

VENTANA MEDICAL SYSTEMS INC

Form 10-Q

April 28, 2006

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**UNITED STATES**  
**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 quarterly period ended March 31, 2006.**

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)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

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

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

**85755**  
(Zip Code)

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

**Not Applicable**

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

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. (See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act).

Large Accelerated Filer ☒

Accelerated Filer ☐

Non-Accelerated Filer ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

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The number of shares outstanding of the registrant's common stock, \$0.001 par value was 36,448,103 as of April 21, 2006.

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**Table of Contents****VENTANA MEDICAL SYSTEMS, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except per share data)****(Unaudited)****Item 1. Financial Statements**

	<b>March 31, 2006 (Unaudited)</b>	<b>December 31, 2005</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 13,901	\$ 17,519
Short-term investments	29,650	27,892
Trade accounts receivable, net of allowance for doubtful accounts of \$1,613 and \$1,536, respectively	38,749	38,170
Inventories, net	13,389	12,888
Deferred tax assets	7,977	7,969
Prepays and other current assets	2,744	2,412
Total current assets	106,410	106,850
Property and equipment, net	55,462	54,195
Deferred tax assets, net of current portion	13,440	13,056
Long-term investments	4,883	6,209
Goodwill	2,804	2,804
Intangible assets, net	8,804	8,779
Capitalized software development costs, net	2,907	2,741
Other assets	1,821	1,898
Total assets	\$ 196,531	\$ 196,532
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 13,859	\$ 10,660
Other current liabilities	30,898	30,954
Total current liabilities	44,757	41,614
Long-term debt	1,975	1,996
Other long-term liabilities	630	618
<b>Commitments and Contingencies</b>		
<b>Stockholders' equity</b>		
Common stock \$.001 par value; 100,000 shares authorized, 36,396 and 36,226 shares issued and outstanding at March 31, 2006 and December 31, 2005 respectively	36	36
Additional paid-in-capital	204,449	199,580
Deferred share-based compensation		(382)
Accumulated income	16,651	11,628
Accumulated other comprehensive loss	(798)	(783)
Treasury stock 2,506 and 2,140 shares, at cost, at March 31, 2006 and December 31, 2005, respectively	(71,169)	(57,775)
Total stockholders' equity	149,169	152,304

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Total liabilities and stockholders' equity	\$ 196,531	\$ 196,532
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**Table of Contents****Ventana Medical Systems, Inc.****Condensed Consolidated Statements of Operations**

(in thousands except per share data)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Sales:</b>		
Reagents and other	\$ 47,174	\$ 38,909
Instruments	6,913	6,113
Total net sales	54,087	45,022
Cost of goods sold (1)	13,304	11,600
Gross margin	40,783	33,422
<b>Operating expenses:</b>		
Research and development (2)	7,359	6,135
Selling, general and administrative (3)	24,982	19,800
Amortization of intangible assets	631	476
Income from operations	7,811	7,011
Interest and other income	426	101
Income before taxes	8,237	7,112
Provision for income taxes	3,214	2,496
Net income	\$ 5,023	\$ 4,616
<b>Net income per common share:</b>		
Basic	\$ 0.15	\$ 0.13
Diluted	\$ 0.14	\$ 0.13
<b>Shares used in computing net income per common share:</b>		
Basic	33,995	34,193
Diluted	35,961	36,805
(1) amounts include share-based compensation expense	\$ 35	\$
(2) amounts include share-based compensation expense	\$ 282	\$ 14
(3) amounts include share-based compensation expense	\$ 1,047	\$

See Notes to Consolidated Financial Statements.

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

(in thousands)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Net income	\$ 5,023	\$ 4,616
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	3,803	2,234
Share-based compensation expense related to employee stock options and employee stock purchases	1,377	
Deferred income taxes	(381)	(3,312)
Tax benefit from employee stock option plans	1,346	4,381
Excess tax benefits from share-based compensation	(1,329)	
Change in operating assets and liabilities:		
Accounts receivable	(579)	925
Inventory	(501)	(366)
Other assets	(420)	329
Accounts payable	2,837	358
Other liabilities	(1)	(574)
Net cash provided by operating activities	11,175	8,591
Cash flows from investing activities:		
Purchase of property and equipment	(4,438)	(3,365)
Purchase of intangible assets	(295)	(533)
Purchases of short-term investments	(34,811)	(1,549)
Proceeds from sale of short-term investments	34,362	1,549
Net cash used in investing activities	(5,182)	(3,898)
Cash flows from financing activities:		
Issuance of common stock	2,484	5,482
Purchases of common stock for treasury	(13,394)	
Excess tax benefits from share-based compensation	1,329	
Repayments of debt	(53)	(56)
Net cash (used in) provided by financing activities	(9,634)	5,426
Effect of exchange rate change on cash and cash equivalents	23	(662)
Net (decrease) increase in cash and cash equivalents	(3,618)	9,457
Cash and cash equivalents, beginning of period	17,519	33,354
Cash and cash equivalents, end of period	\$ 13,901	\$ 42,811
<b>Supplemental cash flow information:</b>		
Income taxes paid	\$ 1,438	\$ 195
Interest paid	\$ 15	\$ 38
Non-cash investing and financing activities:		
Tendered common stock for stock option exercises	\$	\$ 338

See Notes to Consolidated Financial Statements.



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**Ventana Medical Systems, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(in thousands, except per share data)**

**(Unaudited)**

**1. Nature of Business**

Ventana Medical Systems, Inc. ( Ventana or the Company ) develops, manufactures and markets proprietary instruments and reagents that automate diagnostic procedures used for molecular analysis of cells. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Ventana Medical Systems, S.A., Ventana Medical Systems, GmbH, Ventana Medical Systems, Ltd., Ventana Medical Systems, Japan K.K., and Ventana Medical Systems Pty. Ltd. All significant inter-company balances and transactions have been eliminated. We do not have any subsidiaries in which we do not own 100% of the outstanding stock.

The accompanying interim condensed consolidated financial statements of Ventana Medical Systems, Inc have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company s Annual Report on Form 10-K for the year ended December 31, 2005, except for the adoption of Statement of Financial Accounting Standards No. 123R, Share-Based Payment ( SFAS No. 123R ) See Note 2. The financial information is unaudited, but reflects all adjustments, consisting only of normal recurring accruals, which are, in the opinion of the Company s management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The information included in this Form 10-Q should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2005.

**2. Share-Based Compensation**

At March 31, 2006, the Company had six active share-based employee compensation plans. Stock option awards granted from these plans are granted at the fair market value on the date of grant. The option awards vest over a period determined at the time the options are granted, ranging from zero to five years, and generally have a maximum term of ten years. Certain options provide for accelerated vesting if there is a change in control (as defined in the plans). When options are exercised, new shares of the Company s common stock are issued. Prior to January 1, 2006, the Company accounted for share-based employee compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations ( APB Opinion No. 25 ). Under APB Opinion No. 25, for stock options granted at market price, no compensation cost is recognized, and a disclosure is made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with Statement of Financial Accounting Standards No. 123,

Accounting for Stock-Based Compensation ( SFAS No. 123 ). On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123R, which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS No. 123R permits public companies to adopt its requirements using one of two methods: (a) a modified prospective method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date, or (b) a modified retrospective method which includes the requirements of the

**Table of Contents****Ventana Medical Systems, Inc.****Notes to Condensed Consolidated Financial Statements****(in thousands, except per share data)****(Unaudited)**

modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented, or prior interim periods of the year of adoption. Effective January 1, 2006, the Company adopted SFAS No. 123R using the modified prospective method. Other than restricted stock, no share-based employee compensation cost has been reflected in net income prior to the adoption of SFAS No. 123R. Results for prior periods have not been restated.

The adoption of SFAS No. 123R reduced income before income tax expense and net income for the three months ended March 31, 2006 by approximately \$1,400 and \$900, respectively. As a result, basic and diluted earnings per share were reduced by \$0.02 each.

The total value of the stock option awards is expensed ratably over the service period of the employees receiving the awards. As of March 31, 2006, total unrecognized compensation cost related to stock option awards was approximately \$10,100 and the related weighted-average period over which it is expected to be recognized is approximately 1.9 years.

Prior to the adoption of SFAS No. 123R, the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the condensed consolidated statements of cash flows. SFAS No. 123R requires the cash flows resulting from the tax benefits arising from tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The \$1,329 excess tax benefit classified as a financing cash inflow in the Company's accompanying condensed consolidated statements of cash flows for the three months ending March 31, 2006 would have been classified as an operating cash inflow if the Company had not adopted SFAS No. 123R.

A summary of stock option activity within the Company's stock-based compensation plans and changes for the three months ended March 31, 2006 is as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2005	6,688	\$ 19.21		
Granted	2	35.95		
Exercised	(154)	12.60		
Terminated/expired	(75)	22.68		
Balance at March 31, 2006	6,461	\$ 19.33	6.1	\$ 144,955

The intrinsic value of options exercised during the three months ended March 31, 2006 was \$4,051.

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A summary of fully-vested stock options and stock options expected to vest, as of March 31, 2006, is as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding	6,458	\$ 19.33	6.1	\$ 144,906
Exercisable	5,532	\$ 19.52	5.9	\$ 123,100

The fair value of each stock option award is estimated on the date of the grant using the Black-Scholes option pricing model. The following are the weighted average assumptions used for the periods noted:

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Weighted average risk-free interest rate	4.4%	3.9%
Expected life of options (years)	9.0	6.5
Expected stock volatility	55.0	70.1%
Expected dividend yield	0%	0%

The risk-free interest rate is based on the U.S. treasury security rate in effect as of the date of grant. The expected lives of options are based on historical data of the Company. In 2006, the Company determined that a blend of implied and historical volatility is more reflective of market conditions and a better indicator of expected volatility versus using historical volatility alone. The expected dividend yield is based on expected annual dividend to be paid by the Company as a percentage of the market value of the Company's stock as of the date of grant.

The weighted average fair value of stock options granted during the first quarter 2006 and 2005 was \$19.73 and \$22.80, respectively.

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The following table illustrates the effect on net income and net income per common share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all outstanding stock option awards for periods presented prior to the Company's adoption of SFAS No. 123R (amounts in thousands, except per share amounts):

	<b>Three Months Ended</b>
	<b>March 31, 2005</b>
Net income, as reported	\$ 4,616
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,186)
Pro-forma net income	\$ 3,430
Net income per common share	
Basic, as reported	\$ 0.13
Basic, pro-forma	\$ 0.10
Diluted, as reported	\$ 0.13
Diluted, pro-forma	\$ 0.09

The Company also grants restricted stock awards to certain employees. Restricted stock awards are valued at the closing market value of the Company's common stock on the date of grant, and the total value of the award is expensed ratably over the service period of the employees receiving the grants. During the three months ended March 31, 2006, 1.3 shares of restricted stock were granted to certain employees. Share-based compensation expense related to all restricted stock awards outstanding during the three months ended March 31, 2006 and 2005 was approximately \$26 and \$14, respectively. As of March 31, 2006, the total amount of unrecognized compensation cost related to nonvested restricted stock awards was approximately \$359, which is expected to be recognized over a weighted-average period of approximately 2.5 years.

A summary of restricted stock activity within the Company's share-based compensation plans and changes for the three months ended March 31, 2006 is as follows (share amounts in thousands):

	<b>Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Nonvested at December 31, 2005	11.0	\$ 40.13
Granted	1.3	36.28
Vested	(1.2)	35.95
Forefeited		
Nonvested at March 31, 2006	11.1	\$ 40.13

The total fair value of restricted shares vested during the three months ended March 31, 2006 was \$44. No restricted shares vested during the three months ended March 31, 2005.



**Table of Contents****Ventana Medical Systems, Inc.****Notes to Condensed Consolidated Financial Statements****(in thousands, except per share data)****(Unaudited)****3. Comprehensive Income**

The components of comprehensive income, net of tax, for the three months ending March 31, 2006 and 2005 are as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Net income	\$ 5,023	\$ 4,616
Net unrealized losses on available for sale securities	(6)	(38)
Net change in cumulative translation adjustment	(9)	(582)
	\$ 5,008	\$ 3,996

The components of accumulated other comprehensive loss, net of tax, for the three months ending March 31, 2006 and 2005 are as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Net unrealized losses on available for sale securities	\$ (94)	\$ (102)
Cumulative translation adjustment	(704)	(478)
	\$ (798)	\$ (580)

**4. Provision for Income Taxes**

The Company accounts for income taxes during interim periods in accordance with SFAS No. 109, Accounting for Income Taxes, Accounting Principles Board, ( APB ) No. 28, Interim Financial Reporting, and FIN 18, Accounting for Income Taxes in Interim Periods, an interpretation of APB Opinion No. 28. For interim reporting purposes, these rules require that a company determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a year-to-date basis.

On December 31, 2005, the United States research tax credit expired. As a result the Company is not permitted to claim a benefit for twelve months of its research and development credit in its full-year estimated tax rate for purposes of calculating its first quarter tax provision. Consequently, the Company's effective tax rate is approximately 39% for the three months ended March 31, 2006 versus 35% for the three months ended March 31, 2005. If the United States research tax credit would not have expired, the Company's effective tax rate for the three months ended March 31, 2006 would have been approximately 36%. Under paragraph 20 of APB 28, any immediate impact as a result of a change in tax law in this case, reinstatement of the credit should be recognized in the interim period in which the law change is enacted. Therefore, if the credit is reinstated after March 31, 2006, any catch-up adjustment will be recognized when the annual estimated tax rate is remeasured during the applicable reporting period.

The Company took advantage of additional tax deductions available relating to the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.



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Accordingly, the Company recorded a \$1,346 increase to equity with a corresponding increase to deferred tax asset for the three months ended March 31, 2006. Quarterly adjustments for the exercise of non-qualified stock options and disqualified dispositions of incentive stock options may vary as they relate to the actions of the option holder or shareholder. The Company also evaluated the recoverability of its net deferred tax assets and determined that the balances existing at March 31, 2006, represented the amount that is more likely than not of being recovered in the foreseeable future.

**5. Stock Repurchase**

On September 8, 1998, the Company's Board of Directors authorized the Company to repurchase up to 1,500 shares of its common stock in the open market or in privately negotiated transactions. In May 2004, the Board of Directors approved the repurchase of an additional 2,000 shares. During the three months ended March 31, 2006 and 2005, the Company re-purchased 366 and 10 shares of its common stock for \$13,394 and \$338, respectively. The repurchased shares were returned to the status of authorized, but unissued shares. The timing and amount of any future repurchases will depend on market conditions and corporate considerations.

**6. Operating Segment and Enterprise Data**

The Company has two reportable segments: North America (primarily the United States and Canada) and International (primarily France, Germany, United Kingdom, Japan and Australia). Segment information for the three months ended March 31, 2006 and 2005 are as follows:

	<b>Three months ended March 31, 2006</b>			
	<b>North America</b>	<b>International</b>	<b>Elimina- tions</b>	<b>Totals</b>
Sales to external customers	\$ 39,000	\$15,087	\$	\$ 54,087
Depreciation and amortization expense	3,328	475		3,803
Segment profit	4,605	418		5,023
Property and equipment, net	49,017	6,445		55,462
Segment assets	182,403	34,878	(20,750)	196,531
Expenditures for long-lived assets	4,509	224		4,733

  

	<b>Three months ended March 31, 2005</b>			
	<b>North America</b>	<b>International</b>	<b>Elimina- tions</b>	<b>Totals</b>
Sales to external customers	\$ 30,915	\$14,107	\$	\$ 45,022
Depreciation and amortization expense	1,843	391		2,234
Segment profit	1,568	3,048		4,616
Property and equipment, net	43,843	5,434		49,277
Segment assets	179,756	36,852	(22,375)	194,233
Expenditures for long-lived assets	3,396	502		3,898

**Table of Contents****Ventana Medical Systems, Inc.****Notes to Condensed Consolidated Financial Statements****(in thousands, except per share data)****(Unaudited)****7. Short-Term and Long-Term Investments**

The Company's short-term investments and long-term investments are intended to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations, and delivers an appropriate yield in relationship to the Company's investment guidelines and market conditions. At March 31, 2006, the Company has recorded the estimated fair value in available-for-sale securities for short-term investments and long-term investments of \$29,650 and \$4,883, respectively. The following is a summary of available-for-sale securities as of March 31, 2006:

	<b>Adjusted Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Loss</b>	<b>Estimated Fair Value</b>
Federal agency	\$ 11,480	\$ 1	\$ (74)	\$ 11,407
Municipal bonds	2,000			\$ 2,000
Corporate commercial paper and bonds	20,418	3	(74)	20,347
Money market	779			779
	<b>\$ 34,677</b>	<b>\$ 4</b>	<b>\$ (148)</b>	<b>\$ 34,533</b>

During the three months ended March 31, 2006, the Company did not have any gross realized gains or losses on sales of available-for-sale securities. The following table shows the amortized cost and estimated fair value of the available-for-sale securities at March 31, 2006, by maturity. Expected maturities can differ from contractual maturities, because the issuers of the securities may have the right to prepay obligations without prepayment penalties, and the Company views its available-for-sale securities as available for current operations. Contractual maturities of available-for-sale debt securities were as follows:

	<b>March 31, 2006</b>	
	<b>Cost</b>	<b>Estimated Fair Value</b>
Due in one year or less	\$ 27,697	\$ 27,651
Due after one year and through five years	6,980	6,882
	<b>\$ 34,677</b>	<b>\$ 34,533</b>

At March 31, 2006, \$1,999 of the \$6,882 in estimated fair value expected to mature greater than one year has been classified as short-term investments since these investments are in an unrealized gain position and the Company views its available-for-sale securities as available for current operations.

The following table shows the gross unrealized losses and fair value of the Company's investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at March 31, 2006:



**Table of Contents****Ventana Medical Systems, Inc.****Notes to Condensed Consolidated Financial Statements****(in thousands, except per share data)****(Unaudited)**

	<b>Less Than 12 Months</b>		<b>Greater than 12 Months</b>	
	<b>Fair Value</b>	<b>Gross Unrealized Loss</b>	<b>Fair Value</b>	<b>Gross Unrealized Loss</b>
Federal agency	\$ 9,412	\$ 74	\$	\$
Corporate commercial paper and bonds	3,706	3	3,270	71
	\$ 13,118	\$ 77	\$ 3,270	\$ 71

The unrealized losses on the Company's investment in federal agency securities were caused by interest rate increases. The contractual cash flows of those investments are guaranteed by an agency of the U.S. government. Accordingly, it is expected that the securities would not be settled at a price less than the amortized cost of the Company's investment.

The unrealized losses on the Company's investment in corporate commercial paper and bonds were caused primarily by interest rate increases. Generally, the investments are in corporations with a credit rating of AA or higher and consequently the Company does not believe it is probable that it will be unable to collect all amounts due according to the contractual terms of the investments.

Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, it does not consider the investments with unrealized losses to be other-than-temporarily impaired at March 31, 2006.

**8. Inventories**

Inventories consist of the following:

	<b>March 31, 2006</b>	<b>December 31, 2005</b>
Raw material and work-in-process	\$ 5,426	\$ 6,441
Finished goods	7,963	6,447
	\$ 13,389	\$ 12,888

**9. Commitments and Contingencies**

In the ordinary course of business, we are involved in legal actions, both as plaintiff and defendant, and could incur uninsured liability in any one or more of them. Although the outcome of these actions is not presently determinable, it is the opinion of the Company's management, based upon the information available at this time, that the expected outcome of these matters, individually or in the aggregate, will not have a material adverse effect on the results of operations or financial condition of the Company.

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**Ventana Medical Systems, Inc.**

**Management's Discussion and Analysis of Financial Condition and Analysis**

**(Unaudited)**

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

We develop, manufacture and market proprietary instruments and reagents that automate diagnostic procedures used for molecular analysis of cells in anatomical pathology and drug discovery laboratories worldwide. Our products are designed to provide users with automated high-quality and consistent results with high throughput and significant labor savings. Our clinical systems are important tools for anatomical pathology labs in analyzing human tissue to assist in the diagnosis and treatment of cancer and infectious diseases. Our drug discovery systems are used by pharmaceutical and biotechnology companies to accelerate the discovery of new drug targets and to evaluate the safety of new drug compounds. In addition to instruments, we market consumable products, including reagents and other accessories, required to operate our instruments. Our customers include the majority of the top fifty U.S. cancer centers, including recognized leaders in cancer research and treatment, such as Johns Hopkins Hospital, the Mayo Clinic, Memorial Sloan-Kettering Cancer Center, and M.D. Anderson Medical Center.

The following discussion of our financial condition and results of operations 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 our 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 we serve.

**Results of Operations**

*Total Net Sales*

Net sales for the three months ended March 31, 2006 increased 20% compared to the same period in 2005 to \$54.1 million from \$45.0 million due to a 21% increase in reagents and other sales. Reagent and other sales growth was the result of a 12% increase in our installed base from approximately 5,200 in 2005 to approximately 5,800 in 2006 and a 9% year-over-year improvement in the average reagent annuity stream per installed instrument to \$27,800 from \$25,400 in 2005.

By geographic segment, total sales increased in the first quarter of 2006 over 2005 by 26% in North America (\$39.0 million versus \$30.9 million) and 7% internationally (\$15.1 million versus \$14.1 million) due to the reasons mentioned above.

*Gross Margin*

Gross margin for the three months ended March 31, 2006 increased to \$40.8 million from \$33.4 million for the same period in 2005. The Company's gross margin for the quarter ended March 31, 2006 increased to 75.4%, or 75.5% absent share-based compensation expense

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**Ventana Medical Systems, Inc.**

**Management's Discussion and Analysis of Financial Condition and Analysis**

**(Unaudited)**

recognized upon our adoption of SFAS No. 123R, from 74.2% for the same period in 2005, primarily due to the higher mix of reagent and other sales, which have a higher gross margin than instruments.

*Research and Development*

Research and development spending for the three months ended March 31, 2006 increased to \$7.4 million from \$6.1 million for the same period in 2005. Excluding approximately \$0.3 million of share-based compensation expense recognized upon our adoption of SFAS No. 123R, the additional \$1.0 million increase is primarily attributable to our continued new platform development programs and our reagent chemistry application initiatives focused primarily on the histology market.

*Selling, General and Administrative ( SG&A )*

SG&A expense for the three months ended March 31, 2006 increased to \$25.0 million, or \$24.0 million absent share-based compensation expense recognized upon our adoption of SFAS No. 123R, from \$19.8 million for the same period in 2005. The increase is primarily attributable to increased investments in our sales force and associated infrastructure and continued development of our marketing organization. We also continued to invest in further establishing our intellectual property position and defending ourselves in litigation matters. SG&A expense as a percentage of sales increased to 46% in 2006 from 44% in 2005. Excluding share-based compensation expense, SG&A expense as a percentage of sales remained at 44% compared to the same period in 2005.

*Amortization of Intangible Assets*

Amortization expense of intangible assets for the three months ended March 31, 2006 increased to \$0.6 million from \$0.5 million for the same period in 2005. The increase is due to incremental amortization associated with a higher carrying base in intangible assets during the three months ended March 31, 2006. Estimated amortization expense for intangible assets as of March 31, 2006 for each of the five succeeding fiscal years is as follows (all amounts are in thousands): 2006: \$2,596, 2007: \$2,377, 2008: \$2,100, 2009: \$1,913, 2010: \$449.

*Interest and Other Income*

Interest and other income of \$0.4 million for the three months ended March 31, 2006 increased from \$0.1 million for the three months ended March 31, 2005 primarily due to increased investment balances and interest rates.

*Provision for Income Taxes*

Income tax expense increased to \$3.2 million, or 39% of pretax income, for the three months ended March 31, 2006, from \$2.5 million, or 35% of pretax income, in the same period of the prior year. The increased effective tax rate in 2006 is primarily attributable to the expiration of the United States research tax credit. Under paragraph 20 of APB 28, any immediate impact as a result of a change in tax law in this case, reinstatement of the credit should be recognized in the interim period in which the law change is enacted. Therefore, if the credit is reinstated after March 31, 2006, any catch-up adjustment will be recognized when the annual estimated tax rate is remeasured during the applicable reporting period.

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**Ventana Medical Systems, Inc.**

**Management's Discussion and Analysis of Financial Condition and Analysis**

**(Unaudited)**

**Critical Accounting Policies and Estimates**

Our discussion of financial condition and results of operations relies on our condensed consolidated financial statements which are prepared based on certain critical accounting policies and require management to make judgments and estimates that are subject to varying degrees of uncertainty. We believe that investors need to be aware of these policies and how they impact our financial statements as a whole, as well as our related discussion and analysis presented herein. While we believe that these accounting policies are based on sound measurement criteria, actual future events can and often do result in outcomes that can be materially different from these estimates or forecasts. The accounting policies and related risks described in our annual report on Form 10-K as filed with the Securities and Exchange Commission on February 21, 2006 are those that depend most heavily on these judgments and estimates. As of April 21, 2006, we have added an additional critical accounting policy on share-based compensation. There have been no other material changes to any of the critical accounting policies contained therein.

*Share-Based Compensation*

As part of our adoption of SFAS No. 123R as of January 1, 2006, we were required to recognize the fair value of share-based compensation awards as an expense. We apply the Black-Scholes option-pricing model in order to determine the fair value of stock options on the date of grant, and we apply judgment in estimating key assumptions that are important elements in the model, such as the expected stock-price volatility, expected stock option life and expected forfeiture rates. Our estimates of these important assumptions are based on historical data and judgment regarding market trends and factors.

If actual results are not consistent with our assumptions and judgments used in estimating these factors, we may be required to record additional share-based compensation expense or income tax expense, which could be material to our results of operations.

**Liquidity and Capital Resources**

Cash and cash equivalents was \$13.9 million at March 31, 2006. We have funded our capital requirements since inception through sales of equity securities, debt financing and cash flows from operations. Net cash provided by operating activities was \$11.2 million and \$8.6 million for the three months ended March 31, 2006 and 2005, respectively. Net cash provided by operating activities exceeded net income in 2006 primarily due to the effect of depreciation, share-based compensation and amortization and increases in operating liabilities.

We use cash in our investing activities primarily to fund investments in property and equipment and to purchase investments. Net cash used in investing activities for the three months ended March 31, 2006 and 2005 was \$5.2 million and \$3.9 million, respectively. At March 31, 2006, we have \$34.5 million in short-term and long-term investments that primarily consist of corporate and various government agency debt securities. We classify these investments as available-for-sale.

Net cash used in financing activities for the three months ended March 31, 2006 was \$9.6 million, consisting of \$13.4 million in stock repurchases, offset by proceeds from the exercise of stock options and excess tax benefits associated with these exercises. Prior to the adoption of SFAS No. 123R, all tax benefits associated with the exercise of stock options were included

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**Ventana Medical Systems, Inc.**

**Management's Discussion and Analysis of Financial Condition and Analysis**

**(Unaudited)**

within cash flows from operating activities. For the three months ended March 31, 2005, net cash provided by financing activities was \$5.4 million, primarily from proceeds from the exercise of stock options and employee stock purchases.

We believe that our cash flow from operations together with our current cash reserves will be sufficient to fund our projected capital requirements through 2006. In the event that additional capital is required, we will first access our short-term investments. In the event that additional capital is required, we may seek to raise such capital through public or private equity or debt financings. Future capital funding transactions may result in dilution to current shareholders.

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**Ventana Medical Systems, Inc.**

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

For quantitative and qualitative disclosures about market risk affecting Ventana, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2005.

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**Ventana Medical Systems, Inc.**

**Item 4. Controls and Procedures**

**(a) Evaluation of Disclosure Controls and Procedures**

Based on the evaluation of our disclosure controls and procedures (as defined in the Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act )) required by Exchange Act Rules 13a-15(b) or 15d-15(b), our principal executive officer and principal financial officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including the principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**(b) Changes in Internal Controls**

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are 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**

VENTANA v. DAKOCYTOMATION, Civil Action No. 04-1522, was filed in December 2004, in the U.S. District Court, District of Delaware, alleging infringement of U.S. Patent No. 6,827,901 ( Automated Biological Reaction Apparatus ) by the making, using, and selling of the ARTISAN staining system. The suit seeks injunctive relief including a preliminary injunction against the continued making, using, and selling of the instrument and unspecified damages. DakoCytomation filed an Answer to the Complaint in January 2005. A claim construction hearing and mediation were conducted in December 2005. Dako has filed a Motion for Summary Judgment of Non-Infringement. Trial is currently scheduled for July 2006

CYTOLOGIX v. VENTANA, was served in April 2004, in the U.S. District Court, District of Delaware alleging infringement of U.S. Patent No. 6,541,261 B1. In July 2004, the case was transferred to the Federal District Court in Boston, Civil Action No. 04-11783 (RWZ). CytoLogix alleges the manufacture, use, and sale of our BENCHMARK XT slide staining system infringes the 261 patent. We dispute all of these contentions and we will defend ourselves vigorously. CytoLogix has asked for an injunction, unspecified damages, and enhanced damages for willful infringement. Discovery is currently ongoing. CytoLogix has filed a Motion for Summary Judgment of Infringement. Our opposition to the motion was filed April 2006 and the hearing on the matter is now scheduled for May 2006.

CYTOLOGIX v. VENTANA, Civil Action No. 00-12231 REK, was filed in October 2000 in the U.S. District Court, Eastern District of Massachusetts. The complaint alleges, under state-law based unfair competition law, 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, multiple damages (unspecified amount), and an injunction against our further sales of DISCOVERY and BENCHMARK instruments. In February 2002, CytoLogix amended their complaint to add the related claims of attempted monopolization and monopolization under the Sherman Act, and various Lanham Act violations. This matter was consolidated with CYTOLOGIX v. VENTANA, Civil Action No. 01-10178 REK (see below) for purposes of discovery and trial.

CYTOLOGIX v. VENTANA, Civil Action No. 01-10178 REK, was filed in January 2001 in the U.S. District Court, Eastern District of Massachusetts. This complaint alleges we infringed on CytoLogix's patent No. 6,180,061, titled Moving Platform Slide Stainer with Heating Elements , and the Complaint was later amended to add U.S. Patent No. 6,183,693, issued in February 2001, titled Random Access Slide Stainer with Independent Slide Heating Regulation , both assigned to CytoLogix. CytoLogix seeks treble damages for willful infringement (unspecified amount), and an injunction against our further manufacture and sale of DISCOVERY and BENCHMARK instruments.

At the December 2003, conclusion of the trial on the issues of patent infringement and trade secret misappropriation, the jury found Ventana liable for infringement on the two patent cases (no willful infringement). On the trade secret issue, the jury determined we had not misappropriated any trade secrets. A permanent injunction was entered by the Court in April 2004, which prohibits us from making and selling the DISCOVERY/BENCHMARK systems but does not prohibit their continued use by customers and will not prohibit us from servicing the

## **Table of Contents**

### **Ventana Medical Systems, Inc.**

#### **Item 1. Legal Proceedings (continued)**

instruments or supplying reagents to customers. In May 2004, we filed a Notice of Appeal to the Court of Appeals for the Federal Circuit, on the patent infringement claims and CytoLogix, on the willfulness and misappropriation claims. The Appeals Court rendered its decision in September 2005 upholding the infringement finding on most of the claims of the 061 and the 693 patents and remanded the case to District Court for further proceedings. We filed dispositive motions on several of the outstanding issues in January 2006 and a hearing on these matters was conducted in March 2006. No decision has been made by the Court on these motions. As of this date, trial has not been scheduled. The Company has accrued a liability of \$5 million for potential patent infringement damages.

VISION BIOSYSTEMS, LTD v. VENTANA, Civil Action No. 03 CV 10391-GAO was filed in March 2003, in the U.S. District Court, Eastern District of Massachusetts. We were served with a Summons and Complaint by Vision BioSystems (Vision) for a Declaratory Judgment seeking a declaration of no infringement and invalidity of U.S. Patent Nos. 5,355,439 and 6,352,861, both owned by us. In September 2004, the Judge denied Vision's motion for Summary Judgment and ruled in favor of our cross-motion for Summary Judgment that Vision's BOND system infringes claims 1 and 5 of the 861 patent. The Court also dismissed the 439 patent from the case. Trial on the issues of patent invalidity and damages remain. This matter was consolidated with VENTANA v. VISION BIOSYSTEMS, LTD, Civil Action No. 05-10614 (see below). Following the BioGenex claim construction ruling (see *Ventana v. BioGenex*, below) and entry of Judgment in that matter in October 2005, Vision filed a motion for Summary Judgment of Non-Infringement based upon collateral estoppel in both cases. We have filed our opposition. The matter has been taken off the trial calendar and stayed pending further rulings by the Court.

VENTANA v. VISION BIOSYSTEMS, LTD., Civil Action No. 05-10614 GAO, was filed in March 2005, in the U.S. District Court, Eastern District of Massachusetts. This complaint alleges that Vision's BOND OCR system infringes U.S. Patent No. 6,352,861. The suit seeks injunctive relief including a preliminary injunction against the continued making, using and selling of the instrument and unspecified damages. This matter was consolidated with VISION BIOSYSTEMS, LTD v. VENTANA, Civil Action No. 03 CV 10391-GAO for trial (see above). The matter has been taken off the trial calendar and stayed pending the Court's rulings as described in the immediately preceding paragraph.

DIGENE CORPORATION v. VENTANA, Civil Action No. 01-752, was filed in November 2001, in the U.S. District Court, District of Delaware. This Complaint alleges we infringe two U.S. patents held by Digene, U.S. 4,849,331 and 4,849,332, by activities relating to our INFORM® HPV Family 16 and Family 6 probe products. In November 2002, Digene filed a motion to amend its Complaint to add numerous causes of action related to our September 2002 acquisition of Beckman Coulter's (Beckman) HPV business and to add Beckman as a party. Digene seeks, among other remedies, an injunction against the sale of our INFORM HPV products, unspecified monetary damages, cancellation of the Beckman HPV acquisition, and related claims. Several motions were filed by the parties, one of them being a motion to compel arbitration by Beckman and us. In May 2004, the Court ordered arbitration to proceed as against Beckman, only, and stayed the proceedings pending in the District Court until the conclusion of the arbitration. The arbitration was conducted in March 2006 and post-hearing briefs were filed by the parties in April 2006. A decision may be expected in the next few months.

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**Ventana Medical Systems, Inc.**

**Item 1. Legal Proceedings (continued)**

VENTANA v. INSTITUT PASTEUR, ICC No. 12764/FM, was filed in June 2003, Ventana and Beckman filed a request for arbitration with the International Chamber of Commerce in Paris, France, to contest the purported termination by Institut Pasteur of the Sublicense Agreement acquired by us from Beckman in September 2002. The ICC hearing was conducted in September 2004. In a decision rendered in April 2005, the ICC decided that Institut Pasteur did not have standing to terminate the Sublicense Agreement and that Ventana was a proper licensee and sub-licensee of the relevant HPV patents. The ICC further determined that Ventana is entitled to seek damages in an amount to be quantified. The ICC has renewed proceedings on this issue with the hearing on damages scheduled for July 2006

BIOGENEX LABORATORIES, INC. v. VENTANA, Case No. C05 00860 WDB, was filed in March 2005, in the U.S. District Court, Northern District of California, San Jose Division. This Complaint alleges Ventana infringes U.S. Patent No. 6,632,598 held by BioGenex. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. The matter has been joined with BIOGENEX LABORATORIES, INC. v. VENTANA, Case No. C03 03916 JF (see above). We filed a Motion to Dismiss the case with respect to the 452 patent. The motion was heard July 2005 and at the case management conference held in August 2005, the Court dismissed the 452 claim. BioGenex infringement disclosures on the 598 were submitted in early September 2005 and we have filed a Summary Judgment of Non-infringement. The Summary Judgment motion was heard in early 2006. No decision has been made by the Court on the Summary Judgment motion. Discovery is ongoing and no trial dates have been set.

For further discussion of legal proceedings affecting the Company, see Item 3, Legal Proceedings, of our Annual Report on Form 10-K for fiscal year ended December 31, 2005.

We record contingent liabilities resulting from claims against us when it is probable (as that word is defined in Statement of Financial Accounting Standards No. 5) that a liability has been incurred and the amount of the loss is reasonably estimable. We disclose contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. In all of the cases noted where we are the defendant, we believe we have meritorious defenses to the claims in these actions and resolution of these matters will not have a material adverse effect on our business, financial condition, or results of operation; however, the results of the proceedings are uncertain, and there can be no assurance to that effect.

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**Ventana Medical Systems, Inc.**

**Item 1A. Risk Factors**

**FACTORS THAT COULD AFFECT FUTURE RESULTS**

Because of the following factors, as well as other variables affecting our operating results, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods.

**Our products could infringe the intellectual property rights of others, which might 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 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, is 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 until we obtain a license from the owner of the relevant technology or other intellectual property rights, which may not be available to us. Even if a license is available, it may require us to pay substantial royalties. (For further discussion of litigation matters, please refer to Part I, Item 3, Legal Proceedings of this document).

**It is possible that we may be forced to pay damages to CytoLogix which exceed the amounts we have reserved.**

As discussed in more detail *Part II, Item 1, Legal Proceedings* of this document, we have been involved in litigation with CytoLogix, Inc., pursuant to which a jury determined that we infringed certain CytoLogix patents. The patents in question relate to prior versions of our BENCHMARK and DISCOVERY instruments and do not apply to the current versions of the BENCHMARK XT / LT and DISCOVERY XT instruments. In September 2005, the Court of Appeals upheld certain of the jury findings of patent infringement, and the case is expected to proceed to trial on the issue of damages. We have accrued a liability of \$5.0 million in this regard. At trial, CytoLogix may advance arguments for damages several times higher than the amount we have accrued. In view of the complexity of this case and the inherent uncertainty of patent infringement litigation, there is a possibility the amount of damages paid to CytoLogix could be substantially different from the \$5.0 million we have accrued and if substantial, could cause the price of our stock to decline.

**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 Analyte Specific Reagents, we are required to adhere to Quality System regulations, which require us to manufacture our products and maintain records in a prescribed manner. We are subject to future FDA Quality System inspections, and we cannot assure you that we will pass these inspections or maintain compliance. If we are unable to pass these inspections or maintain compliance, our product sales and profitability could suffer.

**Our future growth depends on our ability to develop and successfully introduce new products, product extensions and improvements to existing products to address unmet patient and market needs.**

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**Ventana Medical Systems, Inc.**

**Item 1A. Risk Factors (continued)**

Our future growth is dependent upon, among other factors, our ability to develop, obtain regulatory approval for, manufacture, sell and achieve market acceptance of new products, product extensions and improvements to our existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables. These variables include price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement for our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products, product extensions and improvements to our existing products may also be subject to government regulation, including clearance/approval by the FDA and foreign government agencies. Any failure in our ability to successfully develop, obtain regulatory approval for, manufacture, sell and achieve market acceptance of our new products, product extensions or improvements to our existing products could have a material adverse effect on our operating results and our business.

**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, and if they are successful, our ability to sustain revenue growth and profitably will be adversely affected.

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

Sales of our products in the European Union or EU are subject to strict regulatory requirements, and approval is never certain. All of our products must be in compliance with the *In Vitro* Diagnostics Directive and bear the CE mark before being imported for sale in the EU. The CE mark is a symbol indicating the device conforms to the essential requirements of the applicable directive and can be commercially distributed throughout the EU. The *In Vitro* Diagnostic Directive also subjects our manufacturing facilities to compliance inspections and requires design, manufacturing, and quality process documentation and controls. Some of our products do not bear the CE mark. We cannot assure you that the CE mark will be granted for all our products or that regulatory review will not involve delays that would harm our ability to market and sell our products in the EU.

Further, we ship our products into European markets, which are also subject to governmental environmental regulations such as the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS) which will be effective July 1, 2006, and the Directive on Waste Electrical and Electronic Equipment. These directives focus on limiting the amounts of certain elements, such as lead, in electrical devices, and providing for the authorized disposal of the electrical devices and their components. We cannot assure you that compliance with these regulations will not have a material adverse effect on our operating results and our business.

**Clinical Laboratory Improvement Act or CLIA regulations could harm our business by limiting the potential market for our products.**

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**Ventana Medical Systems, Inc.**

**Item 1A. Risk Factors (continued)**

Customers using our products for clinical use in the United States may be regulated under the 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, 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.

**We are subject to a complex system of domestic and foreign taxation and unanticipated changes in our tax rates or exposure to additional tax liabilities could affect our profitability.**

We are subject to income taxes in both the United States and various foreign jurisdictions, and our domestic and international tax liabilities are subject to the allocation of expenses in different jurisdictions. Our effective tax rates could be adversely affected by changes in the mix of earnings in countries with differing statutory tax rates, in the valuation of deferred tax assets and liabilities or in tax laws, or by material audit assessments, which could affect our profitability. In particular, the carrying value of deferred tax assets, which are predominantly in the United States, is dependent on our ability to generate future taxable income in the United States. In addition, the amount of tax we pay is subject to ongoing audits in various jurisdictions, and a material assessment by a governing tax authority could affect our profitability. Further tax law changes in jurisdictions in which we conduct business could materially affect our profitability.

**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 the materials or reagents 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 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 proves inadequate 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 could bring litigation to enforce our intellectual property rights, which might 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;

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**Ventana Medical Systems, Inc.**

**Item 1A. Risk Factors (continued)**

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 or resulting in their invalidation.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. We also could 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 or inability to protect our patent rights or intellectual property could have serious adverse effects on our business and could affect our profitability.

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 contractual 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, 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 products.

**We cannot assure you that we will be able to fund our future capital requirements through internal sources or from other sources.**

We anticipate 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.

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**Ventana Medical Systems, Inc.**

**Item 1A. Risk Factors (continued)**

We may require additional capital resources and cannot assure you 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 would dilute the interests of our existing stockholders.

**Recent legislation requires us to undertake an annual evaluation of our internal control over financial reporting that may identify internal control weaknesses requiring remediation that could harm our reputation or subject us to investigation and sanctions by regulatory authorities.**

As required by Section 404 of the Sarbanes-Oxley Act of 2002, we are required to annually assess, test, and evaluate the design and operating effectiveness of our internal control over financial reporting, or ICFR. While we have concluded that our ICFR was effective as of December 31, 2005, we cannot predict the outcome of our testing in future periods. If we conclude in future periods that our ICFR is not effective, we may be required to change our ICFR to remediate deficiencies, which could result in lost investor confidence in the reliability of our financial statements, and may subject us to investigation and/or sanctions, by regulatory authorities. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented, or amended from time to time, we may not be able to ensure we can conclude on an ongoing basis that we have effective controls over financial reporting in accordance with Section 404, and our independent auditors may not be able to render the required attestation concerning our assessment and the effectiveness of the internal controls over financial reporting. If we fail to maintain an effective internal control environment or our independent auditors are unable to render the required attestation, it could have a material adverse effect on investor confidence in our reported financial information. Any such events could adversely affect our financial results and/or the market price of our common stock.

**Recent regulations related to equity compensation will affect our earnings and could impact our ability to attract and retain key personnel.**

Since our inception, we have used stock options and other long-term equity incentives as a fundamental component of our employee compensation packages and have accounted for them using the intrinsic value method of APB No. 25, *Accounting for Stock Issued to Employees*. We believe that stock options and other long-term equity incentives directly motivate our employees to maximize long-term stockholder value and, through the use of vesting, encourage employees to remain with us. In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payments*, ( SFAS No. 123R ) which changed U.S. Generally Accepted Accounting Principles in such a way to require us to record a charge to earnings for the fair value of employee stock option grants and other share based compensation beginning in the first quarter of 2006. This regulation will negatively impact our earnings for those share based awards that vest after December 31, 2005.

In addition, regulations implemented by NASDAQ requiring shareholder approval for all stock option plans could make it more difficult for us to grant equity-based awards to employees in the future. To the extent that these or other new regulations make it more difficult or expensive to grant options to employees, we may incur compensation costs, productivity losses, change our equity compensation strategy or find it difficult to attract, retain and motivate employees, each of which could materially and adversely affect our business.

**Table of Contents****Ventana Medical Systems, Inc.****Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities**

On September 8, 1998, our Board of Directors authorized us to repurchase up to 1.5 million shares of our common stock in the open market or in privately negotiated transactions. In May 2004, our Board of Directors approved an additional repurchase of a further 2.0 million shares. During the three months ended March 31, 2006, we re-purchased 365,820 of common stock for \$13.4 million. The repurchased shares were returned to the status of authorized but un-issued shares. The timing and amount of any future repurchases will depend on market conditions and corporate considerations.

**Stock Repurchases During the First Quarter 2006**

Period	Total Number of Shares	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that may yet be Repurchased Under the Plans or Programs
January 1, 2006 - January 31, 2006	36,000	\$ 38.40	36,000	1,341,700
February 1 - February 28, 2006	299,820	36.49	299,820	1,041,880
March 1 - March 31, 2006	30,000	\$ 35.66	30,000	1,011,880

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**Ventana Medical Systems, Inc.**

**Item 3. Defaults Upon Senior Securities**

Not Applicable.

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

Not Applicable.

**Item 5. Other Information**

Not Applicable.

**Item 6. Exhibits**

See Exhibits Index

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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: April 28, 2006

By: /s/ Nicholas Malden  
Nicholas Malden

Senior Vice President, Chief Financial Officer and Secretary

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**EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>	<b>Notes</b>
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),(3)
10.7	2001 Outside Director Stock Option Plan	(4)
10.8	2005 Equity Incentive Plan and forms of agreements thereunder	(5)
10.9	2005 Employee Stock Purchase Plan and forms of agreements thereunder	(5)
31.1	Certification of Chief Executive Officer	
31.2	Certification of Chief Financial Officer	
32.1	Section 1350 Certification of Chief Executive Officer	
32.2	Section 1350 Certification of Chief Financial Officer	

- (1) Filed with the Registration Statement on Form S-1 (Commission File No. 333-4461), declared effective by the Commission July 26, 1996.
- (2) Form of agreements filed with the Registration Statement on Form S-8 (Commission File No. 333-92883), filed with the Commission on December 16, 1999.
- (3) Form of 1998 Nonstatutory Stock Option Plan, as amended, agreements filed with the Registration Statement on Form S-8 (Commission File No. 333-105976), filed with the Commission on June 10, 2003.
- (4) Filed with the Registration Statement on Form S-8 (Commission File No. 333-69658), filed with the Commission on September 19, 2001.
- (5) Filed with the Definitive Proxy Statement on Schedule 14A (Commission File No. 000-20931) on March 31, 2005.