Ramesh Trivrdi

Name: Ramesh Trivedi
Title: Chief Executive Officer

CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-QSB for the quarter ended September 30, 2004 of Integrated Surgical Systems, Inc.;
2. 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;
3. 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;
4. 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) for the small business issuer and have:
 - (a) 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;
 - (b) 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
 - (c) 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
5. 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):
 - (a) 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
 - (b) 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: December 16, 2004

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:

1. I have reviewed this Quarterly Report on Form 10-QSB for the year quarter ended September 30, 2004 of Integrated Surgical Systems, Inc.;
2. 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;
3. 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;
4. 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) for the small business issuer and have:
 - (a) 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;
 - (b) 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
 - (c) 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
5. 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):
 - (a) 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
 - (b) 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: December 16, 2004

By: /s/ CHARLES J. NOVAK

Charles J. Novak
Chief Financial Officer

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:

1. The Quarterly Report on Form 10-QSB of the Company for the quarter ended September 30, 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: December 16, 2004

/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:

1. The Quarterly Report on Form 10-QSB of the Company for the quarter ended September 30, 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: December 16, 2004

/s/ Charles J. Novak

Charles J. Novak
Chief Financial Officer