VENTANA MEDICAL SYSTEMS INC
Form 10-Q
November 02, 2004
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2004.

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 Innovation Park Drive **Tucson, AZ** **(Address of principal executive offices)**	**85737** **(Zip Code)**

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 ¨

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

The number of shares outstanding of the registrant s common stock, $0.001 par value was 17,379,116 as of October 22, 2004.

Table of Contents

Ventana Medical Systems, Inc.

INDEX

Table of Contents

Ventana Medical Systems, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except per share data)

(Unaudited)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,523	$ 19,711
Short-term investments	20,104	19,974
Trade accounts receivable, net	27,358	27,398
Inventories, net	13,102	10,483
Prepaid expenses	1,244	594
Deferred tax assets	3,229	3,200
Other current assets	779	967
Total current assets	86,339	82,327
Property and equipment, net	48,700	42,516
Goodwill	2,804	2,804
Intangible assets, net	5,885	3,982
Deferred tax assets, net of current portion	5,602	5,602
Other assets	4,867	3,983
Total assets	$ 154,197	$ 141,214
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 11,207	$ 10,081
Other current liabilities	21,615	16,497
Total current liabilities	32,822	26,578
Long-term debt	2,041	2,260
Commitments and Contingencies		
Stockholders equity:		
Common stock - $.001 par value; 50,000 shares authorized; 17,378 and 16,709 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	17	17
Additional paid-in capital	162,594	154,395
Accumulated deficit	(22,489)	(35,149)
Accumulated other comprehensive loss	(186)	(171)
Treasury stock - 584 shares and 250 shares at cost at September 30, 2004 and December 31, 2003, respectively	(20,602)	(6,716)
Total stockholders equity	119,334	112,376
Total liabilities and stockholders equity	$ 154,197	$ 141,214

See accompanying notes to condensed consolidated financial statements

Table of Contents

Ventana Medical Systems, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Sales:				
Reagents and other	$ 34,308	$ 25,436	$ 99,199	$ 74,338
Instruments	4,994	6,524	18,929	20,333
Total net sales	39,302	31,960	118,128	94,671
Cost of goods sold	9,236	7,861	29,950	25,715
Gross profit	30,066	24,099	88,178	68,956
Operating expenses:				
Research and development	5,421	5,057	15,741	14,224
Selling, general and administrative	17,638	15,207	54,188	45,515
Special charges	1,758		1,758	
Amortization of intangible assets	307	466	924	1,385
Income from operations	4,942	3,369	15,567	7,832
Interest and other income (expense)	126	(33)	211	350
Income before taxes	5,068	3,336	15,778	8,182
Provision for income taxes	(1,004)	(47)	(3,118)	(176)
Net income	$ 4,064	$ 3,289	$ 12,660	$ 8,006
Earnings per common share:				
Basic	$ 0.24	$ 0.20	$ 0.76	$ 0.49
Diluted	$ 0.23	$ 0.19	$ 0.71	$ 0.47
Shares used in computing earnings per common share:				
Basic	16,805	16,492	16,756	16,387
Diluted	17,918	17,730	17,869	17,165

See accompanying notes to condensed consolidated financial statements

Table of Contents

Ventana Medical Systems, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2004	**2003**
Operating activities:		
Net income	$ 12,660	$ 8,006
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	6,105	6,745
Non-cash intangibles and property and equipment charges	1,758	
Changes in operating assets and liabilities	1,925	2,958
Net cash provided by operating activities	22,448	17,709
Investing activities:		
Purchase of property and equipment	(11,948)	(5,018)
Purchase of intangible assets	(3,605)	(287)
Purchases of short-term investments	(15,348)	
Proceeds from sale of short-term investments	15,135	
Net cash used in investing activities	(15,766)	(5,305)
Financing activities:		
Issuance of common stock	8,199	6,413
Repayments of debt	(219)	(35)
Purchases of common stock for treasury	(13,886)	(1,650)
Net cash (used in) provided by financing activities	(5,906)	4,728
Effect of exchange rate change on cash and cash equivalents	36	(46)
Net increase in cash and cash equivalents	812	17,086
Cash and cash equivalents, beginning of period	19,711	18,708
Cash and cash equivalents, end of period	$ 20,523	$ 35,794

See accompanying notes to condensed consolidated financial statements

Table of Contents

Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

(in thousands, except per share data)

(Unaudited)

1. Organization and Significant Accounting Policies

Organization: Ventana Medical Systems, Inc. (Ventana or the Company) develops, manufactures and markets proprietary 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 Japan K.K., and Ventana Medical Systems Australia Pty. Ltd. All significant intercompany balances and transactions have been eliminated. We do not have any subsidiaries in which we do not own 100% of the outstanding stock.

Basis of Presentation: The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2004. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2003.

Recently Issued Accounting Pronouncements: On October 13, 2004, the Financial Accounting Standards Board (FASB) concluded that Statement 123R, *Share-Based Payment*, which would require all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, would be effective for interim or annual periods beginning after June 15, 2005.

Stock-Based Employee Compensation: At September 30, 2004, the Company has six stock-based employee compensation plans. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

Table of Contents

Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

(in thousands, except per share data)

(Unaudited)

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

1. Organization and Significant Accounting Policies (continued)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
Net income, as reported	$ 4,064	$ 3,289	$ 12,660	$ 8,006
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards, no tax benefit available in 2004 and 2003	(1,538)	(1,519)	(9,615)	(6,117)
Pro-forma net income	$ 2,526	$ 1,770	$ 3,045	$ 1,889
Earnings per share:				
Basic - as reported	$ 0.24	$ 0.20	$ 0.76	$ 0.49
Basic - pro forma	$ 0.15	$ 0.11	$ 0.18	$ 0.12
Diluted - as reported	$ 0.23	$ 0.19	$ 0.71	$ 0.47
Diluted - pro forma	$ 0.14	$ 0.10	$ 0.17	$ 0.11

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

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

2. Inventories

Inventories consist of the following:

	September 30, 2004	December 31, 2003
Raw material and work-in-process	$ 6,902	$ 2,977
Finished goods	6,200	7,506
	$ 13,102	$ 10,483

Table of Contents

Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

(in thousands, except per share data)

(Unaudited)

3. Special Charges

On September 16, 2004, the Company entered into an agreement with TriPath Imaging, Inc. to sell and distribute worldwide a Ventana-branded interactive histology imaging system. Under the terms of the agreement, the Company made an initial payment of $0.5 million for various fixed assets and will be required to make potential additional payments upon the certification that certain development milestones have occurred. As a result of this transaction, the Company incurred a $1.8 million non-cash charge primarily associated with impairments to the certain intangible and fixed assets acquired in the Company s 2001 transaction with Molecular Diagnostics, Inc.

4. Transaction with Quantum Dot Corporation

On August 26, 2004, the Company entered into a supply agreement with Quantum Dot Corporation (QDC) for QDC to supply Qdot® nanocrystals to be incorporated into the Company s next-generation rapid, quantitative and multiplexed assays for cancer diagnosis and disease management. Under terms of the agreement, the Company made an initial payment of $2.0 million which is being amortized on a straight-line basis over five years.

5. Comprehensive Income

The components of comprehensive income for the three and nine months ending September 30, 2004 and 2003 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$ 4,064	$ 3,289	$ 12,660	$ 8,006
Net unrealized gain (loss) on available for sale securities	24		(52)	
Foreign currency translation	481	(59)	36	(46)
Comprehensive income	$ 4,569	$ 3,230	$ 12,644	$ 7,960

Accumulated comprehensive income consists of net unrealized gains on available for sale securities and foreign currency translation adjustments.

6. Provision for Income Taxes

The income tax provision for the three and nine months ending September 30, 2004 and 2003 consists of certain state and international tax expenses for which net operating loss carryforwards do not exist. The Company evaluated the recoverability of its net deferred tax assets and determined that the balances existing at September 30, 2004, represented the amount that is more likely than not of being recovered in the foreseeable future. The Company s valuation reserves are subject to reversal at such time that the benefits are actually utilized or, the domestic operating profits become sustainable at a level that meets the recoverability criteria under SFAS No. 109.

Table of Contents

Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

(in thousands, except per share data)

(Unaudited)

7. Stock Repurchase

On September 8, 1998, the Company s Board of Directors authorized the Company to repurchase up to 750 shares of its common stock in the open market or in privately negotiated transactions. During the nine months ended September 30, 2004 and 2003, the Company purchased 333.2 and 87.4 shares of its common stock for $13,886 and $1,650, 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.

In May 2004, the Company s Board of Directors approved the repurchase of up to an additional one million shares of the Company s common stock. No shares were repurchased under this authorization.

8. Stock Repurchases During the Third Quarter 2004

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
July 1 - July 31, 2004	6.3	$ 47.39	6.3	1,211.4
August 1 - August 31, 2004	45.0	$ 45.44	45.0	1,166.4
September 1 - September 30, 2004				1,166.4

9. Operating Segment and Enterprise Data

The Company has two reportable segments: North America (the United States and Canada) and International (primarily Europe, Japan and Australia). Segment information for the three and nine months ended September 30, 2004 and 2003 are as follows:

	Three months ended September 30, 2004			
	North America	International	Elimina-tions	Totals

Sales to external customers	$ 28,272	$	11,030	$ $ 39,302
Segment profit	1,674		2,390	4,064

	Three months ended September 30, 2003			
	North America	International	Elimina-tions	Totals
Sales to external customers	$ 23,363	$ 8,597	$	$1,960
Segment profit	1,984	1,305		3,289

Table of Contents

Ventana Medical Systems, Inc.

Notes to Condensed Consolidated Financial Statements (continued)

(in thousands, except per share data)

(Unaudited)

9. Operating Segment and Enterprise Data (continued)

	Nine months ended September 30, 2004			
	North America	International	Elimina-tions	Totals
Sales to external customers	$ 82,631	$ 35,497	$	$ 118,128
Segment profit	5,694	6,966		12,660
Segment assets	140,248	31,273	(17,324)	154,197

	Nine months ended September 30, 2003			
	North America	International	Elimina-tions	Totals
Sales to external customers	$ 68,312	$ 26,359	$	$ 94,671
Segment profit	3,701	4,305		8,006
Segment assets	130,102	25,892	(16,892)	139,102

10. Commitments and Contingencies

The Company is litigating several matters with CytoLogix, Inc., a Massachusetts company. The litigation primarily involves intellectual property and related matters associated with the Company s first generation Discovery® and BenchMark® instruments. In December 2003, a jury found Ventana liable for infringing two patents (no willfulness), and not liable for misappropriation of trade secrets. A hearing for an injunction occurred in February 2004. At the hearing, the Judge ruled on several issues, including denying the parties post-trial motions and framing the scope of the injunction. The form of the permanent injunction was filed with the Court in April 2004, and prohibits Ventana from making and selling the Discovery® and BenchMark® systems, but does not prohibit their continued use by customers, and does not prohibit Ventana from supplying reagents to customers. Hearings on the issues of patent damages and antitrust-related claims will not be scheduled until the conclusion of Ventana s appeal to the Federal Circuit on claim construction issues. This appeal is likely to be decided in 2005. Management has not recorded any asset impairment as a result of the injunction, or accrued any liability with respect to this litigation given that management does not believe that a liability exists as defined in SFAS No. 5.

In the ordinary course of business, the Company is involved in a limited number of 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.

Table of Contents

Ventana Medical Systems, Inc.

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

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

Results of Operations

Net Sales

Net sales for the three and nine months ended September 30, 2004 increased 23% and 25% versus the same periods in 2003 to $39.3 million and $118.1 million from $32.0 million and $94.7 million, respectively. This sales growth was attributable to 35% and 33% increases in reagents and other sales for the three and nine month periods ended September 30, 2004, respectively. This growth came from an increase in our installed base and a 13% year-over-year improvement in the average reagent annuity stream per installed instrument to $24,000 in 2004 from $21,200 in 2003.

Total sales increased in the three and nine month periods ended September 30, 2004 compared to the same period in 2003 across both geographic segments: 21% for both periods in North America ($28.3 million and $82.6 million versus $23.4 million and $68.3 million) and 28% and 35% internationally ($11.0 million and $35.5 million versus $8.6 million and $26.4 million), respectively.

Gross Profit

Gross profit for the three and nine months ended September 30, 2004 increased to $30.1 million and $88.2 million, respectively, from $24.1 million and $69.0 million for the same periods in 2003. The Company s gross margin for the three and nine months ended September 30, 2004 increased to 76% and 75% from 75% and 73%, respectively. The primary reason for the gross margin increase is due to a higher mix of reagent and other sales, which have a higher gross margin than instrument sales.

Table of Contents

Ventana Medical Systems, Inc.

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

Research and Development

Research and development spending for the three and nine months ended September 30, 2004 increased to $5.4 million and $15.7 million, respectively, from $5.1 million and $14.2 million for the same periods in 2003. This increase was driven by our continued, aggressive new platform development programs and our reagent chemistry application initiatives focused primarily on the histology market.

Selling, General and Administrative (SG&A)

Presented below is a summary of SG&A expense for the three and nine months ended September 30, 2004 and 2003 (in thousands):

	Three Months Ended September 30				Nine Months Ended September 30			
	2004		2003		2004		2003	
	$	% Net Sales	$	% Net Sales	$	% Net Sales	$	% Net Sales
Sales and marketing	$ 11,920	30%	$ 11,033	35%	$ 38,355	32%	$ 34,090	36%
Administration	5,718	15%	4,174	13%	15,833	14%	11,425	12%
Total SG&A	$ 17,638	45%	$ 15,207	48%	$ 54,188	46%	$ 45,515	48%

SG&A expense for the three and nine months ended September 30, 2004 increased to $17.6 million and $54.2 million, respectively, from $15.2 million and $45.5 million for the same periods in 2003. The increase is primarily attributed to increased investments in our sales force and associated infrastructure and continued development of our marketing organization. We also continued to invest in fortifying our intellectual property position.

Special Charges

On September 16, 2004, the Company entered into an agreement with TriPath Imaging, Inc. to sell and distribute worldwide a Ventana-branded interactive histology imaging system. Under the terms of the agreement, the Company made an initial payment of $.5 million for various fixed assets and will be required to make potential additional payments upon the certification that certain development milestones have occurred. As a result of this transaction, the Company incurred a $1.8 million non-cash charge primarily associated with impairments to the certain intangible and fixed assets acquired in the Company s 2001 transaction with Molecular Diagnostics, Inc.

Amortization of Intangible Assets

Amortization expense of intangible assets for the three and nine months ended September 30, 2004 decreased to $0.3 million and $0.9 million, respectively, from $0.5 million and $1.4 million for the same periods in 2003. The decrease is due to a lower carrying base in intangible assets during 2004. Estimated amortization expense for intangible assets as of September 30, 2004 for each of the five succeeding fiscal years is as follows (all amounts are in thousands): 2005: $1,300, 2006: $1,200, 2007: $900, 2008: $600, 2009: $500.

Table of Contents

Ventana Medical Systems, Inc.

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

Interest and Other Income (Expense)

Interest and other income for the three months ended September 30, 2004 increased to $126,000 from ($33,000) and decreased from $350,000 to $211,000 for the nine months ended September 30, 2004. The three month balance increase is primarily due to decreased interest expense associated with our European facility lease. The nine month balance decrease is primarily due to lower average interest rates on investment returns in 2004 compared to 2003.

Income Taxes

Income tax expense for federal, state and foreign taxes was $1.0 million and $3.1 million for the three and nine months ended September 30, 2004 and $47,000 and $176,000 for the three and nine months ended September 30, 2003. The income tax provision for 2004 is primarily comprised of state and international tax expenses for which net operating loss carryforwards do not exist.

We evaluated the recoverability of our net deferred tax assets and determined that the balances existing at September 30, 2004, represented the amount that is more likely than not of being recovered in the foreseeable future. The valuation reserves are subject to reversal at such time that the benefits are actually utilized or, the operating profits become sustainable at a level that meets the recoverability criteria under SFAS No. 109.

The effective income tax rate for both the three and nine months ended September 30, 2004 was approximately 20%, which differed from the U.S. statutory rate principally due to foreign taxes attributable to foreign operations that differed from the U.S. statutory rate. The effective tax rate for 2003 is not meaningful.

Risk Factors

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

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

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

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

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

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

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

Table of Contents

Ventana Medical Systems, Inc.

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

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

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

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

Third parties may assert patent, trademark or copyright infringement or other intellectual property claims against us based on their patents or other intellectual property. We may be required to pay substantial damages (including treble damages) for past infringement if it is ultimately determined that our products infringe a third party s intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, 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 or continue 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.

If we are unsuccessful in appealing the adverse judgment we received in connection with the Cytologix litigation, we may be forced to pay damages to Cytologix.

As discussed in more detail under *Item 1. Legal Proceedings* under Part II, we have been involved in litigation with Cytologix, Inc., pursuant to which a jury determined that we infringed certain Cytologix patents. We are currently enjoined from further manufacture and sale of our first generation BenchMark® and Discovery® instruments. This action does not apply to the BenchMark® XT/LT and Discovery® XT instruments.

We have appealed the decision. However, our success cannot be guaranteed, and, if we are ultimately unsuccessful in the litigation we may be forced to pay damages including royalties to Cytologix.

Table of Contents

Ventana Medical Systems, Inc.

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

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

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

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.

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

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

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

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

Table of Contents

Ventana Medical Systems, Inc.

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

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

We have numerous competitors in the United States and abroad. These competitors may develop technologies and products that are more effective or less costly than our current or future products or that could render our technologies and products obsolete or noncompetitive. Many of these competitors have greater experience and name recognition. If we are not able to compete effectively, our results would suffer.

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

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

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

Unless otherwise exempt, prior to marketing in the United States, medical devices require approval or clearance. The process of obtaining approvals and clearances necessary to market clinical products can be time-consuming, expensive and uncertain. Clinical products that we may seek to introduce in the future may require FDA approvals or clearances prior to commercial sale in the United States. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of new clinical products. In addition, we cannot assure that regulatory approval or clearances of any clinical products for which we seek such approvals or clearances will be granted by the FDA or foreign regulatory authorities on a timely basis, if at all.

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

Any of the customers using our products for clinical use in the United States may be regulated under the Clinical Laboratory Improvement Act (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.

Table of Contents

Ventana Medical Systems, Inc.

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

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

Sales of our products in the European Union (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 that 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 currently 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.

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

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

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

Our reagent products are formulated from chemical and biological materials using proprietary technology, and standard processing techniques. We purchase components and raw materials used to make our reagent products from single-source vendors. We cannot assure you that 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 is not adequate for use in our instruments, our ability to make instruments in a timely fashion could be impaired and our results of operations would suffer.

We may be held liable for any inaccuracies associated with analysis tests performed using our products, which may require us to defend ourselves in costly litigation.

We may be subject to claims resulting from incorrect results of tests performed using our products. Litigation of these claims can be costly, and we may be forced to expend significant funds during any litigation proceeding brought against us. Further, if a court were to require us to pay damages to a plaintiff in excess of our insurance coverage, then our financial condition may be harmed.

Table of Contents

Ventana Medical Systems, Inc.

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

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

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

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

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

the extent that our products gain market acceptance;

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

the progression of our product development programs;

competing technological and market developments;

expansion of our sales and marketing activities;

the cost of manufacturing scale-up activities;

Possible acquisitions of complementary businesses, products or technologies; and

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

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

Liquidity and Capital Resources

Cash and cash equivalents was $20.5 million at September 30, 2004. We have funded our capital requirements since inception through sales of equity securities, debt financing and

Table of Contents

Ventana Medical Systems, Inc.

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

cash flows from operations. Net cash provided by operating activities was $22.4 million and $17.7 million for the nine months ended September 30, 2004 and 2003, respectively. Net cash provided by operating activities exceeded net income in 2004 primarily due to the effect of depreciation and amortization expense.

We use cash in our investing activities primarily to fund investments in property and equipment and in 2004 to purchase short-term investments. Net cash used in investing activities for the nine months ended September 30, 2004 and 2003 was $15.8 million and $5.3 million, respectively. At September 30, 2004, we have $20.1 million in short-term investments that primarily consist of corporate and various government agency debt securities. We classify these short-term investments as available-for-sale.

Net cash used in financing activities for the nine months ended September 30, 2004 was $5.9 million compared to net cash provided by financing activities for the nine months ended September 30, 2003 of $4.7 million. The increase in cash used in financing activities consisted primarily of our stock repurchases net of 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 2004. In the event that additional capital is required, we will first access our short-term investments or seek to raise such capital through public or private equity or debt financings. Future capital funding transactions may result in dilution to current shareholders.

Table of Contents

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, 2003, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2003.

Table of Contents

Ventana Medical Systems, Inc.

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report (the Evaluation Date). Based on this evaluation, our chief executive officer and chief financial officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective such that the information required to be disclosed in our SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

During the quarter ending on September 30, 2004, there was no change in the Company s internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

Table of Contents

Ventana Medical Systems, Inc.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

CYTOLOGIX v. VENTANA, Case No. 04-04-232, was filed in April 2004, in the Wilmington, Delaware Federal District Court alleging infringement of U.S. Patent No. 6,541,261(261). Cytologix alleges that the manufacture, use and sale of Ventana s BenchMark® XT slide staining system infringes their 261 patent. Cytologix has asked for an injunction, unspecified damages, and enhanced damages for willful infringement. Ventana filed its Answer and Counterclaim to the Complaint in May, 2004 along with a Motion to Transfer the case to the U.S. District Court for the District of Eastern Massachusetts. In July 2004, the Delaware District Court granted the Motion to Transfer. The case has since been transferred to the District Court of Eastern Massachusetts, Case No. 04-CV-11783 RWZ, and the parties are currently awaiting entry of a Scheduling Order.

CYTOLOGIX v. VENTANA, Case No. 00-12231 REK, was filed in October 2000 in U.S. District Court, Eastern District of Massachusetts. 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. (see, related case no. 01-10178 REK and discussion below). In February 2002, CytoLogix filed a motion to amend their complaint to add the related claims of attempted monopolization and monopolization under the Sherman Act, and various Lanham Act violations. The amendment was allowed by the Court.

CYTOLOGIX v. VENTANA, Case No. 01-10178 REK, was filed in January 2001 in the U.S. District Court, Eastern District of Massachusetts. This Complaint claims that Ventana infringed CytoLogix s U.S. Patent No. 6,180,061(061), entitled Moving Platform Slide Stainer with Heating Elements, and the Complaint was later amended to add U.S. Patent No. 6,183,693(693), issued in February 2001, entitled Random Access Slide Stainer with Independent Slide Heating Regulation, assigned to CytoLogix. CytoLogix seeks assignment of our patent applications claiming the independent slide heater idea, 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 that Ventana had not misappropriated any trade secrets Ventana filed post-trial motions for judgment as a matter of law and a new trial. A hearing for a permanent injunction occurred in February 2004. At the hearing, the Judge ruled on several issues, including denying the parties post-trial motions and framing the scope of the injunction. A permanent injunction was entered by the Court in April, 2004, which prohibits Ventana from making and selling the Benchmark®/Discovery® systems, but does not prohibit their continued use by customers, and does not prohibit Ventana from servicing the instruments or supplying reagents to customers. In May, 2004 Cytologix and Ventana filed Notices of Appeal to the Court of Appeals for the Federal Circuit. Hearings on the issues of patent damages and the antitrust-related claims will not be scheduled until the conclusion of the appeal to the Federal Circuit on claim construction issues, likely to be decided in midyear 2005.

Table of Contents

Ventana Medical Systems, Inc.

Item 1. Legal Proceedings (continued)

In March 2003, Ventana was served with a Summons and Complaint by Vision Biosystems, Ltd. (Vision) for a Declaratory Judgment seeking a declaration of no infringement and invalidity of U.S. Patent Nos. 5,355,439 (439) entitled Method and Apparatus for Automated Tissue Assay and 6,352,861 (861) entitled Automated Biological Reaction Apparatus , both owned by Ventana, in the U.S. Federal Court for the Eastern District of Massachusetts. The Complaint alleges that Ventana has asserted that Vision s BOND system infringes both of the aforementioned patents, and that Vision has a reasonable apprehension of being sued. In May 2003, Ventana filed its Answer to the Vision Complaint in the Massachusetts action. In November 2003, Vision filed a motion for Summary Judgment of non-infringement of the 861 patent. In November 2003, Ventana filed a motion to amend our Answer to add a counterclaim for infringement of the 439 and 861 patents by the BOND system. In January 2004, Ventana filed its opposition to Vision s Summary Judgment motion, and filed its own cross-motion for Summary Judgment of infringement. The hearing on both Summary Judgment motions was conducted in May 2004. On September 30, 2004, the Court issued an Order granting Ventana s Motion for Summary Judgment finding that Vision s Bond instruments infringe Ventana s 861 patent. In the Order the Court also denied Vision s Motion for Summary Judgment and dismissed Vision s claims regarding the 439 patent and related motions, leaving only the issue of validity to be decided. The parties are currently conducting discovery.

DIGENE CORPORATION v. VENTANA MEDICAL SYSTEMS, INC., Case No. 01-752, was filed in November 2001 in Delaware Federal District Court. This Complaint alleges that we infringe two U.S. patents held by Digene, U.S. Patent Nos. 4,849,331 and 4,849,332 by commercial activities relating to our INFORM® HPV High-risk and Low-risk probe products. We filed an Answer denying the allegations in February 2002. The parties have filed cross-motions for Summary Judgment. In addition, in November 2002, Digene filed a motion to amend its Complaint to add numerous causes of action related to our September 2002 acquisition of 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 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 Ventana. In May 2003, the judge ordered that further discovery be taken on the issues of arbitrability. In January 2004, the Court held a hearing on the arbitrability issue. In March 2004, the Judge dismissed all of the pending motions in the case, without prejudice and without comment. In May, 2004, the Court ordered that arbitration proceed as against Beckman, only, and stayed the proceedings pending in the District Court until the conclusion of the arbitration. Digene filed a Motion for Reconsideration of the Court s Order, which was denied by the Court in July, 2004. The arbitration proceeding has not presently been initiated.

In June 2003, Ventana and Beckman filed a request for arbitration with the International Chamber of Commerce (ICC) in Paris, France to contest the purported termination by Institut Pasteur of the Sublicense Agreement acquired by Ventana from Beckman in September 2002. Institut Pasteur has responded, and the parties have selected a panel of arbitrators. In December 2003, the panel framed the Terms of Reference, the issues to be heard in the case. In February 2004, Ventana submitted its Statement of Claim. In March 2004, Institut Pasteur filed a Statement of Defenses. Institut Pasteur also filed a Motion to Stay the Arbitration pending the outcome of the Delaware patent litigation, and an oral hearing was conducted in May 2004. The Motion for Stay was denied and in June 2004, Ventana filed its Statement of Reply and rebuttal to Institut Pasteur s defenses. The ICC hearing was conducted in early September, 2004 and the parties are preparing post-hearing submissions.. A decision by the ICC is expected in 2005.

Table of Contents

Ventana Medical Systems, Inc.

Item 1. Legal Proceedings (continued)

In February 2003, we filed a Complaint in Arizona Federal District Court against BioGenex Laboratories, Inc. (BioGenex), for infringement of U.S. Patent No. 6,352,861 (Automated Biological Reaction Apparatus). In September 2003, BioGenex served its Answer to the Complaint denying infringement. In September 2003, BioGenex amended its Answer to Ventana s Complaint adding the defense of invalidity. The parties are currently conducting discovery.

BIOGENEX LABORATORIES, INC., v. VENTANA MEDICAL SYSTEMS, INC., Case No. C03 03913 JF, was filed in August 2003 in the United States District Court for the District Court Northern California, San Jose Division.. This Complaint alleges that Ventana infringes three US patents held by BioGenex, U.S. Patent Nos. 5,578,452, 5,244,787 and 6,451,551. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. Ventana filed its Answer in October 2003. In June, 2004, Biogenex moved to amend its Complaint adding allegations that Ventana also infringes U.S. Patent No. 6,632,598, and has also filed an action for Contempt against us arising out of the BioTek litigation years ago. A show cause hearing on the contempt action originally set for August 2004 was continued and no date scheduled.. The parties are currently conducting discovery.

In July 2003, Ventana filed a patent infringement action against Abbott Laboratories, Inc., and its subsidiary Vysis, Inc., for patent infringement in the Federal Court in Chicago, Illinois alleging that various Vysis DNA probe products infringe U.S. Patent No. 6,025,126 (Methods and Compositions for the Detection of Chromosomal Aberrations) and U.S. Patent No. 6,414,133 (Multiple Fusion Probes). In particular, Ventana alleges that sales of the BCR/ABL probes, amongst others, sold by Vysis infringe one or both of the patents. The U.S. Patent and Trademark Office has declared Interferences between both patents and a University of California patent application, Gray et al., Interference No. 105,207, which are proceeding. In addition, the Court granted a joint motion to stay the litigation in April 2004.

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, after conferring with legal counsel, that we have meritorious defenses to the claims in these actions and that resolution of these matters, both individually and in the aggregate, 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.

Table of Contents

Ventana Medical Systems, Inc.

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

Period	Total Number of Shares	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Maximum Number of Shares that may yet be Repurchased Under the Plans or Programs
			(in thousands)	
July 1 - July 31, 2004	6.3	$ 47.39	6.3	1,211.4
August 1 - August 31, 2004	45.0	$ 45.44	45.0	1,166.4
September 1 - September 30, 2004				1,166.4

(1) On September 8, 1998, the Company s Board of Directors authorized the Company to repurchase up to 750,000 shares of the Company s common stock in the open market or in privately negotiated transactions. In May 2004, the Company s Board of Directors approved the repurchase of up to an additional 1,000,000 shares of the Company s common stock. To date, no shares have repurchased under this authorization. The timing and amount of any future repurchases will depend on market conditions and corporate considerations.

Table of Contents

Ventana Medical Systems, Inc.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

See Exhibits Index

(b) Reports on Form 8-K.

On July 8, 2004, the Company filed a current report on Form 8-K to furnish the Company s press release reporting preliminary results for sales and earnings per share for the quarter ended June 30, 2004. In accordance with SEC Release No. 33-8216, the information, intended to be furnished under Item 12. Results of Operations and Financial Condition, was instead furnished under Item 9. Regulation FD Disclosure.

On July 16, 2004, the Company filed a current report on Form 8-K to furnish the Company s press release reporting final results for the quarter ended June 30, 2004. In accordance with SEC Release No. 33-8216, the information, intended to be furnished under Item 12. Results of Operations and Financial Condition, was instead furnished under Item 9. Regulation FD Disclosure.

Table of Contents

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 1, 2004

By: /s/ Nicholas Malden

Nicholas Malden
Senior Vice President, Chief Financial Officer and Secretary

Table of Contents

EXHIBITS

Exhibit Number	Description	Notes
3.1	Restated Certificate of Incorporation or Registrant	(1)
3.2	Bylaws of Registrant	(1)
4.1	Specimen Common Stock Certificate	(1)
10.1	Form of Indemnification Agreement for directors and officers	(1)
10.2	1988 Stock Option Plan and forms of agreements thereunder	(1)
10.3	1996 Stock Option Plan and forms of agreements thereunder	(1)
10.4	1996 Employee Stock Purchase Plan	(1)
10.5	1996 Directors Option Plan	(1)
10.6	1998 Nonstatutory Stock Option Plan and forms of agreements thereunder	(2),(3)
10.7	2001 Outside Director Stock Option Plan	(4)
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	
32.1	Section 1350 Certifications of Chief Executive Officer	
32.2	Section 1350 Certifications of Chief Financial Officer	

(1) Filed with the Registration Statement on Form S-l (Commission File No. 333-4461), declared effective by the Commission July 26, 1996.
(2) Filed with the Registration Statement on Form S-8 (Commission File No. 333-92883), filed with the Commission on December 16, 1999.
(3) Form of 1998 Nonstatuatory Stock Option Plan, as amended, agreements filed with the Registration Statement on Form S-8 (Commission File No. 333-105976), 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.