BIOVERIS CORP
Form 10-Q
August 09, 2005

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES ACT OF 1934
For Quarter Ended June 30, 2005
Commission File Number: 000-50583
BioVeris Corporation
(Exact name of registrant as specified in its charter)

DELAWARE	80-0076765
(State or other jurisdiction incorporation or organization)	(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 þ No o
Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes þ No o
Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	Outstanding at July 29, 2005
Common Stock, par value $0.001	27,226,950 shares

BIOVERIS CORPORATION
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As used herein, BioVeris , we , us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER 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.

PART 1 FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIOVERIS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

(Unaudited)

	June 30, 2005	March 31, 2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ **31,326**	$ 41,739
Short-term investments	**55,765**	53,890
Accounts receivable, net	**5,746**	4,483
Inventory	**5,015**	5,235
Other current assets	**2,640**	2,813
Total current assets	**100,492**	108,160
Equipment and leasehold improvements, net	**2,673**	3,636
OTHER NONCURRENT ASSETS:		
Note receivable	**4,971**	4,709
Technology licenses	**16,819**	17,306
Other	**353**	354
TOTAL ASSETS	$**125,308**	$ 134,165
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ **4,378**	$ 6,457
Accrued wages and benefits	**2,022**	1,713
Other current liabilities	**1,495**	1,351
Total current liabilities	**7,895**	9,521
NONCURRENT DEFERRED LIABILITIES	**1,458**	1,890
Total liabilities	**9,353**	11,411
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,		
26,728,000 shares issued and outstanding	**27**	27
Additional paid-in capital	**203,464**	203,464
Accumulated deficit	**(93,914)**	(87,238)
Accumulated other comprehensive loss	**(1,122)**	(999)
Total stockholders equity	**108,455**	115,254
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$**125,308**	$ 134,165

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, 2005	June 30, 2004
REVENUES:		
Product sales	$ **4,580**	$ 7,839
Royalty income	**309**	320
Contract fees		86
Total	**4,889**	8,245
OPERATING COSTS AND EXPENSES:		
Product costs	**2,048**	4,604
Research and development	**4,765**	7,176
Selling, general and administrative	**5,681**	9,710
Total	**12,494**	21,490
LOSS FROM OPERATIONS	**(7,605)**	(13,245)
INTEREST INCOME	**1,318**	404
OTHER, NET	**(381)**	(10)
NET LOSS	$ **(6,668)**	$(12,851)
Net loss per common share (basic and diluted)	$ **(0.25)**	$ (0.48)
COMMON SHARES OUTSTANDING (basic and diluted)	**26,728**	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, 2005	June 30, 2004
OPERATING ACTIVITIES**:**		
Net loss	$ **(6,668)**	$ (12,851)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**1,632**	2,011
Loss on disposal of equipment		34
Accretion of interest on note receivable	**(403)**	
Changes in assets and liabilities:		
Increase in accounts receivable	**(1,383)**	(773)
Decrease (increase) in inventory	**220**	(35)
Decrease (increase) in other current assets	**294**	(1,390)
(Decrease)increase in accounts payable and accrued expenses	**(2,024)**	156
(Decrease) increase in accrued wages and benefits	**309**	2,920
(Decrease) increase in other liabilities	**(210)**	91
Net cash used in operating activities	**(8,233)**	(9,837)
INVESTING ACTIVITIES:		
Expenditures for equipment and leasehold improvements	**(182)**	(727)
Purchases of short-term investments	**(9,998)**	(89,708)
Sales of short-term investments	**8,000**	
Net cash used in investing activities	**(2,180)**	(90,435)
FINANCING ACTIVITIES:		
Payment of distribution gain		(20,000)
Net cash used in financing activities		(20,000)
NET DECREASE IN CASH AND CASH EQUIVALENTS	**(10,413)**	(120,272)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	**41,739**	182,509
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ **31,326**	$ 62,237

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.

On February 13, 2004, IGEN International, Inc. (IGEN or Parent) and Roche Holding Ltd (Roche) consummated a transaction pursuant to which Roche acquired IGEN and IGEN simultaneously distributed the common stock of the Company, to its stockholders (the merger). The transaction occurred in the following steps:

- IGEN restructured its operations so that the Company, a newly formed, wholly-owned subsidiary of IGEN at the time, assumed IGEN s biodefense, life science and industrial product lines as well as IGEN s opportunities in the clinical diagnostics and healthcare fields and the ownership of IGEN s intellectual property, IGEN s equity interest in Meso Scale Diagnostics, LLC. (MSD), cash and certain other rights and licenses currently held by IGEN; and
- a wholly-owned subsidiary of Roche merged with and into IGEN, as a result of which IGEN became a wholly-owned subsidiary of Roche and the Company became an independent, publicly-traded company.
- Simultaneously with the completion of the merger, certain ongoing commercial agreements between the Company and certain affiliates of Roche became effective.

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.

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 statement of the results of operations and cash flows for the three month periods ended June 30, 2005 and 2004, and the Company s financial position at June 30, 2005.

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, 2005 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.

The Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 , as revised or FIN 46, as of March 31, 2004. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties.

The Company determined that MSD (a joint venture formed in 1995 by IGEN and Meso Scale Technologies, LLC. (MST), which is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of the Company s chief executive officer) qualified as a variable interest entity with the Company as the primary beneficiary. Accordingly, beginning March 31, 2004, the Company began to consolidate the financial results of MSD.

Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, the Company measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of these assets, liabilities and noncontrolling interests were reflective of their respective carrying amounts had FIN 46 been effective when the Company first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. The Company has historically recorded approximately 100% of MSD s losses. The Company s balance sheet reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses. The statement of operations reclassified amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses.

On August 12, 2004, the Company, MSD and MST entered into a settlement agreement (settlement) that resolved litigation between the parties and constituted a reconsideration event under FIN 46. The Company has determined that it no longer meets the conditions to be designated as the primary beneficiary of MSD. Factors used in this evaluation include the following:

- The Company does not have a significantly large variable interest in MSD to be the primary beneficiary. The Company will hold only a secured note whereas the purchaser, MST, will be at risk for all of its equity;
- After December 13, 2004 and for the remaining life of MSD, the Company will cease to absorb any MSD losses; and
- MST will absorb the majority of the expected losses of MSD.

Accordingly, beginning August 12, 2004, the Company deconsolidated the financial results of MSD and resumed accounting for this investment using the equity method through December 13, 2004, the date of the sale of the Company s interests in MSD.

The balance sheets for periods subsequent to August 12, 2004 reclassified amounts formerly consolidated or presented on a gross basis to be reflected on a net basis as investment in joint venture and effective August 13, 2004, the statement of operations reclassified amounts presented on a gross basis to be reflected on a net basis as equity in loss of joint venture. Accordingly, the statement of operations include the consolidated revenues and expenses of MSD for the period from April 1, 2004 through August 12, 2004, and reflects MSD s net losses for the period from August 13, 2004 through December 13, 2004, the date of the sale of the Company s interests in MSD, as equity in loss of joint venture.

Estimates and Reclassifications - 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. Certain reclassifications have been made to conform prior period financial information to the current presentation.

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, which are all due within one year, 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, 2005 and 2004, 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, 2005:

	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
U.S. Government agencies	$25,328	$	$ (289)	$25,039
Municipal bonds				
U.S. corporate debt	31,559		(833)	30,726
	$56,887	$	$(1,122)	$55,765

Concentration of Credit Risk During the three months ended June 30, 2005 and 2004, agencies of the U.S. government accounted for 32% and 25% of total revenue, respectively, and 36% and 23% of total consolidated accounts receivable as of June 30, 2005 and March 31, 2005, 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 $293,000 and $227,000 at June 30, 2005 and March 31, 2005, 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, 2005	March 31, 2005
	(in thousands)	
Finished Goods	**$1,905**	$ 1,561
Work in process	**663**	749
Raw materials	**2,447**	2,925
Total	**$5,015**	$ 5,235

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, 2005	March 31, 2005
	(in thousands)	
Lab instruments and equipment	**$ 6,693**	$ **6,575**
Office furniture and equipment	**5,000**	**4,936**
Leasehold improvements	**4,005**	**4,005**
	15,698	**15,516**
Accumulated depreciation and amortization	**(13,025)**	**(11,880)**
Total	**$ 2,673**	$ **3,636**

Technology Licenses Simultaneous with the execution of the merger, 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 at royalty rates ranging from 3% to 20% of net sales, depending on the field, the year, the country of sale and the patents covering such products. The Company will also pay royalties of $16 or $25 for every PCR plasma test it performs or has a laboratory perform and royalties ranging from 5% to 20% of net service revenue that the Company receives for diagnostic testing procedures that it performs using PCR technology. 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.

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 the three months ended June 30, 2005 and 2004. Accumulated amortization was $2.7 million and $2.2 million at June 30, 2005 and March 31, 2005, 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, 2005.

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, for which related costs are recorded as incurred.

The following is a reconciliation of the Company s general product warranty reserve:

	Three Months Ended	
	June 30, 2005	June 30, 2004
BioVeris and Wholly-Owned Subsidiaries:		
Balance, beginning of period	**$366**	$ 450
Provisions recorded	**11**	102
Actual costs incurred	**(90)**	(102)
Balance, end of period	**$287**	$ 450

As of March 31, 2005, the Company s general product warranty reserve was $366,000.

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

	Three Months Ended	
	June 30, 2005	June 30, 2004
BioVeris and Wholly-Owned Subsidiaries:		
Deferred revenue, beginning of period	**$ 621**	$ 678
Extended warranties issued	**322**	410
Amortization of extended warranties	**(293)**	(306)
Costs incurred during the period	**238**	216
Settlement during the period of costs incurred	**(238)**	(216)
Balance, end of period	**$ 650**	$ 782

Fair Value of Financial Instruments - The carrying amounts of the Company s financial instruments, which include cash equivalents, 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, 2005 and 2004 was $6.8 million and $12.8 million, respectively. Other comprehensive loss of $123,000 and other comprehensive gain of $31,000 for the three months ended June 30, 2005 and 2004, respectively, 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.

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, 2005, and 2004.

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.

Stock-based Compensation - The Company has elected to follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for employee stock options and, accordingly, will not recognize compensation cost for options granted under its 2003 Stock Incentive Plan whose exercise price equaled the market value of a share of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure An Amendment of SFAS 123 to stock-based employee compensation (in thousands, except per share amounts):

	Three Months Ended June 30,	
	2005	2004
Net loss, as reported	**$(6,668)**	$(12,851)
Deduct: Total stock-based employee compensation expense determined under fair value method	**(63)**	(48)
Pro-forma net loss	**$(6,731)**	$(12,899)
Loss per share:		
Basic and diluted loss per common share as reported	**$ (0.25)**	$ (0.48)
Basic and diluted loss per common share pro forma	**$ (0.25)**	$ (0.48)

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.

The Company did not grant any stock options during the quarters ended June 30, 2005 and 2004. In July 2005, the Company granted 500,000 shares of restricted stock and 266,000 options to purchase common stock under the Company s 2003 Stock Incentive Plan.

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, 2005 and 2004, 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. As the Company incurred a loss for the three months ended June 30, 2005 and 2004, it did not assume exercise of 123,000 and 20,300 outstanding options, respectively, because to do so would have been anti-dilutive.

New Accounting Standards In December 2004, the FASB issued SFAS No. 123 (revised 2004) (SFAS 123(R)), Share-Based Payment. SFAS 123(R) replaces SFAS No. 123, Accounting for Stock Issued to Employees, and supersedes Accounting Principal Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123(R) requires that compensation costs relating to share-based payment transactions be recognized in the consolidated financial statements. Compensation costs will be measured based on the fair value of the equity or liability instruments issued. In April 2005, the SEC issued a rule amending the compliance date which allows companies to implement SFAS 123(R) at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005. As a result, the Company will implement SFAS 123(R) in the reporting period starting April 1, 2006. The Company is currently evaluating the provisions of SFAS 123(R) and has not yet determined whether to use the modified prospective or the modified retrospective methods allowed by SFAS 123(R), nor has it determined the impact on its financial condition, results of operations and liquidity beyond the disclosure on Note 2 of the Notes to Condensed Consolidated Financial Statements.

In December 2004, the FASB issued SFAS 153, Exchange of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions. SFAS 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. The Company is currently evaluating the provisions of SFAS 153 and does not believe that its adoption will have a material impact on its financial condition, results of operations and liquidity.

In May 2005, the FASB issued SFAS No. 154 (SFAS 154), Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including the cumulative effect of the change in the net income of the period. SFAS 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The provisions of SFAS 154 will be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company is currently evaluating the provisions of SFAS 154 and does not believe that its adoption will have a material impact on its financial condition, results of operation and liquidity.

3. MESO SCALE DIAGNOSTICS JOINT VENTURE

MSD was a joint venture formed by IGEN and MST in 1995. MST was established and is 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 in drug discovery 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.

In August 2001, IGEN amended the MSD joint venture agreement, the MSD limited liability company agreement and certain license and other agreements with MSD and MST to continue the MSD joint venture and entered into various related agreements, including employment and consulting agreements with Jacob Wohlstadter. These agreements are collectively referred to as the MSD agreements . An independent committee of the IGEN Board of Directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

As part of the merger and related transactions, IGEN transferred its equity interest in MSD to the Company and assigned the MSD agreements to the Company. On February 13, 2004, the Company replaced IGEN as a member of MSD. Pursuant to the agreements executed in connection with the merger and related transactions, 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 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 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.

Equity interest and capital contributions

Until the time of the sale of its interests in MSD on December 13, 2004, the Company held a 31% voting equity interest in MSD. MST was the only other member of MSD and owned the remaining 69% voting equity interest. 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.

None of the Company s executive officers or directors had any ownership interest in MST or MSD, other than through ownership of interests in the Company and other than the Series B preferred stock of the Company purchased by Samuel Wohlstadter. Mr. Samuel Wohlstadter and Mrs. Nadine Wohlstadter disclaim any ownership interest in MST or MSD as a result of Mr. Jacob Wohlstadter s ownership interest in those entities.

Since inception of the MSD joint venture through March 31, 2004, the equity method had been utilized by the Company to account for this investment. The Company has recorded only its proportionate share of MSD losses, representing approximately 100% of MSD s losses, for each respective period as equity in loss of joint venture consistent with accounting for equity method investments (except for the period from March 31, 2004 through August 12, 2004, during which time the Company consolidated the financial results of MSD, as discussed below).

Effective March 31, 2004, the Company consolidated the financial results of MSD in accordance with FIN 46, which provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. The Company adopted FIN 46 as it determined that MSD qualified as a variable interest entity and the Company was a primary beneficiary. The settlement agreement between the parties was determined to constitute a reconsideration event under FIN 46 and the Company has determined that it no longer meets the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, beginning August 12, 2004, the Company has deconsolidated the financial results of MSD and resumed accounting for this investment on the equity method through December 13, 2004, the date of the sale of the Company s interests in MSD. See Note 2 for a discussion of consolidation accounting for MSD.

During the three months ended June 30, 2005 and 2004, operating costs allocated to MSD by the Company in connection with shared personnel and facilities were approximately $233,000 and $526,000, respectively.

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 and accordingly, the Company no longer holds an equity interest in MSD.

Under the MSD joint venture agreement, the parties are responsible for all fees and costs of the appraiser designated by it and one-half of all fees and costs of the third appraiser. Pursuant to the settlement, the Company paid MSD s share of such fees and costs, which approximated $85,000, which amount was included in the purchase price payable by MST for the Company s interests in MSD. In addition, as more fully described below, MSD s rental and expense payment obligations for subleased property for the period from March 1, 2004 through August 31, 2005, approximating $2.3 million, were included in the purchase price of the Company s interests in MSD in lieu of MSD making current payments.

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% 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 $1.9 million at June 30, 2005.

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 do not materialize, the Company will not receive any additional payments 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 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
Note receivable-recorded at fair value	$ 4,971

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 note receivable which has a balance of approximately $5.0 million at June 30, 2005, and 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 over the term of the expected payments on the note. Total accretion during the three months ended June 30, 2005 was approximately $400,000 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, the net present value of future payments received by the Company could differ from the amount reflected on the balance sheet at June 30, 2005.

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 6.3% 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).

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, consisting primarily of purchasing services support, 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. Each of MSD and the Company may unilaterally terminate any or all of the subleases by providing at least 18 months prior written notice of termination, and on February 29, 2004, the Company elected to terminate all of the subleases effective September 1, 2005. Notwithstanding the termination of any sublease, MSD may elect to remain in the subleased facility after the 18-month period expires for any period of time selected by MSD, but not longer than one day prior to the expiration of the prime lease (including any extensions to the prime lease).

Effective September 1, 2005, MSD is 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 are expected to approximate $2.3 million, were included in the purchase price of the Company s interests in MSD in lieu of MSD making current payments. The estimated future rent obligations of MSD of $251,000 for the period from July 1, 2005 through August 31, 2005 has been recorded as deferred rent and is included with current liabilities on the Company s balance sheet at June 30, 2005. Future rent payments that are related to MSD s rent obligations will be recorded against the deferred rent liability.

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, 2005 and for the three months ended June 30, 2005 and 2004 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, 2005 filed with the SEC.

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, similar expressions have been used to 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 immunodiagnostic and nucleic acid 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 biodefense, life science and industrial markets. The non-clinical diagnostics market includes biodefense 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 biodefense 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 an M-SERIES clinical analyzer that builds on the M-SERIES instruments we sell in the biodefense and life science markets. We are developing the assays using, among other things, improvements licensed from an affiliate of Roche. We believe that these improvements will reduce product development timelines. We also 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 a unique diagnostic panel. We will seek approval from the FDA for the clinical analyzer and other *in vitro* diagnostics products at the appropriate stage of their product development.

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 for biodefense tools 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. We have recently introduced proprietary products for immunogenicity testing. 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. Our M-SERIES product line for the life science market is believed by us to be ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

We have expanded our business model to target the field of vaccines. In conjunction with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we have entered into an exclusive option agreement with Children s Hospital & Research Center at Oakland (CHRCO) for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. We believe that the availability of an effective vaccine that would prevent meningococcal serogroup B, for use by various population groups, could meet a significant unmet medical need.

We have entered into an agreement with the National Research Council of Canada (NRC) for a license to patent rights to candidates for a group B streptococcus (GBS) Type II and Type V vaccine and a group B meningococcus (GBM) vaccine. Under the agreement with the NRC, we acquired worldwide, exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of disease caused by GBS, a leading cause of sepsis, pneumonia, and meningitis among newborns. We received similar worldwide rights, with the exclusion of Canada, to NRC s GBM vaccine technologies for the prevention of meningococcal B meningitis and sepsis.

We have also entered into an option agreement with the University of Massachusetts at Amherst (UMA) for exclusive patent rights to a unique vaccine candidate for Chlamydia, the most frequently reported infectious disease in the United States. Under the agreement with UMA, we acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

In August, 2005, we completed a Technology License Agreement with Baxter Healthcare Corporation for exclusive patent rights to a broad portfolio of vaccine candidates. Vaccines covered by the Agreement include those for the prevention of diseases caused by Group A streptococci, Group B streptococci, Pneumococci, Group B meningococci, anthrax bacilli and urinary tract infection associated with *E coli.* Under that agreement, we receive exclusive rights to patents or know-how related to the manufacture, production, use and commercialization of the vaccine candidates.

Investment in MSD

MSD was a joint venture formed by MST and IGEN in 1995. MSD was formed to develop, manufacture, market and sell products utilizing a combination of MST s multi-array technology together with our ECL technology.

Effective March 31, 2004, we consolidated the financial results of MSD in accordance with FIN 46, which provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We adopted FIN 46 as it was determined that MSD qualified as a variable interest entity and we were the primary beneficiary. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we have measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation.

On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between those parties and constituted a reconsideration event under FIN 46. We have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD, as through the provisions of the settlement agreement, we have transferred our economic interests to MST and reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, beginning August 12, 2004, we have deconsolidated the financial results of MSD.

Except for the period during which we consolidated the financial results of MSD, which was March 31, 2004 through August 12, 2004, we have recorded our proportionate share of MSD losses, representing approximately 100% of MSD s losses. For this consolidation period, we reclassified amounts in the statement of operations formerly recorded on a net basis as equity in loss of joint venture to amounts recorded on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses. As a result, our revenues and expenses for three months ended June 30, 2005 decreased.

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. Fair market value for the purchase of our interests in MSD has been determined in accordance with the valuation process set forth in the MSD joint venture agreement. The fair market value was determined by the independent appraisers to be approximately $9.9 million which equals the average of the two closest determinations, less a 7.5% discount factor. The purchase of our interests was completed on December 13, 2004 and, accordingly, we no longer hold an equity interest in MSD.

MSD or 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 $1.9 million at June 30, 2005, is no longer deemed outstanding.

Upon the sale of our interests in MSD, we recorded a note receivable that had a balance at June 30, 2005 of approximately $5.0 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, 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, 2005. 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 will not receive any additional payments 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 3 .

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 established by IGEN or establish successful new collaborations with corporate partners to develop, manufacture, market and sell products that incorporate our technologies.

Supplemental Consolidated Statements of Operations Data (1):

	Three Months Ended June 30, 2005	Three Months Ended June 30, 2004			
	BioVeris and Wholly-Owned Subsidiaries	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
	(In thousands, except per share data)				
Revenues:					
Product sales	$ 4,580	$ 4,886	$ 2,953	$	$ 7,839
Royalty income	309	320			320
Contract fees		20	66		86
Total	4,889	5,226	3,019		8,245
Operating costs and expenses:					
Product costs	2,048	2,264	2,340		4,604
Research and development	4,765	4,561	2,682	(67)	7,176
Selling, general and administrative	5,681	6,608	3,102		9,710
Total operating costs and expenses	12,494	13,433	8,124	(67)	21,490
Loss from operations	(7,605)	(8,207)	(5,105)	67	(13,245)
Interest income	1,318	404			404
Other, net	(381)	(54)	44		(10)
Equity in loss of joint venture		(4,994)		4,994	
Net loss	$ (6,668)	$(12,851)	$ (5,061)	$ 5,061	$(12,851)
Net loss per common share	$ (0.25)	$ (0.48)	$ (0.19)	$ 0.19	$ (0.48)
Shares used in computing net loss per common share	26,728	26,728	26,728	26,728	26,728

(1) Effective March 31, 2004, we consolidated the financial

results of MSD in accordance with FIN 46. On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between the parties and constituted a reconsideration event under FIN 46. We have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, beginning August 12, 2004, we have deconsolidated the financial results of MSD and have accounted for this investment on the equity method through December 13, 2004, the date of the sale of our interests in MSD.

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Results of Operations

Three months ended June 30, 2005 and 2004

During the three months ended June 30, 2004, MSD s results of operations are consolidated with the results of operations of BioVeris and its wholly-owned subsidiaries.

Revenues. Our consolidated revenues for the quarter ended June 30, 2005 decreased by approximately $3.3 million or 40% to $4.9 million from $8.2 million in the corresponding prior year period. Of the $3.3 million decrease, $3.0 million represents MSD revenues which were consolidated with BioVeris revenues during 2004.

Our consolidated product sales were $4.6 million for the quarter ended June 30, 2005, a decrease of 41%, from $7.8 million in the corresponding prior year period. Of this $3.2 million decrease, $3.0 million represents MSD product sales. BioVeris sales of biodefense products in 2005 were $2.3 million, an increase of $100,000 over the prior year. Sales of products for the life science market were $2.3 million for 2005, a decrease of $300,000 from the prior year. These changes in product sales reflect the change of orders and product deliveries for biodefense and life science products, which are based on our customers requirements.

We anticipate continuing increases in biodefense related sales as a result of our ongoing biodefense initiatives. We have a contract with the DOD pursuant to which the DOD may purchase tests for the detection of specific toxins in environmental samples. Under the contract, the DOD may, at its option, make purchases of up to $23.0 million over a period of up to 48 months through June 2007. Through June 30, 2005, the DOD had purchased approximately $8.5 million of products. 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.

Sales of our products for the life science market are subject to a number of uncertainties, including the fact that we are not a party to significant long-term contracts for the sale of our products for the life science market that would provide predictable sales. Therefore, the volume and timing of product orders from our 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 in the life science market.

Operating Costs and Expenses. Consolidated product costs were $2.0 million (45% of total product sales) for the quarter ended June 30, 2005 compared to $4.6 million (59% of total product sales) in 2004. The current year decrease of $2.6 million consists of $2.3 million due to the consolidation of MSD s product costs in 2004, and a $300,000 reduction in BioVeris costs. BioVeris product costs in 2005, as a percentage of total product sales, were 45% compared to 46% in 2004. 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.

Consolidated research and development expenses were $4.8 million for the quarter ended June 30, 2005, which represents a decrease of 31% over the prior year costs of $7.2 million. The $2.4 million decrease consists of $2.7 million due to the consolidation of MSD s research and development expenses in 2004, and a $300,000 increase in BioVeris costs. BioVeris research and development expenditures increased in the current period due primarily to higher facilities and personnel costs. Research and development expenses primarily relate to ongoing development costs and product enhancements associated with 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 biodefense 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 an exclusive option agreement with CHRCO for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. The agreement provides that we will sponsor up to $800,000 of research at CHRCO over a two-year period and if the option is exercised, make additional payments for license and milestone fees for initiating and completing human clinical trials and receiving regulatory approvals. Payments on this agreement began in October 2004 and totaled $100,000 in the quarter ended June 30, 2005. We have entered into an agreement with the NRC for a license to patent rights to candidates for a group B streptococcus Type II and Type V vaccine and a group B meningococcus vaccine. Under the license agreement, we are required to pay a royalty on product sales, including a minimum $10,000 annual royalty, and we are responsible for conducting or sponsoring the research and development of these vaccine candidates. We have also entered into a Sponsored Research Agreement with UMA under which we will sponsor up to $600,000 of research at UMA through calendar 2006 aimed at developing a vaccine candidate for chlamydia. In addition, we have leased facilities at an annual cost of approximately $600,000 for use in the vaccine programs.

Consolidated selling, general and administrative expenses were $5.7 million in the quarter ended June 30, 2005, which represents a decrease of 41% over the prior year costs of $9.7 million. Of this $4.0 million decrease, $3.1 million represents MSD s selling, general and administrative expenses in 2004. BioVeris decrease in selling, general and administrative costs of $900,000 was primarily attributable to lower professional fees in the current year. Professional fees in the prior year included costs associated with our litigation and settlement with MSD.

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 on going 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 Income. Interest income was $1.3 million and $404,000 in the quarters ended June 30, 2005 and 2004, respectively. Interest income increased in the current year due to higher rates of return on invested funds. Interest income in the current year also includes approximately $400,000 from the accretion of income related to the note receivable from MSD.

Net Loss. The net loss for the quarter ended June 30, 2005 was $6.7 million ($0.25 per common share), compared to a net loss of $12.9 million ($0.48 per common share) in 2004. The decrease in the net loss is primarily caused by operating expenses exceeding our revenues by a lesser amount.

Liquidity and Capital Resources

	June 30, 2005	March 31, 2005
Cash, cash equivalents and short term investments	**$87,091**	$ 95,629
Working capital	**92,597**	98,639

	Three Months Ended	
	June 30, 2005	June 30, 2004
Cash provided by(used in):		
Operating activities	**$(8,233)**	$ (9,837)
Investing activities	**(2,180)**	(90,435)
Financing activities		(20,000)
Capital expenditures (included in investing activities above)	**(182)**	(727)

Cash Used in Operating Activities

Net cash used for operations was $8.2 million and $9.8 million during the three months ended June 30, 2005 and 2004, respectively. The decrease in cash used for operations in the current period resulted primarily from a lower net loss offset by changes in non-cash adjustments to the net loss and increased for higher working capital requirements in the current period.

Cash Used in Investing Activities

We used approximately $200,000 and $700,000 of cash for the acquisition of equipment and leasehold improvements during the three months ended June 30, 2005 and 2004, respectively. During the three months ended June 30, 2005 and 2004, we purchased $10.0 million and $89.7 million, respectively, of short-term investments, and in the current period we received proceeds of $8.0 million from the sale of short-term investments.

Cash Used in Financing Activities

During the three months ended June 30, 2004, we used $20.0 million of cash for the distribution gain payment to Roche associated with the merger and related transactions.

During the three months ended June 30, 2005, we declared and paid a dividend of $57 in respect of shares of series B preferred stock. In July 2005, we declared and paid a dividend of $8,503 in respect of shares of series B preferred stock.

MSD

We made no investment contributions to MSD during the three months ended June 30, 2005 and 2004. During the three months ended June 30, 2005 and 2004, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled $233,000 and $526,000, respectively. The specific nature and amount of our allocations for 2005 and 2004 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 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, if necessary, to fund such commitments.

As of June 30, 2005, our material future obligations were as follows (in thousands):

Years Ended March 31,	Operating Lease Payments	Sponsored Research	Total
2006	$ 3,096	$490	$ 3,586
2007	2,904	463	3,367
2008	2,871		2,871
2009	2,827		2,827
2010	2,241		2,241
2011 and thereafter	558		558
Total	$14,497	$953	$15,450

Included in the operating lease payments above is approximately $600,000 per year of leased facilities for use in our vaccine programs. Subsequent to June 30, 2005, we entered into a ten-year lease agreement for additional facilities for manufacturing and other corporate uses, with an annual base rent commitment of approximately $1.0 million. In August, 2005, we completed a Technology License Agreement with Baxter Healthcare Corporation for exclusive patent rights to a broad portfolio of vaccine candidates. We paid a $200,000 license issue fee and may also make additional future payments for patent costs, milestone fees for initiating and completing human clinical trials and receiving regulatory approvals. We are also required to pay royalties on product sales and beginning in 2010, are required to pay a minimal annual royalty of $500,000 that is creditable against any other milestone payments and royalties.

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, we have not yet completed a business plan for our clinical diagnostic and vaccine products, including immunodiagnostic and PCR technology-based products, do not have definitive product introduction timelines or budgets and have not 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 for 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. 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.

As of June 30, 2005, we had no off-balance sheet arrangements.

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. Our critical accounting polices 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.

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

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. 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.

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.

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.

Joint Venture Accounting For periods prior to March 31, 2004 and for the period from August 13, 2004 through December 13, 2004, we accounted for our ownership in the MSD joint venture on the equity method, as we determined that we do not control MSD s operations.

Factors considered in determining our level of control include the fact that we had less than 50% of the voting equity interest in MSD; that we did not have exclusive authority over MSD decision making and had no ability to unilaterally modify the joint venture agreements; and that we had the right to appoint only one out of two seats on MSD s board of managers. A different assessment of these factors could have provided for the use of consolidation accounting rather than the equity method, in which case a consolidation of our financial statements with those of MSD would have been appropriate. Consolidation accounting would have required certain reclassifications within our consolidated financial statements but would not have materially affected our financial position or net loss. See Part I ITEM 1 Condensed Consolidated Financial Statements Notes to Condensed Consolidated Financial Statements Note 3 Meso Scale Diagnostics Joint Venture.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, as revised, or FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We adopted FIN 46 as of March 31, 2004 and determined that MSD qualified as a variable interest entity based upon the following rationale:

- We had provided substantially all of MSD s funding since inception through capital contributions consisting of Class B and C non-voting equity interests. Such funding was not considered at risk , because the investments did not participate significantly in the profits of MSD given their stated return rates. As such, the at risk equity of MSD was insufficient to absorb MSD s expected future losses.
- We held 31% of the voting rights in MSD and provided 100% of MSD s funding, and were thereby considered to be involved in all of MSD s activities as defined under FIN 46.

Accordingly, as of March 31, 2004, we consolidated the financial results of MSD. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of these assets, liabilities and noncontrolling interests are reflective of their respective carrying amounts had FIN 46 been effective when we first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. We had historically recorded approximately 100% of MSD s losses. The balance sheet as of March 31, 2004 reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses. The statement of operations for the period of consolidation has reclassified amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses.

On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between the parties and constituted a reconsideration event under FIN 46. We have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD. Factors used in this evaluation include:

- We do not have a significantly large variable interest in MSD to be the primary beneficiary. We will hold only a secured note whereas the purchaser, MST, will be at risk for all of its equity;
- After December 13, 2004 and for the remaining life of MSD, we ceased to absorb any MSD losses; and
- MST will absorb the majority of the expected losses of MSD.

Accordingly, beginning August 12, 2004, we deconsolidated the financial results of MSD and have accounted for this investment using the equity method through December 13, 2004, the date of the sale of our interests in MSD.

The balance sheet for periods subsequent to August 12, 2004 reclassified amounts formerly consolidated or presented on a gross basis to be reflected on a net basis as investment in joint venture. Effective August 13, 2004, the statement of operations reclassified amounts presented on a gross basis to be reflected on a net basis as equity in loss of joint venture. Accordingly, the statement of operations for the year ended March 31, 2005 includes the consolidated revenue and expenses of MSD for the period from April 1, 2004 through August 12, 2004 and reflects MSD s net losses for the period from August 13, 2004 through December 13, 2004, the date of the sale of our interests, as equity in loss of joint venture, consistent with accounting for equity method investments.

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 note receivable which has a balance of approximately $5.0 million at June 30, 2005, and which represents 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 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 balance sheet at June 30, 2005.

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.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004) (SFAS 123R), Share-Based Payment. SFAS 123R replaces SFAS No. 123, Accounting for Stock Issued to Employees, and supersedes Accounting Principal Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123R requires that compensation costs relating to share-based payment transactions be recognized in the consolidated financial statements. Compensation costs will be measured based on the fair value of the equity or liability instruments issued. In April 2005, the SEC issued a rule amending the compliance date which allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005. We are currently evaluating the provisions of SFAS 123R and have not yet determined whether to use the modified prospective or the modified retrospective methods allowed by SFAS 123R, nor have we determined its impact on our financial condition, results of operations and liquidity beyond the disclosure on Note 2 of the Notes to Condensed Consolidated Financial Statements.

In December 2004, the FASB issued SFAS 153, Exchange of Nonmonetary Assets , an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions. SFAS 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We are currently evaluating the provisions of SFAS 153 and do not believe that its adoption will have a material impact on our financial condition, results of operations and liquidity.

In May 2005, the FASB issued SFAS No. 154 (SFAS 154), Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including the cumulative effect of the change in the net income of the period. SFAS 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The provisions of SFAS 154 will be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We are currently evaluating the provisions of SFAS 154 and do not believe that its adoption will have a material impact on our financial condition, results of operation and liquidity.

Forward-Looking Information and Risk Factors That May Affect Future Results

Risks Relating to Us and Our Business

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

We incurred net losses of $77.6 million, $93.3 million and $50.9 million for the years ended March 31, 2005, 2004 and 2003, respectively and net losses of $6.7 million and $12.9 million for the three months ended June 30, 2005 and 2004, respectively. 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. 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 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 $16.8 million at June 30, 2005. 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 biodefense 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 from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;

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 increases or decreases based on the products in development; and
sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time;
the amount that we may record related to the potential impairment of the license to use PCR technology;
amounts received from MSD as payment for the purchase of our interests in MSD and the related accretion of income on the note receivable from MSD;
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 health care 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.

IF WE ARE UNABLE TO ESTABLISH NEW COLLABORATIONS, OR 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 you 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 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.

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;
- 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 existing products, such as those which IGEN experienced with the development of M-SERIES instruments. 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 biodefense 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.

Pursuant to the settlement, MST purchased our entire interests 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 will be applied against this credit and not paid to us in cash.

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 will 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 $5.0 million at June 30, 2005. 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 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 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 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 clinical testing or biodefense 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 not successful at identifying and obtaining additional facilities to meet our future growth needs, or we are unable to pay for facility enhancements and improvements, our business would suffer.

WE HAVE NO EXPERIENCE SELLING, MARKETING OR DISTRIBUTING CLINICAL DIAGNOSTIC OR VACCINE PRODUCTS. OUR FAILURE TO ESTABLISH A SALES FORCE WITH TECHNICAL EXPERTISE OR TO ESTABLISH AN EFFECTIVE 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 COULD BE HARMED IF WE HAVE FUTURE DISAGREEMENTS WITH ROCHE OVER THE SCOPE OF THE LICENSE AGREEMENT.

Our business success or failure will depend, in part, on our ability to pursue, obtain, and maintain adequate patent protection for ECL technology 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.

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 over the scope of the license agreement, such as disputes over the field or the types of products that Roche is permitted to develop and sell, 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 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 and other material terms of the improvements license agreement or the PCR license agreements, such as disputes over the field or types of products that we are permitted to develop and sell, 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.

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.

ONGOING COMPLIANCE WITH THE REQUIREMENTS OF SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 AND REVISIONS TO ACCOUNTING STANDARDS, FINANCIAL REPORTING AND CORPORATE GOVERNANCE REQUIREMENTS COULD REQUIRE A SIGNIFICANT EXPENDITURE OF OUR TIME AND RESOURCES.

We must follow accounting standards, financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and other countries where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards, financial reporting and corporate governance requirements and tax laws may require changes to our financial statements, the composition of our board of directors, the composition, the responsibility and manner of operation of various board-level committees, the information filed by us with the governing bodies and enforcement of tax laws against us. Implementing changes required by such new standards, requirements or laws likely will require a significant expenditure of time, attention and resources, especially by our senior management. It is impossible to completely predict the impact, if any, on us of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws.

We have documented and tested our internal control procedures as of March 31, 2005 in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 which we refer to in this Form 10-Q as SOX, and which requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with SOX. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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

Our research and development activities have occasionally 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 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 biodefense 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 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. 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.

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, or EPA, regulate many of our products as well as products that we plan to develop, manufacture, market and sell, including products for the clinical diagnostics, biodefense 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.

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 biodefense 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 contract 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, biodefense and industrial markets. We may not be able to insure 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 24% 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 shareholdings, certain of our executive officers and directors could have significant influence over the outcome of potential transactions, including acquisition transactions, that may be supported 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to changes in exchange rates where we sell direct 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, 2005 had cash, cash equivalents and short-term investments of $87.1 million which is approximately 69% 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, 2005, we had invested $51.0 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 the general level of interest rates. Based on our cash, cash equivalents and short-term investments balance at June 30, 2005, a 1% movement in interest rates would have an approximately $0.9 million 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, 2005, 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 13a-15(e) and 15d-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, 2005, 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. Based upon the evaluation discussed above, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2005, our disclosure controls and procedures were effective at providing such 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 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 6. EXHIBITS

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

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, 2005

/s/ Samuel J. Wohlstadter

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

Date: August 9, 2005

/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)