

VENTANA MEDICAL SYSTEMS INC

Form 10-Q

November 13, 2003

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended September 30, 2003.

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from _____ to _____.

Commission File Number: 000-20931

Ventana Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

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Delaware
(State or other jurisdiction of
incorporation or organization)

94-2976937
(I.R.S. employer
identification no.)

1910 Innovation Park Drive
Tucson, AZ
(Address of principal executive offices)

85737
(Zip Code)

Registrant's telephone number, including area code: (520) 887-2155

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter 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 ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2) of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock, \$0.001 par value, was 16,786,645 as of November 7, 2003.

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Table of Contents**Ventana Medical Systems, Inc.****Condensed Consolidated Balance Sheets**

(in thousands except share data)

(Unaudited)

	September 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,794	\$ 18,708
Trade accounts receivable, net	23,988	22,623
Inventories	10,678	13,901
Prepaid expenses	770	878
Deferred tax assets	2,359	2,386
Other current assets	1,222	1,210
Total current assets	74,811	59,706
Property and equipment, net	43,435	43,777
Goodwill	2,804	2,804
Intangible assets, net	7,721	8,819
Other assets	3,910	3,615
Deferred tax assets, net of current portion	6,421	6,416
Total assets	\$ 139,102	\$ 125,137
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,563	\$ 8,446
Other current liabilities	13,390	12,230
Total current liabilities	21,953	20,676
Long term debt	2,322	2,357
Commitments and Contingencies		
Stockholders' equity:		
Common stock \$.001 par value; 50,000 shares authorized; 16,700 and 16,346 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively	17	16
Additional paid-in capital	151,053	144,641
Accumulated deficit	(33,115)	(41,121)
Accumulated other comprehensive loss	(878)	(832)
Treasury stock 127 shares and 40 shares at cost at September 30, 2003 and at December 31, 2002, respectively	(2,250)	(600)
Total stockholders' equity	114,827	102,104
Total liabilities and stockholders' equity	\$ 139,102	\$ 125,137

See accompanying notes

Table of Contents**Ventana Medical Systems, Inc.****Condensed Consolidated Statements of Operations**

(in thousands except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Sales:				
Reagents and other	\$ 25,436	\$ 20,411	\$ 74,338	\$ 58,046
Instruments	6,524	6,676	20,333	16,974
Total net sales	31,960	27,087	94,671	75,020
Cost of goods sold	7,861	7,989	25,715	22,684
Gross profit	24,099	19,098	68,956	52,336
Operating expenses:				
Research and development	5,057	4,075	14,224	11,546
Selling, general and administrative	15,207	13,060	45,515	37,698
Amortization of intangible assets	466	382	1,385	1,190
Impairment charges and other expenses		1,151		1,151
Income from operations	3,369	430	7,832	751
Interest and other (expense) income	(33)	108	350	174
Income before taxes	3,336	538	8,182	925
Provision for income taxes	(47)	(31)	(176)	(495)
Net income	\$ 3,289	\$ 507	\$ 8,006	\$ 430
Per share data:				
Net income				
Basic	\$ 0.20	\$ 0.03	\$ 0.49	\$ 0.03
Diluted	\$ 0.19	\$ 0.03	\$ 0.47	\$ 0.03
Shares used in computing per share data:				
Basic	16,492	16,308	16,387	16,258
Diluted	17,730	16,609	17,165	16,580

See accompanying notes

Table of Contents**Ventana Medical Systems, Inc.****Condensed Consolidated Statements of Cash Flows**

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2003	2002
Operating activities:		
Net income	\$ 8,006	\$ 430
Adjustments to reconcile net income to cash provided by (used in) operating activities:		
Depreciation and amortization	6,745	5,875
Impairment charges and other expenses		1,151
Changes in operating assets and liabilities	2,958	(2,592)
Net cash provided by operating activities	17,709	4,864
Investing activities:		
Purchase of property and equipment	(5,018)	(6,586)
Purchase of intangible assets, net	(287)	(1,250)
Net cash used in investing activities	(5,305)	(7,836)
Financing activities:		
Issuance of common stock	6,413	3,824
Repayments of debt	(35)	(971)
Repurchase of common stock	(1,650)	
Net cash provided by financing activities	4,728	2,853
Effect of exchange rate change on cash	(46)	126
Net increase in cash and cash equivalents	17,086	7
Cash and cash equivalents, beginning of period	18,708	12,280
Cash and cash equivalents, end of period	\$ 35,794	\$ 12,287

See accompanying notes

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Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements

(in thousands, except per share data)

(Unaudited)

1. Organization and Significant Accounting Policies

Organization: Ventana Medical Systems, Inc. (Ventana or the Company) develops, manufactures and markets proprietary instrument and reagent systems that automate diagnostic procedures used for molecular analysis of tissues and cells. At present, the Company's principal markets are North America, Europe, Japan and Australia.

Basis of Presentation: The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ended December 31, 2003. For further information, refer to the consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

Recent Accounting Pronouncements: In April 2003, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities, which is generally effective for contracts entered into or modified after September 30, 2003 and for hedging relationships designated after September 30, 2003. SFAS 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative as discussed in SFAS No. 133, clarifies when a derivative contains a financing component, amends the definition of an underlying to conform it to the language used in FASB Interpretation No. 45, Guarantor Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others and amends certain other existing pronouncements. The Company does not have any derivative financial instruments. The Company does not anticipate that the adoption of SFAS No. 149 will have an impact on its consolidated balance sheets or statements of operations, shareholders' equity and cash flows.

In May 2003, the FASB issued SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This Statement requires that certain instruments that were previously classified as equity on a company's statement of financial position now be classified as liabilities. The Statement is effective for financial instruments entered into or modified after May 31, 2003, and to all other instruments that exist as of the beginning of the first interim period beginning after June 15, 2003. On October 29, 2003, the FASB voted to defer for an indefinite period the application of the guidance in SFAS 150 to noncontrolling interests that are classified as equity in the financial statements of the subsidiary but would be classified as a liability in the parent's financial statements under Statement 150. The FASB decided to defer the application of Statement 150 to these noncontrolling interests until it could consider some of the resulting implementation issues associated with the measurement and recognition guidance for these noncontrolling interests. The Company currently has no instruments impacted by the adoption of this statement and therefore the adoption did not have an effect on the Company's consolidated financial position, results of operations or cash flows.

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Notes to Condensed Consolidated Financial Statements (continued)

Stock-Based Employee Compensation: At September 30, 2003, the Company has six stock-based employee compensation plans. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (SFAS No. 123), Accounting for Stock-Based Compensation, to stock-based employee compensation:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income, as reported	\$ 3,289	\$ 507	\$ 8,006	\$ 430
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,537)	(1,739)	(5,690)	(5,510)
Pro-forma net income (loss)	\$ 1,752	\$ (1,232)	\$ 2,316	\$ (5,080)
Net income (loss) per share				
Basic as reported	\$ 0.20	\$ 0.03	\$ 0.49	\$ 0.03
Basic pro forma	\$ 0.11	\$ (0.08)	\$ 0.14	\$ (0.31)
Diluted as reported	\$ 0.19	\$ 0.03	\$ 0.47	\$ 0.03
Diluted pro forma	\$ 0.10	\$ (0.08)	\$ 0.13	\$ (0.31)

As required, the pro forma disclosures above include options granted since January 1, 1995. Consequently, the effects of applying SFAS No. 123 for providing pro forma disclosures may not be representative of the effects on reported net income for future years until all options outstanding are included in the pro forma disclosures. For purposes of pro forma disclosures, the estimated fair value of stock-based compensation plans and other options is amortized to expense primarily over the vesting period.

Reclassification: Certain prior year amounts have been reclassified to conform to the current period presentation.

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Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

2. Inventories

Inventories consist of the following:

	September 30, 2003	December 31, 2002
Raw material and work-in-process	\$ 4,479	\$ 5,541
Finished goods	7,213	9,366
Valuation reserve	(1,014)	(1,006)
	<u>\$ 10,678</u>	<u>\$ 13,901</u>

3. Comprehensive Income

The components of comprehensive income for the three and nine months ending September 30, 2003 and 2002 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30	
	2003	2002	2003	2002
Net income	\$ 3,289	\$ 507	\$ 8,006	\$ 430
Foreign currency translation	(59)	(48)	(46)	126
Comprehensive income	<u>\$ 3,230</u>	<u>\$ 459</u>	<u>\$ 7,960</u>	<u>\$ 556</u>

Accumulated other comprehensive loss of \$878 and \$832 at September 30, 2003 and December 31, 2002, respectively, consists exclusively of foreign currency translation adjustments.

4. Provision for Income Taxes

The Company did not recognize income tax expense for U.S. taxes for the three and nine month periods ending September 30, 2003 as the income tax provision for such periods was offset by income tax benefit from previously reserved deferred tax assets. The net deferred tax asset balance has not been assessed by management as being more likely than not of being recovered in the foreseeable future in an amount differing from the recorded balance. The tax expense reported consists of certain state franchise and international taxes.

5. Line of Credit

The Company has a \$12,000 line of credit arrangement with a bank that is subject to renewal in August 2004. Borrowings under the line are collateralized by the Company's receivables, inventories, and machinery and equipment. The line of credit contains certain financial covenants (measured quarterly) with which the Company must comply, prohibits the payment of dividends on the Company's stock and limits the number of treasury shares the Company may purchase. In addition, borrowings are limited to 50% of outstanding accounts receivable plus 25% of the value of finished goods of the Company, which as of September 30, 2003 resulted in available borrowing of \$12,000, of which, \$181 has been committed in support of various standby letters of credit. At September 30, 2003 the Company was in compliance with all covenants.

Table of Contents**Ventana Medical Systems, Inc.**

Notes to Condensed Consolidated Financial Statements (continued)

6. Stock Repurchase

On September 8, 1998, the Company's Board of Directors authorized the Company to repurchase up to 750 shares of its common stock in the open market or in privately negotiated transactions. During the nine months ended September 30, 2003, the Company purchased 87.4 shares of its common stock for \$1,650. The repurchased shares were returned to the status of authorized but unissued shares.

In October 2003, the Company purchased 77 shares of its common stock for \$2,886. The timing and amount of any future repurchases will depend on market conditions and corporate considerations.

7. Operating Segment and Enterprise Data

The Company has two reportable segments: North America (the United States and Canada) and International (primarily Europe, Japan and Australia). Segment information for the three and nine months ended September 30, 2003 and 2002 are as follows:

	Three months ended September 30, 2003			
	U.S.	International	Elimina- tions	Totals
Sales to external customers	\$ 23,363	\$ 8,597	\$	\$ 31,960
Segment profit	1,984	1,305		3,289
	Three months ended September 30, 2002			
	U.S.	International	Elimina- tions	Totals
Sales to external customers	\$ 20,269	\$ 6,818	\$	\$ 27,087
Segment profit (loss)	(763)	1,270		507
	Nine months ended September 30, 2003			
	U.S.	International	Elimina- tions	Totals
Sales to external customers	\$ 68,312	\$ 26,359	\$	\$ 94,671

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Segment profit	3,701	4,305		8,006
Segment assets	130,102	25,892	(16,892)	139,102

Nine months ended September 30, 2002

	U.S.	International	Elimina- tions	Totals
Sales to external customers	\$ 55,861	\$ 19,159	\$	\$ 75,020
Segment profit (loss)	(2,432)	2,862		430
Segment assets	113,720	29,119	(21,369)	121,470

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Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

8. Commitments and Contingencies

CYTOLOGIX v. VENTANA, Case No. 00-12231 REK, filed Oct. 27, 2000 in federal district court in Boston. The complaint claims, under state-law based unfair competition law, that Ventana misappropriated CytoLogix's trade secrets related to individual slide heating and incorporated such secrets into our DISCOVERY® and BENCHMARK® instruments. CytoLogix seeks assignment of our patent applications relating to individual slide heating claiming the idea, treble damages (unspecified amount) and an injunction against our further sales of DISCOVERY® and BENCHMARK® instruments. In February, 2002 Cytologix filed a motion to amend their complaint to add the related claims of attempted monopolization and monopolization under the Sherman Act, and various Lanham Act violations, which was allowed by the court. Previously this case and the patent infringement dispute, Case No. 01-10178 REK (see below) had been consolidated for discovery; they were bifurcated for trial at the January 28, 2003 status conference. This case is presently scheduled to commence trial on the issue of liability under the trade secret claim, on November 24, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however, the results of the proceeding are uncertain and there can be no assurance to that effect.

CYTOLOGIX v. VENTANA, Case No. 4 Ni 54/00 (EU) (Nullity suit), filed November 9, 2000 in the German Federal Patent Court, Munich, Germany. In a decision at the oral hearing March 20, 2002, the German Federal Patent Court ruled that our German patent no. DE 69117052.5, which covers various aspects of our previous generation GENII® automated slide staining system, is invalid. The technology addressed by the German patent is unrelated to the technologies involved in any of the other patent litigations, including the individual slide heating technology that is the subject of the Boston-based patent litigation. The decision affects our ability to enforce this patent in Germany subject to an appeal and final decision on validity. On May 22, 2002, we filed an appeal to the German Federal Court of Justice seeking that the previous judgment be set aside, and that the complaint be dismissed substituting an amended claim into the patent. We have been advised by German patent counsel not to expect a decision on our appeal until the second or third quarter of 2004. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however, the results of the proceeding are uncertain and there can be no assurance to that effect.

CYTOLOGIX v. VENTANA, Case No. 01-10178 REK, filed January 30, 2001 in the U.S. District Court, Eastern District of Massachusetts. This complaint claims that we infringed on CytoLogix's patent No. 6,180,061, entitled "Moving Platform Slide Stainer with Heating Elements, and was later amended to add U.S. Patent No. 6,183,693, issued February 7, 2001, entitled "Random Access Slide Stainer with Independent Slide Heating Regulation," both assigned to CytoLogix. CytoLogix seeks assignment of our patent applications claiming the independent slide heater idea, treble damages (unspecified amount) and an injunction against our further sales of DISCOVERY® and BENCHMARK® instruments. This case is presently scheduled to commence trial on the issue of patent infringement liability together with the trade secrets issue on November 24, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

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Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

8. Commitments and Contingencies (Continued)

On November 19, 2001 a patent infringement claim was filed against Ventana titled DIGENE CORPORATION v. VENTANA MEDICAL SYSTEMS, INC., (Case No. 01-752) in Delaware Federal District Court. This complaint alleges that we infringed two US patents held by Digene, U.S. 4,849,331 and 4,849,332, by activities relating to our INFORM® HPV High-risk and Low-risk probe products. We filed an answer denying the allegations on February 4, 2002. The parties have filed cross-motions for summary judgment. In addition, in November 2002 Digene filed a motion to amend its complaint to add numerous causes of action related to our September 2002 acquisition of BeckmanCoulter's HPV business and to add BeckmanCoulter as a party. Digene seeks, among other remedies, an injunction against the sale of our INFORM HPV products, unspecified monetary damages, cancellation of the BeckmanCoulter HPV acquisition, and related claims. At a hearing held March 5, 2003, the court ruled to add BeckmanCoulter as a party. In a post-hearing decision handed down on May 22, 2003, the judge ordered that further discovery be taken on the issues of the arbitrability of the issues in this case, and that another hearing be held to determine the arbitration motions. On June 19, 2003 the court ordered limited discovery on the issue of BeckmanCoulter's status as a party to an underlying agreement. On October 24, 2003 and without any prior notice, Digene filed a motion for a temporary restraining order against Ventana. By its motion, Digene sought to prevent Ventana from entering into supply, license, product development or similar agreements with third parties involving HPV. The Digene motion was denied on October 27, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

On February 11, 2003, Ventana filed a Complaint in Arizona Federal District Court against BioGenex Laboratories, Inc. (BioGenex), for infringement of U.S. Patent No. 6,352,861 (Automated Biological Reaction Apparatus). On September 2, 2003, BioGenex served its Answer to the Complaint denying infringement. On September 18, 2003, BioGenex amended its Answer to Ventana's Complaint adding the defense of invalidity. The parties are currently conducting discovery. We believe that we have meritorious claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

On July 15, 2003, Ventana filed a patent infringement action against Abbott Laboratories, Inc., and its subsidiary Vysis, Inc., for patent infringement in the Federal District Court in Chicago, Illinois alleging that various Vysis DNA probe products infringe U.S. Patent No. 6,025,126 (Methods and Compositions for the Detection of Chromosomal Aberrations) and U.S. Patent No. 6,414,133 (Multiple Fusion Probes). In particular, Ventana alleges that sales of the BCR/ABL probes, amongst others, sold by Vysis infringe one or both of the patents. We believe that we have meritorious claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

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Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

8. Commitments and Contingencies (Continued)

On August 25, 2003, a patent infringement claim was filed against Ventana entitled BIOGENEX LABORATORIES, INC., v. VENTANA MEDICAL SYSTEMS, INC., in the United States District Court for the District Court of Northern California, San Jose Division. (Case No. C03 03913 JF). This complaint alleges that Ventana infringes three US patents held by BioGenex, U.S. Patent Nos., 5578452, 5244787 and 6451551. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

With respect to each of the matters above in which we are the defendant, management's estimate of the potential loss is not possible given that the amount of loss, if any, is not estimable. It is the opinion of management the ultimate resolution of these contingencies will not have a material adverse effect on the financial condition, results of operations or cash flows of the Company.

We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our financial positions, results of operations, or cash flows.

9. Subsequent Event

In October 2003, the Company reviewed its product offerings and strategic focus for future growth and concluded it should re-locate its Pharma Services business to Tucson, close its Chicago reference lab business and exit certain other product lines and record fourth-quarter charges of approximately \$6,300 or \$0.36 per fully diluted share. Approximately \$5,700 of the total charge relates to non-cash items associated with impairment charges to intangibles, Developed Technology and Acquired Customer Base (\$3,700) and other assets, primarily fixed assets and inventory (\$2,000). The non-cash charges are the result of the write-down of intangibles and other assets related to the 1996 purchase of Biotek Solutions Inc., the 1998 purchase of Biotechnology Tools Inc. and the 2000 purchase of Quantitative Diagnostic Laboratories. The Company expects cash charges of approximately \$600 resulting from severance and lease exit costs associated with its closing of the reference lab business.

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Ventana Medical Systems, Inc.

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

The following discussion of the financial condition and results of operations of the Company should be read in conjunction with the Condensed Consolidated Financial Statements and related Notes thereto included elsewhere in this Form 10-Q. This Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements, by their very nature, contain risks and uncertainties. Accordingly, actual events or results may differ materially from those anticipated by such forward-looking statements. A wide variety of factors could cause or contribute to such differences and could adversely impact revenues, profitability, cash flows and capital needs. Such factors, many of which are beyond the Company's control, include the following: market acceptance of new automated histology products, continued success in asset management, continued improvements in our manufacturing efficiencies, on-schedule launches of our new products, currency exchange rate variability, adverse determinations in various outstanding litigations, competition and competitive pressures on pricing and general economic conditions in the United States and in the regions served by the Company.

Results of Operations

Net Sales

Net sales for the three and nine months ended September 30, 2003 increased 18% and 26% versus the same periods in 2002 to \$32.0 million and \$94.7 million from \$27.1 million and \$75.0 million, respectively. Net sales growth was attributable to 25% and 28% increases in reagents and non-instrument sales for the three and nine month periods respectively. This increase in sales is driven by the growth in the underlying installed base and the expansion of the Company's reagent menu. Instrument sales for the three and nine months ended September 30, 2003 decreased 2% and increased 20% versus the same periods in 2002, primarily due to an increased number of placement conversions generated in the clinical market. Total sales increased in the three and nine month periods ended September 30, 2003, compared to the same periods in 2002 across both geographic segments: In the U.S. by 15% (\$23.4 million up from \$20.3 million) and 22% \$68.3 million up from \$55.9) and internationally by 26% (\$8.6 million up from \$6.8 million) and 38% \$26.4 million up from \$19.2 million).

Gross Profit

Gross profit for the three and nine months ended September 30, 2003 increased to \$24.1 million and \$69.0 million, respectively, from \$19.1 million and \$52.3 million for the same periods in 2002. The Company's gross margin percentage for both the three and nine months ended September 30, 2003 increased 5% and 3% respectively. The primary reasons for the increase in gross profit margin is the higher mix of reagent sales that have a higher gross margin than instruments and improved manufacturing efficiencies as well as higher production volumes which lowered per unit costs due to better absorption of fixed costs.

Table of Contents**Ventana Medical Systems, Inc.****Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations***Research and Development*

Research and development spending for the three and nine months ended September 30, 2003 increased to \$5.1 million and \$14.2 million, respectively, from \$4.1 million and \$11.5 million for the same periods in 2002. The increase results primarily from several major platform development projects underway including the Benchmark XT and the H&E Primary Stainer together with investment in expanding the Company's life science capabilities.

Selling, General and Administrative (SG&A)

Presented below is a summary of SG&A expense for the three and nine months ended September 30, 2003 and 2002:

(in thousands)	Three Months Ended				Nine Months Ended			
	September 30				September 30			
	2003		2002		2003		2002	
	\$	% Net Sales	\$	% Net Sales	\$	% Net Sales	\$	% Net Sales
Sales and marketing	\$ 11,033	35%	\$ 9,450	35%	\$ 34,090	36%	\$ 27,551	37%
Administration	4,174	13%	3,610	13%	11,425	12%	10,147	13%
Total SG&A	\$ 15,207	48%	\$ 13,060	48%	\$ 45,515	48%	\$ 37,698	50%

SG&A expense for the three and nine months ended September 30, 2003 increased to \$15.2 million and \$45.5 million, respectively, from \$13.1 million and \$37.7 million for the same periods in 2002. The increase is primarily attributed to increased investments in our sales and marketing infrastructure and outside service expenses including costs associated with our various legal matters.

Amortization of Intangible Assets

Intangible assets consist primarily of developed technology, customer base, supply and license agreements, and patents. Such assets are amortized on a straight-line basis over estimated useful lives ranging from four to nine years, resulting in quarterly costs approximating \$0.5

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million. Estimated amortization expense for intangible assets as of September 30, 2003 for each of the five succeeding fiscal years is as follows (all amounts are in millions): 2003: \$1.9, 2004: \$1.9, 2005: \$1.6, 2006: \$1.4, 2007: \$0.8.

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Ventana Medical Systems, Inc.

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

Interest and Other Income (Expense)

Interest and other income (expense) for the three and nine months ended September 30, 2003 decreased to (\$33,000) versus \$108,000 for the three months ended and increased to \$350,000 from \$174,000 for the nine months ended. The three month balance decrease is primarily due to increased interest expense with our European facility lease and foreign currency translations. The nine month balance increase is primarily due to higher average investment balances in 2003.

Risk Factors

We may be required to bring litigation to enforce our intellectual property rights, which may result in substantial expense.

We rely on patents to protect our intellectual property rights. The strength of this protection, however, is uncertain. In particular, it is not certain that:

our patents and pending patent applications use technology that we invented first;

we were the first to file patent applications for these inventions;

others will not independently develop similar or alternative technologies or duplicate our technologies;

any of our pending patent applications will result in issued patents; or

any patents issued to us will provide a basis for commercially viable products, will provide us with any competitive advantages or will not face third party challenges or be the subject of further proceedings limiting their scope

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. We could also become involved in opposition proceedings in foreign countries challenging the validity of our patents. In addition, costly litigation could be necessary to protect our patent position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any lawsuit or, if we do prevail, we may not receive commercially valuable remedies. Failure to protect our patent rights or intellectual property could harm us.

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We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect with confidentiality agreements with employees, consultants and others with whom we discuss our business. These individuals may breach our confidentiality agreements and our remedies may not be adequate to enforce these agreements. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and we may not be able to resolve these disputes in our favor. Furthermore, our competitors may independently develop trade secrets and proprietary technology similar to ours. We may not be able to maintain the confidentiality of information relating to our products.

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Ventana Medical Systems, Inc.

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

Our products could infringe the intellectual property rights of others, which may cause us to engage in costly litigation and, if we are not successful, could cause us to pay substantial damages and prohibit us from selling our products.

Third parties may assert patent, trademark or copyright infringement or other intellectual property claims against us based on their patents or other intellectual property. We may be required to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe a third party's intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. If we are not successful in a lawsuit, we may be unable to sell our products or continue to sell our products until we obtain a license from the owner of the relevant technology or other intellectual property rights. Even if a license is available, it may require us to pay substantial royalties.

A review of our current litigation is disclosed in Item 1 Notes to Unaudited Financial Statements. See Notes to Unaudited Financial Statements - Note 8 - *Commitments and Contingencies*. We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our financial positions, results of operations, or cash flows.

If our customers do not receive adequate third-party reimbursement, our products may not be accepted in the market.

In the United States, our products are primarily purchased by medical institutions and laboratories that bill third-party payers such as government health administration authorities, private health coverage insurers, managed care organizations and other similar organizations. Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available to our customers from third-party payers. Third-party payers are increasingly attempting to limit both the coverage and the level of reimbursement of products to contain costs. If third-party payers are successful in such efforts, our ability to sustain revenue growth and profitability will be adversely effected.

If government funding is reduced, the ability of research centers to purchase our products may also be reduced.

Some of our products are sold to universities, research laboratories, private foundations and other institutions where funding is dependent upon grants from government agencies, such as the National Institutes of Health. Research funding by the government could be significantly reduced and could materially affect the ability of many of our research customers to purchase our products.

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Ventana Medical Systems, Inc.

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

If we fail to develop new products, we may not be profitable in the future.

A large part of our future growth and profitability will be dependent on our ability to develop, introduce and market new instruments and reagents used in disease diagnosis and treatment selection. We depend, in part, on the success of medical research done by others in developing new antibodies, nucleic acid probes and clinical diagnostic procedures that can be adapted for use in our systems. We may need to license some of these technologies. We may not be able to enter into these licenses on terms that would allow us to economically develop and market new products. If this were to occur, our operating results would suffer.

We face intense competition and rapid technological change that could result in products that are superior to the products we are developing.

We have numerous competitors in the United States and abroad. These competitors include Sakura Fine Technical, DAKO Cytomation A/S, BioGenex Laboratories, Lab Vision Corporation, Digene Corporation, Genomic Solutions, Vision Bio Systems Ltd., and Molecular Dynamics. These competitors may develop technologies and products that are more effective or less costly than our current or future products or that could render our technologies and products obsolete or noncompetitive. Many of these competitors have greater experience and name recognition. If we are not able to compete effectively, our result would suffer.

We need to convince the medical community of the superiority of our product to be successful.

The use of automated systems to perform diagnostic tests is relatively new. Historically, laboratory personnel have manually performed diagnostic tests that are now performed by our automated systems. Our ability to sell products is dependent on our ability to demonstrate to the medical community the benefits of automated diagnostic testing using our products. The quality and price of our products compared to manual testing and to our competitor's products will affect acceptance and sales of our products. If the medical community were not receptive to our products, our results would suffer.

If we fail to obtain or maintain necessary FDA clearances or approvals for our products, or if clearances or approvals are delayed, we will be unable to commercially distribute and market our products in the United States.

In the United States, the FDA regulates, as medical devices, instruments, diagnostic tests and reagents that are traditionally manufactured and commercially marketed as equipment or finished test kits. Some clinical laboratories, however, purchase clinical products, which are marketed as analytic specific reagents, or ASRs, and develop and prepare their own finished diagnostic tests called "home brews". The FDA restricts the sale of these products to clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, known as CLIA, to perform high complexity testing. We intend to market some diagnostic products as finished test kits and others as individual reagents. Consequently, these clinical products will be regulated as medical devices.

Unless otherwise exempt, medical devices require approval or clearance prior to marketing in the United States. Although we believe our currently marketed products, as well as those ASRs we market, are exempt from 510(k) premarket notification and premarket approval requirements, the process of obtaining approvals and clearances necessary to market clinical products can be time-consuming, expensive and uncertain.

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Ventana Medical Systems, Inc.

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

However, clinical products that we may seek to introduce in the future may require FDA approvals or clearances prior to commercial sale in the United States. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of new clinical products. In addition, we cannot assure you that regulatory approval or clearances of any clinical products for which we seek such approvals or clearances will be granted by the FDA or foreign regulatory authorities on a timely basis, if at all.

If we fail to comply with the FDA's Quality System regulations, our manufacturing operations could be delayed, and our product sales and profitability could suffer.

When manufacturing our medical devices, including ASRs, we are required to adhere to Quality System regulations, which require that we manufacture our products and maintain records in a prescribed manner. We are subject to FDA Quality System inspections in the future, and we cannot assure you that we can pass future FDA audits or maintain compliance.

CLIA regulations could harm our business by limiting the potential market for our products.

Any of our customers using our products for clinical use in the United States may be regulated under CLIA. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of clinical tests, and the standards applicable to a clinical laboratory depend on the level of the tests it performs. CLIA requirements may prevent some clinical laboratories from using our products. Therefore, CLIA regulations and future administrative interpretations of CLIA could harm our business by limiting the potential market for our products.

Complying with international regulatory requirements is an expensive, time-consuming process and approval is never certain.

European sales of our products are subject to strict regulatory requirements. The review process varies from country to country, is typically lengthy and expensive, and approval is never certain. Effective December 7, 2003, all of our products must be in compliance with the In Vitro Diagnostics Directive and bear the CE mark before being marketed in the European Union. The CE mark is a symbol indicating that the device conforms with the essential requirements of an applicable directive, and can be commercially distributed throughout Europe. The In Vitro Diagnostic Directive also subjects our manufacturing facilities to compliance inspections, and requires design, manufacturing, quality process documentation and controls. We cannot assure you that the CE mark will be granted for our products or that regulatory review will not involve delays that would harm our ability to market and sell our products in the European Union.

If we make future acquisitions, such acquisitions may not be profitable.

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We may make additional acquisitions of complementary businesses, products or technologies in the future. Acquisitions of companies, divisions of companies, or products entail numerous risks. We cannot assure that we will not incur problems in any future acquisitions, or that future acquisitions will increase our profitability. We also cannot assure that we will realize value from any acquisitions that would justify the consideration paid.

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Ventana Medical Systems, Inc.

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

We depend on key personnel to grow and sustain our business.

We are dependent upon the retention of principal members of our management, Board of Directors, scientific, technical, marketing and sales staffs and the recruitment of additional personnel. Except as otherwise, described in other sections, we do not have employment agreements with any of our executive officers and we do not maintain key person life insurance on any of our personnel. We compete with other companies, academic institutions, government entities and other organizations for qualified personnel. Our inability to hire or retain qualified personnel could cause our results of operations to suffer.

If we have problems with key suppliers, our product development and commercialization efforts could be delayed or stopped.

Our reagent products are formulated from chemical and biological materials using proprietary technology, and standard processing techniques. We purchase components and raw materials used to make our reagent products from single-source vendors. We cannot assure that the materials or reagents needed will be available in commercial quantities or at acceptable prices. Any supply interruption or yield problems encountered in the use of materials from these vendors could have a significant effect on our ability to manufacture our products. Developing an alternative or additional suppliers could be time consuming and expensive.

A number of components used to manufacture instruments are made on a custom basis to our specifications and are available from a limited number of sources. If the supply of materials or components from any of these vendors were delayed or interrupted for any reason, or if the quality or reliability of the materials or components is not adequate for use in our instruments, our ability to make instruments in a timely fashion could be impaired and our results of operations would suffer.

We deal with hazardous materials and generate hazardous wastes and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. We could also be liable for damages or penalties, if we are involved in a hazardous material or waste spill or other accident.

Our manufacturing processes, primarily those involved in producing some of our reagent products, require the use of potentially hazardous and carcinogenic chemicals. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste. In the event of a hazardous material or waste spill or other accident, we could also be liable for damages or penalties. In addition, we may be liable or potentially liable for injury or contamination that results from our, or a third party's, use of these materials, and our liability could exceed our total assets.

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Ventana Medical Systems, Inc.

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

We cannot assure that we will be able to fund our future capital requirements through internal sources, our existing line of credit or from other sources.

We anticipate that our existing capital resources and borrowing capacity will be adequate to satisfy our capital requirements for the next 12 months. Our future capital requirements will depend on many factors including:

the extent that our products gain market acceptance;

the mix of instruments placed through direct sales, rental or through our PEP program;

the progression of our product development programs;

competing technological and market developments;

expansion of our sales and marketing activities;

the cost of manufacturing scale-up activities;

possible acquisitions of complementary businesses, products or technologies; and

our ability to sustain profitability with the uncertain timing of regulatory approvals.

We may require additional capital resources and cannot assure that capital will be available to the extent required, on terms acceptable to us, or at all. Any such future capital requirements could result in the issuance of equity securities, which may affect the market price of our common stock and would dilute the interests of our existing stockholders.

Liquidity and Capital Resources

As of September 30, 2003, the Company's principal source of liquidity consisted of cash and cash equivalents of \$35.8 million. The Company also had a \$12.0 million revolving bank credit facility of which \$0.2 million has been committed in support of various standby letters of credit. Borrowings under the Company's bank credit facility are secured by the Company's receivables, inventories, machinery and equipment, and intellectual property and bear interest at the bank's prime rate.

During the nine months ended September 30, 2003, net cash provided by operating and investing activities increased to \$12.4 million versus (\$3.0) million in the nine months ended September 30, 2002. The increase was primarily associated with improved profitability in 2003 and lower inventory balances.

We believe that our current cash and cash equivalents, line of credit and cash generated from operations will satisfy funding requirements including working capital and capital expenditures for the foreseeable future.

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Ventana Medical Systems, Inc.

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

Foreign Currency Risk

The value of the U.S. Dollar affects our financial results. Changes in exchange rates may positively or negatively affect our revenues, gross margins, operating expenses and shareholders' equity as expressed in U.S. Dollars. We have determined that hedging of non-U.S. dollar net monetary assets is not cost effective at the present time and instead attempt to minimize currency exposure risk through working capital management. There can be no assurance that such an approach will be successful, especially if a significant or sudden decline occurs in the value of local currencies. We conduct a growing portion of our business in the Euro, Japanese Yen and Australian Dollar.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

At September 30, 2003, our only cash equivalent investments are in money market accounts and overnight reverse repurchase agreements (\$22.3 million) that are reflected as cash equivalents because all maturities are within 90 days. Our interest rate risk with respect to existing investments is limited due to the short-term duration of these arrangements and the yields earned which approximate current interest rates.

At September 30, 2003, we have \$2.3 million in debt obligations and there are \$0.2 million of borrowings under our line of credit facility. As such, our interest rate risk is limited with respect to existing debt. A sizable portion of our revenue and capital spending is transacted in U.S. Dollars. However, we do at times enter into these transactions in other currencies, such as the Euro, the Japanese Yen and the Australian Dollar. No hedging transactions were entered into to limit this exposure.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Ventana Medical Systems, Inc.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

CYTOLOGIX v. VENTANA, Case No. 00-12231 REK, filed Oct. 27, 2000 in federal district court in Boston. The complaint claims, under state-law based unfair competition law, that Ventana misappropriated CytoLogix's trade secrets related to individual slide heating and incorporated such secrets into our DISCOVERY® and BENCHMARK® instruments. CytoLogix seeks assignment of our patent applications relating to individual slide heating claiming the idea, treble damages (unspecified amount) and an injunction against our further sales of DISCOVERY® and BENCHMARK® instruments. In February, 2002 CytoLogix filed a motion to amend their complaint to add the related claims of attempted monopolization and monopolization under the Sherman Act, and various Lanham Act violations, which was allowed by the court. Previously this case and the patent infringement dispute, Case No. 01-10178 REK (see below) had been consolidated for discovery; they were bifurcated for trial at the January 28, 2003 status conference. This case is presently scheduled to commence trial on the issue of liability under the trade secret claim, on November 24, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however, the results of the proceeding are uncertain and there can be no assurance to that effect.

CYTOLOGIX v. VENTANA, Case No. 4 Ni 54/00 (EU) (Nullity suit), filed November 9, 2000 in the German Federal Patent Court, Munich, Germany. In a decision at the oral hearing March 20, 2002, the German Federal Patent Court ruled that our German patent no. DE 69117052.5, which covers various aspects of our previous generation GENII® automated slide staining system, is invalid. The technology addressed by the German patent is unrelated to the technologies involved in any of the other patent litigations, including the individual slide heating technology that is the subject of the Boston-based patent litigation. The decision affects our ability to enforce this patent in Germany subject to an appeal and final decision on validity. On May 22, 2002, we filed an appeal to the German Federal Court of Justice seeking that the previous judgment be set aside, and that the complaint be dismissed substituting an amended claim into the patent. We have been advised by German patent counsel not to expect a decision on our appeal until the second or third quarter of 2004. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however, the results of the proceeding are uncertain and there can be no assurance to that effect.

CYTOLOGIX v. VENTANA, Case No. 01-10178 REK, filed January 30, 2001 in the U.S. District Court, Eastern District of Massachusetts. This complaint claims that we infringed on CytoLogix's patent No. 6,180,061, entitled "Moving Platform Slide Stainer with Heating Elements, and was later amended to add U.S. Patent No. 6,183,693, issued February 7, 2001, entitled "Random Access Slide Stainer with Independent Slide Heating Regulation," both assigned to CytoLogix. CytoLogix seeks assignment of our patent applications claiming the independent slide heater idea, treble damages (unspecified amount) and an injunction against our further sales of DISCOVERY® and BENCHMARK® instruments. This case is presently scheduled to commence trial on the issue of patent infringement liability together with the trade secrets issue on November 24, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

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Ventana Medical Systems, Inc.

Item 1. Legal Proceedings (continued)

On November 19, 2001 a patent infringement claim was filed against Ventana titled DIGENE CORPORATION v. VENTANA MEDICAL SYSTEMS, INC., (Case No. 01-752) in Delaware Federal District Court. This complaint alleges that we infringed two US patents held by Digene, U.S. 4,849,331 and 4,849,332, by activities relating to our INFORM® HPV High-risk and Low-risk probe products. We filed an answer denying the allegations on February 4, 2002. The parties have filed cross-motions for summary judgment. In addition, in November 2002 Digene filed a motion to amend its complaint to add numerous causes of action related to our September 2002 acquisition of BeckmanCoulter's HPV business and to add BeckmanCoulter as a party. Digene seeks, among other remedies, an injunction against the sale of our INFORM HPV products, unspecified monetary damages, cancellation of the BeckmanCoulter HPV acquisition, and related claims. A hearing was held March 5, 2003 on several pending motions, however the court only ruled on one of them, adding BeckmanCoulter as a party. The other motions are awaiting decision. In a post-hearing decision handed down on May 22, 2003, the judge ordered that further discovery be taken on the issues of the arbitrability of the issues in this case, and hold another hearing to determine the arbitration motions. On June 19, 2003 the court ordered limited discovery on the issue of BeckmanCoulter's status as a party to an underlying agreement. On October 24, 2003 and without any prior notice, Digene filed a motion for a temporary restraining order against Ventana. By its motion, Digene sought to prevent Ventana from entering into supply, license, product development or similar agreements with third parties involving HPV. The Digene motion was denied on October 27, 2003. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

On February 11, 2003, Ventana filed a Complaint in Arizona Federal District Court against BioGenex Laboratories, Inc. (BioGenex), for infringement of U.S. Patent No. 6,352,861 (Automated Biological Reaction Apparatus). On September 2, 2003, BioGenex served its Answer to the Complaint denying infringement. On September 18, 2003, BioGenex amended its Answer to Ventana's Complaint adding the defense of invalidity. The parties are currently conducting discovery. We believe that we have meritorious claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

On July 15, 2003, Ventana filed a patent infringement action against Abbott Laboratories, Inc., and its subsidiary Vysis, Inc., for patent infringement in the Federal District Court in Chicago, Illinois alleging that various Vysis DNA probe products infringe U.S. Patent No. 6,025,126 (Methods and Compositions for the Detection of Chromosomal Aberrations) and U.S. Patent No. 6,414,133 (Multiple Fusion Probes). In particular, Ventana alleges that sales of the BCR/ABL probes, amongst others, sold by Vysis infringe one or both of the patents. We believe that we have meritorious claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

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Ventana Medical Systems, Inc.

Item 1. Legal Proceedings (continued)

On August 25, 2003, a patent infringement claim was filed against Ventana entitled BIOGENEX LABORATORIES, INC., v. VENTANA MEDICAL SYSTEMS, INC., in the United States District Court for the District Court of Northern California, San Jose Division. (Case No. C03 03913 JF). This complaint alleges that Ventana infringes three US patents held by BioGenex, U.S. Patent Nos., 5578452, 5244787 and 6451551. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. We believe that we have meritorious defenses to the claims in this action and that resolution of this matter will not have a material adverse effect on our business, financial condition or results of operation; however the results of the proceeding are uncertain and there can be no assurance to that effect.

With respect to each of the matters above in which we are the defendant, management's estimate of the potential loss is not possible given that the amount of loss, if any, is not estimable. It is the opinion of management the ultimate resolution of these contingencies will not have a material adverse effect on the financial condition, results of operations or cash flows of the Company.

We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our financial positions, results of operations, or cash flows.

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Ventana Medical Systems, Inc.

Item 6. Exhibits and reports on Form 8-K

(a) Exhibits

Please refer to the Exhibit Index of this report on 10-Q

(b) Reports on Form 8-K.

On July 11, 2003, the Company filed a current report on Form 8-K to furnish the Company's press release reporting preliminary results for the six months ended June 30, 2003. In accordance with SEC Release No. 33-8216, the information, intended to be furnished under Item 12. Results of Operations and Financial Condition, was instead furnished under Item 9. Regulation FD Disclosure.

On July 18, 2003, the Company filed a current report on Form 8-K to furnish the Company's press release reporting results for the six months ended June 30, 2003. In accordance with SEC Release No. 33-8216, the information, intended to be furnished under Item 12. Results of Operations and Financial Condition, was instead furnished under Item 9. Regulation FD Disclosure.

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SIGNATURE

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

Ventana Medical Systems, Inc.

Date: November 12, 2003

By:

/s/ NICHOLAS MALDEN

**Nicholas Malden, Vice President,
Chief Financial Officer and Secretary**

Table of Contents**EXHIBITS**

Exhibit			
Number	Description	Notes	
3.1	Restated Certificate of Incorporation or Registrant	(1)	
3.2	Bylaws of Registrant	(1)	
4.1	Specimen Common Stock Certificate	(1)	
10.1	Form of Indemnification Agreement for directors and officers	(1)	
10.2	1988 Stock Option Plan and forms of agreements thereunder	(1)	
10.3	1996 Stock Option Plan and forms of agreements thereunder	(1)	
10.4	1996 Employee Stock Purchase Plan	(1)	
10.5	1996 Directors Option Plan	(1)	
10.6	1998 Nonstatutory Stock Option Plan and forms of agreements thereunder	(2)	
10.7	2001 Outside Director Stock Option Plan	(3)	
31.1	Certificate of Principal Executive Officer		
31.2	Certificate of Principal Financial Officer		
32.1	Certificate of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		
32.2	Certificate of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		

(1) Filed with the Registration Statement on Form S-1 (Commission File No. 333-4461), declared effective by the Commission July 26, 1996.

(2) Filed with the Registration Statement on Form S-8 (Commission File No. 333-92883), filed with the Commission on December 16, 1999.

(3) Filed with the Registration Statement on Form S-8 (Commission File No. 333-69658), filed with the Commission on September 19, 2001.