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BIOVERIS CORP  
Form 10-Q  
November 15, 2004

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 September 30, 2004

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  No

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 November 1, 2004

Common Stock, \$0.001 par value

26,728,070

**BioVeris Corporation**

**Form 10-Q**

**For the Quarter Ended September 30, 2004**

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**PART 1   FINANCIAL INFORMATION**

**ITEM 1: CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**BioVeris Corporation**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(In thousands)**

	<b>September 30, <u>2004</u> Unaudited</b>	<b>March 31, <u>2004</u></b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 20,694	\$ 182,509
Short-term investments	88,333	--
Accounts receivable, net	6,235	5,516
Inventory	5,120	8,207
Other current assets	3,250	4,332
	<hr/>	<hr/>
Total current assets	123,632	200,564

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	<b>September 30,</b>	<b>March 31,</b>
Equipment and leasehold improvements, net	4,254	12,565
<b>OTHER NONCURRENT ASSETS:</b>		
Investment in joint venture	7,694	--
Technology licenses	18,281	19,266
Other	354	419
<b>TOTAL ASSETS</b>	<b>\$ 154,215</b>	<b>\$ 232,814</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 5,805	\$ 7,187
Accrued wages and benefits	2,009	1,876
Distribution gain accrual	--	20,000
Deferred liabilities	1,725	2,273
Note payable	--	44
<b>Total current liabilities</b>	<b>9,539</b>	<b>31,380</b>
<b>NONCURRENT LIABILITIES</b>	<b>1,869</b>	<b>54</b>
<b>Total liabilities</b>	<b>11,408</b>	<b>31,434</b>
<b>COMMITMENTS</b>		
<b>MINORITY INTEREST</b>		
SERIES B PREFERRED STOCK, 1,000 shares designated, issued and outstanding	7,500	7,500
<b>STOCKHOLDERS' EQUITY:</b>		
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	(68,134)	(9,665)
Accumulated other comprehensive income (loss)	(50)	--
<b>Total stockholders' equity</b>	<b>135,307</b>	<b>193,826</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 154,215</b>	<b>\$ 232,814</b>

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

**BioVeris Corporation**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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

**Unaudited**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b><u>2004</u></b>	<b><u>2003</u></b>	<b><u>2004</u></b>	<b><u>2003</u></b>
<b>REVENUES:</b>				
Product sales	\$ 7,234	\$ 5,618	\$ 15,073	\$ 10,414
Royalty income	315	297	635	540
Contract fees	302	36	388	70
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	7,851	5,951	16,096	11,024
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
<b>OPERATING COSTS AND EXPENSES:</b>				
Product costs	3,538	3,340	8,142	5,773
Research and development	5,552	5,020	12,728	10,252
Selling, general, and administrative	8,951	4,408	18,661	9,184
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	18,041	12,768	39,531	25,209
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
LOSS FROM OPERATIONS	(10,190)	(6,817)	(23,435)	(14,185)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
OTHER, NET	1,223	(32)	1,617	48
EQUITY IN LOSS OF JOINT VENTURE	(2,751)	(4,450)	(2,751)	(9,680)
LOSS ON JOINT VENTURE IMPAIRMENT	(33,900)	--	(33,900)	--
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
NET LOSS	\$ (45,618)	\$ (11,299)	\$ (58,469)	\$ (23,817)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net loss per common share (Basic and diluted)	\$ (1.71)	\$ (0.42)	\$ (2.19)	\$ (0.89)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
COMMON SHARES OUTSTANDING (Basic and diluted)	26,728	26,728	26,728	26,728
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

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

**BioVeris Corporation**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

Unaudited

	<b>Six months ended</b>	
	<b>September 30,</b>	
	<b><u>2004</u></b>	<b><u>2003</u></b>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (58,469)	\$ (23,817)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	3,698	1,602
Loss on disposal of equipment	84	37
Equity in loss of joint venture	2,751	9,680

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	<b>Six months ended</b>	
Joint venture impairment	33,900	--
Expense related to stock options	--	261
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(2,740)	376
(Increase) decrease in inventory	(1,132)	275
Decrease in other current assets	1,625	986
Increase (decrease) in accounts payable and accrued expenses	1,368	(2,116)
Decrease (increase) in other liabilities	(418)	10
	<hr/>	<hr/>
Net cash used for operating activities	(19,333)	(12,706)
	<hr/>	<hr/>
<b>INVESTING ACTIVITIES:</b>		
Expenditures for equipment and leasehold improvements	(1,132)	(939)
Purchase of short term investments	(103,582)	--
Sale of short-term investments	15,199	--
Investment in joint venture (net)	(3,045)	(15,306)
	<hr/>	<hr/>
Net cash used for investing activities	(92,560)	(16,245)
	<hr/>	<hr/>
<b>FINANCING ACTIVITIES:</b>		
Payment of distribution gain	(20,000)	--
Deconsolidation of joint venture	(29,922)	--
Cash contributed by Parent, net	--	28,951
	<hr/>	<hr/>
Net cash (used for) provided by financing activities	(49,922)	28,951
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(161,815)</b>	<b>--</b>
	<hr/>	<hr/>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>182,509</b>	<b>--</b>
	<hr/>	<hr/>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 20,694</b>	<b>\$ --</b>
	<hr/>	<hr/>

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**1. ORGANIZATION AND BASIS OF PRESENTATION**

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 BioVeris Corporation (the Company), to its stockholders (the merger). The transaction occurred in the following steps:

- o 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 held by IGEN; and
- o 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.

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Prior to the completion of the merger and related transactions, the assets and businesses of the Company had historically been owned and operated by IGEN and IGEN held all cash in a centralized treasury, providing all of the necessary funding for the operations of the Company. The accompanying financial statements have been prepared and are presented as if the Company had been operating as a separate entity using IGEN's historical cost basis in the assets and liabilities and including the historical operations of the businesses and assets transferred to the Company from IGEN as part of the restructuring.

During the three and six months ended September 30, 2003, the Company was fully integrated with IGEN and these financial statements reflect the application of certain estimates and allocations. The Company's consolidated statements of operations for the three and six months ended September 30, 2003 include all revenues and costs that are directly attributable to the Company's businesses. They have been prepared and are presented as if the Company had been operating as a separate entity using IGEN's historical costs basis in the assets and liabilities and including the historical operations of the businesses and assets transferred to the Company from IGEN as part of the restructuring. In addition, certain expenses of IGEN have been allocated to the Company using various assumptions. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs). General and administrative salaries have been allocated primarily based upon an estimate of actual time spent on the businesses of the Company.

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Facilities costs and centralized administrative services have been allocated based upon a percentage of total product sales as well as a percentage of total headcount. Allocated expenses of \$4.4 million and \$9.2 million are included in selling, general and administrative expenses in the accompanying consolidated statements of operations for the three and six months ended September 30, 2003, respectively. These allocated expenses were derived from total IGEN selling, general and administrative expenses of \$5.9 million and \$12.0 million for their three and six months ended September 30, 2003, respectively.

Management believes these allocation methodologies and estimations are reasonable based upon the nature of the related expenses and management's knowledge of the level of effort and space required to support the businesses of the Company. The financial information included herein for the three and six months ended September 30, 2003 may not be indicative of what results of operations and cash flows of the Company would have been had the Company been operating as a stand-alone entity. Results of operations and cash flows for the three and six months ended September 30, 2004 are for the Company when it operated as an independent entity.

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 to present fairly the results of operations and cash flows for the three and six month periods ended September 30, 2004 and 2003, and the Company's financial position at September 30, 2004.

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, 2004 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 FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51, 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.

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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

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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 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, 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 will account for this investment using the equity method through the date of the sale of the Company's interests in MSD, which is expected to occur in December 2004.

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. Accordingly, the balance sheet as of September 30, 2004 records the net assets of MSD 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 operations for the quarter ended September 30, 2004 includes the consolidated revenue and expenses of MSD for the period from July 1, 2004 through August 12, 2004, and reflects MSD's net losses for the period from August 13, 2004 through September 30, 2004 as equity in loss of joint venture. The statement of operations for the six months ended September 30, 2004 includes the consolidated revenues and expenses of MSD for the period from April 1, 2004 through August 13, 2004, and reflects MSD's net losses for the period from August 13, 2004 through September 30, 2004 as equity in loss of joint venture.

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

*Cash and Cash Equivalents* Cash and cash equivalents include cash in banks, money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less. The Company has invested its excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds. 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.

*Short-Term Investments* Short-term investments consist primarily of corporate, federal and municipal debt-securities that are classified as available for sale. 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. As of September 30, 2004, the Company had net unrealized losses on available for sale securities of approximately \$50,000. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which are included in results of operation as generated. For the three and six month periods ended September 30, 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 September 30, 2004:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
U.S. government agencies	\$ 15,204	\$ 40	\$ (9)	\$ 15,235
Municipal Bonds	45,000	--	--	45,000
U.S. corporate debt	28,179	18	(99)	28,098
	<u>\$ 88,383</u>	<u>\$ 58</u>	<u>\$ (108)</u>	<u>\$ 88,333</u>

*Concentration of Credit Risk* During the three months ended September 30, 2004 and 2003, agencies of the U.S. government accounted for 49% and 13% of total revenue, respectively. During the six months ended September 30, 2004 and 2003, agencies of the U.S. government accounted for 37% and 17% of total revenue. As of September 30, 2004 and March 31, 2004, agencies of the U.S. government accounted for 60% and 26% of total accounts receivable, respectively. Additionally, one customer accounted for 12% of revenues for the six months ended September 30, 2004.

*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. Allowance for doubtful accounts was \$206,000 and \$208,000 as of September 30, 2004 and March 31, 2004, respectively.

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

	<b>September 30, 2004</b>	<b>March 31, 2004</b>
	<b>(in thousands)</b>	
<b>BioVeris and Wholly-Owned Subsidiaries:</b>		
Finished Goods	2,061	1,740
Work in process	311	619
Raw materials	2,748	2,654
	<hr/>	<hr/>
Total	\$5,120	5,013
	<hr/>	<hr/>
<b>MSD:</b>		
Finished Goods		757
Work in process		366
Raw materials		2,071
		<hr/>
Total		3,194
		<hr/>
		\$8,207
		<hr/>

*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 life of the lease. Equipment and leasehold improvements consist of the following:

	<b>September 30, 2004</b>	<b>March 31, 2004</b>
	<b>(in thousands)</b>	
<b>BioVeris and Wholly-Owned Subsidiaries:</b>		
Lab instruments and equipment	\$ 6,052	\$ 6,413
Office furniture and equipment	5,316	5,511
Leasehold improvements	4,004	3,980
	<hr/>	<hr/>
	15,372	15,904
Accumulated depreciation and amortization	(11,118)	(10,432)
	<hr/>	<hr/>
Total	\$ 4,254	5,472
	<hr/>	<hr/>
<b>MSD:</b>		
Lab instruments and equipment		7,555
Office furniture and equipment		3,166
Leasehold improvements		1,327
		<hr/>
		12,048
Accumulated depreciation and amortization		(4,686)
		<hr/>
Total		7,362
Consolidating eliminations		(269)
		<hr/>
Total		\$ 12,565
		<hr/>

*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



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certain PCR products within specified fields, while the other agreement grants the Company rights to perform certain PCR services within specified fields.

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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 has 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 and \$975,000 for the three and six months ended September 30, 2004, respectively, and accumulated amortization was \$1.2 million at September 30, 2004. 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. During the three months ended September 30, 2004, the Company recorded a loss from the impairment of the investment in joint venture which resulted in a non-cash charge of \$33.9 million.

*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. At each of September 30, 2004 and March 31, 2004, our warranty reserve was \$450,000. The Company also offers extended warranty arrangements to customers, for which related costs are recorded as incurred.

*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.

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*Comprehensive Income (Loss)* Comprehensive income (loss) is comprised of net income (loss) and other items of comprehensive income (loss). The Company's comprehensive loss for the three and six months ended September 30, 2004 was \$45.7 million and \$58.5 million, respectively. Other comprehensive loss of \$50,000 for the three and six months ended September 30, 2004 includes unrealized gains and losses on available for sale securities that are excluded from net loss. There were no significant elements of comprehensive income (loss) for the three and six months ended September 30, 2003.

*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 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, 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.

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*Research and Development* Research and development costs are expensed as incurred.

*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 and six months ended September 30, 2004 and 2003.

*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. The Company has not recorded an income tax benefit associated with the losses for the three and six months ended September 30, 2004 and 2003 and has recorded a full valuation allowance on its net deferred tax assets as the Company has determined that it is more likely than not that the deferred tax assets will not 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 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):

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b><u>2004</u></b>	<b><u>2003</u></b>	<b><u>2004</u></b>	<b><u>2003</u></b>
Net loss, as reported	\$ (45,618)	\$ (11,299)	\$ (58,469)	\$ (23,817)
Deduct: Total stock-based employee compensation expense determined under fair value method	(26)	(442)	\$ (57)	(896)
<b>Pro-forma net loss</b>	<b><u>\$ (45,644)</u></b>	<b><u>\$ (11,741)</u></b>	<b><u>\$ (58,526)</u></b>	<b><u>\$ (24,713)</u></b>
Loss per share:				
Basic and diluted loss per common share as reported	\$ (1.71)	\$ (0.42)	\$ (2.19)	\$ (0.89)
Basic and diluted loss per common share pro forma	\$ (1.71)	\$ (0.44)	\$ (2.19)	\$ (0.92)

All per share information for the Company is based on the number of shares of common stock of the Company outstanding upon completion of the merger and related transactions. 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. In addition, information for the three and six months ended September 30, 2003 represents options for IGEN common stock which were canceled upon completion of the merger.

The fair value of BioVeris options for the three and six months ended September 30, 2004 was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	<b>Three Months</b>	<b>Six Months Ended</b>
	<b>Ended</b>	<b>September 30, 2004</b>
	<b><u>September 30, 2004</u></b>	<b><u>September 30, 2004</u></b>
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	56.8%	56.8%
Risk-free interest rate	3.47%	3.47%
Expected option term (in years)	3	3

Based on this calculation, the weighted average fair value of BioVeris options granted during the three and six months ended September 30, 2004 was \$1.40 and \$1.40. The Company did not have a stock option plan prior to September 2003.

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The fair value of IGEN options for the three and six months ended September 30, 2003 was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	<b>Three Months Ended September 30, 2003</b>	<b>Six Months Ended September 30, 2003</b>
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	65.0%	65.0%
Risk-free interest rate	3.1%	2.3%
Expected option term (in years)	5	5

Based on this calculation, the weighted average fair value of IGEN options granted during the six months ended September 30, 2003 was \$21.09.

*Loss Per Share* - The Company uses SFAS No. 128 "Earnings per Share" for the calculation of basic and diluted earnings (loss) per share. For the three and six months ended September 30, 2004 and 2003, 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. For the three and six months ended September 30, 2003, the unaudited pro-forma net loss per share is based on the number of common shares outstanding upon completion of the merger and related transactions. As the Company incurred a loss for the three and six months ended September 30, 2004, it did not assume exercise of options because to do so would have been anti-dilutive.

*New Accounting Standards* - For a discussion of FIN 46, see Note 2 - "Summary of Significant Accounting Policies-Consolidation Accounting."

### 3. MESO SCALE DIAGNOSTICS JOINT VENTURE

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#### *General*

MSD is 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 was formed to develop, manufacture, market and sell products utilizing a combination of MST's multi-array technology together with the Company's electrochemiluminescence (ECL) technology. MSD's instrument systems include the Sector HTS and the Sector PR. The Sector HTS is an ultra high throughput drug discovery system engineered for applications such as high throughput screening and large-scale proteomics. The Sector PR is a smaller system designed for benchtop applications such as assay development, research in therapeutic areas, cellular biology and medium throughput screening. MSD also manufactures and markets a line of its own reagents, assays and plates that are used on these systems. During fiscal 2004, MSD had product sales of \$8.4 million and a net loss of \$19.9 million.

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 remains 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. 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. For a more detailed discussion of the settlement, see Note 4 - "Litigation."

#### *Equity interest and capital contributions*

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The Company holds a 31% voting equity interest in MSD. MST is the only other member of MSD and owns the remaining 69% voting equity interest. The Company also holds non-voting interests that entitle it to receive a preferred return on substantially all of its capital contributions.

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As of the completion date of the buyout by MSD or MST of the Company's interests in MSD as described below, the Company will no longer hold these interests and will be entitled to receive only the purchase price in the buyout.

Prior to the settlement agreement, the Company had a right to appoint one of two members of MSD's board of managers. Dr. Richard Massey, the Company's president and chief operating officer, served as its representative on the MSD board of managers and also served as the treasurer and secretary of MSD. Dr. Massey received no compensation from MSD or the Company for serving as the treasurer and secretary of MSD. Pursuant to the settlement agreement, Dr. Massey resigned and the Company executed an amendment to the MSD agreements to change the composition of the MSD board of managers to one person designated by MSD. Neither Dr. Massey nor the Company's other executive officers or directors have 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 disclaims any ownership interest in MST or MSD as a result of Mr. Jacob Wohlstadter's ownership interest in those entities.

Under the MSD agreements, IGEN's funding commitment was based on an annual budget of MSD approved by the Joint Venture Oversight Committee (JVOC), a committee of the IGEN board of directors consisting of independent directors. The JVOC approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of 15%, of which approximately \$19.1 million was spent by MSD and funded by the Company. The funding commitment was satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. MSD asserted that the Company was obligated to pay MSD up to an additional \$4.6 million, which is the difference between the amount spent by MSD and the budgeted amount plus the permitted variance. As part of the settlement between the parties, the Company agreed to pay MSD the net amount of \$3.0 million which represents full and complete satisfaction of amounts due to MSD pursuant to the MSD agreements, including this dispute regarding unsatisfied committed funding obligations.

During the six months ended September 30, 2004 and 2003, the contributions the Company and IGEN made to MSD were \$5.0 million and \$15.3 million, respectively. In August 2004, the Company's capital contribution of \$5.0 million was part of the settlement, of which \$3.0 million was in cash and \$2.0 million was in the form of a credit against payment of the purchase price for the buyout by MSD or MST of the Company's interest in MSD. There were no other contributions in fiscal 2005 and the Company does not expect to make any further capital contributions to MSD.

Since inception of the MSD joint venture through March 31, 2004, the equity method has been utilized by the Company to account for this investment. Prior to July 1, 2001, given MSD's status as a development stage enterprise without having established technological feasibility of its intended product offering, the Company considered its investments in MSD to be other than temporarily impaired.

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As such, any residual investment book value, after recognizing the Company's share of MSD losses in accordance with the equity method, was written off upon contribution. All expenses related to the MSD investment prior to July 1, 2001 were recorded as research and development expenses based upon the significance and character of the MSD losses as substantially all contributions supported research and development initiatives.

Beginning on July 1, 2001, taking into account the progress made by MSD in the development of its products, the Company determined that no additional impairments were required to its prospective contributions and thus ceased writing-off the amount of its contributions to MSD that were in excess of MSD's losses. At that time, MSD was transitioning from a development stage entity to a commercial enterprise and milestones establishing the continued viability of MSD were first achieved in the quarter ended September 30, 2001. For example, prototypes had been assembled demonstrating product feasibility, and MSD was anticipating initial product launch in approximately one year. As a result of this transition, MSD's expenses were no longer primarily research and development. Accordingly, beginning July 1, 2001, 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. The settlement agreement between the parties has been 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 will account for this investment on the equity method through the date of the sale of Company's interests in MSD, which is expected to occur in December 2004. See Note 2 for a discussion of consolidation accounting for MSD.

During the quarter and six months ended September 30, 2004, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$631,000 and \$1.2 million, respectively, and during the quarter and six months ended September 30, 2003, operating costs allocated to MSD by the Company totaled \$3.8 million and \$5.8 million, respectively. From July 1, 2001 through March 31, 2004, and for the period from August 13, 2004 through September 30, 2004, these allocated operating costs reduced certain operating costs and

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expenses and increased Equity in Loss of Joint Venture in the accompanying consolidated statements of operations. MSD-related losses included in equity in loss of joint venture were \$2.8 million for the quarter ended September 30, 2004, and were \$4.5 million and \$9.7 million for the quarter and six months ended September 30, 2003, respectively. At March 31, 2004, the Company's investment in joint venture has been eliminated as part of the consolidation of MSD's balance sheet.

The following is a summary of the Company's investment in the MSD joint venture (in thousands):

Balance April 1, 2003	\$	9,164
Capital contributions		56,660
Equity in loss of joint venture		(19,616)
Valuation adjustment		(33,700)
Charge in accounting principle		33,700
Balance at March 31, 2004	\$	46,208
Capital Contribution		5,045
Equity in loss of joint venture		(10,159)
Valuation adjustment		(33,400)
Balance at September 30, 2004	\$	7,694

### *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. The MSD joint venture agreement sets forth a valuation process for determination of the purchase price, which was to be determined before MSD or MST was required to commit to purchasing the interest. The Company has recorded an approximately \$800,000 and \$1.2 million liability at September 30, 2004 and March 31, 2004, respectively, representing the estimated value of MSD's option to purchase the Company's interests in MSD.

Pursuant to the settlement, MST or MSD will purchase, and the Company will sell, its entire interest in MSD. As contemplated by the MSD joint venture agreement, the purchase price will be equal to fair market value of the Company's interests less a discount factor of 7.5%. Fair market value has been determined in accordance with the valuation process set forth in the MSD joint venture agreement. In the settlement, the Company agreed to certain matters in connection with the valuation process, including the timetable for the appraisals. The Company and MSD each appointed an appraiser and a third appraiser was also appointed. The fair market value was determined to be approximately \$9.9 million which equals the average of the two closest determinations less the 7.5% discount factor. Once the purchase of the Company's interests is completed, which date is referred to as the completion date, the Company will no longer be a member of MSD. Calculating the net present value of future payments that the Company expects to realize from MSD 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 September 30, 2004.

As of August 12, 2004, the book value of the Company's interests in MSD, as recorded in the investment in joint venture account on its unconsolidated balance sheet, was greater than the fair market value purchase price of these interests determined by the appraisal process. Accordingly, during the quarter ended September 30, 2004, the Company recorded a non-cash charge of \$33.9 million, as other expense, representing the estimated amount by which the book value of the Company's interests in MSD exceeded the fair market value.

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 agreed to pay MSD's share of such fees and costs, which approximate \$85,000, and to add this amount to the purchase price payable by MSD or 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, will be added to 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, MSD or MST will be 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 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 MSD 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. 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 in effect on the date that MSD or MST, as the case may be, purchases the

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Company's interests in MSD. The amount of the prepayment credit that is outstanding is the total amount, including accrued interest, reduced from time to time by the amount due and payable to the Company pursuant to the buyout of its interest in MSD.

No further cash payments will be payable by MSD to the Company pursuant to the buyout until the \$2.0 million 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 MSD or MST, as the case may be, for the purchase of its interests in MSD. As security for the payment obligation, the Company will hold a security interest in the interests in MSD that are being purchased. MST or MSD, as the case may be, may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

The holder of the Company's Series B preferred stock will be entitled to a pro-rata share, which approximates 5.8% of the purchase price of \$9.9 million, representing the proportionate amount of the Company's Class C interest in MSD that was funded by the sale of the Series B stock, of the portion of the MSD purchase price (including the \$2.0 million prepayment) that is allocable to the Company's Class C interests.

### *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 information technology and 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.

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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. 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).

After a notice of termination of a sublease has been sent, MSD is required to pay its pro rata share of all rental and other expenses the Company incurs under the prime lease. On February 29, 2004, the Company elected to terminate all of the subleases effective the earlier of September 1, 2005, or the date on which the applicable prime lease terminates. 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, will be added to the purchase price of the Company's interests in MSD in lieu of MSD making current payments. In the event sufficient net sales or third-party financings of MSD do not materialize, the Company will not receive any additional payments from MSD or MST, as the case may be, for the purchase of its interests in MSD.

### *MSD joint venture agreement and MSD limited liability company agreement*

During the term of the MSD joint venture agreement, MSD was IGEN's and MST's exclusive means of conducting the MSD research program, as defined in the MSD agreements and which is referred to as the MSD research program. The MSD research program involves the use in diagnostic procedures, including diagnostic procedures utilizing ECL technology, of:

- o selection and screening methods, including high throughput screening and methods involving large numbers of determinations, in each case relating only to claimed or inventive subject matter of the patents or know-how licensed by MST to MSD;
- o disposable electrodes; and
- o multi-array diagnostic.

IGEN was obligated to refrain from developing or commercializing any products, processes or services that are related to the MSD research program in the diagnostic field, as defined for the purposes of the MSD agreements, or to MSD's research technologies as described in the MSD agreements, subject to certain exceptions. For purposes of the MSD agreements, the diagnostic field is defined to mean all diagnostic devices and procedures for the measurement or detection of identifiable substances for human clinical research, environmental, agricultural, veterinary, food testing, industrial or similar purposes.

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As part of the MSD joint venture agreement, MSD granted to the Company an exclusive, worldwide, royalty-free license to use in the diagnostic field certain defined improvements developed by MSD in the MSD research program. However, the Company may not make, use or sell products, processes or services that use certain defined ECL improvements granted to it by MSD if doing so would compete with MSD in the diagnostic field or use research technologies defined in the MSD agreements. Although the MSD joint venture agreement has expired, the license granted to the Company to use in the diagnostic field certain defined ECL improvements developed by MSD remains in effect. In addition, after the Company ceases to be a member of MSD, MSD may require the Company to distribute MSD's products pursuant to a mutually agreeable distribution agreement, and the Company will be required to pay to MST a royalty of 3% of net sales of MSD products sold by it.

During its term, the MSD joint venture agreement limited the business of MSD to performing the MSD research program and developing, manufacturing, marketing and selling products in the diagnostic field. Because the MSD joint venture agreement has expired, this limitation on MSD's business activity no longer applies.

In the settlement, the parties acknowledged that it is the current intent of MSD that it will operate and do business in technology related fields, including the healthcare field, the software field, and detection and measurement technologies. Furthermore, although the MSD joint venture agreement has expired, the Company remains subject to limitations on its ability to manufacture, market and sell in the diagnostic field, as defined in the MSD agreements, instruments that use an electrode to start the ECL process where the electrode is disposable, consumable or not permanently installed and MST retains sole ownership of all inventions, concepts, know-how and technology developed by MSD as well as all patent applications, patents and copyrights.

In addition, because the MSD joint venture agreement has expired, the restrictions on MSD offering employment to the Company's employees have ceased. Certain of the Company's other obligations under the MSD joint venture agreement survive its termination, including the following:

- o to cooperate and work in good faith and use reasonable best efforts to assist MSD in securing third-party financing;
- o confidentiality obligations;
- o to make available to MSD the benefits of certain agreements with third-party licensors, suppliers, vendors, distributors and other providers;
- o to assign to MSD all proprietary information and intellectual property within the MSD research program or research technologies, as described in the MSD agreements, and to ensure that its employees protect such proprietary information; and
- o to defend and indemnify MSD against all claims arising out of the conduct of the MSD research program and to maintain liability insurance to cover the risk of liability resulting from the conduct of that program.

In addition, the Company is obligated under the MSD limited liability company agreement to indemnify each officer and member of the board of managers of MSD with respect to any action taken by such person during the time IGEN or the Company, as the case may be, was or were a member of MSD by reason of the fact that such person is or was an officer or a member of the board of managers of MSD. Under the settlement, the parties agreed that this indemnification obligation applies only to acts, events or inactions, actual or alleged, occurring on or before the completion date without regard to whether the legal proceeding or other event triggering the indemnification obligation is initiated prior to or after this date.

Prior to the agreement by MSD and MST to purchase the Company's interests in MSD, the Company was required to pay the expenses associated with prosecuting and maintaining the patents licensed by MST to MSD under the MSD, MST license agreement. A portion of the \$3.0 million payment the Company made to MSD in connection with the settlement was made in full and complete satisfaction of any obligation it had in connection with such expenses.

In addition, because MSD and MST have exercised their right to purchase the Company's interests in MSD, the Company is obligated under the MSD joint venture agreement to vote its interests in MSD in the manner requested by MST (subject to certain limitations), provide reasonable cooperation and provide such consents to permit MSD to raise additional capital and terminate the Company's status as a party to the MSD/MST license agreement entered into in connection with the original formation of the joint venture.

### *IGEN/MSD license agreement*

Under the terms of the IGEN/MSD license agreement, which is one of the MSD agreements, IGEN granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to the Company's technology, including ECL technology, for use in MSD's research program. In connection with the merger and related transactions, IGEN assigned the IGEN/MSD license agreement to the Company. The IGEN/MSD license

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agreement survived the expiration of the MSD joint venture agreement and will survive the termination of the Company's status as a member of MSD. In addition, when the Company ceases to be a member of MSD, it will become entitled to receive quarterly royalty payments from MSD of 3% of the net sales price on all products developed and sold by MSD using the patents the Company received as part of the merger and related transactions. The royalty obligation will expire as the relevant patents expire.

In accordance with the terms of the MSD agreements and subject to certain exceptions, the Company consented to the sublicensing by MSD of the licenses granted pursuant to the IGEN/MSD license agreement to any affiliate of MSD. Any such sublicensee is required to, among other things, make royalty payments to the Company in accordance with the IGEN/MSD license agreement.

### *MSD/MST sublicense agreement*

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MST holds a worldwide, perpetual, non-exclusive sublicense from MSD, which is referred to as the MSD/MST sublicense agreement, to use the Company's technology to make, use or sell products or processes applying or related to the technologies used in the MSD research program outside the diagnostic field. Whether or not the Company is a member of MSD, it is entitled to receive quarterly royalty payments from MST of 6% of the net sales price on any products developed and sold by MST using the patents the Company received as part of the merger and related transactions.

The Company assumed IGEN's obligation under the MSD agreements to make its technology available for sublicense by MSD to MST, and these obligations survived the expiration of the MSD joint venture agreement and will survive the termination of the Company's or MST's status as a member of MSD. The Company is not, however, obligated to make available for sublicense by MSD to MST any technology or improvements to the Company's technology developed after the expiration of the MSD joint venture agreement or the termination of the Company's or MST's status as a member of MSD. In addition, the Company may terminate its participation in the MSD/MST sublicense agreement upon MSD's or MST's material breach, after notice and an opportunity to cure the breach.

### *Employment and consulting agreement*

The Company assumed an employment agreement pursuant to which Jacob Wohlstadter is serving as the president and chief executive officer of MSD. The current term of the employment runs through November 30, 2005. The term of the employment agreement will automatically renew for a 12-month period on November 30 of each year unless either MSD or Jacob Wohlstadter gives notice of termination no later than 180 days prior to that renewal date. Most of the Company's obligations under the employment agreement have ended, except that it remains obligated to maintain in effect directors and officers liability insurance coverage for Jacob Wohlstadter, to pay or cause MSD to pay a gross-up for any parachute excise tax that may be imposed and to indemnify Jacob Wohlstadter against certain liabilities, including liability from the MSD joint venture relating to the period of IGEN's or the Company's involvement with MSD.

Jacob Wohlstadter had a consulting agreement with IGEN that the Company assumed and which terminated on August 15, 2004. Pursuant to the consulting agreement, Jacob Wohlstadter was entitled to receive such fees as the Company and Jacob Wohlstadter agree to when consulting services are requested by the Company. The Company did not ask Jacob Wohlstadter to perform, nor did he perform, any compensable consulting services during six months ended September 30, 2004 or the year ended March 31, 2004.

### *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.

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In addition, the Company assumed a letter agreement dated August 15, 2001 among Jacob Wohlstadter, MSD, MST and IGEN. Pursuant to the letter agreement, IGEN agreed to fund reasonable ongoing legal fees and related charges and costs incurred by Jacob Wohlstadter, MSD and MST arising out of or related to IGEN's litigation with Roche. MSD had submitted to IGEN invoices for legal fees and expenses for the period from March 1, 2003 through September 30, 2003 of approximately \$1.3 million. IGEN paid approximately \$423,000 of the submitted expenses, which an independent committee of IGEN's board of directors believed was the maximum amount IGEN was obligated to pay under the letter agreement. A portion of the \$3.0 million payment the Company made to MSD in connection with the settlement was made in full and complete satisfaction of the dispute.

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.



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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.

### 4. LITIGATION

In June 2004, the Audit Committee of the Company's Board of Directors commenced an investigation of MSD that was prompted by the discovery of a series of transactions undertaken by MSD involving the actual or proposed purchase by MSD of residential real property and luxury automobiles having an aggregate cost of approximately \$7 million. The transactions were entered into by MSD upon Jacob Wohlstadter's sole approval and without the Company's knowledge.

On June 15, 2004, the Company filed an action in the Court of Chancery of the State of Delaware, which is referred to as the Court, against Jacob Wohlstadter, MSD and MST, seeking Court confirmation that the Company remained entitled to designate one of the two members of the MSD Board of Managers, and asking the Court to enter an order, pending the outcome of the litigation, prohibiting MSD from taking any actions outside the ordinary course of MSD's business without providing prior notice to the Company. On June 17, 2004, the Court ordered that, pending the Court's final determination of the lawsuit, the Company's representative on the MSD Board of Managers shall remain on the MSD Board of Managers and that MSD would not engage in any transaction outside the ordinary course of business which has a value in excess of \$10,000 without the approval of both members of the MSD Board of Managers.

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Also on June 15, 2004, the Company submitted a formal demand to MSD requesting the right to examine certain books and records of MSD to aid the Audit Committee in its investigation and to permit us to value the Company's interest in MSD.

On June 17, 2004, MSD received \$2.9 million from Jacob Wohlstadter as consideration for the sale by MSD to Jacob Wohlstadter of real property and automobiles, pending approval by the Board of Managers. Jacob Wohlstadter also assumed MSD's purchase obligations with respect to a prospective real property purchase in the approximate amount of \$4.1 million.

Also on June 17, 2004, the Company was informed by the staff of the Securities and Exchange Commission that it had commenced an informal inquiry as to certain issues relating to MSD.

On July 6, 2004, the Company entered into an agreement with MSD, MST and Jacob Wohlstadter pursuant to which it was agreed that the first lawsuit would be stayed, that the parties would not file new litigation against each other, and that the valuation process in connection with MST's and MSD's right to purchase our interest in MSD would be stayed. This stay agreement was intended to permit the parties to engage in substantive negotiations to resolve the disputed matters and in order to permit the Company to finalize its Annual Report on Form 10-K for the year ended March 31, 2004. This stay agreement terminated automatically on July 13, 2004 because MSD's representation letters to the auditors of MSD were not executed. Because the Company was required to consolidate the financial information of MSD pursuant to FIN 46, which was adopted as of March 31, 2004, the Company required the audited financial statements of MSD to complete its Form 10-K. The Company was not able to file its Form 10-K on a timely basis because the MSD financial statements were not available and because the Company was unable to conclude on the appropriate accounting for MSD.

On July 14, 2004, the Company filed a second action with the Court against MSD, MST and Jacob Wohlstadter. The action alleged, among other things, breach of fiduciary duty and contract, and sought relief including the dissolution of MSD and the appointment of a liquidating trustee.

Also in July 2004, the Audit Committee retained an independent special counsel to investigate whether the Company's management had any prior knowledge of the real property and automobile transactions of MSD described above. This special counsel has completed its investigation and issued a report to the Audit Committee that there is no evidence that any member of the Company's management knew of the MSD transactions at issue before they occurred and before the Company learned of the MSD transactions at issue.

On July 16, 2004, the Company received a letter from the staff of the Nasdaq Listing Qualifications Department notifying the Company that its common stock was subject to delisting from The Nasdaq Stock Market, Inc. because the Company had not filed its Form 10-K for the period ending March 31, 2004.

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In accordance with applicable NASD Marketplace Rules, the Company requested a hearing to review the Nasdaq staff determination before a Nasdaq Listing Qualifications Panel, which hearing was held August 19, 2004. As a result of such request, the delisting of the Company's stock was automatically stayed and subsequent to the hearing, the Nasdaq Listing Qualifications Panel determined that the Company's common stock would continue to be listed on the Nasdaq National Market.

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On July 19, 2004, all members of the Board of Directors met to review the MSD litigation and related issues. This review included a consideration of the status of the litigation, as well as the effects of the disputes on us generally, including management's ability to conduct its business and to pursue its strategy and the notification from Nasdaq concerning possible delisting of its common stock as a result of its failure to file a Form 10-K on a timely basis. All members of the Board of Directors participated in this review, although some discussions were conducted by the independent directors without the management directors, Samuel J. Wohlstadter and Richard Massey or other members of management.

As a result of this review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee, or JVOC, the power and authority to (i) initiate, review, evaluate and determine the course of action the Company should pursue with respect to the pending litigation and any additional litigation against MSD, (ii) communicate and negotiate the terms of any proposed settlement of such litigations and any other matters with respect to MSD and (iii) otherwise deal with MSD in a manner the JVOC deemed to be in the best interests of the Company and its stockholders.

The resolution also appointed Messrs. Quinn and Crowley as additional members of the JVOC, resulting in the JVOC consisting of all five independent directors, and provided that action of the JVOC should be by unanimous approval of its members. The resolution also directed the JVOC to consult with management and members of the Board of Directors who are not on the JVOC regarding the MSD matters. In addition, by unanimous vote of the five independent directors without the participation of Messrs. Wohlstadter and Massey, the Board of Directors approved a resolution directing the JVOC to pursue negotiations to settle the litigation and other outstanding disputes with MSD, MST and Jacob Wohlstadter and setting forth general terms that would be acceptable for such a settlement.

Between July 19, 2004 and August 3, 2004, there were meetings, telephone conferences and other communications among representatives of the JVOC, MSD, MST and Jacob Wohlstadter to discuss the terms of a settlement. On July 21, 2004, the Company entered into an agreement with MSD, MST and Jacob Wohlstadter to stay the litigation during these negotiations. During this period the JVOC also communicated from time to time with management (other than Samuel Wohlstadter) concerning various aspects of the settlement. Members of management (other than Samuel Wohlstadter) also communicated directly with MSD, MST and Jacob Wohlstadter on particular aspects of the settlement.

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On August 3, 2004, the JVOC unanimously approved a draft settlement agreement. Following this approval, a telephone meeting of the full Board of Directors was held to review the status of the SEC investigation, the status of the Nasdaq notification regarding possible delisting, and proposed settlement. During this meeting, the management directors, who were previously provided with a copy of the draft settlement agreement, were invited to ask questions or give comments concerning the draft settlement agreement. The management directors informed the independent directors that they had no questions or comments.

On August 12, 2004, the parties entered into the settlement agreement. Under the settlement, the parties agreed to the following:

- o All proceedings relating to the two lawsuits against MSD, MST and Jacob Wohlstadter will be suspended and the parties will file with the Court stipulations dismissing the lawsuits with prejudice.
- o Except for claims to enforce the terms of the settlement and certain of the parties' indemnity and property rights, all claims we may have against MSD, MST and Jacob Wohlstadter or any of their affiliates are fully, finally and forever, dismissed and released with prejudice by the Company, and all claims MSD, MST and Jacob Wohlstadter may have against the Company or any of its affiliates are fully, finally and forever, dismissed and released with prejudice by them.
- o MSD or MST will purchase, and the Company will sell, its interests in MSD pursuant to the buyout process set forth in the MSD joint venture agreement, irrespective of the ultimate purchase price. The parties agreed to certain terms and procedures to determine the purchase price for the buyout, which will be paid over time from a percentage of net sales of MSD or proceeds of certain financings of MSD. MSD is required to provide written reports to the Company within 60 days after the end of each fiscal quarter stating its aggregate net sales (as defined in the MSD agreement) and the net proceeds, if any, realized by MSD during such quarter from the sales of MSD debt or equity securities in any third party financings (as defined in the MSD agreement). The Company also has the right to conduct an audit of such net sales or net proceeds, which will be our sole and exclusive remedy for resolving disputes as to the appropriate amount of payments.
- o Until the second anniversary of the purchase of the Company's interests, unless certain advance notice and approval requirements are met MSD will not purchase certain assets defined as real property that is used or contemplated to be used primarily for residential purposes, any automobile with a value, at the time of purchase, equal to or in excess of \$75,000, or any airplane. MSD may cure any alleged failure to comply with this restriction if it exchanges, contributes, disposes of or otherwise transfers the asset and receives consideration in return equal to the full net purchase price of such asset, and in no event is the company permitted to seek injunctive or declaratory relief.
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In consideration for the prior receipt by MSD of approximately \$2.9 million from Jacob Wohlstadter, MSD will transfer certain real property and automobiles and MSD's limited liability company interests in MSVE, LLC and MS RE, LLC to Jacob Wohlstadter or an entity or entities wholly owned by Jacob Wohlstadter. Jacob Wohlstadter also assumed MSD's obligation to purchase another residential property for \$4.1 million.

- o The Company's representative on the MSD Board of Managers will resign and the Company will execute an amendment to the MSD agreements to change the composition of the MSD Board of Managers to one person designated by MSD.
- o MSD provided the representation letters requested by its and the Company's auditors in connection with MSD's financial statements for the year ended December 31, 2003, concurrently with the execution of the settlement, and subsequently provided to the Company a copy of its audited financial statements for the year ended December 31, 2003. In addition, until such time as the Company is no longer required to consolidate or include the unaudited quarterly or audited annual financial results of MSD in its filings with the Securities and Exchange Commission, MSD will deliver to the Company, per the Company's request, copies of its unaudited and audited financial statements on a timely basis.
- o The Company will pay the fees of MSD's independent auditor in connection with the audit of MSD and will 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, the preparation of MSD financial statements requested by the Company, and with respect to regulatory or legal proceedings and investigations resulting from or related to the fact that the Company is a public company. The Company is not required to indemnify MSD for acts either resulting in a criminal conviction or finally adjudged by a court of competent jurisdiction to constitute fraud or intentional misrepresentation.
- o The Company will pay MSD the net amount of \$3.0 million in full and complete satisfaction of all amounts Jacob Wohlstadter claimed the Company owed MSD pursuant to the MSD agreements, including amounts owed by the Company pursuant to the license agreement between us and MSD and MST, the outstanding dispute regarding unsatisfied committed funding obligations and the outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with settlement of litigation involving Roche and IGEN. The Company's \$3.0 million payment is net of a \$2.0 million credit, which represents a non-refundable prepayment by MSD to the Company for future amounts payable by MSD to the Company pursuant to the buy-out of the Company's interest in MSD. The amount of the pre-payment credit outstanding from time to time shall bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases the Company's interests in MSD. The amount that is deemed outstanding is the total amount of the prepayment credit pursuant to the buyout, including accrued interest, reduced from time to time by the amounts due and payable to the Company pursuant to the buy-out of its interest in MSD. No further cash payments will be payable by MSD to the Company pursuant to the buyout until the \$2.0 million prepayment credit, including accrued interest, is no longer deemed outstanding. A total of \$5.0 million is to be treated as a Class C capital contribution by the Company to MSD. There is no assurance that the Company will be able to realize the value of this additional contribution.

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- o MSD's rent for the lease of certain facilities and related equipment from the Company (including laboratory facilities located in the Company's corporate headquarters) pursuant to the terms of the existing sublease agreements with MSD, for the period from March 1, 2004 through August 31, 2005, will be added into the price payable to the Company for the purchase of its interest in MSD, in lieu of current payments.
  - o In accordance with the terms of the original MSD agreements, subject to certain expectations, the Company consented to the sublicensing by MSD of the license granted pursuant to the IGEN/MSD license agreement to any affiliate of MSD. Any such sublicense is required to, among other things, make royalty payments to the Company in accordance with the IGEN/MSD license agreement.

The Company is involved, from time to time, in various routine legal proceedings arising out of the normal and ordinary operation of its business, which it does not anticipate will have a material adverse impact on its business, financial condition, results of operations or cash flows. However, the Company may in the future be involved in litigation relating to its business, products or intellectual property, which could adversely affect its prospects or impair its financial resources.

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

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This Management's Discussion and Analysis of Financial Condition and Results of Operations as of September 30, 2004, and for the three and six months ended September 30, 2004 and 2003, 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, 2004, 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 revenue growth, market acceptance of new products, business operations, trends and changes in financial or operating performance, technology or product plans. The words may, should, will, expect, could, anticipate, believe, estimate, plan, and 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.

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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. The following important factors are among those that may cause actual results to differ materially from our forward-looking statements:

- o changes in our strategy and business plan, including our plans for vaccines, the clinical diagnostics, biodefense, life science and industrial markets and other healthcare opportunities;
  - o our ability to develop and introduce new or enhanced products, including incorporating unit dose cartridges;
  - o our ability to enter into new collaborations on favorable terms, if at all;
  - o our ability to expand the distribution and increase sales of existing products;
  - o changes in customer demand, the timing of significant orders or the demand for rapid testing products in each of our markets;
  - o our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner, including the completion of pending negotiations for contract manufacturing of one of our instruments;
  - o our ability to develop our selling, marketing and distribution capabilities;
  - o our and our licensees' ability to obtain FDA and other governmental approvals for our and their clinical testing products or for vaccine products, including regulatory changes, uncertainties or delays;
  - o the ability of our licensees to effectively develop and market products based on the technology we license to them;
  - o domestic and foreign governmental and public policy changes, particularly related to healthcare costs, that may affect new investments and purchases made by our customers;
  - o competition from companies with greater financial and capital resources than ours;
  - o availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;
  - o rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective manner;
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- o any potential future disputes regarding the scope, permitted use and other material terms of our license agreements, including those with MSD;

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- o the outcome of the litigation and arbitration commenced against Roche Holding Ltd, which we refer to in this Form 10-Q as Roche, by Applera Corporation and its affiliate Applied Biosystems, which we refer to in this Form 10-Q as Applied Biosystems;
- o protection and validity of our patent and other intellectual property rights and the scope of third party patent rights;
- o relationships between us and certain companies with which we are affiliated; and
- o changes in general economic, business and industry conditions.

These forward-looking statements are found at various places throughout this quarterly report. 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. The foregoing list sets forth some, but not all, of the factors that could have an impact upon our ability to achieve results described in any forward-looking statements. Investors are cautioned not to place undue reliance on such statements that speak only as of the date made. Investors also should understand that it is not possible to predict or identify all such factors and that this list should not be considered a complete statement of all potential risks and uncertainties. Investors should also realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from our projections.

As directed by Section 404 of the Sarbanes Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on our internal controls over financial reporting in our annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. This requirement will first apply to our Annual Report on Form 10-K for the fiscal year ending March 31, 2005. How companies should be implementing these new requirements including internal control reforms, if any, to comply with Section 404's requirements, and how independent auditors will apply these new requirements and test companies' internal controls, are subject to uncertainty. Although we are diligently and vigorously reviewing our internal controls over financial reporting in order to ensure compliance with the new Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. If our independent auditors are not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management's assessment or may issue a report that is qualified.

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

### *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.

Our products are designed to be sold in the worldwide diagnostics markets, including:

*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 are best 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.

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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 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 already being 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 governmental and military organizations around the world, as well as in public health.

We are also selling two types of M-SERIES instruments for life science research to pharmaceutical and biotechnology researchers, as well as to scientists at academic and government research institutions. Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the immunoreactivity of protein-based therapeutics and we have recently introduced proprietary products for immunogenicity testing. 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. It has become increasingly necessary to detect an immune response to protein-based drugs by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events.

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Our M-SERIES product line for the life science market is believed 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 are also expanding our business model to target the fields of vaccines and vaccination services. In conjunction with our efforts to determine an individual's personal immune status through a unique diagnostic test panel, we have entered into an exclusive option agreement with Children's Hospital & Research Center at Oakland (CHRCO) for the right to negotiate 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.

Results of operations in the future are likely to fluctuate substantially from quarter to quarter as a result of various factors, which include:

- o the volume and timing of orders and product deliveries for biodefense products, M-SERIES systems or other products, which orders and deliveries are based on our customers' requirements that may vary over time;
- o the success of M-SERIES system upgrades and enhancements, which upgrades and enhancements involve increased product costs at the time of the upgrade or enhancement, and customer acceptance of those enhancements and upgrades;
- o costs incurred related to expansion into the fields of vaccines and vaccines services;
- o the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;
- o whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;
- o the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;

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- o 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;
- o 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;
- o the amount of expenses we incur in connection with the operation of our business, including:
  - o research and development costs, which increases or decreases based on the product in development; and
  - o sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time;
- o the amount that we will record each quarter related to the amortization or impairment of the license to use PCR technology, which may increase based on the outcome of the litigation and arbitration commenced against Roche by Applied Biosystems relating to Roche's and Applied Biosystems' respective rights to PCR technology;
- o 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;
- o MSD's financial results, which for the three and six months ended September 30, 2004, included losses of \$5.2 million and \$10.3 million, respectively;
- o additional costs which we may incur as we explore new health care opportunities, including costs for acquisitions of technologies, facilities and personnel.

We expect to incur additional operating losses as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs, and the net losses of MSD through the date of the sale of our interests in MSD, which is expected to occur in December 2004. 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.

### *Roche and IGEN Transaction*

On February 13, 2004, IGEN and Roche completed the merger and related transactions pursuant to which Roche acquired IGEN and IGEN simultaneously distributed shares of our common stock to its stockholders. The transaction occurred in the following steps:

- o IGEN restructured its operations so that we, a 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 MSD, cash and certain other rights and licenses currently held by IGEN; and
- o 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 we became an independent, publicly-traded company. Simultaneously with the completion of the merger, certain ongoing commercial agreements between certain affiliates of Roche and us became effective.

Prior to February 13, 2004, our assets and businesses were owned and operated by IGEN. Our financial statements have been prepared and are presented as if we had been operating as a separate entity in periods prior to February 13, 2004, using the historical cost basis in the assets and liabilities of IGEN and including the historical operations of businesses and assets transferred to us from IGEN as part of the merger and related transactions.

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### *Investment in MSD*

MSD is 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 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.

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 the quarter and six months ended September 30, 2004, increased significantly.

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 will purchase, and we will 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. As of August 12, 2004, the book value of our interests in MSD, as recorded in the investment in joint venture account on our unconsolidated balance sheet, was greater than the fair market value purchase price of these interests determined by the appraisal process.

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Accordingly, during the quarter ended September 30, 2004, we recorded a non-cash charge of \$33.9 million as other expense, representing the amount by which the book value of our interests in MSD exceeded the fair market value purchase price.

MSD or MST will be 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 \$2.0 million prepayment credit, including accrued interest, is no longer deemed outstanding.

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 MSD or MST, as the case may be, for the purchase of our interests in MSD.

For a more complete description of this purchase obligation and the MSD agreements, see ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 3, Meso Scale Diagnostics Joint Venture and Note 4, Litigation.

In June and July 2004, we commenced legal actions against MSD, MST and Jacob Wohlstadter in the Court of Chancery in the State of Delaware that were prompted by the discovery of a series of actual and proposed transactions undertaken by MSD without our knowledge. These lawsuits were settled in August 2004. For a more complete description of the lawsuits and related settlement, see ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 4, Litigation for a more complete description of the lawsuits and the related settlement.

For a more detailed description of our business, you should refer to our Annual Report on Form 10-K for the year ended March 31, 2004, filed with the SEC.

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## Supplemental Consolidated Balance Sheet Data (1) :

	<b>September 30, 2004</b>		<b>March 31, 2004</b>		
	<b>BioVeris and Wholly-Owned Subsidiaries</b>	<b>BioVeris and Wholly-Owned Subsidiaries</b>	<b>MSD</b>	<b>Consolidating Eliminations</b>	<b>Consolidated BioVeris</b>
	<i>(In thousands, except per share data)</i>				
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 20,694	\$ 147,398	\$ 35,111	\$ --	\$ 182,509
Short term investments	88,333	--	--	--	--
Accounts receivable, net	6,235	3,417	2,099	--	5,516
Inventory	5,120	5,013	3,194	--	8,207
Other current assets	3,250	2,459	2,053	(180)	4,332
	<u>123,632</u>	<u>158,287</u>	<u>42,457</u>	<u>(180)</u>	<u>200,564</u>
Equipment and leasehold improvements, net	4,254	5,472	7,362	(269)	12,565
Investment in joint venture	7,694	46,208	--	(46,208)	--
Technology licenses	18,281	19,256	10	--	19,266
Other	354	354	65	--	419
	<u>\$ 154,215</u>	<u>\$ 229,577</u>	<u>\$ 49,894</u>	<u>\$ (46,657)</u>	<u>\$ 232,814</u>
<b>Liabilities and Stockholders Equity</b>					
Current Liabilities:					
Accounts payable and accrued expenses	\$ 7,814	\$ 26,220	\$ 3,067	\$ (180)	\$ 29,107
Other current liabilities	1,725	1,977	296	--	2,273
	<u>9,539</u>	<u>28,197</u>	<u>3,363</u>	<u>(180)</u>	<u>31,380</u>
Noncurrent deferred revenue	1,869	54	--	--	54
	<u>11,408</u>	<u>28,251</u>	<u>3,363</u>	<u>(180)</u>	<u>31,434</u>
Minority interest	--	--	--	54	54
Series B preferred stock	7,500	7,500	--	--	7,500
Stockholders Equity:					
Common stock	27	27	--	--	27
Additional paid-in capital	203,464	203,464	116,707	(116,707)	203,464
Accumulated deficit	(68,134)	(9,665)	(70,176)	70,176	(9,665)
Accumulated other comprehensive income (loss)	(50)	--	--	--	--
	<u>135,307</u>	<u>193,826</u>	<u>46,531</u>	<u>(46,531)</u>	<u>193,826</u>
Total liabilities and stockholders equity	<u>\$ 154,215</u>	<u>\$ 229,577</u>	<u>\$ 49,894</u>	<u>\$ (46,657)</u>	<u>\$ 232,814</u>

## Supplemental Consolidated Statements of Operations Data (1):

	Quarter Ended September 30,2003		Quarter Ended September 30, 2004		
	BioVeris and Wholly-Owned Subsidiaries	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales	\$ 5,618	\$ 6,228	\$ 1,006	\$ --	\$ 7,234
Royalty income	297	315	--	--	315
Contract fees	36	12	290	--	302
Total	5,951	6,555	1,296	--	7,851
Operating costs and expenses:					
Product costs	3,340	2,185	1,353	--	3,538
Research and development	5,020	4,559	1,023	(30)	5,552
Selling, general and administrative	4,408	7,551	1,400	--	8,951
Total operating costs and expenses	12,768	14,295	3,776	(30)	18,041
Loss from operations	(6,817)	(7,740)	(2,480)	30	(10,190)
Other, net	(32)	1,187	36	--	1,223
Equity in loss of joint venture	(4,450)	(5,165)	--	2,414	(2,751)
Loss on joint venture impairment	--	(33,900)	--	--	(33,900)
Net loss	\$ (11,299)	\$ (45,618)	\$ (2,444)	\$ 2,444	\$ (45,618)
Net loss per common share (basic and diluted)	\$ (0.42)	\$ (1.71)	\$ (0.09)	\$ 0.09	\$ (1.71)
Shares used in computing net loss per common share (basic and diluted)	26,728	26,728	26,728	26,728	26,728

**Supplemental Consolidated Statements of Operations Data (1):**

	Six Months Ended September 30,2003		Six Months Ended September 30, 2004		
	BioVeris and Wholly-Owned Subsidiaries	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales	\$ 10,414	\$ 11,114	\$ 3,959	\$ --	\$ 15,073
Royalty income	540	635	--	--	635

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	<b>Six Months Ended</b>				
Contract fees	70	32	356	--	388
<b>Total</b>	<b>11,024</b>	<b>11,781</b>	<b>4,315</b>	<b>--</b>	<b>16,096</b>
Operating costs and expenses:					
Product costs	5,773	4,449	3,693	--	8,142
Research and development	10,252	9,120	3,705	(97)	12,728
Selling, general and administrative	9,184	14,159	4,502	--	18,661
<b>Total operating costs and expenses</b>	<b>25,209</b>	<b>27,728</b>	<b>11,900</b>	<b>(97)</b>	<b>39,531</b>
Loss from operations	(14,185)	(15,947)	(7,585)	97	(23,435)
Other, net	48	1,537	80	--	1,617
Equity in loss of joint venture	(9,680)	(10,159)	--	7,408	(2,751)
Loss on joint venture impairment	--	(33,900)	--	--	(33,900)
<b>Net loss</b>	<b>\$ (23,817)</b>	<b>\$ (58,469)</b>	<b>\$ (7,505)</b>	<b>\$ 7,505</b>	<b>\$ (58,469)</b>
Net loss per common share (basic and diluted)	\$ (0.89)	\$ (2.19)	\$ (0.28)	\$ 0.28	\$ (2.19)
Shares used in computing net loss per common share (basic and diluted)	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. Prior to the adoption of FIN 46 on March 31, 2004, including for the three and six months ended September 30, 2003, we did not consolidate MSD's financial results.

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 will account for this investment using the equity method through the date of the sale of our interests in MSD, which is expected to occur in December 2004.

### Results of Operations

#### Three and Six Months Ended September 30, 2004 and 2003

During the three and six months ended September 30, 2004, MSD's results of operations for the period from April 1, 2004 through August 12, 2004 are consolidated with the results of operations of BioVeris and its wholly-owned subsidiaries.

**Revenues.** Our consolidated revenues for the three months ended September 30, 2004 increased by approximately 32% to \$7.9 million from \$6.0 million in the corresponding prior year period. Of this \$1.9 million increase, \$1.3 million represents MSD revenues. Our consolidated revenues for the six months ended September 30, 2004 increased by approximately 46% to \$16.1 million from \$11.0 million in the corresponding prior year period. Of this \$5.1 million increase, \$4.3 million represents MSD revenues.

Our consolidated product sales were \$7.2 million for the three months ended September 30, 2004, an increase of 29% from \$5.6 million in the corresponding prior year period. Of this \$1.6 million increase, \$1.0 million was due to the consolidation of MSD's product sales. Our consolidated product sales were \$15.1 million for the six months ended September 30, 2004, an increase of 45%, from \$10.4 million in the corresponding prior year period. Of this \$4.7 million increase \$4.0 million represents MSD product sales.

BioVeris's sales of biodefense products for the three months ended September 30, 2004 were \$3.9 million, an increase of \$1.9 million, or 97%, over the corresponding prior year period. Sales of biodefense products for the six months ended September 30, 2004 were \$6.1 million, an increase of \$2.7 million, or 79%, over the corresponding prior year period. Sales of biodefense products for the three and six months ended September 30, 2004 included a \$1.3 million sale to the U.S. Air Force under a single order. Sales of products for the life science market were \$2.3 million for the three months ended September 30, 2004, a decrease of \$1.3 million from the corresponding prior year period. Sales of

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products for the life science market were \$5.0 million for the six months ended September 30, 2004, a decrease of \$2.0 million from the corresponding prior year period. These changes in product sales for the three and six months ended September 30, 2004 reflect the change of orders and product deliveries for biodefense and life science products, which orders and deliveries are based on our customers' requirements.

We anticipate continuing increases in biodefense-related sales as a result of our ongoing biodefense initiatives. As part of the merger and related transactions, we assumed a contract between IGEN and 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. As of September 30, 2004, the DOD had purchased approximately \$5.0 million of products during the first fifteen months of the contract. 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.** Our consolidated product costs were \$3.5 million (49% of total product sales) for the three months ended September 30, 2004 compared to \$3.3 million (59% of total product sales) in the corresponding prior year period. The total increase of \$200,000 for the current quarter consists of \$1.4 million due to the consolidation of MSD's product costs, offset by a \$1.2 million reduction in BioVeris costs. Consolidated product costs were \$8.1 million (54% of total product sales) for the six months ended September 30, 2004 compared to \$5.8 million (55% of total product sales) for the corresponding prior year period. The current six month increase of \$2.3 million consists of \$3.7 million due to the consolidation of MSD's product costs, offset by a \$1.4 million reduction in the Bioveris's costs.

BioVeris's product costs, as a percentage of total product sales, decreased due to reduced costs incurred in connection with instrument upgrades and detection module upgrades for existing life science customers. These voluntary upgrades occurred in the prior year and were provided to enhance overall customer satisfaction. The instrument and detection module upgrade programs were substantially completed as of December 31, 2003. 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.

Our consolidated research and development expenses increased 11% to \$5.6 million for the three months ended September 30, 2004 from \$5.0 million in the corresponding prior year period. The increase of \$600,000 for the current quarter consists of \$1.0 million due to the consolidation of MSD's research and development expenses, offset by a \$400,000 reduction in BioVeris's costs. Consolidated research and development expenses increased 24% to \$12.7 million for the six months ended September 30, 2004 from \$10.3 million in the corresponding prior year period. The increase of \$2.4 million for the six month period consists of \$3.7 million due to the consolidation of MSD's research and development expenses, offset by a \$1.3 million reduction in BioVeris's costs.

BioVeris's research and development expenses decreased in the current year periods due primarily to reduced personnel and facilities 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 developing clinical diagnostics and biodefense testing products, including development of a proprietary approach for determining an individual's personal immune status through a unique diagnostic test panel.

We are expanding our business model to target the fields of vaccines and vaccination services which will require substantial research and development expenditures. For example, we have entered into an exclusive option agreement with Children's Hospital & Research Center at Oakland (CHRCO) for the right to negotiate for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. The option agreement contemplates that we will sponsor up to \$800,000 of research at CHRCO over a two-year period and make additional payments for license and milestones fees for initiating and completing human clinical trials and receiving regulatory approvals.

Our selling, general and administrative expenses were \$9.0 million for the three months ended September 30, 2004, compared to \$4.4 million in the corresponding prior year period. Of this \$4.6 million increase, \$1.4 million represents MSD's selling, general and administrative expenses which were consolidated for the first time during the current year. Selling, general and administrative expenses were \$18.7 million for the six months ended September 30, 2004, compared to \$9.2 million for the corresponding prior year period. Of this \$9.5 million increase, \$4.5 million represents MSD's selling, general and administrative expenses which were consolidated for the first time during the current year.

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BioVeris's increase in selling, general and administrative expenses of approximately \$3.2 million and \$5.0 million for the three and six months ended September 30, 2004, respectively, was primarily attributable to higher personnel costs and professional fees in the current periods, including costs associated with our litigation and settlement with MSD. Until the completion of the merger and related transactions on February 13, 2004, we were fully integrated with IGEN and the accompanying consolidated financial statements reflect the application of certain estimates and allocations. For periods prior to February 13, 2004, our consolidated statements of operations include all revenues and costs that were directly attributable to our businesses. In addition, certain expenses of IGEN were allocated to us using various assumptions that, in the opinion of management, are reasonable. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue, or percentage of total headcount, or estimates of actual time spent on businesses, as appropriate. These allocated expenses comprise all of our selling, general and administrative expenses for the three and six months ended September 30, 2003.

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

**Other Income, Net.** Interest income, net of interest and other expense, was \$1.2 million and \$1.6 million for the three and six months ended September 30, 2004, respectively. Prior to the completion of the merger and related transactions, IGEN held all cash in a centralized treasury and provided all of the necessary funding for the operations of BioVeris. Accordingly, prior to February 13, 2004, no cash, cash equivalents or short-term investments were held by us and no interest income was generated. During the quarter ended September 30, 2004, we also recorded a \$400,000 non-cash credit to other income representing a reduction in the value of MSD's option to purchase our interests in MSD.

**Loss on Joint Venture Impairment.** As of August 12, 2004, the book value of our interests in MSD, as recorded in the investment in joint venture account on our unconsolidated balance sheet, was greater than the fair market value purchase price of these interests determined by the appraisal process. Accordingly, during the quarter ended September 30, 2004, we recorded a non-cash charge of \$33.9 million as loss on joint venture impairment, representing the amount by which the book value of our interests in MSD exceeded the fair market value.

**Equity in Loss of Joint Venture.** 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. The August 12, 2004 settlement agreement between the parties has been determined to constitute a reconsideration event under FIN 46 and 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, we have consolidated the financial results of MSD as of March 31, 2004 and for the period from April 1, 2004 through August 12, 2004, and beginning August 13, 2004, we have deconsolidated the financial results of MSD.

For the period from August 13, 2004 through September 30, 2004, we recorded our proportionate share of MSD losses, representing approximately 100% of MSD's losses totaling \$2.8 million, as equity in loss of joint venture consistent with accounting for equity method investments. For the three and six months ended September 30, 2003, we recorded \$4.5 million and \$9.7 million, respectively.

**Net Loss.** The net loss for the three months ended September 30, 2004 was \$45.6 million (\$1.71 per common share) compared to a net loss of \$11.3 million (\$0.42 per common share) for the three months ended September 30, 2003. The net loss for the six months ended September 30, 2004 was \$58.5 million (\$2.19 per common share) compared to a net loss of \$23.8 million (\$0.89 per common share) for the six months ended September 30, 2003. The increase in the net loss is primarily caused by the non-cash charge of \$33.9 million representing the amount by which the book value of our interests in MSD exceeded the fair market value purchase price, and operating expenses exceeding our revenues.

### *Liquidity and Capital Resources*

Our consolidated balance sheet at September 30, 2004 had cash, cash equivalents and short-term investments of \$109.0 million.

Net cash used for operations was \$20.0 million and \$12.7 million for the six months ended September 30, 2004 and 2003, respectively. The increase in cash used for operations in the current year primarily resulted from a higher net loss.

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We used approximately \$1.1 million and \$939,000 of cash for the acquisition of equipment and leasehold improvements during the six months ended September 30, 2004 and 2003, respectively.

Our investment contributions to MSD totaled \$5.0 million (\$3.0 million in cash and a \$2.0 million non-refundable pre-payment by MSD to us for future amounts payable by MSD to us pursuant to the buy-out of our interest in MSD) and \$15.3 million during the six months ended September 30, 2004 and 2003, respectively.

We believe that material commitments for capital expenditures and additional or expanded facilities may be required in a variety of areas, such as product development programs. We are evaluating additional facilities for manufacturing and other corporate uses and are negotiating to secure new space, which if concluded, would result in additional facilities costs. We have not, at this time, made material commitments for any such capital expenditures or facilities and have not secured additional sources, if necessary, to fund such commitments.

As of September 30, 2004, our material future obligations, consisting of operating leases were as follows:

<b><u>Years Ended March 31,</u></b>		<b><u>Operating Lease Payments (in thousands)</u></b>
2005	\$	1,591
2006		3,164
2007		3,241
2008		3,338
2009		3,333
2010 and Thereafter		2,395
Total	\$	17,062

Under the MSD agreements, IGEN's funding commitment was based on an annual budget of MSD approved by the JVOC. The JVOC approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of 15%, of which approximately \$19.1 million was spent by MSD and funded by us. MSD asserted that we were obligated to pay MSD up to an additional \$4.6 million, which is the difference between the amount spent by MSD and the budgeted amount plus the permitted variance. As part of the settlement, we agreed to pay MSD the net amount of \$3.0 million which represents full and complete satisfaction of amounts due to MSD pursuant to the MSD agreements, including this dispute regarding unsatisfied committed funding obligations. Our \$3.0 million payment is net of a \$2.0 million non-refundable pre-payment by MSD to us for future amounts payable by MSD to us pursuant to the buy-out of our interest in MSD. A total of \$5.0 million was treated as a Class C capital contribution during the quarter ended September 30, 2004. The amount of the pre-payment 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 in effect on the date that MSD or MST, as the case may be, purchases our interests in MSD.

The amount of the prepayment credit that is deemed outstanding is the total amount, including accrued interest, reduced from time to time by the amount due and payable to us pursuant to the buy-out of our interest in MSD.

No further cash payments will be payable by MSD to us until the \$2.0 million prepayment credit, including accrued interest, is utilized. In the event sufficient net sales or third-party financings do not materialize, we will not receive any additional payments from MSD or MST, as the case may be, for the purchase of our interests in MSD. As security for the payment obligation, we will hold a security interest in the interests in MSD that are being purchased. MST or MSD, as the case may be, may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

For the quarter and six months ended September 30, 2003, total contributions to MSD were \$5.0 million and \$15.3 million, respectively. The 2003 funding commitment was satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. In accordance with the MSD joint venture agreement, the value of these in-kind contributions is based upon costs incurred by us as determined through allocation methods that include time-spent and square footage utilized. During the quarter ended June 30, 2003, operating costs allocated to MSD in connection with shared personnel and facilities totaled \$2.0 million. There were no operating costs allocated to MSD during the quarter and six months ended September 30, 2004. In August 2004, we made payments to MSD in connection with the settlement as described in the preceding paragraph.

We have no intention to provide additional funding to MSD except that we agreed to pay MSD certain amounts in the August 2004 settlement with respect to certain of its liabilities. See ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 4 Litigation .

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Product development for our clinical diagnostic products is at an early development stage and products based on the PCR technology being licensed from Roche are not yet under development. 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 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, including products based on PCR technology, 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. In this regard, 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.

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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 September 30, 2004, we had no special purpose entities.

### **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 policies include:

*Expense Allocations* Prior to February 13, 2004, our assets and businesses were owned, operated and fully integrated with IGEN. Our financial statements have been prepared and are presented as if we had been operating as a separate entity during the periods shown. In order to fairly present our operating results, these financial statements reflect the application of certain estimates and allocations for periods prior to February 13, 2004. For such periods, our consolidated statements of operations include all costs that were directly attributable to our businesses, as well as certain expenses of IGEN that were allocated to us using various assumptions.

These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue or percentage of total headcount, as appropriate. While management believes that the allocation methodologies are reasonable and appropriate, different allocation methodologies could result in changes to our operating results.

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

Product sales revenue is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21 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, 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.

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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.

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For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21. Revenue is recognized for the instrument upon shipment or delivery, depending on the terms of each order, and is recognized for the installation when complete based upon the residual value method. For instrument and reagent sales, there is no option of return and refund, only the option to repair or replace.

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

Revenue from services performed under contracts is recognized when obligations under the contract have been satisfied. The satisfaction of obligations may occur over the term of the underlying customer contract, if the contract is based on the achievement of certain milestones, or may occur at the end of the underlying customer contract, if based only upon delivery of the final work product. The majority of our product sales and contract fees contain standard terms and conditions. Certain transactions may contain negotiated terms that require contract interpretation to determine the appropriate amount of revenue to be recognized.

In addition, we must assess whether collectibility is reasonably assured. While management believes its interpretations and judgments are reasonable, different assumptions could result in changes in the timing of revenue recognition.

*Joint Venture Accounting* For periods prior to March 31, 2004 and for the period from August 13, 2004 through September 30, 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 have less than 50% of the voting equity interest in MSD; that we do not have exclusive authority over MSD decision making and have 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 (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 3 Meso Scale Diagnostics Joint Venture.

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In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, 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:

- o We have provided substantially all of MSD's funding since inception through capital contributions consisting of class B and C non-voting equity interests. Such funding is not considered at risk as the investments do not participate significantly in the profits of MSD given their stated return rates. As such, the at risk equity of MSD is insufficient to absorb MSD's expected future losses.
- o We hold 31% of the voting rights in MSD while providing 100% of MSD's funding, and are thereby considered to be involved in all of MSD's activities as defined under FIN 46.

Accordingly, beginning 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 have 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



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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 will account for this investment using the equity method through the date of the sale of our interests in MSD, which is expected to occur in December 2004.

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. Accordingly, our balance sheet as of September 30, 2004 records the net assets of MSD 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.

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Accordingly, the statement operations for the quarter ended September 30, 2004 includes the consolidated revenue and expenses of MSD for the period from July 1, 2004 through August 12, 2004, and reflects MSD's net losses for the period from August 13, 2004 through September 30, 2004 as equity in loss of joint venture, consistent with accounting for equity method investments.

The statement of operations for the six months ended September 30, 2004 includes the consolidated revenues and expenses of MSD for the period from April 1, 2004 through August 13, 2004, and reflects MSD's net losses for the period from August 13, 2004 through September 30, 2004 as equity in loss of joint venture.

*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. During the three months ended September 30, 2004, we recorded a loss from the impairment of the joint venture which resulted in a non-cash charge of \$33.9 million. Calculating the net present value of future payments that the Company expects to realize from MSD 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 September 30, 2004.

*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.

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### Recent Accounting Pronouncements

See discussion of FIN 46, Consolidation of Variable Interest Entities, under Critical Accounting Policies above.

### ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Prior to the completion of the merger and related transactions on February 13, 2004, our assets and businesses were owned and operated by IGEN. IGEN held all cash in a centralized treasury and provided all of the necessary funding for our operations. Accordingly, no cash is reflected on our consolidated balance sheets prior to February 13, 2004.

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 September 30, 2004 had cash, cash equivalents and short-term investments of \$109.0 million which is approximately 58% 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

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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 September 30, 2004, we had invested \$88.3 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 September 30, 2004, a 1% basis point movement in interest rates would have an approximately \$1 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

We, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-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 our disclosure controls and procedures provide reasonable assurance that information relating to our company required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the relevant SEC rules and forms.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or internal controls 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. 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.

In addition, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has determined that there was no change in our internal control over financial reporting that occurred during the second quarter of fiscal 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

### ITEM 1 LEGAL PROCEEDINGS

Information regarding legal proceedings involving the Company appears in Part I ITEM 1 of this report under Note 4 to the Condensed Consolidated Financial Statements, which information is incorporated herein by reference.

### ITEM 6: EXHIBITS

Exhibit No.

10.1 Governance Committee Charter

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: November 15, 2004

/s/George V. Migausky

George V. Migausky  
Vice President of Finance and  
Chief Financial Officer

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