# VENTANA MEDICAL SYSTEMS INC Form 10-Q November 14, 2001

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

Form 10-0

[x] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934. For the quarterly period ended September 30, 2001.

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.)

3865 North Business Center Drive Tucson, AZ 85705 (Zip Code)

(Address of principal executive offices)

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

Not Applicable

(Formal 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  $\,$  X  $\,$  No  $\,$ 

Applicable Only to Issuers Involved in Bankruptcy (Formal name, former address and former fiscal year, if changed from last report)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by the court. Yes  $\_$  No  $\_$ 

Applicable Only to Corporate Issuers

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date. Common Stock, \$0.001 par value --- 16,077,313 shares as of October 31, 2001

Ventana Medical Systems, Inc.

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Signature

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Ventana Medical Systems, Inc.
Condensed Consolidated Balance Sheets
(in thousands except share data)
(Unaudited)

ASSETS	September 30, 2001		December 31, 2000	
Current assets:				
Cash and cash equivalents	\$	20,767	\$	38,512
Accounts receivable		16,482		16,682
Inventories		10,364		8,100
Prepaid expenses		293		460
Deferred tax benefit, current portion		4,817		4,817
Other current assets		631		492
Total current assets		53,354		69,063
Property and equipment, net		37,055		22,329
Intangibles, net		10,677		11,887
Other assets		2,797		2,318

		3,985
\$ 107,868	\$	109,582
7,932		13,143
 13,272		19,086
16		15
140,042		134,862
(47,458)		(46,636)
(432)		(553)
(600)		(600)
 •		•
\$ 107,868	\$	
\$ ===:	\$ 107,868 ===================================	\$ 107,868 \$ ==================================

See accompanying notes

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Ventana Medical Systems, Inc.

Condensed Consolidated Statements of Operations

(in thousands except per share data)

(Unaudited)

	Three Mont Septemb	Ni	
	2001	2000	2001
Sales:			
Reagents and other	\$ 15 <b>,</b> 735	\$ 12,703	\$ 44,64
Instruments	5,922	5,196	17 <b>,</b> 63
Total net sales	21,657	17 <b>,</b> 899	62 <b>,</b> 27
Cost of goods sold	6,472	5,786	19 <b>,</b> 69
Gross profit Operating expenses:	15,185	12,113	42 <b>,</b> 57
Research and development	4,137	2,665	11,29
Selling, general and administrative	10,440	9,816	31,42

Nonrecurring expenses Amortization of intangibles	 381	 381	- 1,13
Income (loss) from operations	227	(749)	(1,27
Other income	135	508	76
Income (loss) before taxes and cumulative	2.60	(0.41)	, 5.1
effect of accounting change Provision for income taxes	362 72	(241)	(51 31
Provision for income taxes			
Net income (loss) before cumulative effect of			
accounting change	290	(241)	(82
Cumulative effect of accounting change, net			
of applicable income tax benefit of \$1,436			-
Net income (loss)	\$ 290	\$ (241)	\$ (82
, , , , , , , , , , , , , , , , , , , ,	=======	======	======
Per share data:			
Income (loss) before cummulative effect of			
accounting change:			
Basic	\$ 0.02 ======	\$ (0.02) ======	\$ (0.0 =====
Diluted	\$ 0.02	\$ (0.02)	\$ (0.0
Diracea	=======	======	======
Net income (loss)			
Basic	\$ 0.02	\$ (0.02)	\$ (0.0
	=======	======	======
Diluted	\$ 0.02	\$ (0.02)	\$ (0.0
	=======	======	======
Shares used in computing per share data:			
Basic	16,031 ======	15 <b>,</b> 186	15,83 ======
Diluted	16,784	15,186	15,83
Dirucca	=======	======	======

See accompanying notes

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Ventana Medical Systems, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine Month Septemb	
	2001	2000
Operating activities: Net loss Adjustments to reconcile net loss to cash used in operating activities:	\$ (822)	\$(24,767)

Cumulative effect of accounting change Depreciation and amortization Change in deferred tax benefit Non-cash intangibles and property and equipment charges Changes in operating assets and liabilities	5,011   (8,677)	2,154 4,098 1,255 7,914 7,623
Net cash used in operating activities	(4,488)	(1,723)
Investing activities: Purchase of property and equipment Purchase of intangible assets, net	(18,179)	(10,798) (2,393)
Net cash used in investing activities	(18,179)	(13,191)
Financing activities: (Payments) issuance of debt Net proceeds from private placement Issuance of common stock	(380)  5,181	1,888 46,847 6,687
Net cash provided by financing activities Effect of exchange rate change on cash	4,801 121	55,422 (266)
Net (decrease) increase in cash and cash equivalents Cash and cash equivalents, beginning of period	(17,745) 38,512	40,242 1,787
Cash and cash equivalents, end of period	\$ 20,767 ======	\$ 42,029 ======

See accompanying notes

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

### 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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 generally accepted accounting principles 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-month periods ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001. 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, 2000.

#### 2. Revenue Recognition

The Company recognizes revenue upon shipment of its products that do not require installation at the customer's site. During the year ended December 31, 2000, the Company changed its methods of revenue recognition for its products which do require installation at the customer's site in accordance with Staff Accounting Bulletin (SAB) No. 101 Revenue Recognition in Financial Statements. Previously, the Company had recognized revenue for products upon shipment to the customer,

but prior to installation at the customer's site. The Company had routinely completed such installation services in the past, but a substantive effort is required and the Company is the only one who can perform the service. Under the new accounting method adopted retroactive to January 1, 2000, the Company now recognizes revenue upon the completion of installation of the product at the customer's site. For the three and nine months ended September 30, 2001, the Company recognized revenues of \$57,000 and \$3,676,000, respectively from instruments shipped in the prior year. The effect of that revenue was to increase gross margin by \$41,000 and \$2,965,000 during the three and nine-month periods, respectively.

#### 3. Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized, but will be subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. The company is currently reviewing the impact of SFAS Nos. 141 and 142. At the present time, the Company reviews, on a quarterly basis, the utility of these assets and recognizes any impairment should the condition exist.

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

### 3. Recent Accounting Pronouncements (continued)

The FASB also recently issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," that is applicable to financial statements issued for fiscal years beginning after December 15, 2001. The FASB's new rules on asset impairment supersede SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and portions of APB Opinion 30, "Reporting the Results of Operations." This Standard provides a single accounting model for long-lived assets to be disposed of and significantly changes the criteria that would have to be met to classify an asset as held-for-sale. Classification as held-for-sale is an important distinction since such assets are not depreciated and are stated at the lower of fair value and carrying amount. This Standard also requires expected future operating losses from discontinued operations to be displayed in the period(s) in which the losses are incurred, rather than as of the measurement date as presently required. The provisions of this Standard are not expected to have a significant effect on the Company's financial position or operating results.

In June 1998, the FASB issued SFAS No. 133 ("SFAS 133"), "Accounting for Derivative Instruments and Hedging Activities." This statement provides a comprehensive and consistent standard for the recognition and measurement of derivatives and hedging activities. In July 1999, the FASB issued SFAS No. 137, which deferred the effective date of SFAS 133 for one year. In June 2000, the FASB issued SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities — an amendment to FASB Statement No. 133." This statement amended certain provisions of SFAS No. 133. The Company adopted SFAS 133 in the first quarter of fiscal 2001 with no effect to the Company's financial position or results of operations.

### 4. Inventories

Inventories consist of the following (in thousands):

	September 30, 2001	December 31, 2000
Raw material and work-in-process Finished goods	\$ 4,887 5,477	\$ 3,603 4,497
	\$ 10,364 	\$ 8,100

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

#### 5. Comprehensive Income (Loss)

The components of comprehensive loss for the three and nine months ending September 30, 2001 and 2000 are as follows (in thousands):

	Three Mor Septemb	nths Ended per 30,	Nine Months Ende September 30,		
	2001 2000		2001	2000	
Net income (loss)	\$ 290	\$ (241)	\$ (822)	\$(24,767)	
Foreign currency translation	80	(302)	121	(266)	
Comprehensive income (loss)	\$ 370	\$ (543)	\$ (701)	\$(25,033)	
	=====	=====	=====	=======	

Accumulated comprehensive income (loss) consists exclusively of foreign currency translation adjustments.

### 6. Provision for Income Taxes

Management believes no benefit for corporate income taxes is required for U.S. tax jurisdictions for the three and nine month periods ending September 30, 2001 given that the deferred tax assets generated by the operating loss have not been assessed as being more likely than not of being recovered in the foreseeable future. The actual tax provision reported consists of certain state taxes as well as other international income taxes.

#### 7. Line of Credit

The Company has a \$10.0 million line of credit arrangement with a bank which is subject to renewal May 31, 2002. Borrowings under the line are collateralized by the Company's receivables, inventories, machinery and equipment, and intellectual property. 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. The Company was in compliance with these covenants as of September 30, 2001. In addition, borrowings are limited based on outstanding accounts receivables of the Company, which as of September 30, 2001 resulted in available borrowing of \$10.0 million, of which, \$7.0 million has been committed in support of various standby letters of credit.

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

### 8. Operating Segment and Enterprise Data

Segment assets

The Company has two reportable segments: North America (the United States and Canada) and International (primarily France, Germany, and Japan). Segment information for the three and nine months ended September 30, 2001, and 2000 are as follows (in thousands):

	Three months ended September 30, 2001									
		U.S.	International	Elimina- tions						
Sales to external customers Segment profit	\$	16 <b>,</b> 167 21	\$ 5,490 269	\$ - -	\$ 21,657 290					
		Three months ended September 30, 2000								
		U.S.		Elimina- tions	Totals					
Sales to external customers Segment loss	\$		\$ 4,073 (149)							
			ne months ended Sep							
			International	Elimina-						
Sales to external customers Segment (loss) profit			\$ 16,729 1,307		\$ 62,275 (822)					

Nine months ended September 30, 2000

(15,627)

102,461 21,034

107,868

		U.S.	International	Elimina- tions 	Totals	
Sales to external customers Segment loss Segment assets	\$	39,747 (22,921) 103,720	\$ 14,001 (1,846) 17,234	\$ - (13,876)	\$ 53,748 (24,767) 107,078	

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 Ventana Medical Systems, Inc. ("Ventana" or "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-Qcontains 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, competition and competitive pressures on pricing and general economic conditions in the United States and in the regions served by the Company. A more complete listing of cautionary statements and risk factors is contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

### Overview

Ventana develops, manufactures and markets instrument/reagent systems that automate tissue preparation and slide staining in clinical histology and drug discovery laboratories worldwide. Ventana's clinical systems are important tools used in the diagnosis and treatment of cancer and infectious diseases. Ventana's drug discovery systems are used to accelerate the discovery of new drug targets and evaluate the safety of new drug compounds.

Results of Operations

Net Sales

Net sales for the three and nine months ended September 30, 2001 as compared to the same periods in 2000 increased 21% and 16% to \$21.7 million and \$62.3 million from \$17.9 million and \$53.7 million, respectively. Net sales growth was attributable to 24% and 21% increases in reagent and non-instrument sales for the three and nine month periods respectively. The increase in reagent sales was driven by both the growth in the underlying installed base and revenues associated with the launch of new reagent systems. Instrument sales increased 14% and 5% during the three and nine months ended September 30, 2001,

respectively although electron

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

microscopy product line sales were discontinued after the third quarter of 2000. Sales across both geographic segments were higher in the three and nine month periods ended September 30, 2001 versus the same periods in 2000: 17% and 15% in the US (\$16.2 million and \$45.5 million versus \$13.8 million and \$39.7 million), and 35% and 20% internationally (\$5.5 million and \$16.7 million versus \$4.1 million and \$14.0 million).

### Gross Profit

Gross profit for the three and nine months ended September 30, 2001 increased to \$15.2 million and \$42.6 million, respectively, from \$12.1 and \$23.2 million for the same periods in 2000. The Company's gross margin for the three and nine months ended September 30, 2001 increased to 70% and 68% from 68% and 43% for the same periods in 2000. The increase in gross margin for the nine months is primarily attributable to \$11.8 million of charges taken in the second quarter of 2000.

#### Research and Development

Research and development expenses for the three and nine months ended September 30, 2001 increased to \$4.1 million and \$11.3 million, respectively, from \$2.7 million and \$8.1 million for the same periods in 2000. The increase results primarily from substantial investment in new products, including development of chemistry applications for both DNA microarrays and mRNA tissue testing.

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

Presented below is a summary of SG&A expense for the three and nine months ended September 30, 2001 and 2000 (in thousands):

	Three Months Ended September 30,					Nine Month: Septembe						
	2001			2000	)		2001			20	00	
	90			%		%		%		%		
	\$ Sales		\$	Sales	5	\$	Sales		\$	Sal	les	
Sales and marketing Administration	\$ 8,587 1,853	39% 9%	\$	7,594 2,222			•					
Total SG&A	\$ 10,440	48%	\$	9,816	55%	\$31	<b>,</b> 420	51%	\$32,	706	 61% 	

SG&A expense for the three months ended September 30, 2001 increased to \$10.4 million from \$9.8 million for the same period in 2000. SG&A expense for the nine months ended September 30, 2001 decreased to \$31.4 million from \$32.7 million for the same period in 2000. The primary reason for the decrease is attributable to \$5.7 million of charges taken in the second quarter of 2000. Absent these

charges, SG&A expense would have increased due to the hiring of new sales and marketing personnel for the Molecular Discovery business in both North America and

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Ventana Medical Systems, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Europe together with a significant investment in sales training for our North American clinical histology sales force.

Amortization of Intangibles

Intangible assets consist primarily of goodwill, customer base, and supply agreements resulting from acquisitions and patents. Such assets are amortized on a straight-line basis over estimated useful lives ranging from 5 to 20 years, resulting in quarterly costs approximating \$0.4 million.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized, but will be subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. The company is currently reviewing the impact of SFAS Nos. 141 and 142. At the present time, the Company reviews, on a quarterly basis, the utility of these assets and recognizes any impairment should the condition exist.

Liquidity and Capital Resources

As of September 30, 2001, the Company's principal source of liquidity consisted of cash and cash equivalents of \$20.8 million. The Company also had an unused \$10.0 million revolving bank credit facility of which \$7 million has been committed in support of various standby letters of credit. Any borrowings under the Company's bank credit facility are secured by a pledge of substantially all of the Company's assets and bear interest at the bank's prime rate.

During the nine months ended September 30, 2001, net cash used in operations and investing activities increased to \$22.7 million, versus \$14.9 million in the nine months ended September 30, 2000. Net cash used in operations and investing was primarily associated with \$12.9 million used on the construction of our corporate headquarters and manufacturing facility in suburban Tucson, Arizona and a final payment of \$1.3 million resulting from a prior period acquisition. Additional spending on the corporate headquarters is expected to be approximately \$2.9 million.

The Company believes that its existing capital resources, together with cash generated from product sales and available borrowing capacity under its bank credit facilities will be sufficient to satisfy its working capital requirements for the foreseeable future.

Foreign Currency Risk

The Company does not currently hedge against foreign currency fluctuations, because the Company does not believe it runs a serious risk of experiencing permanent impairment to any material assets denominated in foreign currency. The Company re-evaluates this situation from time to time. As a result, to the

extent local currency revenues and expenses in foreign subsidiaries are translated into U.S. dollars at differing rates over time, the Company may

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Ventana Medical Systems, Inc.

experience fluctuations in operating results. The Company conducts a relatively small but growing portion of its business in the Euro, the Japanese Yen and the Australian Dollar.

PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

In January 1997, four individuals who are former BioTek noteholders who held in the aggregate approximately \$1.1 million in principal amount of BioTek notes filed an action, TSE, ET AL. v. VENTANA MEDICAL SYSTEMS, INC., ET AL. No. 97-37, against the Company and certain of its directors and stockholders in the United States District Court for the District of Delaware. The complaint alleged, among other things, that the company violated federal and California securities laws and engaged in common law fraud in connection with the BioTek shareholders' consent to the February 1996 merger of BioTek into Ventana and the related conversion of BioTek notes into Ventana notes. Plaintiffs seek compensatory damages in excess of the principal amount of their BioTek notes, as well as punitive damages, and fees and costs.

On April 25, 1997, plaintiffs filed an Amended Complaint. The Amended Complaint made the same allegations as the original Complaint and added a claim under North Carolina securities laws. On December 16, 1997, we filed a motion to dismiss plaintiffs' Amended Complaint. On September 23, 1998, the Court issued its Order granting in part and denying in part our motion to dismiss. The Court dismissed plaintiffs' claims based upon the North Carolina securities laws and California's insider-trading statute. Plaintiffs' surviving claims included violations of federal and California securities laws, common law fraud and breach of fiduciary duty. On June 5, 2000, we filed a motion for summary judgment on all of plaintiffs' remaining claims. On November 22, 2000, the Court issued an Order granting our motion for summary judgment in its entirety. Plaintiffs subsequently filed a notice of appeal on December 8, 2000. Briefing has been completed on the appeal and oral arguments are being considered for January 2002 unless the court determines that it can render judgment based on the briefs. Based on the facts known to date, we believe that the claims are without merit and we will vigorously defend this suit.

A related Delaware state court action entitled LEUNG v. VENTANA MEDICAL SYSTEMS, INC., ET AL., C.A. was dismissed with prejudice on our summary judgment motion in February 2000 and an appeal of that decision was denied in May 2001.

On June 15, 1999 we filed a proof of claim against Oncor, Inc. in an action pending in the United States Bankruptcy Court for the District of Delaware titled IN RE ONCOR, INC., No. 9-437 (JJF). Our claims arise out of an Asset Purchase Agreement dated November 23, 1998 and related documents wherein we acquired Oncor's unincorporated In Situ Hybridization Technology Division and rights related thereto. In February 2000, we filed an amended proof of claim alleging, inter alia, that Oncor breached the terms of the Asset Purchase Agreement by purporting to transfer or assign to us Oncor's rights under a license agreement, which were not transferable or assignable under the circumstances then existing. The amended proof of claim seeks damages of no less than approximately \$7.3 million. On August 17, 2000, Oncor filed an Omnibus

Objection to Claims, which included our claims. However, the Omnibus Objection did not set forth any specific allegations with respect to our claims. On July 20, 2001, we filed our

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#### Ventana Medical Systems, Inc.

response to the Omnibus Objection reasserting our original claim and discovery has commenced. We continue to believe our claims are meritorious and that we will prevail, however, the results of the proceedings are uncertain and there can be no assurance to that effect.

On December 9, 1999 we filed an action, VENTANA MEDICAL SYSTEMS, INC. v. CYTOLOGIX CORP., No. CIV99-606 TUC FRZ, alleging that sales of CytoLogix Corporation's ARTISAN(TM) special stainer infringe U.S. Patent No. 5,355,439 (Bernstein), and seeking monetary damages and injunctive relief in the United States District Court in Tucson. The original complaint was amended March 21, 2000 by the addition of another patent to the litigation (U.S. 5,232,664 (Krawzak)). The amended complaint sought an injunction against the continued sale of the ARTISAN instrument, and damages for lost sales. On July 25, 2001, the parties submitted a joint Stipulation and Order dismissing all claims related to the Krawzak patent. We believe the remaining claims are meritorious and that we will prevail, however, because little discovery has been completed, results of the proceedings are uncertain and there can be no assurance to that effect. The trial has been set for May 2002.

CytoLogix Corp. has filed three separate actions against us in various courts. The first action is CYTOLOGIX v. VENTANA, Case No. CV 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. 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, this litigation is in an early stage and the results of the proceeding are uncertain and there can be no assurance to that effect.

The second is CYTOLOGIX v. VENTANA, Case No. 4 Ni 54/00 (EU) (Nullity suit), filed November 9, 2000 in the German Federal Patent Court, Munich, Germany. CytoLogix seeks to invalidate our German patent (no. DE 69117052.5), which covers various aspects of our automated, slide staining system. We believe we can defend this patent through the Nullity proceeding, however because this action is relatively new, results of the proceeding are uncertain and there can be no assurance to that effect. We have responded to this action and now await further orders from the German Federal Patent Court. Oral proceedings are currently scheduled for March 2002.

The third action is 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 Feb. 7, 2001, entitled "Random Access Slide Stainer with Independent Slide Heating Regulation," both assigned to CytoLogix Corporation. CytoLogix seeks assignment of our patent applications

claiming the independent slide heater idea, treble damages (unspecified amount) and an

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Ventana Medical Systems, Inc.

injunction against our further sales of Discovery and BenchMark instruments. 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, this litigation is in an early stage and the results of the proceeding are uncertain and there can be no assurance to that effect. The trial has been set for April 2002.

Item 6. Exhibits and reports on Form 8-K

- (a) Exhibits No Exhibits
- (b) Reports on Form 8-K.

 $\,$  No reports were filed on Form 8-K during the quarter ended September 30, 2001.

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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 14, 2001 By: /s/ Nicholas Malden

\_\_\_\_\_

Nicholas Malden, Vice President, Chief Financial Officer and Secretary

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