INTERNATIONAL REMOTE IMAGING SYSTEMS INC /DE/
Form 10-Q
November 05, 2003

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarter ended	Commission File No.
September 30, 2003	No. 1-9767

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	94-2579751
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

9172 Eton Avenue, Chatsworth, CA.	91311
(Address of principal executive offices)	(Zip Code)

Registrant's Telephone Number: (818) 709-1244

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") during the preceding 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 X No

The registrant had 11,722,986 shares of common stock outstanding as of October 22, 2003.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.

INDEX TO FORM 10-Q

Three and Nine Months Ended September 30, 2003

PART I

FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS

Assets

	At September 30, 2003 (unaudited)	At December 31, 2002
Current assets:		
Cash and cash equivalents	$ 1,039,933	$ 2,336,973
Accounts receivable, net of allowance for doubtful accounts of $268,901 in 2003 and $298,324 in 2002	5,475,114	4,312,965
Inventories	5,761,589	5,423,684
Prepaid expenses and other current assets	492,470	330,245
Investments available for sale	489,421	847,816
Deferred tax asset	998,663	998,663
Total current assets	14,257,190	14,250,346
Property and equipment, at cost, net of accumulated depreciation of $5,505,687 in 2003 and $5,050,140 in 2002	3,627,884	2,896,008
Goodwill	188,911	188,911
Software development costs, net of accumulated amortization of $1,588,675 in 2003 and $1,545,007 in 2002	2,287,889	1,907,782
Deferred tax asset	7,870,728	7,280,718
Loan to related party	--	125,000
Other assets	490,308	574,729
Total assets	$28,722,910	$27,223,494

Liabilities And Shareholders' Equity

Current liabilities:		
Short-term borrowings	$ 2,500,000	$ 1,000,000
Current portion of long-term debt	350,000	1,383,192
Accounts payable	3,186,967	2,654,076
Accrued expenses	2,304,727	1,857,164
Deferred income - service contracts and other	1,155,310	910,515
Total current liabilities	9,497,004	7,804,947
Long term debt	1,854,508	1,862,276
Deferred income - service contracts and other	283,146	206,982
Total liabilities	11,634,658	9,874,205
Shareholders' equity:		
Common stock, $.01 par value; Authorized: 50,000,000 shares Shares issued and outstanding: 2003 - 11,221,996 and 2002 - 10,844,990	112,218	108,448
Additional paid-in capital	42,547,078	41,891,355
Unearned compensation	(111,236)	(16,378)
Accumulated other comprehensive loss	(255,501)	(40,464)
Accumulated deficit	(25,204,307)	(24,593,672)
Total shareholders' equity	17,088,252	17,349,289
Total liabilities and shareholders' equity	$28,722,910	$27,223,494

The accompanying notes are an integral part of these consolidated financial statements.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the three months ended September 30,	
	2003	2002
Sales of IVD systems	$ 2,330,079	$ 1,522,700
Sales of IVD supplies and services	4,379,321	3,945,963
Sales of small instruments and supplies	1,534,873	1,455,107
Royalties and licensing revenues	176,660	148,372
Net revenues	8,420,933	7,072,142
Cost of goods - IVD systems	1,850,473	1,015,922
Cost of goods - IVD supplies and services	1,552,308	1,592,736
Cost of goods - small instruments and supplies	754,192	715,198
Cost of goods sold	4,156,973	3,323,856
Gross margin	4,263,960	3,748,286
Marketing and selling	1,551,107	1,063,659
General and administrative	1,383,649	1,290,348
Research and development, net	1,039,511	1,150,280
Total operating expenses	3,974,267	3,504,287
Operating income	289,693	243,999
Other income (expense):		
Interest income	6,944	13,578
Interest expense	(83,358)	(120,881)
Other income	486	36,294
Income before income taxes	213,765	172,990
Income tax provision	85,506	69,196
Net income	$128,259	$103,794
Net income per common share		
- basic	$0.01	$0.01
- diluted	$0.01	$0.01
Weighted average number of common shares outstanding		
- basic	11,208,431	10,688,591
- diluted	12,450,707	11,501,501

The accompanying notes are an integral part of these consolidated financial statements.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the nine months ended September 30,	
	2003	2002
Sales of IVD systems	$ 3,735,792	$ 3,957,620
Sales of IVD supplies and services	12,691,198	12,169,609
Sales of small instruments and supplies	4,263,300	4,274,014
Royalties and licensing revenues	395,616	404,291
Net revenues	21,085,906	20,805,534
Cost of goods - IVD systems	3,340,848	2,383,442
Cost of goods - IVD supplies and services	4,650,072	4,697,793
Cost of goods - small instruments and supplies	2,173,331	2,088,103
Cost of goods sold	10,164,251	9,169,338
Gross margin	10,921,655	11,636,196
Marketing and selling	3,740,814	3,084,335
General and administrative	4,431,778	3,677,660
Research and development, net	3,526,836	3,250,425
Total operating expenses	11,699,428	10,012,420
Operating income (loss)	(777,773)	1,623,776
Other income (expense):		
Interest income	29,982	42,563
Interest expense	(270,457)	(429,012)
Other income	524	37,570
Income (loss) before income taxes	(1,017,724)	1,274,897
Income tax provision (benefit)	(407,090)	509,959
Net income (loss)	$(610,634)	$764,938
Net income (loss) per common share		
- basic	$(0.06)	$0.07
- diluted	$(0.06)	$0.07
Weighted average number of common shares outstanding		
- basic	11,088,869	10,472,553
- diluted	11,088,869	11,552,302

The accompanying notes are an integral part of these consolidated financial statements.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	For the nine months ended September 30,	
	2003	2002
Operating activities:		
Net income (loss)	$(610,634)	$764,938
Adjustments to reconcile net income (loss) to net cash provided (used) by operations:		
Deferred taxes	(446,652)	437,531
Depreciation and amortization	681,334	751,826
Common stock and stock option compensation amortization	57,738	47,625
Changes in assets and liabilities:		
Accounts receivable, net - trade and other	(1,164,138)	300,918
Service contracts, net	322,948	(115,055)
Inventories	(337,905)	298,669
Prepaid expenses and other current assets	(162,225)	(83,406)
Other assets	(27,438)	(147,832)
Accounts payable	532,891	(567,221)
Accrued expenses	484,070	210,884
Net cash provided (used) by operating activities	(670,011)	1,898,877
Investing activities:		
Acquisition of property and equipment	(1,187,908)	(1,361,410)
Loan to related party	125,000	(125,000)
Software development costs	(423,775)	(604,841)
Net cash used by investing activities	(1,486,683)	(2,091,251)
Financing activities:		
Borrowings under line of credit	7,000,000	3,500,000
Repayments of line of credit	(5,500,000)	(2,500,000)
Borrowings under term loan	--	1,500,000
Repayments of term loan	(235,485)	(2,483,332)
Repayment of notes payable	(875,250)	(875,250)
Payments of capital lease obligations	(36,508)	(25,776)
Issuance of common stock for cash	506,897	556,791
Net cash provided (used) by financing activities	859,654	(327,567)
Net decrease in cash and cash equivalents	(1,297,040)	(519,941)
Cash and cash equivalents at beginning of period	2,336,973	2,312,451
Cash and cash equivalents at end of period	$1,039,933	$1,792,510
Supplemental schedule of non-cash investing and financing activities:		
Issuance of common stock, options and warrants in exchange for services	152,596	10,000
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 146,723	$ 224,741
Cash paid for income taxes	56,064	64,680

The accompanying notes are an integral part of these consolidated financial statements.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited)

	For the three months ended September 30,	
	2003	2002
Net income	$128,259	$103,794
Unrealized loss on investments, net of taxes	(50,869)	(224,289)
Comprehensive income (loss)	$77,390	$(120,495)

	For the nine months ended September 30,	
	2003	2002
Net income (loss)	$(610,634)	$764,938
Unrealized loss on investments, net of taxes	(215,037)	(164,168)
Comprehensive income (loss)	$(825,671)	$600,770

The accompanying notes are an integral part of these consolidated financial statements.

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Formation and Business of the Company.

International Remote Imaging Systems, Inc., (collectively "IRIS" or the "Company") was incorporated in California in 1979 and reincorporated during 1987 in Delaware. International Remote Imaging Systems, Inc. and its subsidiaries design, develop, manufacture and market *in vitro* diagnostic ("IVD") equipment, including IVD imaging systems based on patented and proprietary automated intelligent microscopy ("AIM") technology, as well as special purpose centrifuges and other small instruments for automating microscopic procedures performed in clinical laboratories.

2. Summary of Significant Accounting Policies.

Basis of Presentation of Unaudited Interim Financial Statements:

In the opinion of management, the accompanying unaudited consolidated financial statements contain all normal recurring adjustments necessary to present fairly the financial position of the Company as of September 30, 2003 and 2002 and the results of its operations for the three and nine month periods then ended. These financial statements should be read in conjunction with the financial statements and notes included in the Company's latest annual report on Form 10-K. Interim results are not necessarily indicative of results for a full year.

Use of Estimates:

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 of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting periods.

The significant estimates in the preparation of the consolidated financial statements relate to the assessment of the carrying value of accounts receivables, inventories, purchased intangibles, estimated provisions for warranty costs and deferred tax assets. Actual results could materially differ from those estimates.

Principles of Consolidation:

The consolidated financial statements include the accounts of International Remote Imaging Systems, Inc. and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in the consolidated financial statements.

Stock Based Compensation:

The Company has adopted the disclosure only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation." SFAS 123 defines a fair value based method of accounting for an employee stock option. Fair value of the stock option is determined considering factors such as the exercise price, the expected life of the option, the current price of the underlying stock and its volatility, expected dividends on the stock, and the risk-free interest rate for the expected term of the option. Under the fair value based method, compensation cost is measured at the grant date based on the fair value of the award and is recognized over the service period. Pro forma disclosures for entities that elect to continue to measure compensation cost under the intrinsic method provided by Accounting Principles Board Opinion No. 25 must include the effects of all awards granted. The Company accounts for stock-based awards to non-employees in accordance with SFAS 123. An expense is recognized for common stock, warrants or options issued or re-priced, and for services rendered by non-employees based on the estimated fair value of the security exchanged.

If compensation expense for the stock options had been determined using "fair value" at the grant date for awards in the third quarter and first nine months of 2003 and 2002, consistent with the provisions of SFAS 148, the Company's net income (loss) and income (loss) per share would have been reduced to the pro forma amounts indicated below:

	For the Three Months Ended September 30,	
	2003	2002
Net income, as reported	$ 128,259	$ 103,794
Add: stock based employee compensation expense included in reported income, net of related tax effects	11,811	8,888
Deduct: total stock-based employee compensation expense determined under fair value based methods for all awards, net of related tax effects	107,942	53,415
Pro forma net income	32,128	59,267
Income per basic share as reported	0.01	0.01
Income per basic share pro forma	0.00	0.00
Income per diluted share as reported	0.01	0.01
Income per diluted share pro forma	0.00	0.00

	For the Nine Months Ended September 30,

	2003	2002
Net income (loss), as reported	$ (610,634)	$ 764,938
Add: stock based employee compensation expense included in reported income, net of related tax effects	34,643	28,575
Deduct: total stock-based employee compensation expense determined under fair value based methods for all awards, net of related tax effects	417,099	234,614
Pro forma net income (loss)	(993,090)	558,899
Income (loss) per basic share as reported	(0.06)	0.07
Income (loss) per basic share pro forma	(0.09)	0.05
Income (loss) per diluted share as reported	(0.06)	0.07
Income (loss) per diluted share pro forma	(0.09)	0.05

The pro forma calculations above are for informational purposes only. Future calculations of the pro forma effects of stock options may vary significantly due to changes in the assumptions described above as well as future grants and forfeitures of stock options.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are customer obligations due under normal trade terms. We sell our products to distributors primarily in the healthcare industry. We perform continuing credit evaluations of our customers' financial condition and although we generally do not require collateral, letters of credit may be required from our customers in certain circumstances.

Senior management reviews accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. We include any accounts receivable balances that are determined to be uncollectible, along with a general reserve, in our overall allowance for doubtful accounts. After all attempts to collect a receivable have failed, the receivable is written off against the allowance. Based on the information available to us, we believe our allowance for doubtful accounts as of September 30, 2003 is adequate. However, actual write-offs might exceed the recorded allowance.

Recent Accounting Pronouncements:

In April 2003, the FASB issued SFAS 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments and for hedging activities under SFAS 133, "Accounting for Derivative Instruments and Hedging Activities." The adoption of SFAS 149 did not have a material effect on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The Company does not currently have any such financial instruments and so is not currently affected by SFAS 150.

In November 2002, the FASB Emerging Issues Task Force ("EITF") reached a consensus on Issue 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). In the absence of higher level accounting literature, EITF 00-21 governs how to separate and allocate revenue to goods or services or both that are to be delivered in a bundled sales arrangement. EITF 00-21 applies to revenue arrangements entered into after June 30, 2003 and allows for either prospective application or cumulative adjustment upon adoption. We have adopted the guidance of EITF 00-21 with no material impact on its results of operations and financial condition.

Guarantees and Indemnifications

Under its bylaws, the Company has agreed to indemnify its officers and directors for certain events or occurrences arising as a result of the officer or director's serving in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The Company has a separate indemnification agreement with one of its directors that requires it, subject to certain exceptions, to indemnify him to the fullest extent authorized or permitted by its bylaws and the California Corporation Code. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. However, the Company has a directors and officer liability insurance policy that limits its exposure and enables it to recover a portion of any future amounts paid. As a result of its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal and has no liabilities recorded for these agreements as of September 30, 2003.

The Company enters into indemnification provisions under (i) its agreements with other companies in its ordinary course of business, typically with business partners, contractors, and customers, landlords and (ii) its agreements with investors. Under these provisions the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities or, in some cases, as a result of the indemnified party's activities under the agreement. These indemnification provisions often include indemnifications relating to representations made by the Company with regard to intellectual property rights. These indemnification provisions generally survive termination of the underlying agreement. In addition, in some cases, the Company has agreed to reimburse employees for certain expenses and to provide salary continuation during short-term disability. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of September 30, 2003.

Reclassifications:

Certain reclassifications have been made to the 2002 financial statements to conform to the 2003 presentation.

3. Comprehensive Income.

The Company's components of comprehensive income are net income (loss) and unrealized losses on investments. The income tax effect allocated to the unrealized losses on available for sale securities for the three and nine months ended September 30, 2003 was a benefit of $33,913 and $143,358, respectively.

The following is a reconciliation of accumulated other comprehensive income (loss) balance for the three and nine months ended September 30, 2003:

	Three months	Nine months
Beginning balance	$(204,632)	$(40,464)
Current period change	(50,869)	(215,037)
Ending balance	$(255,501)	$(255,501)

4. Inventories.

Inventories are carried at the lower of cost or market on a first-in, first-out basis and consist of the following:

	At September 30, 2003	At December 31, 2002
Finished goods	$1,798,672	$1,972,320
Work-in-process	334,797	167,839
Raw materials, parts and sub-assemblies	4,561,019	4,081,424
	6,694,488	6,221,583
Reserved for obsolescence	(932,899)	(797,899)

Net inventories	$5,761,589	$5,423,684

5. Related Party Transaction

In April 2002, the Company made a $125,000 loan to Dr. John A. O'Malley, then the Chairman, CEO and President of the Company (and currently, the Chairman of the Board of the Company), in accordance with his employment agreement. The loan bore interest at the rate of five percent per annum and had a term of five years. In June 2003, Dr. O'Malley repaid the loan in full, including interest.

6. Short-Term Borrowings and Notes Payable.

The Company has an $8.0 million credit facility with California Bank and Trust, which consists of a $500,000 term loan, a $1.0 million term loan and a $6.5 million revolving line of credit. The $500,000 term loan is payable in 60 equal monthly installments. The $1.0 million term loan carried interest only for the first 12 months, followed by 48 months of equal principal payments plus interest, commencing in March, 2003. The $6.5 million credit line matures in June 2004. Borrowings under the line of credit are limited to a percentage of eligible receivables and inventory. Dependent on the Company's debt service coverage ratio, the entire credit facility bears interest at a rate range between the lender's prime rate (4.0% at September 30, 2003), or LIBOR rate plus 2.0% and the lender's prime rate plus 1.0% or LIBOR rate plus 3.0%.

At September 30, 2003, the Company was not in compliance with certain of its debt covenants; however California Bank and Trust has executed a forbearance agreement with the Company relieving it of compliance with these certain debt covenants for the third quarter of 2003. As part of that agreement, the Company has agreed to maintain a minimum excess borrowing availability of $400,000 under its line of credit.

At September 30, 2003, the outstanding amounts under the Company's credit facility consist of $333,000 under the first term loan, $833,000 under the second term loan and $2.5 million under the revolving line of credit. An additional $1.3 million was available under the line of credit at that date, after allowing for the $400,000 minimum excess borrowing availability requirement mentioned above.

At September 30, 2003, the outstanding principal balance on the unsecured Subordinated Note Payable was $1.1 million. The note is payable in monthly installments of approximately $97,000 plus interest on the unpaid balance. The note bears interest at the prime rate (4.0% on September 30, 2003) plus 2.0% and matures on July 31, 2004. However, on September 30, 2003, California Bank and Trust invoked its rights under the Subordination Agreement to stop the Company from making future payments of the amounts owed on the Subordinated Note Payable until further notice. Since the timing of future payments is indeterminate, the remaining balance of the note is classified as non-current in the financial statements.

7. Capital Stock.

Stock and Stock Option Issuances:

During the nine months ended September 30, 2003, the Company (i) issued 347,517 shares of common stock from the exercise of options, (ii) issued options to purchase 278,500 shares of common stock under the Company's stock option plans, (iii) issued options to purchase 290,000 shares of common stock under special inducement grants and (iv) cancelled options to purchase 62,984 shares of common stock. At September 30, 2003, options to purchase 2,833,709 shares of common stock were issued and outstanding under the Company's stock options plans and special inducement grants. The outstanding options expire by the end of 2012. The exercise price for these options ranges from $0.69 to $4.38 per share. At the Company's annual meeting in June 2003, shareholders approved a 1.0 million share increase in the number of shares available for future grants under the Company's 1998 Stock Option Plan. At September 30, 2003, there were 947,718 shares of common stock available for the granting of future options under all of the Company's stock option plans.

On October 20, 2003, the Company completed a private placement of 500,000 shares of unregistered common stock at a price of $3.37 per share with a group of institutional investors, yielding proceeds to the Company of $1.685 million. The investors were given certain registration rights as part of the transaction.

Warrants:

During the nine months ended September 30, 2003, the Company issued warrants to purchase 34,722 shares of common stock. As of September 30, 2003, the following warrants to purchase common stock were outstanding and exercisable:

Number of Shares	Per Share Price	Expiration Date
853,040	$1.90	July 31, 2004
50,000	2.13	October 31, 2005
45,045	2.22	October 1, 2006
34,722	1.92	October 1, 2007

8. Income Taxes.

The income tax provision for the nine month period ended September 30, 2003 was a benefit of $407,090 as compared to an expense of $509,959 for the comparable period last year. The income tax provision differs from the federal statutory rate due primarily to state income taxes and permanent differences between income reported for financial statement and income tax purposes.

Realization of deferred tax assets associated with Net Operating Losses (NOL) and tax credit carry forwards is dependent upon generating sufficient taxable income prior to their expiration. Management believes that there is a risk that certain of these NOL and credit carryforwards may expire unused and accordingly, has established a valuation reserve against them. Although realization is not assured for the remaining deferred tax assets, management believes it is more likely than not that they will be realized through future taxable income or alternative tax strategies. However, the net deferred tax assets could be reduced in the near term if management's estimates of taxable income during the carryforward period are significantly reduced or alternative tax strategies are not available. The Company will continue to review its valuation allowances and make adjustments, if necessary. Should the Company undergo an ownership change as defined in Section 382 of the Internal Revenue Code, the Company's NOL generated prior to the ownership change would be subject to an annual limitation. If this occurred, a further adjustment of the valuation allowance would be necessary.

9. Earnings Per Share (EPS).

The computation of per share amounts for the three and nine months ended September 30, 2003 and 2002 is based on the average number of common shares outstanding for the period. Options and warrants to purchase 36,600 and 628,830 shares of common stock outstanding during the three months ended September 30, 2003 and 2002, respectively, were not considered in the computation of diluted EPS because their inclusion would have been antidilutive. Likewise, options and warrants to purchase 3,816,516 and 430,830 shares of common stock outstanding during the nine months ended September 30, 2003 and 2002, respectively, were not considered in the computation of diluted EPS because their inclusion would have been antidilutive.

The following is a reconciliation of shares used in computing basic and diluted earnings per share amounts.

	Three Months Ended	
	September 30, 2003	September 30, 2002
Weighted average number of shares - basic	11,208,431	10,688,591

Effects of Dilutive Securities		
Options	774,059	524,835
Warrants	468,217	208,046
Preferred Stock	--	80,029
Weighted average number of shares - diluted	12,450,707	11,501,501

	Nine Months Ended	
	September 30, 2003	September 30, 2002
Weighted average number of shares - basic	11,088,869	10,472,553
Effects of Dilutive Securities		
Options	--	580,079
Warrants	--	302,944
Preferred Stock	--	196,726
Weighted average number of shares - diluted	11,088,869	11,552,302

10. Segment and Geographic Information.

The Company's operations are organized on the basis of products and related services and under SFAS No.131 operates in two segments: (1) urinalysis and (2) small instruments.

The urinalysis segment designs, develops, manufactures and markets IVD imaging systems based on patented and proprietary AIM technology for automating microscopic procedures for urinalysis. The segment also provides ongoing sales of supplies and service necessary for the operation of installed urinalysis workstations. In the United States, these products are sold through our direct sales force; internationally, these products are sold through distributors.

The small instruments segment designs, develops, manufactures and markets a variety of benchtop centrifuges, small instruments and supplies. These products are used primarily for manual specimen preparation and dedicated applications in coagulation, cytology, hematology and urinalysis. These products are sold worldwide through distributors.

The accounting policies of the segments are the same as those described in the "Summary of Significant Accounting Policies" included in the Company's report on Form 10-K for the year ended December 31, 2002. The Company evaluates the performance of its segments and allocates resources to them based on earnings before income taxes, excluding corporate charges ("Segment Profit").

The tables below present information about reported segments for the three and nine month periods ended September 30, 2003 and 2002:

Three Months Ended September 30, 2003:

	Urinalysis	Small Instruments	Unallocated Corporate Expenses	Total

Revenues	$6,886,060	$1,534,873	--	$8,420,933
Interest income	$6,780	$164	--	$6,944
Interest expense	$1,988	--	$81,370	$83,358
Depreciation and amortization	$241,316	$22,536	$20,030	$283,882
Segment profit (loss)	$842,803	$235,894	$(864,932)	$213,765
Segment assets	$17,502,865	$2,350,654	$8,869,391	$28,722,910
Investment in long-lived assets	$617,234	$8,295	--	$625,529

Three Months Ended September 30, 2002:

	Urinalysis	Small Instruments	Unallocated Corporate Expenses	Total
Revenues	$5,617,035	$1,455,107	--	$7,072,142
Interest income	$13,134	$444	--	$13,578
Interest expense	$1,608	--	$119,273	$120,881
Depreciation and amortization	$246,091	$20,765	$13,019	$279,875
Segment profit (loss)	$506,431	$396,475	$(729,916)	$172,990
Segment assets	$15,741,009	$2,342,312	$8,521,100	$26,604,421
Investment in long-lived assets	$739,650	$9,380	--	$749,030

Nine Months Ended September 30, 2003:

	Urinalysis	Small Instruments	Unallocated Corporate Expenses	Total
Revenues	$16,822,606	$4,263,300	--	$21,085,906
Interest income	$29,425	$557	--	$29,982
Interest expense	$6,484	--	$263,973	$270,457
Depreciation and amortization	$613,230	$66,406	$59,436	$739,072
Segment profit (loss)	$1,125,168	$646,627	$(2,789,519)	$(1,017,724)
Investment in long-lived assets	$1,571,942	$39,741	--	$1,611,683

Nine Months Ended September 30, 2002:

	Urinalysis	Small Instruments	Unallocated Corporate Expenses	Total

Revenues	$16,431,520	$4,374,014	--	$20,805,534
Interest income	$41,406	$1,157	--	$42,563
Interest expense	$4,634	--	$424,378	$429,012
Depreciation and amortization	$694,227	$62,293	$42,931	$799,451
Segment profit (loss)	$2,286,433	$1,171,376	$(2,182,912)	$1,274,897
Investment in long-lived assets	$1,939,894	$26,357	--	$1,966,251

Substantially all long-lived assets were located in the United States and totaled $6,594,992 at September 30, 2003, and $5,567,430 at December 31, 2002.

11. Subsequent Event.

In October 2003, the Company completed a private placement of 500,000 shares of its unregistered common stock with a group of institutional investors. The shares were sold at a price of $3.37 per share, yielding proceeds to the Company of $1,685,000. The investors were given certain registration rights as part of the transaction.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We generate revenues primarily from sales of our urinalysis workstations, an *in vitro* diagnostic, or IVD, imaging system based on our patented and proprietary AIM technology, and the related supplies and service required to operate this workstation. We also earn revenues from sales of ancillary lines of small instruments and supplies and royalties and licensing of our technology.

We make significant investments in research and development for new products and enhancements to existing products. We fund our research and development primarily from internal sources, but we also receive partial funding from time to time under grants from the National Institute of Health and joint development projects with third parties.

The following table summarizes total product technology expenditures for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Research and development expense, net	$1,040,000	$1,150,000	$3,527,000	$3,250,000
Capitalized software development costs	144,000	169,000	424,000	605,000
Reimbursed costs for research and development grants and contracts	333,000	214,000	676,000	697,000
Total product technology expenditures	$1,517,000	$1,533,000	$4,627,000	$4,552,000

Results of Operations

Comparison of Quarter Ended September 30, 2003 to Quarter Ended September 30, 2002

Net revenues for the quarter ended September 30, 2003 increased to $8.4 million from $7.1 million last year, an increase of 19%. Sales of IVD imaging systems increased to $2.3 million from $1.5 million in the same period last year, an increase of $807,000 or 53%. The increase was due to the release for sale of the Company's new iQ200 System, which commenced in August 2003.

Sales of IVD imaging system supplies and services were $4.4 million in the quarter, compared to $3.9 million in the same period last year, an increase of $433,000 or 11%. The increase was primarily due to the larger installed base of urinalysis workstations. Sales of small instruments and supplies increased $80,000 to $1.5 million, an increase of 5%. The increase is due to increased sales of supplies and increased service revenue from new service agreements. Royalties and licensing revenues increased to $177,000 from $148,000 in the comparable period from the prior year.

Revenues from the urinalysis segment totaled $6.9 million in the current period as compared to $5.6 million in the comparable period last year, an increase of $1.3 million or 23%. This increase is primarily due to higher systems sales attributable to commencement of sales of the new iQ200. Revenues from the small instruments segment increased $80,000 from the comparable period last year to $1.5 million. This increase is due primarily to increased sales of supplies and service in that segment.

Cost of goods for IVD systems as a percentage of sales of IVD imaging systems totaled 79% in the current period as compared to 67% in the comparable period from last year. This large increase is due to a number of factors. Our lower pre-launch production levels in the first month of the current period provided a smaller volume of product over which production overhead could be absorbed. Also, with the commencement of production of the new iQ200 in the quarter, we experienced the typical inefficiencies and learning curve associated with the start up of production of a major new product. Cost of goods for IVD imaging system supplies and services as a percentage of sales of such products was 35% for the current period as compared to 40% in the same period last year. This decrease is primarily due to efficiencies in the manufacture of chemical reagents resulting from the improvements made to the production facilities over the past year. Cost of goods for small instruments and supplies as a percentage of sales of such products totaled 49% for the current period, unchanged from the third quarter of last year. The aggregate gross margin totaled 51% for the quarter ended September 30, 2003 as compared to 53% in the comparable period of the prior year.

Cost of goods sold as a percentage of revenues from the urinalysis segment totaled 49%, as compared to 46% in the third quarter of last year. Cost of goods for the small instruments segment as a percentage of revenues totaled 49% in the current period, unchanged from the third quarter of the prior year.

Marketing and selling expenses totaled $1.6 million, compared to $1.1 million for the comparable prior year period, an increase of $487,000, or 46%. This increase is due primarily to the addition of sales persons, higher commissions due to higher revenues, as well as increased marketing efforts for our products. Marketing and selling expenses as a percentage of net revenues were 18% in the quarter ended September 30, 2003, as compared to 15% in the same period last year.

General and administrative expenses were $1.4 million, compared to $1.3 million in the comparable period in the prior year, an increase of $93,000 or 7%. The increase in 2003 is due to higher overhead allocations as well as increases in administrative salaries, partly due to the addition of two support staff. General and administrative expenses for the period as a percentage of net revenue were 16% as compared to 18% in the same period in the prior year.

Net research and development expenses were $1.0 million for the quarter ended September 30, 2003, down $111,000 or 10% from the level of the third quarter of last year. Net research and development expenses as a percentage of revenues were 12% in the quarter ended September 30, 2003, as compared to 16% in the same period in the prior year. Total product technology expenditures, including capitalized software development costs and

reimbursed costs under research and development grants and contracts, were unchanged from the prior year at $1.5 million. The continued high level of total product technology expenditures is due primarily to the iQ200 project, begun in 1999. The iQ200 began production in August 2003. Accordingly, our net research and development expenses have peaked and have commenced a gradual decline which we expect to continue through the rest of the year.

The operating income for the quarter ended September 30, 2003 was $290,000 as compared to $244,000 in the comparable quarter of the prior year, primarily as a result of higher sales in the current period.

Interest expense decreased to $83,000 in the quarter ended September 30, 2003 from $121,000 in the comparable prior year period, as a result of lower interest rates and reduced indebtedness.

For the quarter ended September 30, 2003, urinalysis segment profits increased to $843,000 from $506,000 in the comparable quarter of the prior year. This increase is attributable to higher sales in the current quarter. Segment profits for the small instruments segment totaled $236,000, as compared to $396,000 in the comparable quarter of the prior year. The decrease results from higher operating expenses. Unallocated corporate expenses totaled $865,000 in the current period as compared to $730,000 in the same period last year.

The income tax provision for the quarter ended September 30, 2003 was $86,000, as compared to $69,000 in the quarter ended September 30, 2002. The change is a function of the taxable income or loss.

The net income was $128,000, or $0.01 per diluted share, for the quarter ended September 30, 2003, as compared to $104,000, or $0.01 per diluted share, for the same period of the prior year.

Comparison of Nine Months Ended September 30, 2003 to Nine Months Ended September 30, 2002

Net revenues for the nine months ended September 30, 2003 increased to $21.1 million from $20.8 million last year, an increase of 1%. Sales of IVD imaging systems decreased to $3.7 million from $4.0 million in the same period last year, a decrease of $222,000 or 6%. This decline in IVD imaging system sales was expected and reflects a slowdown in orders for the older models of our urinalysis workstation for the first seven months of the year as customers awaited the availability of our new upgraded iQ200 System. The iQ200 became available for sale in August 2003 and has generated substantial revenues since that time.

Sales of IVD imaging system supplies and services increased to $12.7 million from $12.2 million, an increase of $522,000 or 4% over the same period last year, primarily due to the larger installed base of urinalysis workstations. Sales of small instruments and supplies were unchanged from the year ago period at $4.3 million. Royalties and licensing revenues decreased slightly to $396,000 from $404,000 in the comparable period from the prior year.

Revenues from the urinalysis segment totaled $16.8 million in the current period as compared to $16.4 million in the comparable period last year, an increase of $391,000 or 2%. This increase is due to higher supplies and services sales, partially offset by lower systems sales as explained in the preceding paragraphs. Revenues from the small instruments segment decreased $111,000 from the comparable period last year to $4.3 million. This decline is due primarily to a decline in royalty revenue.

Cost of goods for IVD systems as a percentage of sales of IVD imaging systems totaled 89% in the current period as compared to 60% in the comparable period from last year. This large increase is due to a number of factors. Our lower production levels in the first seven months of the current period provided a smaller volume of product over which production overhead could be absorbed, as well as costs associated with training and non-recurring start-up costs related to the production of the new iQ200, which began in the third quarter of 2003. Also, a large portion of this period's sales were low margin international sales, whereas there were few international instrument sales in the year ago period. We also increased our reserve for inventory obsolescence by 13% in the nine month period which further

contributed to the increase in this sector's cost of goods. Cost of goods for IVD imaging system supplies and services as a percentage of sales of such products was 37% for the current period as compared to 39% in the same period last year. This decrease is primarily due to efficiencies in the manufacture of chemical reagents resulting from the improvements made to the production facilities over the past year. Cost of goods for small instruments and supplies as a percentage of sales of such products totaled 51% for the current period, as compared to 49% in the first nine months of last year. This increase is due primarily to increased costs resulting from smaller production runs in the current period. The aggregate gross margin totaled 52% for the nine months ended September 30, 2003 as compared to 56% in the comparable period of the prior year.

Cost of goods sold as a percentage of revenues from the urinalysis segment totaled 48%, as compared to 43% in the first six months of last year. Cost of goods for small instruments as a percentage of revenues totaled 51% in the current period, as compared to 49% in the first nine months of the prior year.

Marketing and selling expenses totaled $3.7 million, compared to $3.1 million for the comparable prior year period, an increase of $656,000, or 21%. This increase is due primarily to the addition of a Vice-president of sales, the addition of four sales persons, increased commissions due to higher revenues, and increased marketing efforts for our products. Marketing and selling expenses as a percentage of net revenues were 18% in the nine months ended September 30, 2003, as compared to 15% in the same period last year.

General and administrative expenses were $4.4 million, compared to $3.7 million in the comparable period in the prior year, an increase of $754,000 or 21%. The increase is due primarily to non-recurring costs of $400,000 associated with the change in the Company's CEO, and includes a $285,000 accrual for retirement benefits, duplicate salaries during the transition, and relocation costs. The balance of approximately $300,000 was due to increased legal and auditing fees, insurance premiums and investor relations expenses. General and administrative expenses for the period as a percentage of net revenue were 21% as compared to 18% in the same period in the prior year.

Net research and development expenses were $3.5 million for the nine months ended September 30, 2003, up $276,000 or 9% from the level of the first nine months of last year. Net research and development expenses as a percentage of revenues were 17% in the nine months ended September 30, 2003, as compared to 16% in the same period in the prior year. Total product technology expenditures, including capitalized software development costs and reimbursed costs under research and development grants and contracts, were up $75,000 from the prior year to $4.6 million. The continued high level of total product technology expenditures is due primarily to the major iQ200 project begun in 1999 to improve our urinalysis workstation product line. Production of the iQ200 began in the third quarter of 2003. Accordingly, we expect that our net research and development expenses have peaked and will commence a gradual decline through the rest of the year.

Operating income for the nine months ended September 30, 2003 was a loss of $778,000 as compared to income of $1.6 million in the comparable period of the prior year, primarily as a result of lower profit margins and higher operating expenses in the current period.

Interest expense decreased to $270,000 in the nine months ended September 30, 2003 from $429,000 in the comparable period of the prior year as a result of lower interest rates and reduced indebtedness.

For the nine months ended September 30, 2003, urinalysis segment profits decreased to $1.1 million from $2.3 million in the comparable period of the prior year. This decrease is attributable to under-absorbed manufacturing overhead and higher operating expenses in the current period. Segment profits for the small instruments segment totaled $647,000, as compared to $1.2 million in the comparable period of the prior year. The decrease results from lower sales volume, lower margins and higher expenses in that segment. Unallocated corporate expenses totaled $2.8 million in the current period as compared to $2.2 million in the same period last year. The increase in 2003 is due to the transitional and other expenses detailed previously.

The income tax provision for the nine months ended September 30, 2003 was a benefit of $407,000, as compared to an expense of $510,000 in the nine months ended September 30, 2002. The change is a function of the taxable income or loss.

Net income decreased to a loss of $611,000, or $0.06 per diluted share, for the nine months ended September 30, 2003, as compared to a profit of $765,000, or $0.07 per diluted share, for the same period of the prior year.

Contractual Obligations and Contingent Liabilities and Commitments

The following table aggregates the Company's expected contractual obligations and commitments subsequent to September 30, 2003:

	Payments Due by Period (in Thousands)					
Contractual Obligations	2003	2004	2005	2006	2007	Totals
Long term debt	$ 87	$1322	$350	$350	$60	$2,518
Capital lease commitments	$ 16	$ 61	$ 40	$ 18	$ 3	$ 153
Operating lease commitments	$136	$ 523	$462	$428	$ 0	$1,686
Total Contractual cash commitments	$239	$1,906	$852	$796	$63	$4,357

The reduction in the long-term debt in 2003 is as a result of the Company's main lender, California Bank and Trust, invoking its rights under the Subordination Agreement and instructing the Company to stop making payments of the amounts owed on the Subordinated Note Payable until further notice. Accordingly, this debt is now classified as long-term.

Liquidity and Capital Resources

The Company's primary source of liquidity is cash from operations, which depends not only on sales of our urinalysis workstations, but also on the sales of related supplies and services. Shipment of our new automated, benchtop iQ200 urinalysis system, the first fully-automated system capable of performing both chemistry and microscopy in a walk-away system, commenced in August 2003. The success of this new product will depend on acceptance by the market, and failure to achieve this objective would have a material and adverse affect on workstation sales, and, consequently, our liquidity. This is an inherent risk in any major upgrade to products in our industry.

Historically, cash from operations, credit terms from vendors and bank borrowing have met the Company's liquidity needs. Management believes that these sources should be sufficient to fund currently anticipated cash requirements for the foreseeable future.

Cash and cash equivalents decreased to $1.0 million at September 30, 2003 from $2.3 million at December 31, 2002. Operating activities resulted in a net use of cash in the amount of $670,000 for the nine months ended September 30, 2003 as compared to net cash provided of $1.9 million in the comparable period last year. This decrease in cash provided by operations is due primarily to the net loss incurred in the current nine-month period, as well as the increase in receivables, inventory, accounts payable and accrued expenses that are consistent with the beginning of production of the iQ200 and the high levels of sales of that product in the month of September.

Cash used by investing activities totaled $1.5 million for the nine months ended September 30, 2003, as compared to $2.1 million in the same period last year. This decrease is due to the reduction in expenditures for property and

equipment and software development from prior year levels. Our effort to expand and upgrade our facilities is largely complete and, the software development connected with the development of the iQ200 is also substantially completed.

Net cash provided by financing activities totaled $860,000 and consisted primarily of additional borrowings of $1.5 million under our line of credit and funds received from the exercise of stock options, partially offset by principal payments made on the subordinated note, and the term loans under our credit facility. As of September 30, 2003, we owed $1.2 million on the term loans and $2.5 million on the revolving line of credit and were eligible to borrow an additional $1.3 million under the revolving credit line.

We have an $8.0 million credit facility with California Bank and Trust which consists of a $500,000 term loan, a $1.0 million term loan and a $6.5 million revolving line of credit. The $500,000 term loan is payable in 60 equal monthly installments. The $1.0 million term loan carried interest only for the first 12 months, followed by 48 months of equal principal payments plus interest, commencing in March, 2003. The $6.5 million credit line matures in June 2004. Borrowings under the line of credit are limited to a percentage of eligible receivables and inventory. Dependent on the Company's debt service coverage ratio, the entire credit facility bears interest at a rate range between the lender's prime rate (4.0% at September 30, 2003), or LIBOR rate plus 2.0% and the lender's prime rate plus 1.0% or LIBOR rate plus 3.0%. The Company obtained a forbearance agreement with the bank, relieving it of compliance with certain debt covenants through September 30, 2003. As part of that agreement, the Company has agreed to maintain a certain minimum excess borrowing availability under its line of credit. In September, the Company re-negotiated its debt covenants and the Bank agreed to reduce this minimum excess from $1 million to $400,000.

In addition, California Bank and Trust invoked its rights under the Subordination Agreement and instructed the Company to stop making payments of the amounts owed on the Subordinated Note Payable until further notice.

We expect to continue to incur high levels of research and development expenditures in 2003. We plan to fund these expenditures primarily with cash generated from operations.

Although we borrowed an additional $1.5 million under the line of credit, we reduced our outstanding long term debt by more than $900,000 in the first nine months of 2003. Our scheduled principal payments total $350,000 during the next twelve months, excluding the suspended payments on the Subordinated Note Payable discussed above. We believe that our current cash on hand, the cash from the sale of $1.685 million of our common stock which occurred on October 20, 2003, together with cash generated from operations over the next twelve months, as well as cash available under the credit facility will be sufficient to fund normal operations and pay principal and interest on outstanding debt for at least a year.

Critical Accounting Policies and Estimates

Our critical accounting policies upon which our financial position and results of operations depend are those related to revenue recognition, inventory valuation, and income tax assets and liabilities. We summarize our most critical accounting policies below.

Revenue Recognition

We recognize revenue when goods are shipped and title passes to the customer provided that: there are no uncertainties regarding customer acceptance; persuasive evidence of an arrangement exists; the sales price is fixed or determinable; and collectibility is probable. Revenue is recognized net of an allowance for discounts when the sale is recorded.

IRIS derives revenue from the sale of IVD imaging systems, sales of supplies and services for its IVD imaging systems and sales of small instruments and related supplies. For sales of supplies and small instruments, IRIS

generally recognizes product revenues once all of the following conditions have been met: a) an authorized purchase order has been received in writing, b) customer credit worthiness has been established, and c) delivery of the product based on shipping terms.

Certain of IRIS's domestic IVD system sales generally require installation and training to be performed. Management believes that installation and training is not essential to the functionality of the product and accordingly, the Company recognizes revenue on delivery based on shipping terms, provided title has transferred, collectibility of the resulting receivable is probable, the Company has received an authorized purchase order and the price is fixed and determinable. The estimated fair value of installation and training is deferred and recognized as these services are performed. Sales of IVD systems internationally are recognized on delivery based on shipping terms, provided collectibility of the resulting receivable is probable, the Company has received an authorized purchase order and the price is fixed and determinable.

IRIS recognizes service revenues ratably over the term of the service period, which typically ranges from twelve to sixty months. Payments for service contracts are generally made in advance. Deferred revenue represents the revenues to be recognized over the remaining term of the service contracts.

Inventory Valuation

We value inventories at the lower of cost or market. Inventory costs are based on standard costs, which are updated periodically and supported by actual cost data. We include materials, labor and manufacturing overhead in the cost of inventories. In determining inventory market values, we give substantial consideration to the expected product's selling price based on historical recovery rates. In determining our expected selling prices, we consider various factors including estimated quantities of slow-moving inventory by reviewing on-hand quantities, outstanding purchase obligations and forecasted sales. We then estimate expected selling prices based on our historical recovery rates for sale of slow-moving inventory through various channels and other factors, such as market conditions and current customer preferences. As a result of this analysis, we have established a reserve for excess and obsolete inventory, which we believe adequately adjusts the overall inventory value to the lower of cost or market.

Income Tax Assets and Liabilities

In establishing our deferred income tax assets and liabilities, we make judgments and interpretations based on enacted tax laws and published tax guidance that are applicable to our operations. We record deferred tax assets and liabilities and evaluate the need for valuation allowances to reduce the deferred tax assets to realizable amounts. The likelihood of a material change in our expected realization of these assets is dependent on future taxable income, our ability to use tax credit carryforwards and the effectiveness of our tax planning strategies in the various relevant jurisdictions. We are also subject to examination of our income tax returns for multiple years by the Internal Revenue Service and other tax authorities. We periodically assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes. Changes to our income tax provision or in the valuation of the deferred tax assets and liabilities may affect our annual effective income tax rate.

Inflation

We do not foresee any material impact on our operations from inflation.

Risk Factors

In evaluating the Company, various risk factors and other information should be carefully considered. The risks and uncertainties described below are not the only ones that impact the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also have an adverse impact on us. Among other things, this discussion contains forward-looking statements that are based on certain assumptions about future risks

and uncertainties. We believe that our assumptions are reasonable. Nonetheless, it is likely that at least some of these assumptions will not come true. Accordingly, our actual results will probably differ from the outcomes contained in any forward-looking statements. These differences could be material. Factors that could cause or contribute to such differences include, among other things, those discussed below, as well as those discussed elsewhere in our Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

Our success depends largely on sales of laboratory instruments.

Historically, we derived most of our revenues from the sale of urinalysis workstations. Relatively modest declines in unit sales or gross margins for this product line could diminish our revenues and profits.

Our success depends largely on the acceptance of our new iQ 200 operating platform.

The transition to our new iQ 200 operating platform is both in response to the changing market needs and to the technical obsolescence of key components in our current product design. We have made end of life buys for many of these components and have initiated sustaining engineering projects to identify alternative sources for others. Our ability to build new systems of the old design is finite. The failure to successfully and timely complete this transition to the new workstation would have an adverse affect on new system sales. As with any new platform introduction, the desirability of the older system will fall off and our ability to move the remaining inventory may become problematic.

We rely on some single-source suppliers for key components of our instruments, and if any of these suppliers discontinue production of these components, or we are unable to replace unavailable components, it could harm our business.

Certain key components of our instruments are manufactured by single-source suppliers. For example, Roche Diagnostics is the sole source for our proprietary CHEMSTRIP/IRIStrip urine test strips and related urine test strip readers, both used in certain models of our urinalysis workstations. Any of our single-source suppliers could encounter production problems. If any single-source supplier has an interruption in its production or discontinues a key component, the volume of our instrument sales could be diminished and could harm our business, financial condition and operating results.

Roche Diagnostics has exercised their right to terminate in 2003 the contracts relating to the supply of CHEMSTRIP/IRIStrip urine test strips and related urine test strip reader. Roche will continue to supply test strips and replacement readers to our installed base of workstations for six years after termination of these contracts, but they will not supply strips or readers for new workstation placements. We believe that we can successfully phase out their strips and readers with the introduction of our new iQ200 without interruption in the sale of our workstations. However, the failure to successfully and timely complete this task would have a material adverse affect on our instrument sales and the revenue growth for system supplies and service.

In the past, single-source suppliers have discontinued their production of key components and we have successfully replaced those discontinued components with satisfactorily replacements components. However, if we are unable to replace unavailable components in the future, we are likely to experience a decrease in instrument sales.

The intensifying competition we face from both established entities and new entries in the market may adversely affect our revenues and profitability.

There are many companies with active research and development programs both in and outside of the clinical laboratory imaging systems field. Many of these companies have considerable experience in areas of competing interest to us. Additionally, we cannot determine if other firms are conducting potentially competitive research, which could result in the development and introduction of products that are either comparable or superior to the products we sell. Specifically, if a competitor introduces a new product that is comparable or superior to any model of our

urinalysis workstation, then our unit sales or gross margins could be diminished. This in turn could have a material adverse effect on our overall financial condition and operations. Further, new product introductions, product enhancements and the use of other technologies by our competitors could lead to a loss of market acceptance and cause a decline in sales or gross margins.

Our success depends on our ability to attract, retain and motivate management and other skilled employees.

Our success depends in significant part upon the continued services of key management and skilled personnel. Competition for qualified personnel is intense and there are a limited number of people with knowledge of, and experience in, our industry. We do not have employment agreements with most of our key employees. However, we generally enter into agreements with our employees regarding patents, confidentiality and related matters. We do not maintain life insurance polices on our employees. Our loss of key personnel, especially without advance notice, or our inability to hire or retain qualified personnel, could have a material adverse effect on our instrument sales and our ability to maintain our technological edge. We cannot guarantee that we will continue to retain our key management and skilled personnel, or that we will be able to attract, assimilate and retain other highly qualified personnel in the future.

Any failure to successfully introduce our future products and systems into the market could adversely affect our business.

The commercial success of our future products and systems depends upon their acceptance by the medical community. Our future product plans include capital-intensive laboratory instruments. We believe that these products can significantly reduce labor costs, improve precision and offer other distinctive benefits to the medical research community. However, there is often market resistance to products that require significant capital expenditures or which eliminate jobs through automation. We can make no assurance that the market will accept our future products and systems, or that sales of our future products and systems will grow at the rates expected by our management.

If we fail to meet changing demands of technology, we may not continue to be able to compete successfully with our competitors.

The market for our products and systems is characterized by rapid technological advances, changes in customer requirements, and frequent new product introductions and enhancements. Our future success depends upon our ability to introduce new products that keep pace with technological developments, enhance current product lines and respond to evolving customer requirements. Our failure to meet these demands could result in a loss of our market share and competitiveness and could harm our revenues and results of operations.

Any failure or inability to protect our technology and confidential information could adversely affect our business.

Patents. Our commercial success depends in part on our ability to protect and maintain our automated intelligent microscopy (or AIM) and other proprietary technology. We have received patents with respect to portions of the technologies of AIM. However, ownership of technology patents may not insulate us from potentially damaging competition. Patent litigation relating to clinical laboratory instrumentation patents (like the ones we own) often involves complex legal and factual questions. Therefore, we can make no assurance that claims under patents currently held by us, or our pending or future patent applications, will be sufficiently broad to adequately protect what we believe to be our proprietary rights. Additionally, one or more of our patents could be circumvented by a competitor. We believe that our proprietary rights do not infringe upon the proprietary rights of third parties. However, third parties may assert infringement claims against us in the future. If we are unsuccessful in our defense against any infringement claim our patents, or patents in which we have licensed rights, may be held invalid and unenforceable.

Trade Secrets. We have trade secrets, unpatented technology and proprietary knowledge related to the sale, promotion, operation, development and manufacturing of our products. We generally enter into confidentiality agreements with our employees and consultants. However, we cannot guarantee that our trade secrets, unpatented technology or proprietary knowledge will not become known or be independently developed by competitors. If any of this proprietary information becomes know to third parties, we may have no practical recourse against these parties.

Copyrights. We claim copyrights in our software and the ways in which it assembles and displays images. We also claim trademark rights in the United States and other foreign countries. However, we can make no assurance that we will be able to obtain enforceable copyright and trademark protection, nor that this protection will provide us a significant commercial advantage.

Potential litigation expenses. Offensive or defensive litigation regarding patent and other intellectual property rights could be time-consuming and expensive. Additionally, litigation could demand significant attention from our technical and management personnel. Any change in our ability to protect and maintain our proprietary rights could materially and adversely affect our financial condition and results of operations.

We operate in a consolidating industry which creates barriers to our market penetration.

The healthcare industry in recent years has been characterized by consolidation. Large hospital chains and groups of affiliated hospitals prefer to negotiate comprehensive supply contracts for all of their supply needs at once. Large suppliers can often equip an entire laboratory and offer these hospital chains and groups one-stop shopping for laboratory instruments, supplies and service. Larger suppliers also typically offer annual rebates to their customers based on the customer's total volume of business with the supplier. The convenience and rebates offered by these large suppliers are administrative and financial incentives that we do not offer our customers. Our plans for further market penetration in the urinalysis market will depend in part on our ability to overcome these and any new barriers resulting from continued consolidation in the healthcare industry.

Since we operate in the medical technology industry, our products are subject to government regulation that could impair our operations.

Most of our products are subject to stringent government regulation in the United States and other countries. These regulatory processes can be lengthy, expensive and uncertain. Additionally, securing necessary clearances or approvals may require the submission of extensive official data and other supporting information. Our failure to comply with applicable requirements could result in fines, recall or seizure of products, total or partial suspension of production, withdrawal of existing product approvals or clearances, refusal to approve or clear new applications or notices, or criminal prosecution. If any of these things occur, they could harm our business. Changes in existing federal, state or foreign laws or regulations, or in the interpretation or enforcement of these laws, could also materially and adversely affect our business.

Changes in government regulation of the healthcare industry could adversely affect our business.

Federal and state legislative proposals are periodically introduced or proposed that would affect major changes in the healthcare system, nationally, at the state level or both. Future legislation, regulation or payment policies of Medicare, Medicaid, private health insurance plans, health maintenance organizations and other third-party payors could adversely affect the demand for our current or future products and our ability to sell our products on a profitable basis. Moreover, healthcare legislation is an area of extensive and dynamic change, and we cannot predict future legislative changes in the healthcare field or their impact on our industry or our business.

We are subject to anti-takeover provisions in our charter that could delay or prevent an acquisition of our company, even if such an acquisition would be beneficial to our stockholders.

Certain provisions of our certificate of incorporation, our bylaws and Delaware law could, together or separately, delay or prevent a third party from acquiring us, even if doing so might be beneficial to our stockholders. These provisions may also limit the price that investors might be willing to pay for shares of our common stock. Some of these provisions:

- establish a classified board of directors;
- authorize the issuance of preferred stock with rights and privileges which could be senior to the common stock, without prior stockholder approval;
- limit the right of stockholders to call a special meeting of stockholders; and
- prohibit stockholder action by written consent.

Additionally, in December 1999, the Board of Directors of IRIS approved and adopted a shareholders rights plan. Under the terms of the plan, each share of common stock now includes the right to purchase shares of a new Series C Preferred Stock under certain circumstances. Each share of Series C Preferred Stock is the economic equivalent of 1,000 shares of IRIS Common Stock. The rights will be exercisable only if a person or group acquires 20% or more of the IRIS Common Stock, or announces a tender offer for 20% or more of the IRIS Common Stock, without board approval. If the rights are triggered, all stockholders (except the hostile party) will be entitled to purchase shares of the Series C Preferred Stock at a price based on a substantial discount from the market price of the IRIS Common Stock. The Board of Directors may terminate the plan at any time or redeem the rights prior to their becoming exercisable.

We also are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested stockholder" for a period of three years following the date that such stockholder became an interested stockholder.

Defective products may subject us to liability.

Our products are used to gather information for medical decisions and diagnosis. Accordingly, the manufacture and sale of our products entails an inherent risk of product liability arising from an inaccurate, or allegedly inaccurate, test result. We currently maintain product liability insurance coverage for up to $1.0 million per incident and up to an aggregate of $2.0 million per year. We also currently maintain a product liability umbrella policy for coverage of claims aggregating more than $10.0 million. Although management believes this liability coverage is sufficient protection against future claims, there can be no assurance of the sufficiency of these policies. We have not received any indication that our insurance carrier will not renew our product liability insurance at or near current premiums; however, we cannot guarantee that this will continue to be the case. In addition, any failure to comply with Federal Drug Administration regulations governing manufacturing practices could hamper our ability to defend against product liability lawsuits.

Healthcare Reform Policies

In recent years, an increasing number of legislative proposals have been introduced or proposed in Congress and in some state legislatures that would effect major changes in the healthcare system, nationally, at the state level or both. Future legislation, regulation or payment policies of Medicare, Medicaid, private health insurance plans, health maintenance organizations and other third-party payors could adversely affect the demand for our current or future products and our ability to sell our products on a profitable basis. Moreover, healthcare legislation is an area of extensive and dynamic change, and we cannot predict future legislative changes in the healthcare field or their impact on our business.

We May Face Interruption of Production and Services Due to Increased Security Measures in Response to Terrorism

Our business depends on the free flow of products and services through the channels of commerce. Recently, in response to terrorists' activities and threats aimed at the United States, transportation, mail, financial and other services have been slowed or stopped altogether. Further delays or stoppages in transportation, mail, financial or other services could have a material adverse effect on our business, results of operations and financial condition. Furthermore, we may experience an increase in operating costs, such as costs for transportation, insurance and security as a result of the activities and potential activities. We may also experience delays in receiving payments from payers that may have been affected by the terrorist activities and potential activities and any economic downturn could adversely impact our results of operations, impair our ability to raise capital or otherwise adversely affect our ability to grow our business.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views about future events and financial results. We have made these statements in reliance on the safe harbor created by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include our views on future financial results, financing sources, product development, capital requirements, market growth and the like, and are generally identified by phrases such as "anticipates," "believes," "estimates," "expects," "intends," "plans" and similar words. Forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors which could cause the actual results to differ materially from the forward-looking statement. These uncertainties and other factors include, among other things,

- unexpected technical and marketing difficulties inherent in major product development efforts such as our current project to improve our urinalysis workstation product line,
- the potential need for changes in our long-term strategy in response to future developments,
- future advances in diagnostic testing methods and procedures, as well as potential changes in government regulations and healthcare policies, both of which could adversely affect the economics of the diagnostic testing procedures automated by our products,
- rapid technological change in the microelectronics and software industries, and
- increasing competition from imaging and non-imaging based in-vitro diagnostic products.

Stockholders should understand that the uncertainties and other factors identified in this Quarterly Report and in Exhibit 99 to the Annual Report are not a comprehensive list of all the uncertainties and other risk factors which may affect forward-looking statements. We do not undertake any obligation to update or revise any forward-looking statements or the list of uncertainties and other factors which could affect those statements.

Item 3. Quantitative And Qualitative Disclosures About Market Risk.

There was no material change in the Company's exposure to market risk on September 30, 2003 as compared to its market risk exposure on December 31, 2002. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2002.

Item 4. Controls and Procedures

The Company maintains controls and procedures designed to ensure that it is able to collect the information it is required to disclose in the reports it files with the SEC and to approve, summarize and disclose this information within the time periods specified in the rules of the SEC. The Company's Chief Executive Officer and Chief Financial Officer are responsible for establishing and maintaining these procedures, and, as required by the rules of the SEC, evaluate their effectiveness. Based on their evaluation of the Company's disclosure controls and procedures which took place as of a date within 90 days of the filing date of this report, the Chief Executive and Chief Financial Officers believe that these procedures are adequate and effective to ensure that the Company is able to collect, process and disclose the information it is required to disclose in the reports it files with the SEC within the required time periods.

Disclosure controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving an entity's disclosure objectives. The likelihood of achieving such objections is affected by limitations inherent in disclosure controls and procedures. These include the fact that human judgment in decision-making can be faulty and that breakdowns in internal control can occur because of human failures such as simple errors or mistakes or intentional circumvention of the established process.

Changes in Internal Controls

The Company maintains a system of internal controls designed to provide reasonable assurance that transactions are executed in accordance with management's general or specific authorization; transactions are recorded as necessary (1) to permit preparation of financial statements in conformity with generally accepted accounting principles, (2) to maintain accountability for assets, and (3) to ensure that access to assets is permitted only in accordance with management's general or specific authorization; and the recorded accountability for access is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

Since the date of the most recent evaluation of the Company's internal controls by the Chief Executive Officer and Chief Financial Officers, there have been no significant changes in such controls or in other factors that could have significantly affected those controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

We are not presently involved in any litigation.

Item 6. Exhibits And Reports On Form 8-K.

(a) Exhibits

Exhibit Number	Description	Reference Document
10.10	Common Share Purchase Agreement	
32	Statement Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 By Principal Executive Officer and Principal Financial Officer	
31.1	Statement Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 By the Principal Executive Officer regarding the Facts and Circumstances related to the Exchange Act Filings	
31.2	Statement Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 By the Principal Financial Officer regarding the Facts and Circumstances related to the Exchange Act Filings	

(b) Reports on Form 8-K

The Company filed one Current Report on Form 8-K during the quarter ended September 30, 2003. On August 12, 2003, the Company filed a Form 8-K reporting an Item 9 Regulation FD Disclosure, specifically the issuance of a press release on that date.

SIGNATURE

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

Date: November 5, 2003

INTERNATIONAL REMOTE IMAGING SYSTEMS, INC.

By: /s/ John Caloz
John Caloz
Corporate Vice President, Finance
And Chief Financial Officer