BIOVERIS CORP
Form 10-Q
August 09, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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FORM 10-Q

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

For the quarterly period ended June 30, 2006

OR

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

Commission File Number: 000-50583

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BioVeris Corporation

(Exact name of registrant as specified in its charter)

DELAWARE	80-0076765
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

16020 INDUSTRIAL DRIVE, GAITHERSBURG, MD 20877

(Address of principal executive offices) (Zip Code)

301-869-9800

(Registrant s telephone number, including area code)

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 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 o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

27,238,969 shares of common stock, par value $0.001, issued and outstanding at July 28, 2006

BIOVERIS CORPORATION

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As used herein, BioVeris , we , us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER, BIOVERIFY and BIOVERIS are our trademarks. This Form 10-Q also contains disclosure relating to brand names, trademarks or service marks of other companies, and these brand names, trademarks or service marks are the property of those other holders.

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PART 1 FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIOVERIS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

(Unaudited)

		June 30, 2006		March 31, 2006
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$	**37,266**	$	29,693
Short-term investments		**24,226**		39,938
Accounts receivable, net		**2,920**		3,360
Inventory, net		**6,476**		5,429
Other current assets		**2,329**		2,508
Total current assets		**73,217**		80,928
Equipment and leasehold improvements, net		**3,340**		3,456
OTHER NONCURRENT ASSETS:				
Note receivable, net		**5,857**		5,666
Technology licenses		**14,869**		15,356
Other		**447**		447
TOTAL ASSETS	$	**97,730**	$	105,853
LIABILITIES AND STOCKHOLDERS EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued expenses	$	**5,055**	$	5,362
Accrued wages and benefits		**1,267**		1,862
Other current liabilities		**1,739**		1,520
Total current liabilities		**8,061**		8,744
NONCURRENT DEFERRED LIABILITIES		**135**		546
Total liabilities		**8,196**		9,290
SERIES B PREFERRED STOCK, 1,000 shares designated, issued and outstanding		**7,500**		7,500
STOCKHOLDERS EQUITY:				
Preferred stock, par value $0.01 per share, 15,000,000 shares authorized, issuable in series:				
Series A, 600,000 shares designated, none issued		**-**		-
Common stock, par value $0.001 per share, 100,000,000 shares authorized, 27,239,000 and 27,238,000 shares issued and outstanding at June 30, 2006 and March 31, 2006, respectively		**27**		27
Additional paid-in capital		**204,593**		205,997
Deferred compensation		**-**		(1,688)
Accumulated other comprehensive loss		**(47)**		(128)
Accumulated deficit		**(122,539)**		(115,145)
Total stockholders' equity		**82,034**		89,063
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	**97,730**	$	105,853

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

BIOVERIS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended	
	June 30, 2006	June 30, 2005
REVENUES:		
Product sales	$ **3,590**	$ 4,580
Royalty income	**498**	309
Total	**4,088**	4,889
OPERATING COSTS AND EXPENSES:		
Product costs	**2,384**	2,048
Research and development	**4,262**	4,765
Selling, general, and administrative	**6,202**	5,681
Total	**12,848**	12,494
LOSS FROM OPERATIONS	**(8,760)**	(7,605)
INTEREST INCOME	**1,201**	1,318
OTHER, NET	**187**	(381)
NET LOSS	$ **(7,372)**	$ (6,668)
Net loss per common share (basic and diluted)	$ **(0.27)**	$ (0.25)
COMMON SHARES OUTSTANDING (basic and diluted)	**26,880**	26,728

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

BIOVERIS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended	
	June 30, 2006	June 30, 2005
OPERATING ACTIVITIES**:**		
Net loss	$ **(7,372)**	$ (6,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amoritization	**935**	1,632
Loss on disposal of equipment	**18**	-
Accretion of interest on note receivable	**(549)**	(403)
Amortization of premium on short-term investments	**49**	-
Stock based compensation	**284**	-
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	**440**	(1,383)
(Increase) decrease in inventory	**(1,239)**	220
Decrease in other current assets	**179**	294
(Increase) in accounts payable and accrued expenses	**(312)**	(2,024)
(Decrease) increase in accrued wages and benefits	**(595)**	309
Increase (decrease) in other liabilities	**149**	(210)
Net cash used in operating activities	**(8,013)**	(8,233)
INVESTING ACTIVITIES:		
Expenditures for equipment and leasehold improvements	**(158)**	(182)
Purchases of short term-investments	**(19,994)**	(9,998)
Sales and maturities of short-term investments	**35,738**	8,000
Net cash provided by (used in) investing activities	**15,586**	(2,180)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**7,573**	(10,413)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	**29,693**	41,739
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ **37,266**	$ 31,326
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Transfer of inventory into fixed assets	$ **192**	$ **-**

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

BioVeris Corporation (the Company) is a global integrated healthcare company developing proprietary technologies in diagnostics and vaccinology. The Company is dedicated to the commercialization of innovative products and services for healthcare providers, their patients and their communities.

The Company was organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted into BioVeris Corporation, a newly formed Delaware corporation on September 22, 2003. On February 13, 2004, IGEN International, Inc. (IGEN or Parent) and Roche Holding Ltd (Roche) consummated a merger transaction pursuant to which Roche acquired IGEN and IGEN simultaneously distributed the common stock of the Company to its stockholders.

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements have been condensed or omitted. In the opinion of the Company s management, the financial statements reflect all adjustments necessary for a fair presentation of the results of operations and cash flows for the three month periods ended June 30, 2006 and 2005, and the Company s financial position at June 30, 2006. The year end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

The results of operations for the interim periods are not necessarily indicative of the results for any future interim period or for the entire year. These financial statements should be read together with the audited financial statements and notes contained in the Company s Annual Report on Form 10-K for the year ended March 31, 2006 filed with the Securities and Exchange Commission (SEC).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation Accounting The consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany transactions and balances have been eliminated.

Estimates The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents Cash and cash equivalents include cash in banks, money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less.

Short-Term Investments Short-term investments consist primarily of corporate, federal and municipal debt-securities that are classified as available-for-sale. The Company invests its excess cash in accordance with a policy approved by the Company s Board of Directors. This policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on the Company s investment by terms and concentrations by type and issuer. These available-for-sale securities are accounted for at their fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive gain or loss in stockholders equity. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which are included in results of operations as generated. For the three months ended June 30, 2006 and 2005, the Company did not have any realized gains or losses.

The following is a summary of the Company s available-for-sale marketable securities as of June 30, 2006:

	June 30, 2006 *(in thousands)*			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Certificates of deposit	$ 2,500	$ -	$ -	$ 2,500
U.S. government agencies	5,000	-	(49)	4,951
U.S. corporate debt	4,504	-	(4)	4,500
Asset-backed securities	12,269	6	-	12,275
Total	$ 24,273	$ 6	$ (53)	$ 24,226

	March 31, 2006 *(in thousands)*			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificates of deposit	$ 5,000	$ -	$ -	$ 5,000
U.S. government agencies	15,000	-	(84)	14,916
U.S. corporate debt	20,066	-	(44)	20,022
Total	$ 40,066	$ -	$ (128)	$ 39,938

Concentration of Credit Risk The Company places its cash and cash equivalents and short-term investments with highly rated financial institutions. At June 30, 2006 and March 31, 2006, the Company had $61.1 million and $69.2 million, respectively, of cash and cash equivalents and short-term investments in excess of federally insured limits. The Company has not experienced any losses on these accounts related to amounts in excess of insured limits. During the three months ended June 30, 2006 and 2005, agencies of the U.S. government accounted for 30% and 32% of total revenues, respectively. As of June 30, 2006 and March 31, 2006, agencies of the U.S. government accounted for 42% and 43% of total consolidated accounts receivable, respectively.

Allowance for Doubtful Accounts The Company maintains reserves on customer accounts where estimated losses may result from the inability of its customers to make required payments. These reserves are determined based on a number of factors, including the current financial condition of specific customers, the age of accounts receivable balances and historical loss rates. Amounts later determined and specifically identified to be uncollectible are charged or written-off against the reserve. Historically, the Company has not experienced significant credit losses related to an individual customer or group of customers and estimated losses have been within the Company s expectation. Allowance for doubtful accounts was $101,000 and $253,000 at June 30, 2006 and March 31, 2006, respectively.

Inventory Inventory is recorded at the lower of cost or market using the first-in, first-out method and consists of the following:

	June 30, 2006	March 31, 2006
	(in thousands)	
Finished Goods	**$ 1,910**	$ 2,058
Work in process	**1,152**	865
Raw materials	**3,414**	2,506
Total	**$ 6,476**	$ 5,429

Equipment and Leasehold Improvements Equipment and leasehold improvements are carried at cost, less accumulated depreciation and amortization. Depreciation on equipment, which includes lab instruments and furniture, is computed over the estimated useful lives of the assets, generally three to five years, using the straight-line method of depreciation. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life or the term of the lease. Equipment and leasehold improvements consist of the following:

	June 30, 2006	March 31, 2006
	(in thousands)	
Lab instruments and equipment	**$ 7,781**	$ 7,579
Office furniture and equipment	**4,683**	4,659
Leasehold improvements	**4,202**	4,194
	16,666	16,432
Accumulated depreciation and amortization	**(13,326)**	(12,976)
Total	**$ 3,340**	$ 3,456

Technology Licenses Simultaneous with the execution of the merger transaction with Roche (see Note 1), the Company entered into worldwide, non-exclusive polymerase chain reaction (PCR) license agreements with certain affiliates of Roche. One agreement grants the Company rights to make, import, use and sell certain PCR products within specified fields, while the other agreement grants the Company rights to perform certain PCR services within specified fields.

The Company paid Roche a license fee of $50 million in fiscal 2004 and will also pay royalties on sales of the licensed products in the licensed fields and on any instrument, accessory, device or system sold for use with the licensed products in the licensed fields depending on the field, the year, the country of sale and the patents covering such products. During fiscal 2004, the Company performed a valuation of the PCR technology licenses and recorded a value of $19.5 million and reflected a $30.5 million adjustment reducing the amount recorded for consideration paid by Roche with respect to the merger and related transactions with IGEN.

These PCR licenses are being amortized over an estimated useful life of ten years, which is based upon a consideration of the range of patent lives and the weighted average remaining life of the most important underlying patents, as well as a consideration of technological obsolescence and product life cycles. Amortization expense was $488,000 for each of the three months ended June 30, 2006 and 2005. Accumulated amortization was $4.6 million and $4.1 million at June 30, 2006 and March 31, 2006, respectively. Amortization expense is expected to approximate $2.0 million for each year through March 31, 2014.

Evaluation of Long-lived Assets The Company evaluates the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. In evaluating the recoverability of an asset,

management s policy is to compare the carrying amount of an asset with the projected undiscounted future cash flow. An impairment loss is measured and recorded based on discounted estimated future cash flows. Management believes that no impairment of these assets exists as of June 30, 2006.

Warranty Reserve - The Company warrants its products against defects in material and workmanship for one year after sale and records estimated future warranty costs at the time revenue is recognized. A reserve for future warranty claims is recorded based upon management s review of historical claims, supplemented by expectations of future costs. The Company also offers extended warranty arrangements to customers, under which revenue recognition for the payment is initially deferred and amortized over the contract period, and related costs are recorded as incurred.

The following is a reconciliation of the Company s general product warranty reserve (in thousands):

	Three Months Ended	
	June 30, 2006	June 30, 2005
Balance, beginning of period	**$ 390**	$ 366
Provisions recorded	**87**	11
Actual costs incurred	**(147)**	(90)
Balance, end of period	**$ 330**	$ 287

The following is a reconciliation of the Company s deferred revenue related to extended warranty contracts and includes a summary of the revenue and cost components associated with extended warranties (in thousands):

	Three Months Ended	
	June 30, 2006	June 30, 2005
Deferred revenue, beginning of period	**$ 670**	$ 621
Extended warranties issued	**358**	322
Amortization of extended warranties	**(281)**	(293)
Costs incurred during the period	**376**	238
Settlement during the period of costs incurred	**(376)**	(238)
Balance, end of period	**$ 747**	$ 650

Fair Value of Financial Instruments - The carrying amounts of the Company s financial instruments, which include cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses, approximate their fair value due to their short maturities.

Comprehensive Loss- Comprehensive loss is comprised of net loss and other items of comprehensive loss. The Company s comprehensive loss for the three months ended June 30, 2006 and 2005 was $7.3 million and $6.8 million, respectively. For the three months ended June 30, 2006, other comprehensive income was $81,000 and for the three months ended June 30, 2005, other comprehensive loss was $123,000. Other comprehensive income or loss includes unrealized gains and losses on available-for-sale securities that are excluded from net loss.

Revenue Recognition- The Company derives revenue principally from three sources: product sales, royalty income and contract fees.

Product sales revenue is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21) Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized for the instrument upon shipment or delivery, depending on the terms of each order, and is recognized for the installation when complete using the residual value method. For instrument and reagent sales, there is no option of return and refund and instead there is only the option to repair or replace the product.

Other than the installation required for the instruments and the standard warranty, there are no contingencies, allowances or other post-sale obligations. For instrument leases, the instrument rental and related minimum reagent purchases are considered to be separate elements under EITF 00-21 and, accordingly, the sales price is allocated to the two elements based upon their relative fair values. Instrument rental revenue is recognized ratably over the life of the lease agreements and the related reagent revenue is recognized upon shipment. Revenue associated with extended warranty arrangements is recognized over the term of the extended warranty contract.

Royalty income is recorded when earned, based on information provided by licensees.

Revenue from services performed under contracts is recognized when obligations under the contract have been satisfied. The satisfaction of obligations may occur over the term of the underlying customer contract, if the contract is based on the achievement of certain milestones, or may occur at the end of the underlying customer contract, if based only upon delivery of the final work product.

Research and Development Research and development costs are expensed as incurred and are comprised of costs incurred in performing research and development activities including salaries, benefits, facilities costs, overhead costs, contract services and other outside costs. The Company has entered into several license and option agreements providing patent rights to certain technology under which the Company is responsible for conducting or sponsoring the research and for which it paid approximately $456,000 and $247,000 for the three months ended June 30, 2006 and 2005, respectively. These amounts are included as research and development costs.

Foreign Currency - Gains and losses from foreign currency transactions such as those resulting from the settlement of foreign receivables or payables, are included in the results of operations as incurred. These amounts were not material during the three months ended June 30, 2006 and 2005.

Income Taxes - Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Share-based Payments Effective April 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, a revision of SFAS 123, Share-Based Payments, which requires that companies recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option model. See Note 3 for a complete discussion on accounting for share-based payments.

Loss Per Share - The Company uses SFAS No. 128 Earnings per Share for the calculation of basic and diluted loss per share. For each of the three months ended June 30, 2006 and 2005, the Company incurred a net loss; therefore, net loss per common share does not reflect the potential dilution that could occur to common shares related to outstanding stock options and it did not assume exercise of 888,900 and 123,000 outstanding options, respectively, because to do so would have been anti-dilutive.

New Accounting Pronouncements - In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes and interpretation of FASB Statement No. 109 (FIN 48), to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. While the Company is currently evaluating FIN 48, this pronouncement is not currently expected to have a significant impact on the Company s results of operations and financial condition.

3. SHARE-BASED PAYMENTS

In December 2004, the FASB issued SFAS No. 123R, a revision of SFAS 123, Share-Based Payments. SFAS 123R requires that companies recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). SFAS 123R is effective for the Company s fiscal year beginning April 1, 2006. The Company has adopted SFAS 123R using the modified prospective transition method. Under this method, compensation expense is reflected in the financial statements beginning April 1, 2006 with no restatement of prior periods. As such, compensation expense is recognized for awards that are granted, modified, repurchased or cancelled on or after April 1, 2006 as well as for the portion of awards previously granted that have not vested as of April 1, 2006. The Company has implemented the straight-line expense attribution method.

Prior to the adoption of SFAS No. 123R, the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25, as allowed under SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). Under the intrinsic value method, no employee stock-based compensation expense had been recognized in its Consolidated Statements of Operations for any period prior to its adoption of SFAS No. 123R on April 1, 2006, as the exercise price of the stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

Stock Option Plan In September 2003, the Board of Directors of the Company adopted the 2003 Stock Incentive Plan (Stock Plan) under which 5.3 million shares of common stock have been reserved for issuance upon exercise of options granted to employees, non-employee directors or consultants of the Company and its subsidiaries. The Stock Plan was approved by an affirmative vote of the IGEN stockholders prior to the completion of the merger and related transactions with Roche.

The Stock Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, non-statutory stock options, restricted stock awards and other share-based awards, including the grant of shares based upon certain conditions, the grant of securities convertible into common stock of the Company and the grant of stock appreciation rights. Incentive stock options may only be granted to employees of the Company and its subsidiaries. The Stock Plan also provides that on the day following each annual meeting of the Company s stockholders each non-employee director will receive an automatic grant of options to purchase 4,000 shares of the Company s common stock. In addition, any person who is appointed or elected as a non-employee director at any other time will receive an automatic grant of options to purchase 4,000 shares of the Company s common stock on the date of such appointment or election. Each grant will have an exercise price equal to fair market value on the date of grant and will vest in full on the first anniversary of the grant date.

Adoption of SFAS 123R Share-based compensation expense recognized during the three months ended June 30, 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company recorded share-based compensation expense during the three months ended June 30, 2006, associated with its Stock Plan as follows (in thousands):

Product costs	**$ 4**
Research and development	**9**

Selling, general, and administrative		**124**
Total	**$**	**137**
Effect on net loss per common share (basic and diluted)	**$**	**(0.51)**

As of June 30, 2006, total compensation cost related to non-vested stock options not yet recognized was $2.0 million, which is expected to be allocated to expense and production costs over a weighted-average period of 3.86 years.

Pro-forma Information for Period Prior to Adoption of SFAS123R : The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions to share-based employee compensation during the quarter ended June 30, 2005 (in thousands, except per share amounts):

Net loss, as reported		**$ (6,668)**
Deduct: Total stock-based employee compensation expense determined under fair value method		**(63)**
Pro-forma net loss		**$ (6,731)**
Loss per share:		
Basic and diluted loss per common share	as reported	**$ (0.25)**
Basic and diluted loss per common share	pro forma	**$ (0.25)**

The pro-forma net loss and pro-forma net loss per share disclosed above is not representative of the effects on net loss and net loss per share on a pro-forma basis in future periods, as future periods may include grants by the Company of options for the Company s common stock.

No options were granted during the three months ended June 30, 2005.

Stock Option Activity - Activity related to options under the Stock Plan was as follows:

	Shares		Weighted Average Exercise Price	Weighted Average Remaining Term		Aggregate Intrinsic Value
Outstanding at April 1, 2006	458,000	$	5.87			
Granted	432,000	$	7.68			
Exercised	-	$	-			
Cancelled/forfeited	(1,100)	$	15.80			
Outstanding at June 30, 2006	888,900	$	6.74	9.38	$	1,166,000
Options exercisable at June 30, 2006	178,900	$	6.79		$	225,000
Options available for future grant	3,899,081					

There were no options that expired during the three months ended June 30, 2006.

Summary information about the Company s stock options outstanding at June 30, 2006 is as follows:

Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Years of Contractual Life	Weighted Average Exercise Price	Total Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Total Intrinsic Value
$4.33-$6.62	447,900	8.94	$ 5.21		149,900	$ 5.26	
$7.84-$11.85	420,000	9.93	$ 7.92		8,000	$ 11.85	
$15.80	21,000	7.75	$ 15.80		21,000	$ 15.80	
Total	888,900	9.38	$ 6.74	$ 1,166,000	178,900	$ 6.79	$ 225,000

The fair value of the Company s options for the three months ended June 30, 2006 was estimated at the date of grant using a Black-Scholes option pricing model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The assumptions used are as follows:

Expected dividend yield	0%
Expected stock price volatility	55%
Risk-free interest rate	5.08%
Expected option term (in years)	7.5

Based on this calculation, the weighted average fair value of options granted during the three months ended June 30, 2006 was $4.85.

Restricted Stock - During the year ended March 31, 2006, the Company granted 510,871 shares of restricted stock under the Stock Plan. The fair value of the restricted stock awards on the date of grant is amortized on a straight line basis over the vesting period. Deferred compensation of $2,533,000 was initially recorded based on the fair value of the shares on the respective grant dates and is being recognized as compensation expense on a straight line basis over the vesting term through July 2010. The Company did not deem a discount appropriate for post-vesting restrictions and did not use a discount in the calculation of the total deferred compensation. In accordance with SFAS 123R, deferred share-based compensation is no longer reflected as a separate component of stockholders equity in the condensed consolidated balance sheet. As a result, the Company reclassified its deferred share-based compensation at March 31, 2006 to additional paid-in capital.

Activity related to the restricted stock is as follows:

Non-vested shares at April 1, 2006	301,493
Granted	1,148
Vested	(27,652)
Forfeited	-
Non-vested shares at June 30, 2006	274,989

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4. NOTE RECEIVABLE FROM MESO SCALE DIAGNOSTICS

Meso Scale Diagnostics, LLC. (MSD) was a joint venture formed by IGEN and Meso Scale Technologies, LLC. (MST) in 1995. MST was established and was wholly-owned by Mr. Jacob Wohlstadter, a son of the Company s chief executive officer, and Jacob Wohlstadter is the president and chief executive officer of MSD. MSD develops, manufactures, markets and sells products utilizing a combination of MST s multi-array technology together with the Company s electrochemiluminescence (ECL) technology. MSD s Sector line of instrumentation is used for high throughput screening, high content screening, multiplexing and target validation. MSD also manufactures and markets a line of its own reagents, assays and plates that are used on these systems.

Pursuant to the agreements executed in connection with the merger and related transactions between IGEN and Roche, the MSD joint venture agreement expired upon the completion of the merger on February 13, 2004. However, the MSD limited liability company agreement continued (and the Company remained a member of MSD) and many provisions of the MSD joint venture agreement survived its expiration. In addition, certain other MSD agreements, including certain licenses, subleases and other arrangements with MSD, MST and Jacob Wohlstadter assigned to the Company by IGEN continue indefinitely in accordance with their terms.

In August 2004, an independent committee of the Company s Board of Directors, with the advice of independent counsel, negotiated and approved an agreement with MSD, MST and Jacob Wohlstadter to settle pending litigation and other disputes, pursuant to which MSD or MST agreed to purchase the Company s interest in MSD, as provided for in the MSD Agreements (the settlement). The Company also agreed to further amendments to the MSD limited liability company agreement and certain of the other MSD agreements that continue to be in effect. On December 13, 2004, the Company completed the sale to MST of its interests in MSD.

Until the time of the sale of its interests in MSD, the Company held a voting equity interest in MSD. The Company also held non-voting interests that entitled it to receive a preferred return on substantially all of its capital contributions. Following the completion of the buyout of the Company s interests in MSD on December 13, 2004, the Company no longer holds these interests and is entitled to receive only the buyout purchase price.

Buyout of the Company s interest in MSD

Pursuant to the MSD joint venture agreement, MSD and MST had a joint right to purchase the Company s entire interest in MSD upon termination or expiration of the MSD joint venture agreement at a price equal to fair market value less a discount that depended on the circumstances giving rise to termination or expiration of the agreement. Pursuant to the settlement, MST agreed to purchase, and the Company agreed to sell, its entire interest in MSD. The purchase of the Company s interests was completed on December 13, 2004.

The following table summarizes the adjustments provided in the joint venture and settlement agreements (in thousands):

Fair market value purchase price	$9,898
Add:	
Appraisal fees and costs	85

Rent payment obligations (March 1, 2004 through August 31, 2005)	2,335
Less:	
Prepayment credit	(2,000)
Total	$10,318

Upon closing of the sale of the Company s interests in MSD, the total purchase price balance was approximately $10.3 million (net of the $2.0 million prepayment by MSD). The Company recorded a discounted note receivable which had an original balance of $4.5 million. This note receivable had a balance of approximately $5.9 million at June 30, 2006, which represents the net present value of future payments that the Company expects to realize from the sale of its interests in MSD. The note receivable will be accreted to fair value using the effective interest method over the term of the expected payments on the note. Total accretion during the three months ended June 30, 2006 and 2005 was approximately $500,000 and $400,000, respectively, and has been recorded as a component of interest income. Calculating the net present value of future payments that the Company expects to realize as payment for the purchase price requires assumptions about MSD, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, which are assessed and updated periodically, the net present value of future payments received by the Company could differ from the amount reflected on the balance sheet at June 30, 2006.

As provided in the MSD joint venture agreement, MST is required to pay the Company the outstanding purchase price plus simple (cumulated, not compounded) interest at the fixed annual rate of 0.5% over the prime rate, or 5.5%, in effect on the purchase date. The purchase price is payable over time in installments equal to the sum of 5.0% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of the Company s interest in MSD.

As part of the settlement, the Company received a $2.0 million non-refundable prepayment from MSD for future amounts payable by MST to the Company for the purchase price in the form of a credit against amounts the Company agreed to pay MSD pursuant to the settlement. This prepayment was recorded as a deferred liability on the Company s balance sheet. The amount of the prepayment credit outstanding from time to time will bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate, or 5.0%, in effect on the date that MST purchased the Company s interests in MSD. The amount of the prepayment credit that is outstanding was approximately $900,000 at June 30, 2006.

No further cash payments will be payable by MST to the Company pursuant to the buyout until the prepayment credit, including accrued interest, is no longer deemed outstanding. In the event sufficient net sales or third-party financings of MSD do not materialize, the Company may not receive all payments due from MST for the purchase of its interests in MSD. As security for the payment obligation, the Company holds a security interest in the interests in MSD that have been purchased. MST may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

The holder of the Company s Series B preferred stock is entitled to a pro-rata share of payments from the sale of the Company s MSD interests. This pro-rata share approximates 6.03% of the $9.9 million sale price, representing the proportionate amount of the Company s Class C interest in MSD that was funded by the sale of the Series B stock (including payments allocated to the $2.0 million prepayment).

When the company ceased to be a member of MSD, it became entitled to receive quarterly royalty payments from MSD of 3% of the net sales price on all products developed and sold by MSD using the patents licensed from the Company. During the three months ended June 30, 2006 and 2005, the Company received and recognized royalties of approximately $200,000 and $100,000, respectively.

Transitional services and subleases

When the MSD joint venture agreement expired, the Company was no longer required to provide research personnel and corporate services to MSD. The Company has continued, and expects that it will continue, to provide limited corporate services to MSD on a transitional basis at MSD s expense. The Company bills MSD for the cost of these services on a periodic basis.

MSD leases certain facilities and related equipment from the Company (including laboratory facilities located in the Company s corporate headquarters) pursuant to sublease agreements which remained in effect following the expiration of the joint venture agreement. The term of each sublease will expire one day prior to the expiration of the prime lease for that facility. Each sublease agreement provides that, subject to certain exceptions, the Company must exercise all available extension rights under the prime lease.

Effective September 1, 2005, MSD was required to pay its pro-rata share of all rental and other expenses the Company incurs under the prime lease. As described above, as part of the settlement, MSD s rental and expense payment obligations for the period from March 1, 2004 through August 31, 2005, which approximate $2.3 million, were included in the purchase price of the Company s interests in MSD in lieu of MSD making payments to the Company.

During the three months ended June 30, 2006 and 2005, operating costs allocated to MSD by the Company in connection with shared personnel and facilities were approximately $27,000 and $200,000, respectively. The specific nature and amount of our allocations are being reviewed by MSD. At June 30, 2006 and March 31, 2006, other current assets include $800,000 and $820,000, respectively, for net amounts due from MSD for these allocated operating costs.

Certain indemnification agreements and obligations

Jacob Wohlstadter and JW Consulting Services, L.L.C., a company established and wholly-owned by Jacob Wohlstadter, have an indemnification agreement with IGEN that the Company assumed. Pursuant to the indemnification agreement, the Company will indemnify Jacob Wohlstadter and JW Consulting Services, L.L.C. against any claims arising out of the performance or non-performance of services to or for the benefit of the Company.

The Company agreed under the settlement to indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses arising out of or related in any way to past, current or future audits of MSD, or the preparation of MSD audited or unaudited financial statements requested by the Company.

In addition, the Company agreed to indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses with respect to regulatory (Securities and Exchange Commission or otherwise) or legal proceedings and investigations resulting from or related to the fact that the Company is (or its predecessor, IGEN, was) an issuer of publicly traded securities. The Company is not required to indemnify MSD, MST or Jacob Wohlstadter for acts either resulting in a criminal conviction or finally adjudged by a court of competent jurisdiction to constitute fraud or intentional misrepresentations.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Condition and Results of Operations as of June 30, 2006 and for the three months ended June 30, 2006 and 2005 should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the year ended March 31, 2006 filed with the SEC.

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This quarterly report contains forward-looking statements within the meaning of the safe harbor provision of the Private Securities Litigation Reform Act of 1995. All statements in this quarterly report that are not historical facts are hereby identified as forward-looking statements including any statements about markets and potential markets, market growth for diagnostic products, potential impact of competitive products, our expectations regarding future revenue, the potential market for products in development, the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, the need for and availability of additional capital and other forward-looking statements. The words may, should, will, expect, could, anticipate, believe, estimate, plan, intend and similar expressions hav identify certain of the forward-looking statements. These forward-looking statements are based on management s current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. These statements are not guarantees of future performance, involve certain risks, uncertainties, and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein.

In any forward-looking statement in which we express an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this quarterly report. We undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this quarterly report or to reflect the occurrence of unanticipated events.

Overview

We develop, manufacture and market our M-SERIES family of products, which can serve as a platform for diagnostic systems to be used for the detection and measurement of biological or chemical substances. We incorporate our technologies into our instrument systems, tests and reagents, which are the biological and chemical components used to perform such tests. Using the M-SERIES platform, we intend to integrate technologies and products to develop small, expandable and modular systems that can perform a wide variety of tests for the following markets:

Clinical diagnostics. The clinical diagnostics market includes the testing of patient samples to measure the presence of disease and monitor medical conditions. We are developing products to be used in the clinical diagnostics market and believe that our products will be ideally suited for the immunodiagnostic and nucleic acid testing market segments of the clinical testing market.

Non-clinical diagnostics for the biosecurity, life science and industrial markets. The non-clinical diagnostics market includes biosecurity products for the detection of bacteria, viruses and toxins that may pose a military or public health threat; life science testing for drug discovery and development that is performed by pharmaceutical and biotechnology companies; and industrial testing for the detection of foodborne and waterborne disease causing pathogens.

We believe that the emergence of simple, more accurate and cost-effective clinical diagnostic products is shifting the site of clinical diagnostic testing from clinical reference laboratories and central hospital laboratories to decentralized patient care centers, such as physicians offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories and nurses stations, which are collectively referred to as clinical point-of-care sites.

Our own product development efforts are focused on M-SERIES instruments and tests for the biosecurity market and for the clinical diagnostics market, particularly for point-of-care sites. We are seeking to develop, market and sell products for the clinical point-of-care market segment

through a combination of direct efforts and collaborative arrangements. We also are pursuing opportunities in the clinical reference laboratory and central hospital laboratory market segments through collaborative arrangements.

The first clinical diagnostic system being developed by us is a clinical analyzer that builds on the M-SERIES instruments we sell in the biosecurity and life science markets. We believe that the clinical analyzer will provide results to a physician rapidly with the same levels of sensitivity, accuracy or consistency as a large instrument in a clinical reference laboratory or in a central laboratory, thereby permitting the physician to make a more timely decision regarding the patient s course of treatment. Among the applications that we plan to develop is a proprietary approach for determining an individual s personal immune status through unique diagnostic panels. We will seek approval from the Food and Drug Administration (FDA) for the clinical analyzer and other *in vitro* diagnostics products at the appropriate stage of their product development. There can be no assurance that such approval will be obtained.

Our M-SERIES instruments are used in biodefense programs for homeland security, including by the Department of Defense, or DOD. We believe there will be an increasing opportunity to sell our products as biosecurity tools for use by commercial, governmental and military organizations around the world, as well as in public health.

We are also selling two types of M-SERIES instruments for life science research to pharmaceutical and biotechnology researchers, as well as to scientists at academic and government research institutions. Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the ability of protein-based therapeutics to stimulate an immune response. Antibodies that result from an immune response to a protein-based drug can reduce its efficacy and cause significant side effects, such as allergic reactions. Because of serious side effects that have been reported over the last year, it has become increasingly necessary to determine if an immune response to protein-based drugs develops in patients by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events. Immunogenicity testing is done during pre-clinical studies and may continue through the clinical trials required for regulatory approval. In some cases, the FDA requires additional testing after a drug has been approved. We believe our M-SERIES product line for the life science market is ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

In fiscal 2005, we expanded our business model to target the field of vaccines and have rights to certain vaccine candidates through license and option agreements. These vaccine candidates include:

Neisseria meningitidis serogroup B;

Group B Streptococcus;

Chlamydia;

Group A Streptococcus;

Candida albicans;

Pneumococcus;

Anthrax bacilli; and

Urinary tract infection (*E coli*).

It is our intention to continue to license rights to or acquire other vaccine candidates.

In connection with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we entered into a license and research agreement with Jewish General Hospital (JGH) in Montreal under which we received an exclusive, worldwide license to the use of a JGH database that contains demographic data and the serologic status of an immigrant population linked to numerous infectious diseases.

We expect to incur additional operating losses as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, and general and administrative costs. Our ability to become profitable in the future will be affected by, among other things, our ability to expand the distribution and increase sales of existing products, upgrade and enhance the M-SERIES family of products, introduce new products into the market, generate higher revenue, develop marketing, sales and distribution capabilities cost-effectively, and continue collaborations originally established by IGEN or establish successful new collaborations with corporate partners to develop, manufacture, market and sell products that incorporate our technologies.

Results of Operations

Three months ended June 30, 2006 and 2005

Revenues. Total revenues for the quarter ended June 30, 2006 decreased to $4.1 million from $4.9 million in the corresponding period in the prior year. Our consolidated product sales were $3.6 million for the quarter ended June 30, 2006, a decrease of $1.0 million from $4.6 million in the corresponding period in the prior year. Royalty income increased to $500,000 for the quarter ended June 30, 2006 from $300,000 in the corresponding period in the prior year.

Sales of biosecurity products for the three months ended June 30, 2006 decreased to $1.5 million from $2.3 million in 2005. Sales of products for the life science market for the three months ended June 30, 2006 decreased to $2.1 million from $2.3 million in 2005. These changes in product sales reflect the change of orders and product deliveries which are based on customers requirements.

Sales of our products for the biosecurity and life science markets are subject to a number of uncertainties, including the fact that we generally are not a party to significant long-term contracts for the sale of our products that would provide predictable sales. Therefore, the volume and timing of product orders from our biosecurity and life science customers are based on their requirements, which may vary over time. As a result, we believe that we do not have sufficient information to reasonably project our future sales.

Operating Costs and Expenses. Product costs were $2.4 million (66% of total product sales) for the quarter ended June 30, 2006 compared to $2.0 million (45% of total product sales) in the corresponding prior year period. The current year increase includes approximately $100,000 of costs incurred in connection with detection module upgrades for certain existing customers. We may incur an additional cost of approximately $1.3 million related to these voluntary upgrades during the remainder of fiscal 2007 to enhance overall customer satisfaction. Product costs also increased due to higher service costs related to detection modules. Our future profit margin is subject to change due to a number of uncertainties relating to, among other things, the launch of new instrument systems.

Research and development expenses were $4.3 million for the quarter ended June 30, 2006, which represents a decrease of 10% from the prior year costs of $4.8 million. Research and development expenditures decreased in the current period due primarily to lower facilities and personnel costs. Research and development expenses primarily relate to ongoing development costs and product enhancements associated with vaccines, the M-SERIES family of products, development of new assays and research and development of new systems and technologies, including point-of-care products. We expect research and development costs to increase as product development and core research expand, including costs associated with our efforts in vaccines, developing clinical diagnostics and biosecurity testing products, and development of a proprietary approach for determining an individual s personal immune status through unique diagnostic test panels.

We have expanded our business model to target the field of vaccines which will require substantial research and development expenditures. For example, we have entered into several license and option agreements for patent rights to unique vaccine candidates. Under these agreements, we are responsible for conducting or sponsoring the research and development of these vaccine candidates and may be required to make additional payments for license and milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals. Payments on these agreements totaled $456,000 and $247,000 in the three months ended June 30, 2006 and 2005, respectively.

Selling, general and administrative expenses were $6.2 million in the quarter ended June 30, 2006, which represents an increase of 9% over the prior year costs of $5.7 million. Our increase in selling, general and administrative costs in the quarter ended June 30, 2006 was primarily attributable to an increase in professional and outside service costs related to our continued compliance with Section 404 of the Sarbanes-Oxley Act of 2002, compensation expense associated with the implementation of SFAS 123R, and to fees incurred in conjunction with our review of Roche s compliance with the restrictions in its license to our ECL technology.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increases in general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Interest and Other Income / Expense. Interest and other income was $1.4 million and $900,000 in the quarters ended June 30, 2006 and 2005, respectively. Interest income includes approximately $500,000 and $400,000, respectively, from the accretion of income related to the note receivable from MSD. Other income includes approximately $200,000 of foreign currency gains for the three months ended June 30, 2006, compared to approximately $200,000 of foreign currency losses for the three months ended June 30, 2005.

Share-base Payments. In December 2004, the FASB issued SFAS No. 123R, a revision of SFAS 123, Share-Based Payments. SFAS 123R requires that companies recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments under APB 25, Accounting for Stock Issued to Employees . SFAS 123R is effective for the Company s fiscal year beginning April 1, 2006. We have adopted SFAS 123R using the modified prospective transition method. Under this method, compensation expense is reflected in the financial statements beginning April 1, 2006 with no restatement of prior periods. As such, compensation expense is recognized for awards that are granted, modified, repurchased or cancelled on or after April 1, 2006 as well as for the portion of awards previously granted that have not vested as of April 1, 2006. We have implemented the straight-line expense attribution method.

Prior to the adoption of SFAS No. 123R, we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25, as allowed under SFAS No. 123, Accounting for Stock-Based Compensation . Under the intrinsic value method, no employee stock-based compensation expense had been recognized in our Consolidated Statements of Operations for any period prior to our adoption of SFAS No. 123R on April 1, 2006, as the exercise price of the stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

During the three months ended June 30, 2006, we recorded pre-tax share-based compensation expense associated with our 2003 Stock Incentive Plan of $137,000, including $4,000 to product costs, $9,000 to research and development, and $124,000 to selling, general and administrative

costs.

Net Loss. The net loss for the quarter ended June 30, 2006 was $7.4 million ($0.27 per common share), compared to a net loss of $6.7 million ($0.25 per common share) in the corresponding prior year period. The increase in the net loss is primarily caused by a decrease in revenue that was not fully offset by decreased operating expenses.

Liquidity and Capital Resources

		June 30, 2006		March 31, 2006
Cash, cash equivalents and short-term investments	**$**	**61,492**	$	69,631
Working capital		**65,156**		72,184

		Three Months Ended **June 30, 2006**		June 30, 2005
Cash provided by(used in):				
Operating activities	**$**	**(8,013)**	$	(8,233)
Investing activities		**15,586**		(2,180)
Financing activities		**-**		-
Capital expenditures (including in investing activities above)		**(158)**		(182)

Effective in February 2004, we granted Roche a worldwide, non-exclusive, royalty-free license to patents and information relating to our proprietary ECL technology, subject to certain limitations described in the relevant license agreement. The license may be used by Roche to commercially exploit only certain ECL products and is royalty-free provided such products are used in a specified field. Our right to terminate the license is restricted, except under certain circumstances.

Pursuant to the license agreement, the parties can jointly engage an independent field monitor to review Roche s compliance with the license on an annual basis. We and Roche have engaged a field monitor to review placements and sales of products and services by Roche in 2005. The field monitor has been tasked with preparing a written report, including a list of any sales or placements of products and services that were not within the licensed field and identifying sales or placements of products or services in violation of the license grant. Pursuant to the license agreement, Roche must pay to us, within 30 days after receiving the field monitor s report, 65% of all undisputed revenues earned through out-of-field sales of products for 2005. Although Roche may not knowingly sell or actively market outside the field, they may continue the identified out-of-field sales until we notify Roche in writing that they are prohibited from making any further such sales. For a more complete description of the Roche license, refer to the agreement on file with the SEC.

We believe that the potential payment to us for out-of-field sales may be material to our financial position, results of operations and cash flows. Based on its 2005 Annual Report, Roche reported ECL (Elecsys) product sales for the year ending December 31, 2005 of CHF 989 million. For each 1% of Roche s total sales that were out-of-field during 2005, as determined by the field monitor, there would be approximately a $5.3 million positive impact on our financial position, results of operations and cash flows (using the currency conversion rate of Swiss Francs to U.S. Dollars at August 4, 2006 of 0.8191). Actual differences in the amount of Roche ECL (Elecsys) sales or placements or in the currency rates used would change this amount.

The amount and timing of any payment that we might receive from Roche relating to out-of-field sales in 2005 is uncertain because, among other things: (1) the amount of such sales and placements has not yet been determined; and (2) there may be disputes between Roche and us concerning the agreement and/or the field monitor s findings. Although a field monitor has not been engaged to address 2004, we believe that we are entitled to payment for out-of-field sales during 2004. We are attempting to resolve this matter with Roche.

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Product development for our clinical diagnostic and vaccine products are at an early development stage. Product development is subject to a number of technical and commercial uncertainties and in part depends upon our ability to enter into new collaborative arrangements. Accordingly, the business plan for our clinical diagnostic and vaccine products, including immunodiagnostic and PCR technology-based products, is evolving and does not have definitive product introduction timelines or budgets and we have not yet determined the additional funding, personnel, facilities, equipment or technology that may be required to implement our plans.

Our ability to become profitable in the future will depend on, among other things, the introduction of new products to the market. If we are unable to develop new products, our business prospects and financial results would be adversely affected. Furthermore, we will need substantial amounts of money to fund our operations on an ongoing basis. We expect our available cash to be sufficient to fund our operations for at least one year, but we cannot predict how long our available cash will be sufficient to fund our operations thereafter.

We expect that we will from time to time have discussions with third parties, including multinational corporations, regarding various business arrangements including distribution, marketing, research and development, joint venture and other business agreements, which could provide us with substantial up-front fees or payments. We cannot assure you that we will successfully complete any of the foregoing arrangements and access to funds could be adversely impacted by many factors, including the volatility of the price of our common stock, continuing losses from our operations, establishment of new business arrangements, the status of new product launches, general market conditions and other factors. If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs, which we have the ability to do. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures or collaborations, on terms that may not be favorable to us.

Cash Used in Operating Activities

Net cash used for operations was $8.0 million and $8.2 million during the three months ended June 30, 2006 and 2005, respectively. The decrease in cash used for operations in the current period resulted primarily from a higher net loss, partially offset by lower non-cash adjustments, and further decreased by lower working capital requirements in the current period. The non-cash adjustments for the three months ended June 30, 2006 were primarily due to depreciation and amortization and the accretion of interest income.

Cash Provided by or Used in Investing Activities

We used approximately $200,000 of cash for the acquisition of equipment and leasehold improvements during each of the three months ended June 30, 2006 and 2005. During the three months ended June 30, 2006 and 2005, we purchased short-term investments of $20.0 million and $10.0 million, respectively, and we received proceeds of $35.7 million and $8.0 million, respectively, from the sale and maturity of short-term investments.

Cash Used in Financing Activities

During the three months ended June 30, 2006, we declared dividends with respect to shares of series B preferred stock

of $22,000, which were paid subsequent to June 30, 2006. During the three months ended June 30, 2005 we declared and paid dividends of $57.

MSD

The MSD joint venture agreement expired upon completion of the merger. As a result, MSD and MST had the option to purchase our interests in MSD and pursuant to the settlement, MSD or MST agreed to purchase, and we agreed to sell, our entire interest in MSD. The purchase of our interests was completed by MST on December 13, 2004.

MST is required to pay us the outstanding purchase price over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interests in MSD. As part of the settlement, we received a $2.0 million non-refundable prepayment from MSD for future amounts payable by MSD to us for the purchase price in the form of a credit against amounts we agreed to pay MSD pursuant to the settlement. No further cash payments will be payable by MSD to us pursuant to the buyout until the prepayment credit, which has a balance of $900,000 at June 30, 2006, is no longer deemed outstanding.

Upon the sale of our interests in MSD, we recorded a discounted note receivable of $4.5 million that had a balance at June 30, 2006 of approximately $5.9 million, which represented the net present value of future payments that we expect to realize from the sale of our interests in MSD. Calculating the net present value of future payments that we expect to realize from MSD as payment for the purchase price, requires assumptions about MSD, which are assessed and updated periodically, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, the net present value of future payments received by us could differ from the amount reflected on the balance sheet at June 30, 2006. We expect that MSD will require substantial additional funding for its ongoing operations. If MSD is not able to obtain this funding, or in the event sufficient net sales or third-party financings of MSD do not materialize, we may not receive all payments due from MST for the purchase of our interests in MSD.

For a more complete description of the sale of our MSD interests and the MSD agreements, see Part I ITEM 1, Condensed Consolidated Financial Statements Notes to Condensed Consolidated Financial Statements Note 4 .

During the three months ended June 30, 2006 and 2005, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled $27,000 and $200,000, respectively. The specific nature and amount of our allocations are being reviewed by MSD.

Contractual Obligations

We have contractual obligations associated with ongoing business activities which will result in cash payments in future periods. In addition, we believe that material commitments for capital expenditures may be required in a variety of areas, such as product development programs, sponsored research and the build-out of new facilities. We have not, at this time, made material commitments for any such capital expenditures and have not secured additional sources to fund such commitments if they become necessary in the future.

As of June 30, 2006, our material future obligations were as follows (in thousands):

Years Ended March 31,	Operating Leases	Sponsored Research	Total
2007	$ 3,164	$ 479	$ 3,643
2008	4,208	228	4,436
2009	4,122	196	4,318
2010	3,531	98	3,629
2011	1,734	-	1,734
2012 and thereafter	5,401	-	5,401
	22,160	1,001	23,161
Less: sublease income	(4,532)	-	(4,532)
Total	$ 17,628	$ 1,001	$ 18,629

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Under vaccine license agreements, we are responsible for conducting or sponsoring the research and development of vaccine candidates and may be required to make additional payments for patent costs, milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals, and royalties on future sales.

As of June 30, 2006, we had no off-balance sheet arrangements, as defined by SEC Regulation S-K, Item 303 (a) (4).

Critical Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial position and results of operations and requires the application of difficult, subjective or complex judgments by management. As a result, critical accounting policies are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on our management s experience, terms of existing contracts, observance of trends in the industry, information provided by customers, and information available from other outside sources, as appropriate. Significant changes to these estimates could have a material impact on our consolidated financial statements. Our critical accounting policies include:

Revenue Recognition We derive revenue principally from three sources: product sales, royalty income and contract fees.

Product sales revenue is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21. Revenue is recognized for the instrument upon shipment or delivery, depending on the terms of each order, and is recognized for the installation when complete based upon the residual value method. For instrument and reagent sales, there is no option of return and refund, only the option to repair or replace the product.

Other than the installation required for the instruments and the standard warranty, there are no contingencies, allowances or other post-sale obligations. For instrument leases, the instrument rental and related minimum reagent purchases are considered to be separate elements under EITF 00-21 and, accordingly, the sales price is allocated to the two elements based upon their relative fair values. Instrument rental revenue is recognized ratably over the life of the lease agreements and the related reagent revenue is recognized upon shipment. Revenue associated with extended warranty arrangements is recognized over the term of the extended warranty contract.

Royalty income is recorded when earned, based on information provided by licensees.

Revenue from services performed under contracts is recognized when obligations under the contract have been satisfied. The satisfaction of obligations may occur over the term of the underlying customer contract, if the contract is based on the achievement of certain milestones, or may occur at the end of the underlying customer contract, if based only upon delivery of the final work product.

The majority of our product sales and contract fees contain standard terms and conditions. Certain transactions may contain negotiated terms that require contract interpretation to determine the appropriate amount of revenue to be recognized. In addition, we must assess whether collectibility is reasonably assured. While management believes its interpretations and judgments are reasonable, different assumptions could result in changes in the timing of revenue recognition.

Share-based Payments - In December 2004, the FASB issued SFAS No. 123R, a revision of SFAS 123, Share-Based Payments. SFAS 123R requires that companies recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments under APB 25, Accounting for Stock Issued to Employees . SFAS 123R is effective for the Company s fiscal year beginning April 1, 2006. We have adopted SFAS 123R using the modified prospective transition method. Under this method, compensation expense is reflected in the financial statements beginning April 1, 2006 with no restatement of prior periods. As such, compensation expense is recognized for awards that are granted, modified, repurchased or cancelled on or after April 1, 2006 as well as for the portion of awards previously granted that have not vested as of April 1, 2006. We have implemented the straight-line expense attribution method.

The fair value of stock option grants during the three months ended June 30, 2006 were estimated on the date of grant using a Black-Scholes option valuation model that uses the following assumptions:

Expected dividend yield	0%
Expected stock price volatility	55%
Risk-free interest rate	5.08%
Expected option term (in years)	7.5

Expected volatility is based primarily upon our historical volatility. The expected term of options granted is derived from assumed exercise rates based on historical exercise patterns, and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate used is determined by the market yield curve based upon the risk-free interest rates established by the Federal Reserve, or non-coupon bonds that have maturities equal to the expected term. The dividend yield is based upon the fact that we have not historically granted cash dividends on our common stock, and do not expect to issue dividends in the foreseeable future. Stock options granted prior to April 1, 2006 were valued based on the grant date fair value of those awards, using the Black-Scholes option pricing model, as previously calculated for pro-forma disclosures under SFAS 123 Accounting for Stock-based Compensation. Alternative estimates and judgments could yield materially different results.

Inventory We record our inventory at the lower of cost or market using the first-in, first-out method. We regularly review inventory quantities on hand and record a reserve for excess and obsolete inventory based primarily on an estimated forecast of product demand and production requirements for the next twelve months. Reserves are recorded for the difference between the cost and the market value. Those reserves are based on significant estimates. Our estimates of future product demand may prove to be inaccurate, in which case we may have understated or overstated the provision required for excess and obsolete inventory. In addition, our industry is characterized by technological change, frequent new product development and product obsolescence that could result in an increase in the amount of obsolete inventory quantities on hand. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand or technological developments could have a significant impact on the values of our inventory and our reported operating results.

Evaluation of Long-lived Assets We have different long-lived assets recorded on our balance sheet that include equipment and leasehold improvements, investments, licenses and other assets. We evaluate the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. In evaluating the recoverability of an asset, management s policy is to compare the carrying amount of an asset with the projected undiscounted cash flow. An impairment loss is measured and recorded based on discounted estimated future cash flows.

We recorded a discounted note receivable which had an original balance of $4.5 million. This note receivable has a balance of approximately $5.9 million at June 30, 2006, which represents the net present value of future payments that we expect to realize from the sale of our interests in MSD. We accrete to fair value using the effective interest method. Calculating the net present value of future payments that we expect to realize as payment for the purchase price requires assumptions about MSD, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, the net present value of future payments received by us could differ from the amount reflected on the consolidated balance sheet at June 30, 2006.

Warranty Reserve We warrant our products against defects in material and workmanship for one year after sale and record estimated future warranty costs at the time revenue is recognized. A reserve for future warranty claims is recorded based upon management s review of historical results, supplemented by expectations of future costs. Unanticipated changes in actual warranty costs could impact our operating results.

New Accounting Pronouncements In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes and interpretation of FASB Statement No. 109 (FIN 48), to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. While we are currently evaluating FIN 48, this pronouncement is not currently expected to have a significant impact on our results of operations and financial condition.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to changes in exchange rates where we sell products directly in local currencies, primarily in the United Kingdom and Germany. Certain other foreign sales are denominated in U.S. dollars and have no exchange rate risk. Gains and losses resulting from foreign currency transactions have historically not been material.

Our balance sheet at June 30, 2006 had cash, cash equivalents and short-term investments of $61.5 million, which is approximately 63% of total assets. We invest excess cash in accordance with a policy approved by our Board of Directors. The policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on our investments by terms and concentrations by type and issuer. We invest our excess cash in money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less. At June 30, 2006, we had invested $24.2 million in securities of the U.S. government, municipal bonds, and U.S. corporate debt, which were recorded as short-term investments.

Our invested cash is sensitive to changes in interest rates. Based on our cash, cash equivalents and short-term investments balance at June 30, 2006, a 1% movement in interest rates would have an approximately $600,000 impact on our annual interest income and annual net loss. Actual changes in rates may differ from the hypothetical assumption used in computing this exposure.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

For the quarterly period ended June 30, 2006, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13(a)-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2006, our disclosure controls and procedures were effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met and our disclosure controls and procedures are designed to provide this reasonable assurance. Because of the inherent limitations in all control systems, no evaluation of control can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the first quarter of fiscal 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1A. RISK FACTORS

Risks Relating to Us and Our Business

OUR BUSINESS HAS A HISTORY OF LOSSES AND WE EXPECT TO HAVE FUTURE LOSSES AND NEGATIVE CASH FLOW.

We incurred net losses of $27.9 million, $77.6 million and $93.3 million for the years ended March 31, 2006, 2005 and 2004, respectively, and a net loss of $7.4 million for the three months ended June 30, 2006. We expect to continue to incur operating losses and negative cash flow as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, and general and administrative costs.

While we seek to attain profitability, we cannot be sure that we will ever achieve product or other revenue sufficient for us to attain this objective. Our ability to become profitable in the future will depend on, among other things, our ability to:

- expand the distribution and increase sales of certain of our products;
- upgrade and enhance the M-SERIES family of products;
- introduce new products into the market;

develop our marketing, sales and distribution capabilities cost-effectively; and

continue existing collaborations and establish successful new collaborations with corporate partners to develop and market products that incorporate our technologies and provide necessary funding.

TO ACHIEVE COMMERCIAL SUCCESS, WE MUST COMPLETE THE DEVELOPMENT OF OUR PRODUCTS AND THOSE PRODUCTS MUST GAIN MARKET ACCEPTANCE OR OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

Many of our potential products, including certain M-SERIES products, are at an early stage of development and we have not introduced any clinical diagnostics products into the marketplace. Products under development require additional research and development efforts, including clinical testing and regulatory approval, prior to commercial use. Our potential products are subject to the risks of failure inherent in the development of products based on new technologies. These risks include the possibilities that:

our design or approach may not be successful;

our products may not be compatible with existing technology or may rely on technology that has become obsolete;

our products may be found ineffective or fail to meet the applicable regulatory standards or receive necessary regulatory clearances;

our estimates of the market size and potential for our products may prove incorrect;

third parties may market superior or equivalent products;

our products may not be recognized or accepted in the market due to unfamiliar brand names; or

our product development costs may outweigh potential future cash flows associated with those products.

Our business, business prospects and financial results would be hurt if our products are not accepted as alternatives to other existing or new products and do not gain market acceptance.

In addition, we have licensed certain PCR technology from Roche that we plan to integrate into certain of our new instrument systems. Although we do not currently sell any product based on the PCR technology licensed from Roche, any products that we may develop using PCR technology will be also subject to the risks of failure inherent in the development of products based on new technologies as described above.

We have recorded a net book value for the PCR licenses of $14.9 million at June 30, 2006. If we are unable to successfully develop any products using PCR technology because such PCR technology has become obsolete or the future cash flows attributable to products using PCR technology are insufficient to realize the remaining carrying value of the license, we would be required to write-off the remaining net book value or record an impairment of the value of the PCR license. Such a write-off or the recording of such an impairment could have a material adverse effect on our future results of operations.

OUR QUARTERLY OPERATING RESULTS MAY FLUCTUATE SIGNIFICANTLY, AND THESE FLUCTUATIONS MAY CAUSE OUR STOCK PRICE TO BE VOLATILE.

Our quarterly operating results will depend upon:

the volume and timing of orders and product deliveries for biosecurity products, M-SERIES systems or other products, which are based on our customers requirements that may vary over time;

the success of M-SERIES system upgrades and enhancements and customer acceptance of those enhancements and upgrades;

costs incurred related to expansion into the field of vaccines;

the amount of revenues recognized or collectible from royalties and other contract revenues, which revenues are dependent upon the efforts and compliance of our licensees and collaborators, including Roche;

whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;

the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;

the volume and timing of product returns and warranty claims, which, if products are returned or have warranty claims that are unexpected, may involve increased costs in excess of amounts reserved for returns or claims;

our competitors introduction of new products, which may affect the purchase decision of or timing of orders by our customers and prospective customers while the competitors product is assessed;

the amount of expenses we incur in connection with the operation of our business, including:

research and development costs, which increase or decrease based on the products in development;

sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time; and

expenses associated with share-based compensation arrangements, including employee stock options;

the amount that we may record related to the potential impairment of the license to use PCR technology;

amounts received from MSD or MST as payment for allocated operating costs, the purchase of our interests in MSD and the related accretion of income on the note receivable from MST;

unexpected termination of government contracts or orders, which could result in decreased sales and increased costs due to excess capacity, inventory, personnel and other expenses; and

additional costs which we may incur as we explore new healthcare opportunities, including costs for acquisitions of technologies, facilities and personnel.

These factors may cause our quarterly operating results to fluctuate significantly, which in turn, may cause our stock price to be volatile. In addition, because our revenues and operating results are expected to be volatile and difficult to predict, we believe that period-to-period comparisons of our results of operations are not a reliable indication of our future performance.

WE MAY CHANGE THE FOCUS OF OUR BUSINESS OR ENTER INTO NEW HEALTHCARE FIELDS, WHICH COULD RESULT IN THE INCURRENCE OF ADDITIONAL COSTS AND EXPOSURE TO ADDITIONAL OR DIFFERENT BUSINESS RISKS.

We have broad discretion in determining the future strategy and focus of our business and may enter new healthcare fields in which we have limited or no experience. During fiscal 2005, we expanded our business model to target the field of vaccines. A significant change in the focus of our business could result in a loss of our investment, the incurrence of additional costs, including research and development costs, and exposure to additional or different business risks. Incurrence of additional costs and exposure to additional risks could materially adversely affect our business.

IF WE ARE UNABLE TO ESTABLISH NEW COLLABORATIONS, OR IF ANY COLLABORATIONS WE ESTABLISH DO NOT RESULT IN THE SUCCESSFUL INTRODUCTION OR MARKETING OF NEW PRODUCTS BASED ON OUR TECHNOLOGY, OUR GROWTH MAY BE SLOWED AND OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

One aspect of our strategy is to enter into collaborative relationships with established healthcare and other companies to assist us in developing our technologies or manufacturing or marketing our products for certain markets. We may not be able to enter into collaborations on terms that are favorable to us, if at all. In addition, we cannot assure that third parties, including our licensees, suppliers or others will not object to possible new collaborations.

As a result of this strategy, we may have no, or only limited, control over the amount of resources that our collaborators will devote to the development or marketing of products based on our technology. For instance, our collaborators:

- may decide not to, or may fail to successfully, develop, market or sell products based on our technology;
- may not devote sufficient resources to the development, marketing or sale of these products based on our technology; or,
- may terminate their agreements with us.

If any of these events occur with respect to one of the companies we are collaborating with, we would not receive the benefits of the collaboration and our growth could be slowed and our business could be materially adversely affected.

WE MAY NOT BE ABLE TO RAISE SUFFICIENT ADDITIONAL CAPITAL TO SUCCESSFULLY DEVELOP OUR BUSINESS.

We will need substantial amounts of money to fund our operations on an ongoing basis. We expect our available cash to be sufficient to fund our operations for at least one year, but cannot predict how long our available cash will be sufficient to fund our operations thereafter.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including:

- for research and development to successfully develop our technologies, including future payment obligations under license or option agreements;
- to obtain regulatory approval for our products;
- to file and prosecute patent applications to protect our technology;
- to respond to innovations that our competitors develop;
- to retain qualified employees, particularly in light of competition for qualified scientists and engineers;
- to make new arrangements to market our technology;

to manufacture products ourselves or through a third party;

to provide funding for expanded or new facilities; and

to market different products to different geographic markets, either through expanding our sales and distribution capabilities or relying on a third party.

The failure to raise sufficient additional capital for us to develop our business would adversely affect our business prospects.

OUR ACCESS TO FUNDS COULD BE NEGATIVELY IMPACTED BY MANY FACTORS, INCLUDING VOLATILITY IN THE PRICE OF OUR COMMON STOCK, LOSSES FROM OPERATIONS AND CAPITAL MARKET CONDITIONS.

We may not have access to enough funds on favorable terms, if at all, to successfully operate and develop our business. We may try to raise necessary additional capital by issuing additional debt or equity securities. Holders of debt securities would have priority over our equity holders with respect to the proceeds from the sale of our assets in the event of liquidation of our business, and any debt financings that we obtain may contain restrictive terms that limit our operating flexibility. If we raise additional capital by selling additional common or preferred stock, the holdings of existing stockholders would be diluted.

If we are unable to raise additional capital, we may have to consider pursuing arrangements with other companies that may not be available on terms favorable to us. In addition, we may have to scale back, or even eliminate, some of our programs.

WE MAY EXPERIENCE DESIGN, DEVELOPMENT, IMPLEMENTATION AND OTHER DIFFICULTIES THAT COULD DELAY OR PREVENT OUR INTRODUCTION OF NEW OR ENHANCED PRODUCTS OR AFFECT THE PERFORMANCE OF EXISTING PRODUCTS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS. IN ADDITION, IF THE MARKETS FOR OUR PRODUCTS CHANGE OR EVOLVE IN AN UNEXPECTED MANNER, OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

The development of new or enhanced products is a complex and uncertain process that requires the accurate anticipation of technological and market trends, as well as precise technological execution. We may experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products, or products that we may develop, manufacture or market with third parties or affect the performance of our existing products. These difficulties and delays may cause expenses to increase and our product sales to fluctuate. In addition, if we experience design, development or implementation difficulties in developing, manufacturing, distributing or marketing these instruments, we would sell fewer of our products and our business prospects would be adversely affected.

We expect the markets for our products to change and evolve. These changes could facilitate the market demand for our new or enhanced products, including the need for products that could be utilized in clinical point-of-care sites and field-testing of environmental samples in the biosecurity market. If market demand does not change or evolve as we anticipate or if we are not able to develop products that meet the evolving market demand, our business prospects would be adversely affected.

In addition, the markets for our products are characterized by evolving industry standards and government regulations, the need for updated and effective technology and new product introductions. Our success will depend in part upon our ability to profitably enhance existing products and develop and introduce new products. We may not be able to avoid the obsolescence of our products due to technological change and evolving industry standards and government regulations.

If we experience design, development, implementation or other difficulties that delay or prevent our introduction of new or enhanced products or if the markets change or evolve in an unexpected manner, our business could be materially adversely affected.

VACCINE DEVELOPMENT IS A LONG, EXPENSIVE AND UNCERTAIN PROCESS, AND DELAY OR FAILURE CAN OCCUR AT ANY STAGE OF THE PROCESS.

To develop vaccine candidates, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrates adequate safety and immune response. Statistically significant effectiveness of our vaccine product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for commercial sale. Vaccine development to show adequate evidence of effectiveness in animal models and safety and immune response in humans is a long, expensive and uncertain process, and delay or failure can occur at any stage of our animal studies or clinical trials. Any delay or significant adverse clinical events arising during any of our clinical trials could force us to abandon a vaccine candidate altogether or to conduct additional clinical trials in order to obtain approval from the FDA or foreign regulatory bodies. These development efforts and clinical trials are lengthy and expensive and the outcome is uncertain. If we are unable to successfully develop our vaccine candidates, our business could suffer.

WE EXPECT TO RELY ON SALES OF THE M-SERIES PRODUCT FAMILY FOR A SIGNIFICANT PORTION OF OUR REVENUES, AND A DECLINE IN SALES OF THESE PRODUCTS COULD CAUSE ADVERSE FINANCIAL RESULTS AND NEGATIVELY AFFECT OUR BUSINESS PROSPECTS.

We expect to derive a significant portion of our revenues from sales of M-SERIES products. Our current and potential life science customers are from the pharmaceutical and biotechnology industries and are subject to risks faced by those industries, including the availability of capital, reduction and delays in research and development expenditures, government regulation and the uncertainty resulting from technological change. In addition, the ongoing consolidation of the pharmaceutical and biotechnology industries could reduce the number of potential customers and they may develop their own competing products or in-house capabilities.

Any factor adversely affecting the pricing or demand of M-SERIES products, including market acceptance of competing products, could cause our revenues to decline, resulting in adverse financial results and negatively affecting our business prospects.

Additionally, we intend to market M-SERIES products in markets in which we have little or no experience. We may not be able to successfully market the M-SERIES family of products in those markets, which could cause an adverse affect on our business prospects.

MST HAS PURCHASED OUR INTERESTS IN MSD BUT THERE IS NO ASSURANCE THAT WE WILL RECEIVE THE FULL PURCHASE PRICE.

MST purchased our entire interest in MSD and is required to pay us the outstanding purchase price over time, plus simple (cumulated, not compounded) interest at the fixed annual rate of 5.5%. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interests in MSD. We received a prepayment credit of $2.0 million against our payment obligations to MSD in connection with the settlement, and therefore the initial installment payments are being applied against this credit and not paid to us in cash. No further cash payments will be payable to us pursuant to the buyout until the prepayment credit, which has a balance of $900,000 at June 30, 2006, is no longer deemed outstanding.

Because the purchase price is payable only out of a percentage of MSD s net sales or future financings, our receipt of the purchase price is dependent on MSD s future performance. In the event sufficient future net sales of MSD or third-party financings do not materialize, we may not receive the full purchase price for our interests in MSD.

We have recorded the net present value of the receivable due to us from the sale of our interests in MSD in the amount of $5.9 million at June 30, 2006. If we do not receive the full purchase price over time, from the sale of our interests in MSD, we would be required to write off the remaining net present value or record an impairment of the value of the receivable. Such a write-off or the recording of such an impairment could have a material adverse effect on our future results of operations.

OUR COMPETITORS AND POTENTIAL COMPETITORS MAY HAVE OR DEVELOP DIAGNOSTIC AND VACCINE PRODUCTS AND TECHNOLOGIES THAT ARE MORE ATTRACTIVE THAN OUR EXISTING OR FUTURE DIAGNOSTIC AND VACCINE PRODUCTS.

Our business will be subject to intensive competition from established companies, development stage companies and research and academic institutions, and we expect this competition to intensify. Many of these companies and institutions have one or more competitive advantages over us, including, among other things:

- more money to invest;
- more established diagnostic or vaccine products;
- longer-standing relationships with customers;
- greater expertise and resources in developing, manufacturing, marketing and selling diagnostic or vaccine products;
- a larger, more experienced workforce; and
- more experience in obtaining regulatory approval for clinical testing or vaccine products.

As a result, our competitors may develop, manufacture, market or sell diagnostic or vaccine products that are more effective or commercially attractive than our current or future diagnostic or vaccine products. In addition, these competitors may offer broader product lines, discounts and may have greater name recognition than us. Furthermore, we compete against companies that utilize ECL technology licensed to them by us, including Roche and MSD.

As a result, we may not be able to compete successfully against our competitors. This could have a material adverse effect on our business, financial condition and revenues.

WE HAVE LIMITED MANUFACTURING EXPERIENCE, WHICH PUTS US AT A COMPETITIVE DISADVANTAGE AND COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION AND REVENUE.

We lack experience in large-scale manufacturing and have no experience in the manufacturing of clinical diagnostic or vaccine products, which could hamper our ability to manufacture existing products or new products that we develop. We have two options to address this competitive disadvantage. First, we could expand our internal ability to manufacture products, which, to date, has only been done in a limited way. Second, we could contract with a third party to manufacture products for us based on our technology, which, to date, we have not done.

If we are unable to expand our own manufacturing capability or find a suitable manufacturer on acceptable terms in a timely manner, we may be unable to meet demand for existing products and could be delayed in introducing new products to the market. Failure to meet demand for existing products or delays in introducing new products could put us at a competitive disadvantage and could have a material adverse effect on our business, financial condition and revenue.

WE HAVE LIMITED MANUFACTURING FACILITIES FOR OUR CURRENT PRODUCTS AND WE MAY NOT FIND ADDITIONAL FACILITIES SUITABLE FOR FUTURE GROWTH, WHICH COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS AND PROSPECTS.

We face risks inherent in operating a single facility for the manufacture of our current products. We do not have

alternative production facilities available should our Gaithersburg, Maryland manufacturing facility cease to function. If our facility were not operational for an extended period of time, including due to an unforeseen plant shutdown, then our business and future prospects could be materially adversely affected.

In addition, we may need to expand and enhance our research, development and production facilities. We may also be required to make material capital expenditures at a new facility at a time when we have limited capital resources available to us.

We may also experience difficulties or delays in integrating our operations into new facilities. These difficulties might include delays in the availability of a new facility or problems associated with equipment installation. In addition, any facility that we obtain for production of vaccines, clinical testing or biosecurity products will be subject, on an ongoing basis, to a variety of regulatory requirements including quality systems regulations, international quality standards and other regulatory standards. We may encounter difficulties expanding our manufacturing operations in accordance with these regulations and standards, which could result in manufacturing delays and an inability to meet product demand and our business prospects could be materially adversely affected.

If we are unable to pay for facility enhancements and improvements to meet our future growth needs, our business would suffer.

WE HAVE NO EXPERIENCE SELLING, MARKETING OR DISTRIBUTING CLINICAL DIAGNOSTIC OR VACCINE PRODUCTS. OUR FAILURE TO ESTABLISH AN EFFECTIVE SALES FORCE OR TO ESTABLISH AN EFFICIENT DISTRIBUTION SYSTEM FOR OUR CLINICAL DIAGNOSTIC OR VACCINE PRODUCTS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS PROSPECTS AND REVENUES.

We need to develop selling, marketing and distribution capabilities for our planned clinical diagnostic and vaccine products. To market clinical diagnostic or vaccine products directly to customers, and not through a licensee or third party distributor or collaborator, we will need to develop a substantial sales force with technical expertise. We will also need to establish a distribution system to support our sales force. Alternatively, we could license or contract with another company to provide sales and distribution services for our products. We may not be able to develop a sufficient sales and distribution force or find a suitable company to fill that role for us, which could materially adversely affect our business prospects and revenues.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We expect to grow by increasing our presence in existing markets and introducing new products we develop into new potential markets. Our growth strategy will place a strain on our management and our operating and financial systems.

As we grow, our personnel, systems, manufacturing capabilities and resources, procedures and controls may be inadequate to support future operations and we will need to hire, train and retain additional personnel. We may also need to improve and expand our financial and management controls, reporting systems and operating systems as well as other aspects of our infrastructure, including research and

development or manufacturing facilities. We may encounter difficulties integrating additional personnel, as well as improving, expanding and integrating new systems or facilities, which could adversely affect our business.

THE SUCCESS OF OUR BUSINESS DEPENDS ON PATENTS THAT WILL EXPIRE OVER TIME AND THAT MUST BE ACTIVELY PURSUED, OBTAINED, MAINTAINED AND PROTECTED.

Our business success or failure will depend, in part, on our ability to pursue, obtain, and maintain adequate patent protection for ECL technology, vaccines and our other technologies. Our patents may not adequately protect our technology from being used by our competitors.

Our business depends heavily on patents that will expire over time and may be challenged or circumvented by competitors. Patents allow us, for a time, to prevent others from using our inventions to compete against us.

Companies may challenge or seek to invalidate patents or circumvent valid claims in patents, all of which could make it necessary for us to defend our patents in litigation. Litigation over patents poses the following risks to our business:

- litigation costs can be extremely high, which could drain our financial resources; and
- litigation over our patents could discourage other companies from working with us to develop and market new products based on the technology covered by those disputed patents.

If we lose some patent protection, our competitive advantage could be eroded, third parties may be able to use our technology without paying us and our financial condition and business prospects would be adversely affected.

OUR BUSINESS COULD BE HARMED IF WE HAVE FUTURE DISAGREEMENTS WITH ROCHE OVER THE SCOPE OF THE LICENSE AGREEMENT.

Roche, through one of its affiliates, has been licensed by us to exploit ECL technology, subject to the limitations of the license agreement. Although the terms of the license agreement were negotiated in an effort to minimize the areas of potential future disputes, there are no assurances that we and Roche will continue to agree on the scope, permitted use and other material terms of the license agreement. Future disputes with Roche, or any licensee, over the scope of the license agreement, such as disputes over the field, the types of products that Roche is permitted to develop and sell, or royalties owed, including payments for out-of-field sales by Roche of licensed products that employ ECL technology and which are outside the licensed field, might lead to lengthy and costly legal proceedings, which could adversely affect our financial condition and future business prospects.

OUR BUSINESS COULD BE HARMED IF WE INFRINGE, OR OUR LICENSEES ARE ALLEGED TO HAVE INFRINGED, THE INTELLECTUAL PROPERTY OF OTHERS.

If our products or services were to infringe the intellectual property (including patent rights) of others, we or our licensees could:

- be required to alter, or abandon products or processes;
- be required to obtain a license from the intellectual property holder;

lose customers that are reluctant to continue using our or our licensees products or services;

be forced to abandon development work with respect to these products; and

be required to pay damages that could be substantial.

If we or our licensees infringe the intellectual property (including patent rights) of others, our business could be damaged if we were unable to make necessary alterations or obtain a necessary license on acceptable terms, if at all.

In addition, if our products or services were alleged to have infringed the intellectual property (including patent rights) of others, we would be forced to defend ourselves in litigation and might be enjoined from further sale of our products or required to pay monetary damages or amounts in settlement of the suit, which could adversely affect our prospects, drain our financial resources and discourage other companies from working with us.

WE INTEND TO DEVELOP PRODUCTS THAT ARE BASED ON PATENTS AND TECHNOLOGY THAT WE HAVE LICENSED FROM OTHERS AND THE OWNERS OF THOSE PATENTS AND TECHNOLOGY MIGHT CLAIM THAT PRODUCTS DEVELOPED OR SOLD BY US VIOLATE THOSE LICENSES. ADDITIONALLY, A THIRD PARTY MIGHT OBJECT TO A LICENSE THAT WE HOLD OR TO THE SCOPE OF THE LICENSE GRANTED TO US.

Our success or failure will also depend, in part, on the patent rights and technology of others, including patents and technology being licensed to us from affiliates of Roche. We have been licensed by affiliates of Roche to exploit certain improvements from Roche Diagnostics and certain PCR technology, subject to certain limitations. Although the terms of the improvements license agreement and the PCR license agreements were negotiated in an effort to minimize the areas of potential future disputes, there are no assurances that we and Roche will continue to agree on the scope, permitted use and other material terms of the improvements license agreement or the PCR license agreements. Future disputes with Roche over the scope, permitted use, obligations owed and other material terms of the improvements license agreement or the PCR license agreements, such as disputes over the field, types of products that we are permitted to develop and sell, or other obligations may lead to lengthy and costly legal proceedings, or could interfere with or preclude us from proceeding with one or more development programs, whether conducted independently or through a collaborative arrangement. In addition, third parties may object to the scope, permitted use and other material terms of one or more of the licenses granted to us by certain Roche affiliates.

We also license technology from other companies and academic institutions. Because access to this technology is necessary to operate our business, we must be certain that we comply with these license agreements. Our business could be harmed if we breached any of these license agreements and lost the rights to use this patented technology or if we were unable to renew existing licenses on acceptable terms, if at all, or get additional licenses that we may need on acceptable terms, if at all. In addition, we may need to litigate the scope and validity of patents held by others and such litigation could be a substantial cost for us.

WE AND MSD MAY HAVE DIFFERENT VIEWS OF THE SCOPE OF THE EXCLUSIVE LICENSE TO OUR TECHNOLOGY PREVIOUSLY GRANTED TO MSD AND THE SCOPE OF MSD S RIGHTS UNDER THE FORMER JOINT VENTURE AGREEMENT WITH US, WHICH COULD AFFECT OUR ABILITY TO EXPAND OUR BUSINESS DIRECTLY OR THROUGH COLLABORATIONS.

We intend to expand our business through internal development programs and through new or expanded collaborative arrangements. MSD may view the scope of its exclusive license and other rights under its license agreement and other agreements with us in a way that interferes with or precludes us from proceeding with one or more development programs. There are no assurances that MSD will not object to our future business plans, whether conducted independently or through a collaborative arrangement. Additionally, MSD may believe that we must obtain MSD s consent prior to entering into proposed collaborative arrangements. The other party to a proposed collaboration with us may also require us to obtain MSD s consent to avoid any future disputes or disagreements. For example, in connection with the merger and related transactions, Roche required IGEN to obtain MSD s consent to the execution and delivery of the license agreement. If we are required to obtain MSD s consent for any reason, there are no assurances that we will be able to obtain that consent at all or on terms that would not have an adverse effect on our business, financial condition or results of operations. In addition, if we choose not to obtain MSD s consent, MSD may sue us to enforce rights it believes it has. Such a lawsuit could materially harm our business and future business prospects.

WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, WHICH COULD HARM OUR BUSINESS IF THEY WERE DISCLOSED TO OR INDEPENDENTLY DEVELOPED BY OTHERS.

In addition to patents, we also rely in our business on trade secrets, know-how and other proprietary information. If this information were disclosed to or independently developed by competitors, our business would suffer.

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We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants that prohibit these parties from disclosing our confidential information. These agreements may not provide adequate protection for our trade secrets, know-how and other proprietary information or ensure that the information we share with others during the course of our business will remain confidential. We may not have sufficient legal remedies under the agreements or otherwise to correct or compensate for unauthorized disclosures or sufficient resources to seek redress.

If we are not able to be adequately redressed for the unauthorized disclosure of our trade secrets, know-how or other proprietary information, our competitive position may be undermined and our business may suffer.

WE DEPEND ON A LIMITED NUMBER OF SUPPLIERS FOR MATERIALS USED IN THE MANUFACTURING OF OUR PRODUCTS, AND ANY INTERRUPTION IN THE SUPPLY OF THOSE MATERIALS COULD HAMPER OUR ABILITY TO MANUFACTURE PRODUCTS AND MEET CUSTOMER ORDERS.

We depend on vendors to supply key materials that we use in our products. Some of these materials are available only from limited sources. From time to time, suppliers may extend lead time, limit supplies or increase prices due to capacity constraints or other factors. In the event of a reduction in, interruption of, or degradation in, the quality of the supply of any of the materials required by us, or an increase in the cost of obtaining those materials, we would be forced to locate an alternative source of supply. If no alternative source were available or if an alternative source were not available on a timely basis, at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of our products would be delayed or halted.

Any changes in sources of supply may require additional engineering or technical development to ensure consistent and acceptable performance of our products. If any of these events occur, our product costs may increase, we might be unable to deliver products in a timely fashion, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE MAY NOT BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

We need to hire staff and retain our staff, both of which are difficult in a competitive marketplace. Because we are a technology company, we depend heavily on scientists and engineers to develop products and to build a successful business. Research and development efforts could suffer if we are not able to hire and retain enough qualified scientists and engineers, which would adversely affect our business. We compete with other technology companies and research and academic institutions for experienced scientists. Many of these companies and institutions have greater resources than we do and thus may be in a better position to attract desirable candidates.

In addition to scientists, we also need to hire managers who have regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business could suffer.

OUR ABILITY TO DEVELOP PRODUCTS MAY BE NEGATIVELY AFFECTED BY SOCIAL ISSUES RELATING TO ANIMAL TESTING.

Our research and development activities have involved, and in the future might involve, limited testing in mice and rats. In addition, testing in the future may involve other animals. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation of such activities and by other means. Our ability to develop products may be negatively affected by a ban on animal testing or by action taken by groups or individuals opposed to these tests.

Risks Relating to Regulation and Government Contracts

OUR ABILITY TO OBTAIN AND RETAIN U.S. GOVERNMENT CONTRACTS IS SUBJECT TO UNCERTAINTIES, AND OUR U.S. GOVERNMENT CONTRACTS MAY BE TERMINATED, WHICH COULD MATERIALLY ADVERSELY AFFECT OUR FINANCIAL CONDITION, OPERATING RESULTS, BUSINESS AND PROSPECTS.

Our ability to secure or retain U.S. government contracts is subject to uncertainties related to the government s future funding commitments. The prospects for our biosecurity business are also highly sensitive to changes in national and international government policies and funding priorities. Changes in domestic or foreign government policies or priorities, including funding levels through agency or program budget reductions by the U.S. Congress or executive agencies, could materially adversely affect our ability to retain or obtain U.S. government contracts, and our business prospects could suffer.

The U.S. government can terminate, suspend or modify any of its contracts with us either for its convenience or if we default by failing to perform under the terms of the applicable contract. A termination or suspension for convenience could result in our having excess capacity, inventory, personnel, unreimbursable expenses or charges, or other adverse effects on our financial condition. A termination arising out of our default could expose us to claims for damages and may have a material adverse effect on our ability to compete for future U.S. government contracts and orders.

U.S. government contracts may span one or more years and may include multiple renewal options in favor of the U.S. government. U.S. government agencies generally have the right not to exercise these option periods for any reason, including lack of funding, or if the agency is not satisfied with the counterparty s performance of the contract. If the U.S. government terminates any of our contracts, our financial condition and operating results could be materially adversely affected.

In addition to unfavorable termination provisions, certain of our U.S. government contracts contain provisions that grant to the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to use inventions made by us in the course of performing such contracts, or have such inventions used by or on behalf of the U.S. government, for research or other government purposes. New U.S. government contracts we enter into may also include similar provisions.

WE MUST OBTAIN FDA CLEARANCE OR APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC AND VACCINE PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING. IF WE DO NOT OBTAIN THE NECESSARY CLEARANCES OR APPROVALS, OUR BUSINESS PROSPECTS WOULD SUFFER.

The manufacture, packaging, labeling, advertising, promotion, distribution and sale of clinical diagnostic products and vaccines are subject to governmental regulation by national and local government agencies in the United States and abroad. The FDA regulates many of the areas in which we conduct our research and in which we are and expect to be developing, manufacturing and marketing products. In particular, we must obtain FDA clearance or approval before we can market clinical diagnostic or vaccine products. The process of obtaining necessary clearances or approvals is often costly, time consuming and uncertain.

We have very limited experience obtaining FDA clearance and approval and may not be successful in obtaining FDA clearance or approval for any of our clinical diagnostic products, which would materially adversely affect our business prospects. Further, clearance or approval may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed.

To obtain permission from the FDA to market clinical diagnostic products in the U.S., we, or the companies we work with, will need to either obtain Section 510(k) pre-market notification clearance or approval of a pre-market approval application from the FDA. To obtain clearance for marketing, we, or the companies we work with, must demonstrate substantial equivalence to a similar legally marketed product by submitting a pre-market notification to the FDA. The FDA may require preclinical and clinical data to support a substantial equivalence determination. Clinical trials for gathering supporting data can take extended periods of time to complete and there can be no assurance that the FDA will find a device substantially equivalent.

If we do not successfully demonstrate substantial equivalence, or if we are required to obtain pre-market approval, we would have to conduct extensive clinical testing of these diagnostic products, which could take years to complete. Extensive testing could involve substantial additional costs and might delay bringing clinical diagnostic products to market, weakening our competitive position. If we fail to obtain FDA clearance or approval for new clinical diagnostic products altogether, we will be unable to market these products at all for clinical use in the U.S. We may begin to distribute reagents specifically for research use under an exemption. If the FDA disagrees with our classification of, or the manner in which we market and sell those reagents, it may impose restrictions on our business operations and subject us to sanctions that could adversely affect our business prospects.

Our vaccine candidates are in pre-clinical stages of development and have not received regulatory approval from the FDA or foreign regulatory authorities to be marketed and sold. The FDA or foreign regulatory authorities may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied and they may require additional testing for safety or effectiveness.

WE ARE SUBJECT TO COMPREHENSIVE GOVERNMENT REGULATION, WHICH MAY INVOLVE SIGNIFICANT COSTS AND MAY RESTRICT OUR ABILITY TO CONDUCT BUSINESS.

We expect that certain of our future products will be subject to continuing FDA requirements, including compliance with the FDA s Good Manufacturing Practices and the FDA s medical device reporting regulations. We expect that we may need to spend a substantial amount of money to comply on an ongoing basis with government regulations. Government agencies, such as the FDA, Department of Homeland Security, Department of Commerce and the Environmental Protection Agency regulate many of our products as well as products that we plan to develop, manufacture, market and sell, including products for the clinical diagnostics, biosecurity and industrial markets. The costs of complying with governmental regulations and any restrictions that government agencies might impose could have a significant impact on our business. If we increase our manufacturing and expand our product offerings, these costs will increase.

Whether we directly manufacture products or contract with another company to manufacture products based on our technology, the FDA and other government agencies will continually review and periodically inspect the manufacturing process. If any of these agencies were to discover a problem with our products, the manufacturing process or the manufacturing facility, they could place restrictions on these products and on the manufacturer and impose sanctions. For example, the FDA could require us to recall, or even totally withdraw, a product from the market or close a manufacturing facility.

In addition to FDA regulations, the process of manufacturing products is subject to a variety of environmental laws and regulations, including laws and regulations governing the use, management and disposal of hazardous, radioactive and infectious materials and wastes, the discharge of pollutants into the air and water, and the cleanup of contaminated sites. We could incur substantial costs, including cleanup costs, fines and penalties, claims for damages, such as personal injury or property damages, and loss of permits required for our operations, if we fail to comply with these laws or regulations. Our operations are also subject to various employee health and safety laws and regulations, including those concerning occupational injury and illness and employee exposure to hazardous, radioactive and infectious materials.

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While we have procedures in place to protect employees from exposure to such materials, we cannot assure you that potentially harmful exposure will not occur or that we will not be liable to employees as a result. In addition, because of the limited information currently available regarding some of the hazardous, radioactive and infectious materials used in our businesses, there may be unknown risks involved with the use of and exposure to such materials. In some circumstances there may be no body of knowledge or standard protocols for dealing with these risks. Costs associated with such environmental, health and safety matters could have a material adverse effect on our business and financial condition.

Our biosecurity products are subject to stringent Federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution and export. In addition, the U.S. government has adopted, and is expected to continue to adopt laws, regulations and rules governing the research, development, procurement and handling of pathogens that may be used in a bioterrorist attack or other agents that may cause a public health emergency and to permit government inspection and oversight of facilities engaged in the research, development, manufacture or sale of select agents. Under several statutes recently enacted, the Department of Homeland Security, FDA, Department of Commerce and various other regulatory authorities have been charged with establishing and implementing programs designed to enhance the security of food and water supplies, as well as the environment, from terrorist attacks. These legislative initiatives include recordkeeping, registration, notification, import, export, manufacturing and various other compliance measures. This is a rapidly evolving regulatory landscape and many of the possible rules and regulations have not yet been proposed or adopted. We may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon our ability to do business. In addition, the DOD or other government agencies may require additional security measures to be implemented at our facility, which could cause us to incur substantial additional costs.

OUR BUSINESS COULD BE ADVERSELY AFFECTED BY A NEGATIVE AUDIT BY THE U.S. GOVERNMENT.

U.S. government agencies routinely audit and investigate government contractors. These agencies review a contractor s performance under its contracts. If an audit results in a finding of improper activities, we may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. In addition, we could suffer serious harm to our business reputation if allegations of impropriety were made against us.

COST OVER-RUNS ON CONTRACTS WITH THE U.S. GOVERNMENT COULD SUBJECT US TO LOSSES OR ADVERSELY AFFECT OUR FUTURE BUSINESS.

Our U.S. government contracts are fixed-price contracts and therefore we receive a fixed price irrespective of the actual costs we incur in connection with the performance of the contracts. Consequently, we will be required to absorb any costs in excess of the fixed price that may be set forth in the contract. If we are unable to control the costs we incur in performing under these contracts, our financial condition and operating results could be materially adversely affected. Cost over-runs also may adversely affect our ability to sustain our performance under the contracts and obtain future U.S. government contract awards.

RESTRICTIONS ON HEALTHCARE COSTS AND HEALTHCARE AND INSURANCE FINANCING PRACTICES COULD LIMIT DEMAND FOR OUR PRODUCTS, WHICH WOULD HURT OUR BUSINESS AND BUSINESS PROSPECTS.

In the U.S. and elsewhere, demand for clinical diagnostic testing is dependent, in part, on consumers ability to be reimbursed for the cost of the tests by third-party payers, such as government agencies, health maintenance organizations and private insurers. Medicaid and other third-party payers are increasingly challenging the prices charged for medical services, including clinical diagnostic tests. They are also attempting to

contain costs by limiting their coverage of, and the amount they will reimburse for, clinical diagnostic tests and other healthcare products.

Without adequate coverage and reimbursement, consumer demand for clinical diagnostic tests may decrease. Decreased demand would likely cause potential sales of our clinical diagnostic products, and sales by our licensees, to decrease because fewer tests would be performed or prices would be lowered, or both. Reduced sales or royalty income would hurt our business and business prospects.

In many foreign markets, governments directly set the prices that clinical diagnostic companies may charge for their

products and services. In the U.S., a number of legislative and regulatory proposals aimed at changing the healthcare system have been proposed in recent years and we expect this to continue. Foreign and domestic legislative and regulatory initiatives that limit healthcare coverage may have a material adverse effect on our business and business prospects.

Risks Relating to the Industry

WE ARE EXPOSED TO PRODUCT LIABILITY RISKS THAT, IF NOT ADEQUATELY COVERED BY INSURANCE, MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION.

Product liability is a major risk in marketing products for vaccines and for the clinical diagnostics, biosecurity and industrial markets. We may not be able to insure ourselves adequately against risk of product liability. We may face product liability for claims and lawsuits brought by customers. Damages awarded in product liability cases can be very large. While we have product liability insurance, this coverage is limited.

We may not have adequate product liability insurance to cover us against our potential liabilities or be able to maintain current levels of product liability insurance on acceptable terms, if at all. Claims or losses in excess of our product liability insurance coverage or not covered by our product liability insurance could have a material adverse effect on our financial condition.

Risks Relating to Our Common Stock

OUR EXECUTIVE OFFICERS AND DIRECTORS EXERCISE SIGNIFICANT INFLUENCE OVER US AND MAY HAVE SIGNIFICANT INFLUENCE OVER THE OUTCOME OF PROPOSED CORPORATE ACTIONS SUPPORTED OR OPPOSED BY OTHER STOCKHOLDERS.

Our executive officers and directors, in the aggregate, own approximately 25% of the outstanding shares of our common stock. Our chairman and chief executive officer owns approximately 19% of the outstanding shares of our common stock. As a result, certain of our executive officers or directors may have significant influence over the election of directors and may be able to significantly influence the outcome of proposed corporate actions supported or opposed by other stockholders. In addition, as a result of their stockholdings, certain of our executive officers and directors could have significant influence over the outcome of potential transactions, including any acquisition transactions, that may be supported or opposed by other stockholders.

PROVISIONS IN OUR CHARTER DOCUMENTS MAY DISCOURAGE POTENTIAL ACQUISITIONS OF US, EVEN THOSE WHICH THE HOLDERS OF A MAJORITY OF OUR COMMON STOCK MAY FAVOR, WHICH MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK, REDUCE THE LIKELIHOOD OF OFFERS TO ACQUIRE US AND PREVENT CHANGES IN OUR MANAGEMENT.

Our certificate of incorporation and by-laws contain provisions that may have the effect of discouraging a third party from acquiring us by means of a tender offer, proxy contest or otherwise. Our certificate of incorporation and by-laws:

classify our board of directors into three classes, with directors of each class serving for a staggered three-year period;

provide that our directors may be removed only for cause and only upon the approval of the holders of at least a majority of the voting power of all our shares entitled to vote generally in the election of such directors then outstanding, voting together as a single class;

prohibit our stockholders from calling special meetings and prohibit action by our stockholders by written consent;

require at least 66 2/3% of the voting power of all our shares entitled to vote generally in the election of directors then outstanding, voting together as a single class, to alter, amend or repeal certain provisions, including the provisions relating to our classified board, the election, appointment and removal of our directors and action by stockholders by written consent described above;

permit our board of directors to fill vacancies and newly created directorships on our board of directors; and

contain advance notice requirements for stockholder proposals.

In addition, under our certificate of incorporation, our board of directors also has the authority to issue up to 15,000,000 shares of preferred stock in one or more series. Our board of directors can fix the powers, preferences and rights of any such series without stockholder approval. Our board of directors could, therefore, issue, without stockholder approval, preferred stock with voting and other rights that could adversely affect the voting power of the holders of our common stock or otherwise make it more difficult for a third party to gain control of us. Such provisions would make the removal of incumbent directors more difficult and time-consuming and may have the effect of discouraging a tender offer or other takeover attempt not previously approved by our board of directors.

In addition, we have adopted a stockholder rights agreement, pursuant to which one right attached to each share of our common stock outstanding. These rights will in most cases cause substantial dilution to a person that attempts to acquire or merge with us without the approval of our board of directors by permitting the holders of these rights (other than the person attempting to acquire or merge with us) to, upon the occurrence of specified circumstances, purchase, at a substantial discount, shares of our Series A participating cumulative preferred stock or shares of common stock of the person that attempts to acquire or merge with us. Accordingly, the existence of these rights may deter potential acquirers from making a takeover proposal or a tender offer.

WE DO NOT PLAN TO PAY ANY CASH DIVIDENDS ON OUR COMMON STOCK.

We have no plans to pay cash dividends on our common stock in the foreseeable future, if at all.

WE MAY NEED TO RAISE ADDITIONAL CAPITAL IN THE FUTURE AND WE MAY GRANT OPTIONS OR OTHER EQUITY-BASED AWARDS TO OUR EXECUTIVE OFFICERS, DIRECTORS, EMPLOYEES AND CONSULTANTS, FROM TIME TO TIME, EITHER OF WHICH WOULD RESULT IN DILUTION TO OUR STOCKHOLDERS.

Your investment in our common stock could be diluted if we issue additional shares of our common stock or securities convertible into, or exercisable for, shares of our common stock in the future, which we may need to do to raise funds for our business. Sales of additional shares of our common stock or the conversion of securities into, or the exercise of securities for, shares of our common stock could cause the market price of our common stock to decrease.

Under the BioVeris 2003 stock incentive plan, our executive officers, directors, employees and consultants are from time to time granted options or other equity-based awards, such as phantom stock or restricted stock, to purchase up to 5.3 million shares of our common stock. If our executive officers, directors, employees and consultants exercise their options or other equity-based awards, if and when granted and exercisable, and purchase shares of our common stock, your investment in our common stock will be diluted.

THE EXON-FLORIO ACT MAY INHIBIT POTENTIAL ACQUISITION BIDS, WHICH MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK.

Section 721 of Title VII of the Defense Production Act of 1950, also known as the Exon-Florio Act, authorizes the President of the U.S. or his designees to initiate an investigation into the potential effects on national security of a business combination of a U.S. corporation and a foreign entity that could result in foreign control of the U.S. corporation. Subject to certain exceptions, under the Exon-Florio Act, the President may suspend or prohibit any foreign acquisition, merger or takeover of a U.S. corporation if there is credible evidence that the foreign entity exercising control might take action that threatens national security and there is no provision of law adequate to protect national security. Due to our current and potential future involvement in the biodefense industry, the Exon-Florio Act could inhibit potential acquisition bids from foreign entities, which could adversely affect the market price of our common stock.

ITEM 6. EXHIBITS

Exhibit No.	
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended
32.2	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended

SIGNATURES

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

BioVeris Corporation

Date: August 9, 2006

/s/ Samuel J. Wohlstadter
Samuel J. Wohlstadter
Chief Executive Officer
(On behalf of the Registrant and as Its Principal Executive Officer)

Date: August 9, 2006

/s/ George V. Migausky
George V. Migausky
Vice President of Finance

Chief Financial Officer
(On behalf of the Registrant and as Its Principal Financial Officer)