

BIOVERIS CORP  
Form 10-Q  
August 17, 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 June 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  X  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes   No  X

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

<u>Class</u>	<u>Outstanding at July 30, 2004</u>
Common Stock, \$0.001 par value	26,728,070



**BioVeris Corporation**  
**Form 10-Q**  
**For the Quarter Ended June 30, 2004**

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**ITEM 1: CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**BioVeris Corporation**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	<b>June 30, 2004 Unaudited</b>	<b>March 31, 2004</b>
	<u>                    </u>	<u>                    </u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 62,237	\$182,509
Short term investments	89,739	
Accounts receivable, net	6,289	5,516
Inventory	8,319	8,207
Other current assets	5,722	4,332
	<u>                    </u>	<u>                    </u>
Total current assets	172,306	200,564
Equipment and leasehold improvements, net	11,658	12,565
<b>OTHER NONCURRENT ASSETS:</b>		
Technology licenses	18,778	19,266
Other	419	419
	<u>                    </u>	<u>                    </u>
<b>TOTAL ASSETS</b>	<b>\$203,161</b>	<b>\$232,814</b>
	<u>                    </u>	<u>                    </u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 7,051	\$ 7,187
Accrued wages and benefits	2,212	1,876
Other liabilities	2,920	
Distribution gain accrual		20,000
Deferred revenue	2,349	2,273
Note payable		44
	<u>                    </u>	<u>                    </u>
Total current liabilities	14,532	31,380
	<u>                    </u>	<u>                    </u>
<b>NONCURRENT LIABILITIES</b>	<b>69</b>	<b>54</b>
	<u>                    </u>	<u>                    </u>
Total liabilities	14,601	31,434

COMMITMENTS		
MINORITY INTEREST	54	54
SERIES B PREFERRED STOCK, 1,000 shares designated, issued and outstanding	7,500	7,500
STOCKHOLDERS EQUITY:		
Preferred stock, par value \$0.01 per share, 15,000,000 shares authorized, issuable in series:		
Series A, 600,000 shares designated, none issued		
Common stock, par value \$0.001 per share, 100,000,000 shares authorized, 26,728,000 shares issued and outstanding	27	27
Additional paid-in capital	203,464	203,464
Accumulated deficit	(22,516)	(9,665)
Accumulated other comprehensive income	31	
	<u>181,006</u>	<u>193,826</u>
Total stockholders equity	181,006	193,826
	<u>\$203,161</u>	<u>\$232,814</u>
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$203,161	\$232,814

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>June 30, 2004</b>	<b>June 30, 2003</b>
REVENUES:		
Product sales	\$ 7,839	\$ 4,796
Royalty income	320	243
Contract fees	86	34
	8,245	5,073
OPERATING COSTS AND EXPENSES:		
Product costs	4,604	2,433
Research and development	7,176	5,232
Selling, general, and administrative	9,710	4,776
	21,490	12,441
LOSS FROM OPERATIONS	(13,245)	(7,368)
OTHER, NET	394	80
EQUITY IN LOSS OF JOINT VENTURE		(5,230)
	(12,851)	(12,518)
NET LOSS	\$ (12,851)	\$ (12,518)
Net loss per common share (Basic and Diluted)	\$ (0.48)	\$ (0.47)
COMMON SHARES OUTSTANDING (Basic and Diluted)	26,728	26,728

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

**BioVeris Corporation**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
**Unaudited**

	<b>Three months ended</b>	
	<b>June 30, 2004</b>	<b>June 30, 2003</b>
	<u>          </u>	<u>          </u>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (12,851)	\$(12,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,011	852
Loss on disposal of equipment	34	
Equity in loss of joint venture		5,230
Expense related to stock options		89
Changes in assets and liabilities:		
Increase(decrease) in accounts receivable	(773)	735
Increase (decrease) in inventory	(35)	118
(Increase) decrease in other current assets	(1,390)	457
Increase (decrease) in accounts payable and accrued expenses	156	(1,652)
Increase in other liabilities	2,920	
Increase (decrease) in deferred revenue	91	(27)
	<u>          </u>	<u>          </u>
Net cash used in operating activities	(9,837)	(6,716)
	<u>          </u>	<u>          </u>
<b>INVESTING ACTIVITIES:</b>		
Expenditures for equipment and leasehold improvements	(727)	(799)
Purchase of short term investments	(89,708)	
Investments in joint venture		(10,909)
	<u>          </u>	<u>          </u>
Net cash used in investing activities	(90,435)	(11,708)
	<u>          </u>	<u>          </u>
<b>FINANCING ACTIVITIES:</b>		
Payment of distribution gain	(20,000)	
Cash contributed by Parent, net		18,424
	<u>          </u>	<u>          </u>
Net cash (used in) provided by financing activities	(20,000)	18,424
	<u>          </u>	<u>          </u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	(120,272)	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	182,509	
	<u>          </u>	<u>          </u>



CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 62,237	\$
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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:

IGEN restructured its operations so that the Company, a newly formed, wholly-owned subsidiary of IGEN at the time, assumed IGEN's biodefense, life science and industrial product lines as well as IGEN's opportunities in the clinical diagnostics and healthcare fields and the ownership of IGEN's intellectual property, IGEN's equity interest in Meso Scale Diagnostics, LLC. (MSD), cash and certain other rights and licenses currently held by IGEN; and

A wholly-owned subsidiary of Roche merged with and into IGEN, as a result of which IGEN became a wholly-owned subsidiary of Roche and the Company became an independent, publicly-traded company. Simultaneously with the completion of the merger, certain ongoing commercial agreements between the Company and certain affiliates of Roche became effective.

The Company was organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted into BioVeris Corporation, a newly formed Delaware corporation on September 22, 2003.

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 quarter ended June 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 statement of operations for the quarter ended June 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. 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 \$4.8 million are included in selling, general and administrative expenses in the accompanying consolidated statements of operations for the three months ended June 30, 2003. These allocated expenses were derived from total IGEN selling, general and administrative expenses of \$6.1 million.

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 months ended June 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 quarter ended June 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 month periods ended June 30, 2004 and 2003, and the Company's financial position at June 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 for the year ended March 31, 2004 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. In addition, the Company adopted FIN 46 as of March 31, 2004 and has determined that MSD (a joint venture formed in 1995 by IGEN and Meso Scale Technologies, LLC., or MST, which is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of the Company's chief executive officer), qualifies as a variable interest entity and the Company is the primary beneficiary. Accordingly, beginning March 31, 2004, the Company has consolidated the financial results of MSD.

All significant intercompany transactions and balances have been eliminated.

Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, the Company has measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests are 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 balance sheet reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses. The statement of operations reclassified amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses.

*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.

The Company's consolidated balance sheet at June 30, 2004 had cash, cash equivalents and short-term investments of \$152.0 million. Of this amount, \$32.1 million represented the cash, cash equivalents and short-term investments of MSD. The Company has no rights or access to these funds or any other capital resources of MSD. The amount of cash, cash equivalents and short-term investments to which the Company and its wholly-owned subsidiaries have unrestricted use is \$119.9 million at June 30, 2004.

*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 June 30, 2004, the Company had unrealized gains on available for sale securities of approximately \$31,000. 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 quarter ended June 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 June 30, 2004:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	\$20,203	\$ 26	\$ 9	\$20,220
Municipal Bonds	44,850			44,850
U.S. corporate debt	24,655	23	9	24,669
	\$89,708	\$ 49	\$ 18	\$89,739

*Concentration of Credit Risk* The Company has not experienced any losses on its investments due to credit risk. During the quarters ended June 30, 2004 and 2003, agencies of the U.S. government accounted for 25% and 21% of total revenue, respectively, and 23% and 26% of total accounts receivable as of June 30 and March 31, 2004, respectively. Additionally, one customer accounted for 11% of revenues for the quarter ended June 30, 2004 and 21% of accounts receivable as of June 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.

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

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	June 30, 2004	March 31, 2004
	<u>                    </u>	
	(in thousands)	
<i>BioVeris and Wholly-Owned Subsidiaries:</i>		
Finished Goods	\$1,972	\$1,740
Work in process	624	619
Raw materials	2,265	2,654
	<u>                    </u>	<u>                    </u>
Total	4,861	5,013
	<u>                    </u>	<u>                    </u>
<i>MSD:</i>		
Finished Goods	1,595	757
Work in process	608	366
Raw materials	1,255	2,071
	<u>                    </u>	<u>                    </u>
Total	3,458	3,194
	<u>                    </u>	<u>                    </u>
	<u>                    </u>	<u>                    </u>
	\$8,319	\$8,207
	<u>                    </u>	<u>                    </u>

*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 straight-line. Leasehold improvements are amortized on a straight-line basis over the life of the lease. Equipment and leasehold improvements consist of the following:

	June 30, 2004	March 31, 2004
	<u>                    </u>	
	(in thousands)	
<i>BioVeris and Wholly-Owned Subsidiaries:</i>		
Lab instruments and equipment	\$ 5,960	\$ 6,413
Office furniture and equipment	5,561	5,511
Leasehold improvements	4,010	3,980
	<u>                    </u>	<u>                    </u>
	15,531	15,904
Accumulated depreciation and amortization	(10,779)	(10,432)
	<u>                    </u>	<u>                    </u>
Total	4,752	5,472

	_____	_____
<i>MSD:</i>		
Lab instruments and equipment	8,204	7,555
Office furniture and equipment	3,185	3,166
Leasehold improvements	1,294	1,327
	_____	_____
	12,683	12,048
Accumulated depreciation and amortization	(5,575)	(4,686)
	_____	_____
Total	7,108	7,362
Consolidating eliminations	(202)	(269)
	_____	_____
Total	\$ 11,658	\$ 12,565
	_____	_____

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

The Company paid Roche a license fee of \$50 million in fiscal 2004 and will also pay royalties on sales of the licensed products in the licensed fields and on any instrument, accessory, device or system sold for use with the licensed products in the licensed fields at royalty rates ranging from 3% to 20% of net sales, depending on the field, the year, the country of sale and the patents covering such products. It 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. The Company has performed a valuation of the PCR technology licenses and has recorded their 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 licenses are being amortized over an estimated useful life of ten years which is based upon a consideration of the range of patent lives and the weighted average remaining life of the most important underlying patents, as well as a consideration of technological obsolescence and product life cycles. Amortization expense was \$488,000 for the quarter ended June 30, 2004 and accumulated amortization was \$731,000 at June 30, 2004. Amortization expense is expected to approximate \$2.0 million for each year through March 31, 2009.

*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. Management believes no impairment of these assets exists as of June 30, 2004.

*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 June 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.

*Other Current Assets* Other current assets include certain assets of MSD aggregating \$2.7 million that represent automobiles and deposits on real property. On June 17, 2004, MSD received \$2.9 million from Mr. Jacob Wohlstadter, as consideration for the proposed sale by MSD of real property and automobiles, pending approval by the MSD Board of Managers, which is recorded as an other liability. Jacob Wohlstadter, also assumed MSD's purchase obligations with respect to a prospective real property purchase in the approximate amount of \$4.1 million. In August 2004, MSD transferred the real property and automobiles and MSD's limited liability company interests to Jacob Wohlstadter.

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

*Comprehensive Income (Loss)* Comprehensive income (loss) is comprised of net income (loss) and other items of comprehensive income (loss). Other comprehensive income for the quarter ended June 30, 2004 includes unrealized gains on available for sale securities that are excluded from net loss. There were no significant elements of comprehensive income (loss) for the quarter ended June 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 and 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 and is recognized for the installation when complete based upon the residual value method. For instrument and reagent sales, there is no option of return and refund, only the option to repair or replace the product. Other than the installation required for the instruments, there are no contingencies, allowances or other post-sale obligations. For instrument leases, the instrument rental and related minimum reagent purchases are considered to be separate elements under EITF 00-21 and, accordingly, the sales price is allocated to the two elements based upon their relative fair values. Instrument rental revenue is recognized ratably over the life of the lease agreements and the related reagent revenue is recognized upon shipment. Revenue associated with extended warranty arrangements is recognized over the term of the extended warranty contract.

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

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

*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 quarters ended June 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 quarters ended June 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 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>Quarter Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>
Net loss, as reported	\$(12,851)	\$(12,518)
Deduct: Total stock-based employee compensation expense determined under fair value method	(145)	(455)
Pro-forma net loss	<u>\$(12,996)</u>	<u>\$(12,973)</u>
Loss per share:		
Basic and diluted loss per common share as reported	\$ (0.48)	\$ (0.47)
Basic and diluted loss per common share pro forma	\$ (0.49)	\$ (0.49)

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 quarter ended June 30, 2003 represents options for IGEN common stock which were canceled upon completion of the merger.

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

Expected dividend yield	0.00%
Expected stock price volatility	64.06%
Risk-free interest rate	3.89%
Expected option term (in years)	3

Based on this calculation, the weighted average fair value of BioVeris options granted during the quarter ended June 30, 2004 was \$7.19. The Company did not have a stock option plan prior to September 2003.

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

Expected dividend yield	0.00%
Expected stock price volatility	65.00%
Risk-free interest rate	2.30%
Expected option term (in years)	5

Based on this calculation, the weighted average fair value of IGEN options granted during the quarter ended June 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 quarters ended June 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 quarter ended June 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 quarter ended June 30, 2004, it did not assume exercise of 20,300 options because to do so would have been anti-dilutive.

*New Accounting Standards* For a discussion of FASB Interpretation No. 46, see Note 2- Summary of Significant Accounting Policies-Consolidation Accounting.

### 3. MESO SCALE DIAGNOSTICS JOINT VENTURE

MSD is a joint venture formed by MST and IGEN in 1995. As part of the merger and related restructuring, IGEN transferred its equity interest in MSD to the Company and assigned the MSD agreements to the Company. MSD was formed for the development, manufacture, marketing and sale of products utilizing a combination of MST's multi-array technology together with IGEN's technology.

MST is a company established and wholly-owned by Mr. Jacob Wohlstadter. In August 2001, there were amendments to 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 various related agreements (the MSD agreements). An independent committee of IGEN's board of directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements. As part of the merger agreement and related transaction agreements, the Company, IGEN and MSD agreed that the MSD joint venture agreement would expire upon completion of the merger and related transactions.

MSD manufactures, markets and sells instrument systems, including the Sector HTS and the Sector PR, which combine MST's multi-array technology and the Company's ECL technology. 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. MSD commenced product sales in October 2002.

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 an August 2004 settlement agreement 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, certain intellectual property matters, and the previously outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with its participation and involvement in the merger and related transactions. The Company's \$3.0 million payment will be net of a \$2.0 million non-refundable pre-payment by MSD to the Company for future amounts payable by MSD to the Company pursuant to the buyout of the Company's interest in MSD. The Company made no contributions to MSD in the quarter ended June 30, 2004. For the quarter ended June 30, 2003, the total contributions made to MSD was \$10.9 million.

After the restructuring, and subject to MSD's and MST's right to buy the Company's interests in MSD, the Company replaced IGEN as a member of MSD and holds a 31% voting equity interest in MSD and is entitled to a preferred return on approximately \$114 million of the funds previously invested by IGEN in MSD through the date of the merger and on the additional funds invested by the Company thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings of MSD, generally before any payments are made to other equity holders.

The Company and MST are the sole members of MSD, and each held one seat on MSD's two-member board of managers. Dr. Richard Massey, the Company's president and chief operating officer, was the Company's representative on the MSD board of managers and also served as the treasurer and secretary of MSD. The other member of the MSD board of managers is Mr. Jacob Wohlstadter, who is the sole owner of MST and serves as president and chief

executive officer of MSD. As part of an August 2004 settlement agreement between the parties, the Company's representative on the MSD board of managers has resigned and the Company has executed an amendment to the MSD agreements for the purpose of changing the composition of the MSD board of managers to one person designated by MST.

Under the terms of one of the MSD agreements, IGEN granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to IGEN's technology, including ECL technology, for use in MSD's research program, defined in the MSD agreements. If the Company ceases to be a member of MSD, it will become entitled to receive royalty payments from MSD on all products developed and sold by MSD using the Company's patents.

MST holds a worldwide, perpetual, non-exclusive sublicense from MSD for certain non-diagnostic applications of the Company's technology. The Company is entitled to receive royalty payments from MST on any products developed and sold by MST using the patents the Company received as part of the restructuring.

Upon completion of the merger and related transactions, the MSD joint venture agreement expired. As a result, MSD and MST have the option to purchase the Company's interest in MSD and as part of an August 2004 settlement agreement between the parties, they agreed to do so. As of June 30, 2004 and March 31, 2004, the Company has recorded a \$1.2 million liability representing the value of MSD's option to purchase the Company's interests in MSD.

The purchase price will be equal to fair market value (determined in accordance with the MSD agreements), which includes third-party appraisal if the parties are unable to agree on fair market value) minus a 7.5% discount factor. The parties have commenced the valuation process and the initial appraisers' reports are due on August 30, 2004. If those reports do not reflect fair market value calculations within 10% of each other, then a third appraiser will be appointed to provide a report on or about October 15, 2004. The average of the two closest appraisals will be the purchase price. 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. There is no assurance the purchase price will be paid in full. The Company expects that MSD will require substantial additional funding for its ongoing operations. If MSD is not able to obtain this funding, it may not be able to pay the purchase price in full and we could lose our ability to realize the value of most or all of our \$41.2 million investment in MSD.

As part of an August 2004 settlement agreement between the parties, the Company received a \$2.0 million non-refundable pre-payment from MSD for future amounts payable by MSD to the Company pursuant to the buy-out of its 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 of the outstanding credit balance of the prepayment credit, including accrued interest, shall be reduced for amounts due and payable to the Company pursuant to the buy-out of its interest in MSD and no further cash payments will be payable by MSD to the Company until the \$2.0 million prepayment credit, including accrued interest, is utilized. In the event future net sales or third-party financings in excess of the prepayment credit and accrued interest do not materialize, the Company will not receive any additional payments from MSD or MST, as the case may be, for the purchase of the Company's interest 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, 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 \$2.0 million that is allocable to our Class C interests.

Upon expiration of the MSD joint venture agreement, many of the licenses and other arrangements with MSD and MST assigned to the Company continue indefinitely in accordance with their terms and the Company may not use the 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.

Following the expiration of the MSD joint venture agreement, MSD is entitled to continue to lease 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. The term of each sublease will expire one day prior to the expiration of the prime lease for that facility. Each sublease agreement provides that, subject to certain exceptions, the Company must exercise all available extension rights under the prime lease. Each of MSD and the Company may unilaterally terminate any or all of the subleases by providing at least 18 months prior written notice of termination and on February 29, 2004, the Company elected to terminate all of the subleases effective the earlier of September 1, 2005, or the date on which the applicable prime lease terminates. As part of an August 2004 settlement agreement between the parties, MSD's rental and expense payment obligations under the sublease agreements, for the period from March 1, 2004 through August 31, 2005, for approximately \$2.2 million will be added into the price payable to the Company for the purchase of its interest in MSD, in lieu of current payments. MSD may elect, notwithstanding any termination of the sublease, 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 of the prime lease). In that event, MSD will be required to pay rent in cash for any additional rental period MSD may elect.

MSD has an employment agreement with Mr. Jacob Wohlstadter, its president and chief executive officer, the current term of which 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 Mr. Jacob Wohlstadter gives notice of termination no later than 180 days prior to that renewal date. That employment agreement provides for a salary at the annual rate of \$250,000 through November 30, 2004, and 2005. Thereafter, the salary is to be increased as agreed to by MSD and Mr. Jacob Wohlstadter. In addition, Mr. Jacob Wohlstadter is also eligible to receive an annual cash bonus in an amount not to exceed 20% of his annual salary upon the achievement of agreed-upon performance factors. Mr. Jacob Wohlstadter is also entitled to receive pension, welfare and fringe benefits comparable to those received by senior executives of the Company and other insurance benefits. If MSD terminates the employment agreement without cause, or Mr. Jacob Wohlstadter terminates the employment agreement for good reason (which includes a change in control of the Company, as defined), Mr. Jacob Wohlstadter will be entitled to receive, in addition to salary and pro rata bonus and adjustments earned through the 60th day following the notice of termination, an amount equal to from 3 to 12 times (depending on the reason for the termination) the monthly pro rata salary, bonus and adjustments in effect at the time of the termination. Under the employment agreement Mr. Jacob Wohlstadter is also entitled to receive a gross-up for any parachute excise tax that may be imposed on payments made or benefits provided pursuant to the agreement. The Company is obligated to maintain in effect directors and officer's liability insurance coverage for Mr. Jacob Wohlstadter and to pay Mr. Jacob Wohlstadter the applicable salary, pro rata bonus and adjustments in effect at the time of termination as described above and a gross-up for any parachute excise tax that may be imposed.

MSD and Mr. Jacob Wohlstadter have each agreed that the merger and related transactions did not constitute a change in control for purposes of the MSD agreements and the employment agreement. The Company will also indemnify Mr. Jacob Wohlstadter against certain liabilities, including certain liability from the MSD joint venture relating to the period of IGEN's or the Company's involvement with MSD.

In addition, the Company will be obligated to the extent provided in the MSD agreements to indemnify each board member or officer of MSD with respect to any action taken by such person prior to the termination of the MSD joint venture agreement by reason of the fact that such person is or was a board member or an officer of MSD. In connection with the audit of MSD, the Company 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. With respect to such indemnification obligations, there are no pending or known matters covered by these indemnification provisions that would have a material effect on the Company's financial position or results of operations.

Since inception of the MSD joint venture through March 31, 2004, the equity method has been utilized 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. 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, since 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.

MSD-related losses included in equity in loss of joint venture were \$5.2 million for the quarter ended June 30, 2003. Beginning March 31, 2004, the Company has consolidated the financial results of MSD. During the quarters ended June 30, 2004 and June 30, 2003, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$526,000 and \$2.0 million, respectively. Since July 1, 2001 and through March 31, 2004, these allocated operating costs reduced certain operating costs and expenses and increased Equity in Loss of Joint Venture in the accompanying consolidated statements of operations. At June 30, 2004 and March 31, 2004, the Company's investment in joint venture has been eliminated as part of the consolidation of MSD's balance sheet. See Note 2 for a discussion of consolidation accounting for MSD.

#### 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 we refer to in this Form 10-K as the court, against Jacob Wohlstadter, MSD and MST, seeking Court confirmation that we 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 us. 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. 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. Beginning late June, MSD permitted the Company's to examine the requested books and records.

On June 17, 2004, MSD received \$2.9 million from Jacob Wohlstadter as consideration for the proposed 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 us to finalize our Form 10-K. 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 is required to consolidate the financial information of MSD pursuant to FASB interpretation No. 46, which was adopted as of March 31, 2004, the Company requires the audited financial statements of MSD to complete its Form 10-K. The Company was not able to file its Form 10-K on 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 our management knew of the MSD transactions at issue before they occurred.

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.

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 is scheduled for August 19, 2004. As a result of such request, the delisting of the Company's stock was automatically stayed.

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 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.

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:

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.

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.

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.

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 are we permitted to seek injunctive or declaratory relief.

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 from \$4.1 million.

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.

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.

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.

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 us 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.

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.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations as of June 30, 2004 and for the three months ended June 30, 2004 and 2003 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in 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, intend and shall have been used to identify certain of the forward-looking statements. These forward-looking statements are based on management's current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. These statements are not guarantees of future performance, involve certain risks, uncertainties, and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein.

In any forward-looking statement in which we express an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. The following important factors are among those that may cause actual results to differ materially from our forward-looking statements:

changes in our strategy and business plan, including our plans for the clinical diagnostics, biodefense, life science and industrial markets and other healthcare opportunities;

our ability to develop and introduce new or enhanced products, including incorporating unit dose cartridges;

our ability to enter into new collaborations on favorable terms, if at all;

our ability to expand the distribution and increase sales of existing products;

the demand for rapid testing products in each of our markets;

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;

our ability to develop our selling, marketing and distribution capabilities;

our and our licensees' ability to obtain FDA and other governmental approvals for our and their clinical testing products;

the ability of our licensees to effectively develop and market products based on the technology we license to them;

domestic and foreign governmental and public policy changes, particularly related to healthcare costs, that may affect new investments and purchases made by our customers;

availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;

rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective manner;

any potential future disputes regarding the scope, permitted use and other material terms of our license agreements, including those with MSD;

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;

protection and validity of our patent and other intellectual property rights;

statements regarding relationships between us and certain companies with which we are affiliated; and

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 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.

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. 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.





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:

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

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.

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

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;

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;

the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;

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

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

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

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

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

research and development costs, which increases or decreases based on the product in development and

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

the amount that we 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;

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;

MSD's financial results, which for the years ended December 31, 2003 and 2002 included losses of \$20.4 million and \$17.1 million, respectively, and which we have commenced consolidating as of March 31, 2004; and

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 loss of MSD, whose financial results have been consolidated with ours beginning as of March 31, 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.

#### *Investment in MSD*

MSD is a joint venture formed by MST and IGEN in 1995. MSD was formed for the development, manufacture, marketing and sale of products utilizing a proprietary combination of MST's multi-array technology together with our ECL technology. We have recorded our proportionate share of MSD losses, representing approximately 100% of MSD's losses.

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 have determined that MSD qualifies as a variable interest entity. Accordingly, beginning as of March 31, 2004 we have consolidated the financial results of MSD. 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.

The amounts of the 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. Beginning with the quarter ended June 30, 2004, 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 ended June 30, 2004 increased significantly.

The MSD joint venture agreement expired upon completion of the merger and related transactions. As a result, MSD and MST had the option to purchase our interest in MSD. As of March 31, 2004, the value of such option was \$1.2 million. Pursuant to the settlement, MSD or MST will purchase, and we will sell, our entire interest in MSD. We are in the process of evaluating the impact of this purchase on the future of accounting treatment for MSD under the provisions of FIN 46. For a more complete description of this purchase right and the MSD agreements, see Part I ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 4 Litigation.

We expect that MSD will require substantial additional funding for its ongoing operations. If MSD is not able to obtain this funding, we could lose our ability to realize the value of most or all of our investment of approximately \$41.2 million at June 30, 2004 in MSD.

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 Part I 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 filed with the SEC.

#### Supplemental Consolidated Balance Sheet Data:

	March 31, 2004			
	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated BioVeris
<b>Assets</b>				
Current Assets:				
Cash and cash equivalents	\$ 147,398	\$ 35,111	\$	\$ 182,509
Accounts receivable, net	3,417	2,099		5,516
Inventory	5,013	3,194		8,207
Other current assets	2,459	2,053	(180)	4,332
Total current assets	158,287	42,457	(180)	200,564
Equipment and leasehold improvements, net	5,472	7,362	(269)	12,565

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Investment in joint venture	46,208		(46,208)	
Technology licenses	19,256	10		19,266
Other	354	65		419
<hr/>				
Total assets	\$229,577	\$ 49,894	\$ (46,657)	\$232,814
<hr/>				
<b>Liabilities and Stockholders Equity</b>				
Current Liabilities:				
Accounts payable and accrued expenses	\$ 26,220	\$ 3,067	\$ (180)	\$ 29,107
Other current liabilities	1,977	296		2,273
<hr/>				
Total current liabilities	28,197	3,363	(180)	31,380
Noncurrent liabilities	54			54
<hr/>				
Total liabilities	28,251	3,363	(180)	31,434
<hr/>				
Minority interest			54	54
Series B preferred stock	7,500			7,500
Stockholders Equity:				
Common stock	27			27
Additional paid-in capital	203,464	116,707	(116,707)	203,464
Net investment by parent				
Accumulated deficit	(9,665)	(70,176)	70,176	(9,665)
<hr/>				
Total stockholders equity	193,826	46,531	46,531	193,826
<hr/>				
Total liabilities and stockholders equity	\$229,577	\$ 49,894	\$ 46,657	\$232,814
<hr/>				

**Supplemental Consolidated Balance Sheet Data:****June 30, 2004**

	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated BioVeris
<b>Assets</b>				
Current Assets:				
Cash and cash equivalents	\$ 30,148	\$ 32,089	\$	\$ 62,237
Short term investments	89,739			89,739
Accounts receivable, net	4,128	2,161		6,289
Inventory	4,861	3,458		8,319
Other current assets	3,065	3,477	(820)	5,722
	<u>131,941</u>	<u>41,185</u>	<u>(820)</u>	<u>172,306</u>
Equipment and leasehold improvements, net	4,752	7,108	(202)	11,658
Investment in consolidated joint venture	41,214		(41,214)	
Technology licenses	18,768	10		18,778
Other	354	65		419
	<u>197,029</u>	<u>48,368</u>	<u>(42,236)</u>	<u>203,161</u>
	<u>\$ 197,029</u>	<u>\$ 48,368</u>	<u>\$ (42,236)</u>	<u>\$ 203,161</u>
<b>Liabilities and Stockholders Equity</b>				
Current Liabilities:				
Accounts payable and accrued expenses	\$ 6,389	\$ 3,694	\$ (820)	\$ 9,263
Other current liabilities	2,065	3,204		5,269
	<u>8,454</u>	<u>6,898</u>	<u>(820)</u>	<u>14,532</u>
Total current liabilities	8,454	6,898	(820)	14,532
Noncurrent liabilities	69			69
	<u>8,523</u>	<u>6,898</u>	<u>(820)</u>	<u>14,601</u>
Total liabilities	8,523	6,898	(820)	14,601
Minority interest			54	54
Series B preferred stock	7,500			7,500

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Stockholders' Equity:				
Common stock	27			27
Additional paid-in capital	203,464	116,707	(116,707)	203,464
Accumulated deficit	(22,516)	(75,237)	75,237	(22,516)
Accumulated other comprehensive income	31			31
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total stockholders' equity	181,006	41,470	(41,470)	181,006
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total liabilities and stockholders' equity	\$ 197,029	\$ 48,368	\$ (42,236)	\$ 203,161
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

**Supplemental Consolidated Statements of Operations Data:**

	Quarter Ended June 30, 2003	Quarter Ended June 30, 2004			
	BioVeris and Wholly-Owned Subsidiaries(1)	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
	<i>(In thousands, except per share data)</i>				
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales	\$ 4,796	\$ 4,886	\$ 2,953	\$	\$ 7,839
Royalty income	243	320			320
Contract fees	34	20	66		86
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	5,073	5,226	3,019		8,245
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Operating costs and expenses:					
Product costs	2,433	2,264	2,340		4,604
Research and development	5,232	4,561	2,682	(67)	7,176
Selling, general and administrative	4,776	6,608	3,102		9,710
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total operating costs and expenses	12,441	13,433	8,124	(67)	21,490
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Loss from operations	(7,368)	(8,207)	(5,105)	67	(13,245)
Other, net	80	350	44		394
Equity in loss of joint venture	(5,230)	(4,994)		4,994	
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net loss	<u>\$ (12,518)</u>	<u>\$ (12,851)</u>	<u>\$ (5,061)</u>	<u>\$ 5,061</u>	<u>\$ (12,851)</u>
Net loss per common share (Basic and Diluted)	\$ (0.47)				\$ (0.48)
Shares used in computing net loss per common share (Basic and Diluted)	<u>26,728</u>				<u>26,728</u>



- (1) For the quarter ended June 30, 2003, we did not provide information for MSD or consolidating eliminations as we did not consolidate MSD's financial results prior to our adoption of FIN 46 as of March 31, 2004.

*Results of Operations*

Quarters Ended June 30, 2004 and 2003

**Revenues.** Our consolidated revenues for the quarter ended June 30, 2004 increased by approximately \$3.1 million or 63% to \$8.2 million from \$5.1 million in the corresponding prior year period. Of the \$3.1 million increase, \$3.0 million represents MSD revenues which were consolidated with BioVeris' revenue for the first time during this current quarter.

Our consolidated product sales were \$7.8 million for the quarter ended June 30, 2004, an increase of 64%, from \$4.8 million in the corresponding prior year period. The \$3.0 million increase was due to the consolidation of MSD's product sales.

BioVeris' s product sales in the current quarter were from biodefense products, an increase over the same quarter the prior year of \$800,000 to \$2.3 million, and products for the life science market, decreased \$700,000 to \$2.6 million. These changes in product sales in the current quarter reflect the change of orders and product deliveries for biodefense products, which orders and deliveries are based on our customers' requirements.

We anticipate 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 June 30, 2004, the DOD had purchased approximately \$4.4 million of products during the first year of the 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 \$4.6 million (59% of total product sales) for the quarter ended June 30, 2004 compared to \$2.4 million (51% of total product sales) in the corresponding prior year period. The total increase of \$2.2 million consists of \$2.3 million due to the consolidation of MSD offset by a \$100,000 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 chance due to a number of uncertainties relating to, among other things, the launch of new instrument systems.

Our research and development expenses increased \$1.9 million, or 37%, to \$7.2 million for the quarter ended June 30, 2004 from \$5.2 million in the corresponding prior year period. The increase consists of \$2.7 million from the consolidation of MSD' s expenses, offset by a \$700,000 reduction in the Company' s expenses.

BioVeris' s research and development expenses decreased in the current quarter 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, and as we explore other opportunities in the healthcare field.

Our selling, general and administrative expenses were \$9.7 million for the quarter ended June 30, 2004, an increase of \$4.9 million (103%) from \$4.8 million in the corresponding prior year period. Of the total increase, \$3.1 million was due to the consolidation of MSD expenses and \$1.8 million was an increase in Bioveris' s expenses.

BioVeris' s increase in selling, general and administrative expenses of approximately \$1.8 million was primarily attributable to higher personnel costs and professional fees in the current quarter, including costs associated with our litigation 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 months ended June 30, 2003.

**Interest Expense and Other.** Interest income, net of interest and other expense, was \$394,000 for the quarter ended June 30, 2004 and \$80,000 in the corresponding prior year period. This increase in net interest income resulted from a growth in interest earned in the current year period due to a higher balance of invested funds.

**Equity in Loss of Joint Venture.** We recorded our proportionate share of MSD losses, representing approximately 100% of MSD' s losses for the quarter ended June 30, 2003. Accordingly, equity in loss of joint venture for the three months ended June 30, 2003 totaled \$5.2 million.

We adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity. Accordingly, we have consolidated the financial results of MSD as of March 31, 2004 and including the quarter ended June 30, 2004. For the quarter ended June 30, 2004, the statement of operations reflects amounts formerly recorded on a net basis as equity in loss of joint venture that are reclassified and reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses.

**Net Loss.** The net loss for the quarter ended June 30, 2004 was \$12.9 million (\$0.48 per common share, compared to a net loss of \$12.5 million (\$0.47 per common share) for the quarter ended June 30, 2004. The increase in the net loss is primarily caused by operating expenses exceeding our revenues.

#### *Liquidity and Capital Resources*

Beginning as of March 31, 2004, we have consolidated the financial results of MSD in accordance with the requirements of FIN 46. Our consolidated balance sheet at June 30, 2004 had cash, cash equivalents and short-term investments of \$152.0 million. Of this amount, \$32.1 million represented the cash, cash equivalents and short-term investments of MSD. BioVeris has no rights or access to these funds or any other capital resources of MSD. The amount of cash, cash equivalents and short-term investments to which BioVeris and its wholly-owned subsidiaries have unrestricted use is \$119.9 million at June 30, 2004. In addition, our consolidated balance sheet includes the accounts receivable, inventory and other assets and liabilities of MSD. We have no rights or access to MSD' s assets and we do not have obligations with respect to MSD' s liabilities, except that we agreed to pay MSD certain amounts in the August 2004 settlement in respect of certain of its liabilities. See Part I Item 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 4 Litigation .

Net cash used in operations was \$9.8 million and \$6.7 for the quarters ended June 30, 2004 and 2003, respectively. Cash used for operations for the quarter ended June 30, 2004 primarily resulted from the net loss partially offset by changes in working capital.



Cash used for operations for the quarter ended June 30, 2003 primarily resulted from the net loss, partially offset by an adjustment for the equity in loss of joint venture.

We used approximately \$700,000 and \$800,000 of cash for the acquisition of equipment and leasehold improvements during the quarters ended June 30, 2004 and 2003, respectively. We made no investment payments to MSD for the quarter ended June 30, 2004. Our investment payments to MSD totaled \$10.9 million for the quarter ended June 30, 2003.

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 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 June 30, 2004, our material future obligations were as follows:

Contractual Obligations (in thousands)	Total	Years Ending March 31,					
		2005	2006	2007	2008	2009	2010 and Thereafter
<b>BioVeris and Wholly-Owned Subsidiaries:</b>							
Operating leases	\$17,857	\$2,386	\$3,164	\$3,241	\$3,338	\$3,333	\$2,395
MSD Payment	3,046	3,046					
Total contractual obligations	\$20,903	\$5,432	\$3,164	\$3,241	\$3,338	\$3,333	\$2,395

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, certain intellectual property matters, and the previously outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with its participation and involvement in the merger and related transactions.

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. 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. A total of \$5.0 million is to be treated as a Class C capital contribution. There is no assurance that we will be able to realize any value from the additional contribution.

For the quarter ended June 30, 2003, total contributions to MSD were \$10.9 million. The 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 ended June 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 in respect of certain of its liabilities. See Part I ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Condensed Consolidated Financial Statements (Unaudited) Note 4 Litigation . We cannot predict whether MSD will obtain additional funding. If MSD is not able to obtain this funding, we could lose our ability to realize the value of most or all of our investment in MSD.

As noted above, MSD or MST will purchase our interest in MSD for a purchase price equal to fair market value less a discount of 7.5%, with fair market value to be determined by an appraisal process. The current book value of our investment is \$41.2 million. There is no assurance that the purchase price will enable us to recover the book value of our investment. In addition, because the purchase price is payable in installments from a percentage of future MSD net sales or financings, there is no assurance that we will receive all or any portion of the purchase price, other than the \$2.0 million prepayment credit we received in connection with the settlement, and we could lose our ability to realize the value of most or all of our investment in MSD.

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.



We cannot assure you that we will successfully complete any of the foregoing arrangements and access to funds could be adversely impacted by many factors, including the volatility of the price of our common stock, continuing losses from our operations, establishment of new business arrangements, the status of new product launches, general market conditions and other factors. If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures or collaborations, on terms that may not be favorable to us.

As of June 30, 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 generally recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed and determinable, collectibility is reasonably assured and the product is shipped to the customers thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21. Revenue is recognized for the instrument upon shipment 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, we accounted for our ownership in the MSD joint venture on the equity method, as we have 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 have 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.

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 have adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity based upon the following rationale:

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.

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 have consolidated the financial results of MSD. 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. The amounts of the 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 periods subsequent to March 31, 2004 have 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.

*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. While management believes that its projections are reasonable and that no impairment of these assets exists, different assumptions could affect these evaluations and result in impairment charges against the carrying value of these assets.

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

### **Recent Accounting Pronouncements**

See discussion of FASB Interpretation No. 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.

Beginning as of March 31, 2004, we have consolidated the financial results of MSD in accordance with the requirements of FIN 46. Our consolidated balance sheet at June 30, 2004 had cash, cash equivalents and short-term investments of \$152.0 million. Of this amount, \$32.1 million represented cash and cash equivalents of MSD. We have no rights or access to these funds. The amount of cash, cash equivalents and short-term investments to which we and our wholly-owned subsidiaries have unrestricted use is \$119.9 million, which is 59.8 % of total consolidated assets at March 31, 2004.

We invest excess cash in accordance with a policy approved by our Board of Directors. The policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on our investments by terms and concentrations by type and issuer. We invest our excess cash in money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less. Also, as of June 30, 2004, we had invested \$89.7 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 and cash equivalents balance at June 30, 2004, a 100 basis point movement in interest rates would have an approximately \$1.2 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 are effective in timely making known to them material information relating to our company required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934.

#### PART II OTHER INFORMATION

ITEM 1 LEGAL PROCEEDINGS See Part I ITEM 1 Condensed Consolidated Financial Statements (Unaudited) Notes to Consolidated Financial Statements (Unaudited) Note 4 Litigation.

Item 6: Exhibits and Reports on Form 8-K.

(a) Exhibits:

- 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 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K:

During the quarter ended June 30, 2004, we filed reports on Form 8-K with the Securities and Exchange Commission on the dates indicated below:

May 5, 2004, reporting on Item 5 Other Events and Regulation FD Disclosure;

May 27, 2004, reporting on Item 5 Other Events and Regulation FD Disclosure; and

June 15, 2004, reporting on Item 5 Other Events and Regulation FD Disclosure.

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.

Date: August 17, 2004

BioVeris Corporation

/s/ George V. Migausky

George V. Migausky

Vice President of Finance and  
Chief Financial Officer

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